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NALLUR, JAFFNA

No. _____

Proceedings of the **FIRST INTERNATIONAL SCIENTIFIC CONGRESS**

Appropriate Technology Services

121, POINT P. C. ROAD
NALLUR, JAFFNA

No. _____

of the
**FAMILY PLANNING ASSOCIATION
OF SRI LANKA**

COLOMBO 1974

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of the

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SCIENTIFIC CONGRESS**

of the

**FAMILY PLANNING ASSOCIATION
OF SRI LANKA**

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21 - 26 January 1974

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HISTORY OF THE FAMILY PLANNING ASSOCIATION OF SRI LANKA

MRS. E. C. FERNANDO

The Sri Lanka Family Planning Association owes a great deal of its growth and development to six persons – Dr. Abraham Stone, Mrs. Dorothy Brush, Margaret Sanger, Mrs. Otessen Jensen and Mr. & Mrs. George Cadbury who were also pioneers of the International Family Planning movement.

On a world tour focussed on Bombay in 1952 where the International Planned Parenthood Federation (IPPF) was inaugurated, Mrs. Margaret Sanger, Mrs. Dorothy Brush and Dr. Abraham Stone broke journey in Ceylon. They met a group of persons brought together by members of the All Ceylon Women's Conference, who for some years had been interested in starting a family planning movement in Ceylon. This meeting led to the formation of the Association in January 1953, and to the visit to Ceylon of a philanthropist, Dr. Clarence Gamble, also a pioneer interested in finding a cheap and effective contraceptive suitable for the underprivileged millions in Asia. He sent the Association free supplies of contraceptives and later a social worker and money to finance a clinic located in the premises of a Social Service League situated in a poor overcrowded area of the city of Colombo.

In 1954 through the good offices of Mr. George Cadbury the Association was elected a member of the I.P.P.F. Through the years this Agency has been the Association's main source of guideline and assistance.

The senior officials of the Department of Health in Sri Lanka have shown interest in the activities of the Association since its inception. Permission was given to a consultant obstetrician of the premier maternity hospital in the island to turn his post-natal clinic into a Women's Welfare Clinic where family planning advice could be offered. From the outset, those with too few or no children were helped as well as those with too many.

Ceylon's campaign to abolish malaria had been so successful that the resulting population increase amounted to about 3 per cent per year. The health officers who had achieved this success were beginning to feel that apart from successfully controlling the death rate, they had some responsibility to control the birth rate. This interest was utilised by the Association which circularised all health officers informing them that training in Family Planning was available at the De Soysa Maternity Hospital, and that materials could be obtained from the Association for distribution at a nominal cost to the patient.

Mrs. Dorothy Brush visited Ceylon in 1959 and visited almost all the 24 clinics and six centres in the country, covering about 800 miles.

During the sixties, work proceeded apace especially after office premises were rented and more staff engaged by the Association.

The Plantations Programme was started in co-operation with the medical officer of the Planters' Health Scheme. A van donated by the Brush foundation facilitated this work.

A grant of \$10,000 for work in the Eastern Province was utilised to purchase another vehicle, two film projectors and several copies of Tamil and English versions of films for educational work.

The Government donated a piece of land to the Association. In order to start building operations and take possession of the land, the Association became registered under Company Law. In 1965 it had also been made a Registered Charity.

From the seventies, the Government has accepted a major and direct responsibility for family planning and signed a four-year agreement for \$6 million with the United Nations

Fund for Population Activities (UNFPA). It thus became necessary for the Association to make a critical examination of the objectives and achievements of its existing programme and select only those aspects which would make the most significant contribution to the progress of family planning in Sri Lanka.

Programmes in the past had developed mainly as urgent responses to needs on an *ad hoc* basis, very relevant in the first phase of Family Planning in Sri Lanka.

The Association now considers its activities as having entered the second phase. Its objectives now had to be more precise and targets more specific, limited to particular time-spans and areas of activity. It is reckoned that the programmes should

- (a) Be extensive and capable of concentrated effort.
- (b) Exploit to the full the essential stature of the FPA as a voluntary organisation.
- (c) Incorporate new and innovative approaches to family planning.
- (d) Be so designed as to indicate the position of volunteers of the Association as opinion leaders and opinion makers in new fields.

With these criteria in mind, our main thrust is towards limitation of family size rather than spacing for over fifty per cent of the population having three or more children. Vasectomy being a simple method, the Association concentrates on this in its Plantations Programme, Operation Industrial Sector covering business firms and Corporations mainly in Colombo and the suburbs, in co-operation with the Municipality of Colombo. Motivational programmes in the districts of Kandy and Batticaloa direct those seeking methods of family planning to Government Medical Institutions. In Kandy, Colombo and its suburbs the Association runs its own clinics, but these are not equipped to undertake female sterilisation. The Vasectomy Programme of the Association pioneered the popularisation of this method in Sri Lanka.

Similarly the oral contraceptive pill and the IUD were first tried in the Association Clinics. Injection methods are still mainly controlled by the Association. Newest methods of sterilisation are being popularised in co-operation with specialists in Government Maternity Institutions.

Advertising through the newspapers was started in the late sixties and has been expanded in recent years. Radio advertising began in the seventies, and programmes of 5, 15 and 30 minutes' duration were tried for cost-effectiveness. The use of commercial radio has not so far been intensively attempted although more attention is being paid to reaching the public by this means. In addition, there are plans for making use of folk media found to be effective in reaching rural masses with little or no access to conventional media.

In recent times a determined effort has been made to start pilot projects in rural areas in Kandy and Batticaloa, in co-operation with the District and decentralised medical administration.

Tentative beginnings have been made to approach the youth of the country as well as the indigenous medical practitioners on whom the bulk of rural folk rely for medical needs.

The Association's goal can be summed up by a quotation from the closing address of Professor Abel Smith, Professor of Social Administration, London School of Economics delivered at the 21st Anniversary Conference of the IPPF.

"Work will not be finished until no child is unplanned, unsought, or unwanted and until there is a safe and prosperous future for every child born."

MESSAGES

Professor D. A. Ranasinghe

President

Family Planning Association of Sri Lanka

It gives me great pleasure to contribute a message on the occasion of the 21st Anniversary of the Family Planning Association of Sri Lanka, and it is most appropriate that the International Scientific Congress organised to celebrate this event falls within World Population Year 1974.

The Family Planning Association started in a small and unobtrusive way in a clinic in Deans Road, Colombo 10, in 1953. The population in Sri Lanka at that time was 8,097,895. According to the Provisional Census in 1971 the population escalated in a period of 18 years to 12,747,755 – a rate of increase so staggering that even those who used to see no danger signal in this tide of population must surely recognise it now for what it is – namely a threatening disaster unless curbed.

The reason for what is happening is clear and wellknown enough. After thousands of years of increasing slowly, Man has begun to multiply fast. It is not merely that we are more fertile, but that many more of us remain alive. In the old days deaths were nearly as numerous as births; to-day, for every one who dies three are born to take his place. Immense effort has been made to probe the possibilities of delaying and preventing death. Pestilences are largely under control, better medical care and mass campaigns against infections and previously deadly diseases have helped the death-rate to drop sharply. The net result is that, while still within living memory Man had to bury many of his babies, to-day he has to bring them up instead. And while we have put all this effort into studying the delay of death we are only at the very beginning of investigations into the prevention of births.

The gathering speed with which world population is rising is perhaps the most frightening factor of all. It has taken us our full history to reach the present population figure. But at the present rate of increase we will double our population by the end of century, and after that, were the birth-rate to persist at this level, we will go on doubling at shorter and shorter intervals.

The dilemma of the rising populations which swallow up the economic effort made to raise the general standard of living is now at last being appreciated. What is the answer? Well there is no room for compromise. Either the death-rate must go up, or there must be a decrease in births.

It is a hopeful sign that awareness all over the world has grown significantly. National policies in favour of family planning are being more and more implemented. Fifteen years ago only India had drawn up a national policy to promote family planning. To-day more than fifty per cent of the developing world has similar programmes. This includes Hong Kong, Taiwan, South Korea, Iran, Turkey, Egypt, Tunisia, Morocco, Malaysia, Nepal, China, Pakistan, Barbados, Kenya, Jamaica, India and Sri Lanka, among others.

Then also, public interest in limited child bearing is growing and having a demonstrable effect. In traditional agrarian societies motivation for restricting fertility is not usually high

as many of the beliefs, customs and attitudes have not changed for centuries. Nevertheless, surveys conducted in some twenty developing countries have shown that a large number of couples are interested in restricting their families. And this attitude is not only prevalent in towns, but has spread throughout the community into the villages as well. Villagers are kept up-to-date by the various news media—the radio, films and newspapers—and there is a growing desire to educate their children to give them a better life. They realise that the more children survive the more mouths there are to feed, and that in the present health context a smaller family will still provide enough surviving adults to care for them in their old age.

Contraceptive technology is improving constantly, and two methods especially have been produced that are cheap and effective. These are the Intra-Uterine Device and oral steroids. They have gone a long way towards meeting the needs of couples who will not otherwise take troublesome precautions. And lastly, for the first time in history have several oriental governments agreed to advocate the practice of birth control in order to put down their crippling birth rate.

All this does not mean the effects will be immediately visible. But it is a beginning. At last the newly developing nations have realised the seriousness of the problem, and the extent to which their hard efforts at economic development are being frustrated by a too rapid increase in population. Their growing awareness of the urgency of the problem is a most hopeful sign.

Some countries have already been successful in reducing their birth rates: Hong Kong and Singapore, South Korea, Taiwan and Japan. Here in Sri Lanka the Government has now inaugurated an island wide family planning programme. It conducts 480 clinics in the 15 divisions of the Superintendents of Health Services, while the Family Planning Association conducts 11 Centres. These Centres not merely distribute the "Pill" and Intra-uterine Devices but also give valuable information. They educate fertile couples providing them with the know-how of family limitation, and also assist sub-fertile couples in starting a family. Vasectomy sessions which were initially conducted in the Family Planning Headquarters have now been extended to the Plantation areas and to the Industrial sector. Female sterilisation, which is carried out in the island's hospitals, is becoming more popular. It is gratifying to note that in 1972 a total of 71,044 couples are known to have practised some form of contraception method ranging from the "Pill" and IUD to Tubectomy and Vasectomy. This, I am sure, is due to the mass propaganda and education programmes organised by Sri Lanka's Health Services and Family Planning Association.

The problem of the "Grand-multipare" is foremost in the minds of many an Obstetrician practising in Sri Lanka; We hope that with the support and assistance offered by the State and the Family Planning Association it will disappear from our country in the not too distant future.

I must thank Dr. (Miss) Siva Chinnatamby, the Honorary Medical Director of the Family Planning Association of Sri Lanka, for the excellent work she has done and the amount of time and effort she has devoted to furthering our activities. Secondly, I extend my gratitude to the many voluntary workers who have been the mainstay of the Association at all times, and without whom we could not function. And, lastly, I thank the many workers of our Staff at all levels, who have devotedly worked for the Association over the years.

Antonio Carrillo

On behalf of **Dr. K. Waldheim**

On behalf of the Secretary-General, Dr. K. Waldheim, and as Secretary-General of the World Population Conference I request you to convey best wishes to Family Planning Association of Sri Lanka, the International Planned Parenthood Federation, The Planned Parenthood Federation of Canada and Canadian International Development Authority for the success of Conference to mark 1974 as World Population Year which is convening in Colombo, to review recent developments in medical and scientific aspects of regulation of fertility and their implication in the implementation of population programmes.

Miss Julia Henderson

Secretary-General, I.P.P.F.

In wishing your Scientific Congress every possible success may I take this opportunity to emphasise that the physician's role in family planning, as indeed in health care generally, is changing rapidly? He is the leader of a team. He is a planner, innovator, teacher, and supervisor. His tremendous prestige is to be harnessed to further the utilisation of all possible community resources including Ayurvedic Physicians, health personnel generally and communications and extension services agents for bringing family planning information and services to all those who need them. This will ensure success in giving service in ways acceptable to all human beings.

H. E. Miss Marion A. Macpherson

Canadian High Commissioner

I should like to extend all best wishes for success to the International Scientific Congress on Family Planning and also my congratulations to the Family Planning Association of Sri Lanka which is celebrating its 21st Anniversary this month. I am particularly pleased that the Family Planning Federation of Canada has given a generous contribution towards this Conference and has obtained an additional contribution from the Government of Canada.

Mr. C. Hart Schaaf

Resident Representative

United Nations Development Programme and

Director, United Nations Information Centre

I am very pleased indeed to give this message to the President of the Family Planning Association of Sri Lanka for their twenty-first anniversary souvenir and press supplement.

As the year 1974 has been designated World Population Year by the United Nations, which aims at increasing awareness throughout its member nations of the character, complexity and magnitude of population questions and their bearing on human affairs, I am glad to find that the Family Planning Association of Sri Lanka, so active in this field for more than two decades, is organising in this connection an International Congress to which scientists and doctors from all parts of the world are being invited, as part of the 21st Anniversary celebrations.

Human health and opportunity are subjects I have been involved in for the past 25 years, and I am thus very pleased at this opportunity to emphasize the vital importance of family planning today, especially in the developing countries.

Today, in many parts of the world over-population has become a very grave problem, manifesting itself in food shortages, insufficient housing, lowered health, poor education services and high unemployment. Thus the UN, following the earlier lead of such organisations as the Family Planning Association (FPA) of Sri Lanka, and International Planned Parenthood Federation (IPPF), has launched an effort to induce all nations and all people to adopt methods to bring down the population growth and thereby increase benefits of civilised living for all. A vital part of this effort is the United Nations Fund for Population Activities (The Population Fund). Today UNFPA works closely with the UNDP, which is the world's largest source of pre-investment and technical assistance to low income countries.

In Sri Lanka, the government has finalised a basic population agreement which contemplates the funding of eleven Population Projects throughout the country at a value of \$6 million, spread over a period of four years, to be carried out by the Health, Education and Labour Ministries in co-operation with the UNDP, UNFPA, WHO, UNESCO and ILO. This new Programme makes Sri Lanka the highest recipient in the world, on a per capita basis, of United Nations aid in connection with population activities.

I wish the 21st anniversary celebration of the Family Planning Association of Sri Lanka all success, and am confident that the results of the International Congress, organised in this connection, will have an important impact on the people of Sri Lanka.

Prof. Emeritus C.C. de Silva
Ex-President
Family Planning Association of Sri Lanka

As one of the Founder members of the Sri Lanka Family Planning Association it gives me very great pleasure to send this message of good wishes.

Twenty-one years is a goodly proportion of a single individual's life; it marks often the transit from immaturity to maturity, from relative irresponsibility to total responsibility, from taking ad hoc decisions about one's daily life to a more planned, long-term directed way of life. Though 21 years will, we hope, be only an infinitesimal part of our Association's total life, yet we pray that it will be a turning point both from an administrative as well as from a technical point of view. Plans are already afoot to streamline the administrative sector. During this year, we should consummate our plans with regard to its re-structure.

From the technical point of view we are moving forward from family spacing methods to family limitation, from hormonal and "interruptive" methods to surgical measures which are, up to the time of writing, largely irreversible. I wish the Association Godspeed in all due reverence. This means the achievement of a zero rate of growth of population within the next two decades. Else we are lost and will retrogress physically, mentally, technically, economically, socially and culturally. So let us brace ourselves to go forward and not slip backwards. Every man and woman must put their shoulders to the wheel in this war against the population explosion if we are to win.

I believe with all my heart that there will always be room, and a place for a voluntary organisation like ours, however efficient and effective the State plans may be. The stronger and the wiser the State, the more it should call upon volunteers to help in mass Family Planning Campaigns, but these volunteers must first be properly trained and dedicated to achieve the aims and objectives of such campaigns.

In these training programmes both the Government and Family Planning Association must play their respective roles. Motivations, in my opinion, would be much more effectively carried out by volunteers at the village level by the villagers themselves who have had a short-term crash population educational training course. They should not be highly educated personnel at a different level of culture from themselves. This to my mind is fundamentally important.

Lastly, unless the Ayurvedic Physician, the village school teacher and the Bhikkhu are enlisted in our campaign, it will take at least three times as long to achieve our objectives.

The Association should concentrate on motivating these three groups in the near future. I believe our whole policy should be re-oriented so that we take family planning to the people rather than expect the people to come to family planning! This is being done at present on a fairly low key; we must move it up the scale so that it has top priority.

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**We record with regret the death of Dr. Edward T. Tyler on the 31st of July, 1975.
He made a very valuable contribution to this First International Scientific Congress.*

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No. _____

INAUGURAL ADDRESS

INAUGURAL ADDRESS

The Hon'ble the Prime Minister, Mrs. Sirimavo Bandaranaike

President, Members of the Family Planning Association, Hon'ble Ministers, Deputy Minister of Health, Distinguished Delegates, Ladies and Gentlemen:

I wish to thank the President and Members of the Family Planning Association for having invited me to inaugurate the First International Scientific Congress on the Medical and Scientific Aspects of Control of Fertility. Let me extend to the distinguished visitors from abroad a very warm welcome to Sri Lanka. I hope that once you have finished your deliberations at this Scientific Congress you will find the time to relax and enjoy yourselves and see something of our beautiful country.

I am glad that this First International Scientific Congress on Control of Fertility is being held in Sri Lanka. I am also told it is the 21st Anniversary of the Family Planning Association of Sri Lanka. Let me offer my felicitations to the Family Planning Association on their "coming of age", and congratulate them on the good work they have done in their field. I wish the Family Planning Association of Sri Lanka a busy and rewarding future.

Family planning or population control, has its proponents and opponents in Sri Lanka as well as in other parts of the world. I am aware that there are religious prejudices to family planning. I am also aware that there are groups in Sri Lanka who, apart from any religious bias, oppose family planning on the grounds that if implemented on a big scale it will mean the extermination of one race or the other. I do not think a properly planned programme of family planning will mean the extermination of any race. Control, surely, does not mean eradication or extermination. To these prophets of gloom I would ask them to take a look at the world and at Sri Lanka and ponder over the economic situation facing the world today. Can we in Sri Lanka or any country in the world provide all the facilities and amenities that are necessary for a decent standard of life, such as schools and education, hospitals and health services, employment, clothing and, above all, food to an ever-increasing population—a population which appears to be increasing in geometric progression? Scientists have warned us that the rapid expansion of population the world over, will result in a population explosion sooner or later. Such an explosion will have incalculably disastrous effects on the future of the human race.

Today we hear of shortages all over the world, of food, raw materials, mineral resources and all other things necessary for the welfare or even the existence of man. These shortages are largely due to the ever-increasing usage by an ever-increasing population. Shortage of goods mean an inevitable rise in prices, scarcities and general human discontent. The question has to be asked, as to how far and how long the human race can go on in this manner. We have to be realistic and plan for the future, and a plan for the future must necessarily include some plan for population control.

In this respect, I am reminded of the speech made by my late husband when he was Minister of Health, at the 4th Plenary Meeting of the Second World Health Assembly held in Rome in June, 1949. Referring to family planning, he said:

"Another subject I should like to see some consideration of, is one on which we have been hitherto discreetly silent. There is a growing need for the consideration of the problem of birth control on an international plane. Do you realise that the very health work we are doing is making that problem increasingly urgent? Without asking for any decision in this Assembly I do suggest that that subject receive some consideration; that a beginning be made in the preparation of the necessary statistics

and data with the help of the appropriate specialised agencies of the United Nations, so that later on, even next year, we can consider this problem which is becoming a most urgent one in the world today."

This is an extract from a speech which was made 25 years ago.

If this problem was considered urgent by intelligent and perceptive people at that time, I do not have to point out to the enlightened audience that is present today the imperative urgency of the problem now.

There is one other aspect of family planning which I would like to refer to. And that is, to point out that there is a great deal of confusion in the popular mind that all family planning has to do, is with the prevention of births. I think it is very necessary to dispel ignorance on this particular aspect and educate the people to the fact that family planning is a vital element in ensuring the health and well-being of the mother as well as the children. It is essential to educate people to realise that uncontrolled births would inevitably lead to serious deterioration of the health of the mother as well as her children and that, particularly under present day conditions, large families would inevitably bring privation and squalor for all, whilst a small family would mean a high standard of health, nutrition and opportunity. If this message is effectively put across, there is no doubt that people will not only think that there is merit in these arguments but, what is more important, they would feel so. This is a matter on which there should be both intellectual and emotional realisation as a prelude to success.

As far as Sri Lanka is concerned, it could be said that we came to support the activities of the Family Planning Association from 1954 onwards, and have continued to lend financial support to this day. The total Government contribution to family health programmes to date is over 13 million rupees. I would here like to express our gratitude to the Swedish International Development Authority who started contributing to our Family Planning Programme in May, 1958. Since 1958 we have received increasing support from this organisation. The United Nations Fund for Population Activities has also come in a significant way to help us in our programmes since last year. We hope that with this generous support we will be able to achieve our goals in the near future.

I would like to make one final point before I conclude. And that is that in carrying forward activities connected with family planning it is vitally necessary that we do not over-emphasise the scientific as opposed to socio-economic factors; for if we lose sight of the socio-economic background of the people, their cultural patterns, traditional beliefs and their religious attitudes, no amount of scientific reasoning would help to make these programmes either possible or even understood. It is in the context of these considerations that strategy should be designed to tackle problems relating to population. If we fail to take cognisance of these factors, however enthusiastic family planners may be, whatever the quantity of finances that would go into these programmes and whatever expertise we plough into these schemes, success will elude us. Therefore, I commend this for your thoughtful consideration.

I am particularly happy to see that an important place is accorded to our Ayurvedic physicians at this International Congress. They number almost twice as many as our western-qualified doctors and they are the best means of reaching our rural people. Therefore I consider this to be a positive step in the education of the masses of this country in these matters.

I do not wish to delay you any longer. I would therefore like to leave you now to your important discussions and deliberations. Before I conclude, I would like to take this opportunity of wishing this Congress every success.

OPENING ADDRESS

PROFESSOR D. A. RANASINGHE

President of the Family Planning Association of Sri Lanka

Madam Prime Minister, Ministers of State, Your Excellencies, Deputy Ministers, Ladies and Gentlemen:

I welcome you all on behalf of the Family Planning Association of Sri Lanka. We are indeed happy, and relieved, that so many of you were able to join us in spite of the problems of travel. To those who have come from other parts of the world as ambassadors of good-will, I extend our best wishes to you, and to your people, and we hope that you will enjoy and benefit from your short stay in our country. We are also very grateful to our Prime Minister for taking time off from her arduous duties to grace this occasion, which is a very important one for our Association. This International Scientific Congress on the Medical and Scientific Aspects of Control of Fertility has been organised to celebrate the 21st Anniversary of the Family Planning Association of Sri Lanka, and it is most appropriate that this event should fall within the United Nations World Population Year.

The world is only just beginning to wake up to the fact that Family Planning is a desperate need — that the ever-accelerating population growth has to be curbed. It took more than 1,800 years for the world population to increase from 210 million to one billion. The second billion was added in a century and a quarter. The third billion took 30 years, and the fourth only fifteen. If the present rate of growth continues, the world population — which now stands at four billion — will double itself in 35 years. And by the end of this century the world population will increase at the rate of one billion every 8 years. A truly terrifying prospect.

The situation in the developing nations of Asia, Africa and Latin America is also terrifying. Their populations are expanding thrice as fast as those of the developed countries, yet their resources to cope with education, health, and economic and social problems are totally inadequate. This was so before the fuel crisis. Now the situation may well be disastrous.

After thousands of years of a slowly increasing population growth rate, man has begun to multiply fast. It isn't merely that we are more fertile, but that many more of us remain alive. In the old days deaths were nearly as numerous as births. Today for every ONE who dies, THREE are born to take his place.

We have made immense efforts to probe the possibilities of delaying death. Pestilences are largely under control. Better medical care and mass campaigns against infections and previously deadly diseases have helped to reduce the general death rate, the maternal mortality rate and the perinatal and infant mortality rates. While we have succeeded in our efforts to reduce the number of deaths, we are only at the beginning of investigating the prevention of births.

We know that we must bring the birth rate down drastically through whatever devices available. Improved standards of living, with all that this means — such as an increase in per capita income, more and better food, improved access to education and health care, and more opportunity for gainful employment — can only be achieved if we reduce the birth rate.

We are also aware that we need better methods of preventing conception; that, although we have a number of traditional and modern devices, the ideal has not yet been found. At the moment a great deal of research is being done, and many valuable discoveries have been made in this field. And this then is the purpose of our Congress — that the experts and investigators, including the pioneers from different parts of the world who have assembled here today, should

exchange experiences and information; that they should let us share their knowledge regarding recent developments in the medical and scientific aspects of control of fertility, and their implications in the implementation of population programmes.

We have asked representatives from all the different groups who are concerned with population control in this country to participate, so that they will help us spread family planning to the remotest corners of the island. There are the medical specialists, the general practitioners, the Government and Municipal medical officers, the Ayurvedic doctors, nurses and midwives, who reach our people at grass root level all over the country. I must make special mention of the interest the Commissioner of Ayurveda and the Ayurvedic doctors have taken in this conference, and I sincerely hope that everyone who has come to listen and to learn will feel at the end of our Congress that they have benefited, and that they will be able to pass on their new knowledge for the good of all our people.

On the brighter side of things: there are some countries that have managed to lower their birth rates. Here in Sri Lanka we now have a national, island-wide Family Health Programme, implemented through the Health Services. We have been greatly assisted by the United Nations Fund for Population Activities, the World Health Organisation, the International Planned Parenthood Federation, the Swedish International Development Agency, the Canadian International Development Agency and the Colombo Plan Population Division. All have encouraged us and helped us most generously, and we are deeply grateful to them.

Activities connected with family planning in Sri Lanka have been carried out by the Family Planning Association since 1953. The birth rate was then 38.5 per 1000. Since 1965 the Ministry of Health has joined us in our efforts and the birth rate was reduced to 29.4 by 1970. The Government's Five Year Plan gives very high priority to the diffusion of family planning facilities amongst the adult population. Provision has been made for the establishment of Family Planning Clinics integrated with child welfare work in all centres throughout the island. While the Government conducts the Family Health Programme as a national, island-wide scheme the Family Planning Association conducts some clinics and assists the Government scheme in the field of information and education, as well as in the plantation and industrial sectors.

We must thank Dr. (Miss) Siva Chinnatamby who conceived the idea of the Congress in the first place, and who has expended vast amounts of time, energy, thought and effort to make the idea become a reality. Let us all work hard this week so that we may derive maximum benefit from what is being offered to us. The task is urgent. Time is running out.

As Robert MacNamara said: "What we must comprehend is this: The population problem will be solved, one way or the other. Our only fundamental option is whether it is to be solved rationally and humanely — or irrationally and inhumanely. Are we to solve it by famines? Are we to solve it by riot? By insurrection, by the violence that desperately starving men can be driven to? Are we to solve it by wars of expansion and aggression? Or are we to solve it rationally, humanely — in accord with the dignity of Man?"

ADDRESS

MR. W. P. G. ARIYADASA
The Hon. Minister of Health

I am very thankful to the Family Planning Association of Sri Lanka for inviting me to the inauguration of the International Scientific Congress on Family Planning in connection with its Twenty-first Anniversary celebrations.

Family Planning activities were established in this country through the pioneering endeavours of the Family Planning Association. Though it started its activities on a small scale twenty-one years ago, through persistent efforts and dynamic leadership, it has today created a favourable public opinion towards family planning. This International Scientific Congress, the first of its kind in our country organised by the Family Planning Association could be considered another laudable undertaking to popularise family planning.

Sri Lanka is one of the many countries in Asia where over-population is having serious consequences on the economy of the country and nutrition of her people. Our death rate has declined to 8 per thousand, which is one of the lowest in the world, whereas our birth rate of nearly 29 per 1,000 population still ranks high giving an annual increase of over 2 per cent. The Government has taken cognizance of the alarming rate of population growth and given high priority in its Five Year Plan to family planning which has been integrated into the Maternal and Child Health Programme.

The Family Planning Association has a proud record of service to the nation. The Scientific Congress inaugurated today to celebrate its 21st Anniversary will, I am sure, be a landmark in its record of progress.

I am glad to express my sincere appreciation for the assistance and co-operation extended by the Association towards the activities of my Ministry.

I wish the 21st Anniversary Celebrations of the Family Planning Association and the First International Scientific Congress on Family Planning in Sri Lanka every success.

ADDRESS

MRS. SIVA OBEYSEKERA
Deputy Minister of Health

Madam Prime Minister, Hon. Minister of Health, Distinguished Guests, Members of the Family Planning Association.

It is a privilege to be associated with you, Madam Prime Minister, and you, Mr. Minister, at the inauguration of the International Scientific Congress of the Family Planning Association of Sri Lanka. This ceremony is a unique occasion, in that we are here to commemorate the 21st Anniversary of the Family Planning Association. I thank all members of the Association for giving me this opportunity of addressing such a very distinguished gathering. From distant parts of the globe, many eminent medical personnel, dedicated pioneers and workers in the Family Planning Movement, representatives of the I.P.P.F. and other non-Governmental and Governmental organisations, have gathered together, despite the fuel crisis, to share their knowledge and experience with men and women of Sri Lanka. It is worthy of note that we are meeting in this Hall, which is a memorial to one who realised the importance of population control way back in the 1950s. The late Mr. Bandaranaike's vision and foresight has helped his wife, the present Prime Minister, to give importance and priority to a Family Health Project, in order that development programmes will prove to be meaningful, and the aims and aspirations of our people be fulfilled. This is the goal we look forward to, and we are confident that it will be achieved, if the objectives of the Family Health Project are correctly understood.

The Family Planning Association was founded by Dr. Mary Rutnam, because of her concern for the numerous children who suffered from malnutrition and mothers who were anaemic. She was able to gather as her founder members many eminent and dedicated social service workers, some of whom, had they lived today, would indeed have been very happy to see the progress that has been made. However, we are glad that there are still many founder members with us, including Dr. L. O. Abeyratne and his wife, Dr. (Mrs.) Abeyratne - pioneers in children's welfare, Prof. C. C. de Silva - possibly the first to focus attention on an important aspect, namely nutrition, and Mrs. Sylvia Fernando, the life and soul of the Family Planning Association. They must justly be proud of their worthwhile efforts and achievements, for which they have given such selfless service. Today, the Association has many others in the field, working with the same spirit. Among them is Dr. Siva Chinnatamby, whose dynamic and persuasive disposition has made this Congress possible. Dr. Mary Rutnam was also one who believed in the advancement of rural women, and in this connection she started one of the most important women's organisations in the country, namely the Lanka Mahila Samiti, which reaches out far and wide into the humblest of homes. Accordingly, we must harness the services of such organisations in order to convey the message of family planning to the rural areas. The thoughts expressed by Brian Able-Smith, at the I.P.P.F. Conference held recently at Brighton, are worth considering. He said "Family Planning should be a way of life; a popular movement. A popular movement requires a broad-based membership. Voluntary work is not just the privilege of a few, but voluntary work is undertaken in many countries, by people from every section of the community."

Within the larger context of the Government's Family Health Programme, every individual, man and woman alike, has to understand the entire concept, which covers a vast field, such as nutrition, immunisation, environmental health, population dynamics, economy, the legal implications, etc., and, in societies such as ours, it is important that male motivation and acceptance is necessary to make any impact on controlling birth rates. We of the Government are indebted to S.I.D.A. for the support and assistance we have received since 1958. The results of the work done in 16 pilot Community Health Projects in 1971 gave our Prime Minister

and her Government confidence to sanction priority to family planning within the wider scope of our Family Health Programme. This has enabled Sri Lanka to receive enhanced aid from S.I.D.A. and to qualify for an agreement with the UNFPA together with other U.N. Agencies for assistance of 6 million dollars over the next four years, in order to implement the Government's Family Health Programme. Work has commenced, and we are glad that already there are certain specific results. For example, the population growth rate which was 2.72% in 1963, and 2.32% in 1971, has now dropped to 2.2%. Maternal mortality which was 1.8% in 1970, and 1.6% in 1971, is now 1.2%. Infant mortality which was 50 per thousand in 1970, was 48 per thousand in 1971, dropped to 43.4 per thousand in 1972. The death rate which was 8 per thousand in 1971 is now 7.5 per thousand. Birth rate which was 32 per thousand in 1971 is now 29.4 per thousand, and we hope to reach a much lower figure next year. All family planning methods are available at government medical institutions and from all health personnel and health workers. The demand is on the increase and we now average 1,500 sterilisations a month in our provincial and base hospitals. Indeed, this is heartening, and the response from the people has so far been encouraging. However, much remains to be done, and we are now commencing an intensive community health education programme. It would be relevant to quote here from the Financial Times, which says - "The fact is, wrong education is at the root of the population problem. This world needs desperately to be re-educated, and taught how to farm, how to plan families, how to conserve land, what to eat, and how to live." Our training programmes have commenced and within the next four years half a lakh of Health Department personnel, 10,000 registered Ayurvedic physicians, and a similar number of community leaders and social service workers will be trained and educated. For the first time in Sri Lanka, indigenous medical practitioners will play an important role both in the education, nutrition and services aspect of this Family Health Programme.

Therefore, it is opportune that just at this moment, the Family Planning Association of Sri Lanka should have organised this Scientific Congress in order to give a further impetus to our programme. I was speaking to one of the distinguished professors present here, who was impressed by the skills of our surgeons and doctors, despite the lack of modern and sophisticated equipment. Indeed, we are proud of our medical and paramedical personnel, for they are second to none, and could do more if they had better facilities. Still, these are the problems a developing country has to cope with, and through the generous assistance we are receiving, we hope to solve them.

The Family Planning Association of Sri Lanka, with assistance from I.P.P.F. and other organisations, can supplement and assist the Government Programme in many areas of work, and some of them are motivating and educating the public and so creating awareness of the population problems and its possible solution, assisting in family counselling, organising youth involvement activities, evaluation of projects, research into the usage of new methods of contraception, and influencing national and international organisations to support the movement. Recently, U.N. realising the importance of women's efforts in fertility control, organised a series of regional seminars for the status of women in family planning, the findings of which are to be discussed next month at a Forum on the role of women in the integrated effort for development. The results of this Forum will be included in the agenda and discussions of the World Population Conference to be held this year in Rumania. Mr. R. Sallas, Executive Director of UNFPA, has said, "The success of World Population Year will depend on the extent to which Governments gain a new understanding of population, on the extent to which communities and groups adopt population as a matter of urgent concern and on the extent to which the ordinary individual is motivated to take personal action."

Now that the Government has developed a policy and programme, we are grateful to the Family Planning Association of Sri Lanka for all the assistance we are receiving from them. Today, the population problem is not the concern of the Health Ministry alone. Several other Ministries, including Labour, Education, Information, Communications, Agriculture, Industries, Rural Development, Local Government, Justice and voluntary organisations like the Family Planning Association, are all committed to make their contributions towards ensuring the success of the Programme. What is needed is to co-ordinate the efforts of all those involved and participating at National level, and at this stage a National Population Council or Commission is important for the smooth functioning of our Population Programmes.

Populations are growing so fast that they are outstripping science's challenge, and today we are faced with the fact that over-population will exhaust all our resources. Many factors have to be considered in finding a solution. Family planning has to play a major role in solving this urgent problem so that, as a whole, the quality of living will improve.

While implementing these Programmes, however, it must be borne in mind that one of our chief concerns must be to preserve the moral values of our people, and in no way must such Programmes be interpreted or used to disturb the family unit, or undermine the very foundations on which our traditional way of life has been built over thousands of years.

Mr. Chairman and Members of the Family Planning Association of Sri Lanka, I wish your forthcoming deliberations all success and the Family Planning Association of Sri Lanka many years of valuable service.

ADDRESS

MRS. E. C. FERNANDO

Founder Member, Family Planning Association of Sri Lanka

Chairman, the Hon'ble Prime Minister, Hon'ble Ministers, Deputy Minister of Health, other distinguished guests and inveterate family planners, it is not given to every grandmother to see the coming of age of a grandchild ushered in by such an august assemblage.

The accouchement of this grandchild was supported in the nineteen thirties by three volunteers of the Ceylon Social Service League headed by the late Dr. Mary Rutnam and, in the late forties, by some members of the All Ceylon Women's Conference, among them its distinguished President the late Mrs. Ezlynne Deraniyagala, the late Mrs. Meegama and her sister Mrs. Basnayake who continues to be an extremely devoted, reliable and favourite aunt.

A few weeks before the accouchement, expert on-the-spot advice was preferred by an honoured trio no longer with us, Margaret Sanger, Mrs. Dorothy Brush and Dr. Abraham Stone. The accouchement itself was conducted in a very hush hush manner by fourteen persons among them three Past Presidents, Dr. (Mrs.) Abeyratne, Dr. P. R. Thiagarajah and Professor C. C. de Silva who continues to be a tower of strength.

The new baby was kept hidden for a while, though through the efforts of its God-parents including our distinguished President, Senior Officials of the Department of Health and others, the child grew apace.

However, to no one, I repeat to no one, did the infant now grown to adulthood owe more than to our devoted Hony. Medical Director, Dr. (Miss) Siva Chinnatamby. This coming of age ceremony would not have materialised if not for the courage, resolution, optimism and a twenty-four hour devotion of Dr. (Miss) Chinnatamby.

The next few days will epitomise the aims and work of the Association. In 1953 we recognized a problem, we tackled it there and then with what resources we could muster. The growth and development of 21 years has today resulted in the gathering together of expert personnel from Sri Lanka and abroad, who will view the problem, discuss at the highest level what is available or likely to be available for tackling the problem that faces us and finally what the 21-year-old youth is doing about it and will in the future do about it.

To use a Latin phrase *Labor Omnia Vincit*.

KEYNOTE ADDRESS

WORLD POPULATION PROBLEMS

SIR JOHN PEEL

May I begin by saying how very much I appreciate the invitation to attend this important Conference. I understand that this is the first scientific Congress to be organised by the Family Planning Association of Sri Lanka, and appropriately enough, it coincides with the coming of age of the Association founded 21 years ago. I would like to extend my warmest congratulations to the Association for its 21 years of highly successful endeavour, and to bring greetings from the sister organisation in the United Kingdom.

1974 is Population Year, and your Congress theme and scientific programme will be concentrating especially on this aspect of family planning services. That there is an alarming rise in the world's total population needs no emphasis from me. The facts are there for all to see. The world's population is currently growing at the rate of about 2 per cent per annum. There was an increase from 2,500 million to 3,300 million in the 15 years between 1950 and 1965, and the rise has been even greater since. At a 2 per cent increase per annum the population will double in 35 years. These are simple global figures, and in isolation would seem to create a crisis situation demanding urgent and decisive action. However, it is important to remember that there are a large number of variables and constantly changing factors affecting population growth. This makes it extremely difficult to forecast with any degree of accuracy what the population is likely to be in any individual country at any particular date in the future. Population projection statistics are notoriously inaccurate. This is not a criticism of the methods employed, but simply an expression of the fact that certain assumptions have to be made in trying to work out actual figures, and these assumptions may ultimately prove to have been incorrect. As an example, the forecast of population size in the United Kingdom for the year 2,000 A.D. which was made in 1960, put the figure expected

at 63.8 million. The sums were done again in 1965 with certain changed situations, and then the figure was put at 74.6 million. Revision in 1970 quoted 66.1 million and a further estimate made in 1972 leads to the expectation of the population being 62.1 million in the year 2,000. These were official estimates and they reflect the most accurate statistical methods available at the time. The wide variation in the figures serves to emphasise the complexity of the problem of population dynamics, particularly population projections into the future.

Leaving aside the long-term projections, and looking at what has been happening in the past few years and is almost certain to continue into the next few, a striking feature of the global picture is the wide variation in population growth rates in different countries. Those countries which have the most alarming increase in population are the very ones which can least afford to support such increases from the economic and social point of view.

In Europe many countries have annual birth rates now below what is needed for long-term replacement. These countries include the Scandinavian countries, Germany, Switzerland, as well as Austria, Hungary and Czechoslovakia. The United Kingdom is alone in Western Europe at the present time in having active pressure groups arguing strongly in favour of an active Governmental Population Control Programme, and that in spite of the fact that the birth rate has reached the lowest level in the present century. On the other hand, in many of the countries of South America, Africa and Asia, birth rates of 40 and 50 per thousand are still to be found. This means an annual growth rate of population of between 3 and 4 per cent—double the overall world figure.

If we exclude the results of war, famine, pestilence and mass immigration, population growth depends at any time on an excess of births over deaths. Although these factors

cannot be eliminated completely as causes of death in some parts of the world even today we all profoundly hope that this contribution will be a steadily decreasing one. Death rates from natural causes on the other hand, from diseases and epidemics, are likely to fall still further, as medical services improve. With a larger number of people living longer into old age, population numbers would increase even if birth rates remain stationary. Hence, birth rate is the vital factor in determining the rate of population growth in any community.

Apart from actual birth rates, total family size is an equally important indicator of the direction that any population is likely to move, and it is estimated that an average family size of between 2.1 and 2.2 would lead in any country to a stable population. Illegitimate children, though creating a major social problem in developed countries, do not contribute in a very large measure to population growth. Glass estimated that in the United Kingdom they contributed only 2.5 per cent of the total fertility rate.

Many factors apart from birth control as we know it today affect both birth rates and total family size. In the United Kingdom average family size fell from 6 to 2 between 1860 and 1930, and that at a time when legal abortion was performed only for serious medical conditions, when sterilisation was rare, and modern contraceptive knowledge totally undeveloped. What then are some of the factors accounting for this sort of variation in birth rate? First, the steady fall in the perinatal and infant mortality. I think it is true to say that in every country in the world, the greater the chance of a new born infant surviving to adulthood, the lower will be the tendency of the mother to conceive again. With only a few exceptions, large family size tends to correlate with poverty and ignorance, and with high perinatal and infant mortality rates. Put in another way, this emphasises the well documented evidence that reproductive efficiency improves with rise in social class. In the United Kingdom, improvement in infant and prenatal mortality have been due to many factors, including improvement in the health and hygiene of the population at large, and of the young women in particular, to better pre and intranatal

care of the expectant mother, to improved maternity and paediatric services, to the better training of doctors and midwives, and all of these factors are prerequisites to lowering birth rate in any country in the world.

A second factor influencing the fertility of women in the reproductive age group is the number who marry, and the age at which they do so. A slight rise in the birth rate in the United Kingdom took place between 1930 and 1965, after which it began to fall again. This was in considerable measure due to an increase in the number of women marrying (reaching a figure of over 95%), while at the same time there was a steady lowering of the average age of marriage. A third factor is the fashion in family size, which has varied through the ages, and is based upon a variety of social and cultural customs, and ethnic and geographic variables. It is difficult to estimate the contribution that such factors make to population growth or restriction in any country. I would refer those who are interested to a recent paper in the *Journal of Biosocial Sciences* by J. C. Mitchell from the University of Manchester. This not only makes very interesting reading, but indicates how important these variables are in determining population trends in different countries.

Fourthly, birth rates are obviously influenced by attitudes to, the acceptance of, and the effective use of family planning facilities. I mention this last, not because I think it is the least important, but in order to stress that it is not the only factor of importance in reducing birth rates, and so influencing population growth, and I shall refer to this point again later.

Before turning to some of the problems of family planning and population control in the so-called developing countries, I should like to refer to some of the experiences in Europe, because they have direct relevance to these problems, even though the policies which must be put into practice in the developing countries if the avalanche of over-population there is to be stemmed must of necessity be more radical. Most European countries have now achieved birth rates well below 20 per thousand, and even France with its traditional

pro-natalist policies had a birth rate of 17.1 in 1971. Similarly, Italy and Spain had birth rates of 16.8 and 19.6 respectively in the same year. The United Kingdom in 1971 had a figure of 16.2 and in the last 2 years it has fallen to 14.1. The countries of Eastern Europe also have low rates. It is often stated that it is impossible to stop the tide of population growth without the application of liberalised abortion laws, and the full and free application of this service. In the developing countries with a dramatic lowering of the death rates, if population reduction is a prime consideration, a policy of liberalised abortion laws would seem to be an essential policy for governments to adopt. However, low birth rates have been achieved in some of the European countries such as Germany and France without a change in the abortion laws, and in some of those countries that have had such laws in operation for many years, it has been found necessary to reconsider such policies. For example, in Czechoslovakia, recent figures show that nearly 40% of all pregnancies are being terminated by abortion, and a stable population has thereby been achieved for the last decade. However the emphasis now is on the need for some increase in the population, and so restrictions are being introduced over the last 4 years, partly for medical and social reasons, including a very high rate of premature deliveries in subsequent pregnancies, with consequent adverse effect on perinatal mortality and morbidity, and serious imbalances in the age-distribution of the population, leading to a serious shortage of younger men and women to fill the jobs required by the commercial and industrial sectors. Japan has had liberal abortion laws for over 20 years, and has reached the stage of having more abortions than live births 6 or 7 years ago. This led to a fall in average family size to 1.92, well below replacement levels. Both Hungary and Czechoslovakia are now introducing policies designed to encourage larger families, and Japan may have to do the same in the future. In the United Kingdom we seem to be pursuing a rather median course. The birth rate began to fall before the introduction of the Abortion Act in 1967, and has fallen more rapidly since, and now stands at 14.1 per 1,000. In a country with a very much longer tradition of acceptance and practice of contraception, it is unlikely

that the abortion rates will ever reach the high proportions that they have done in some other countries, and at the same time our population will stabilise during the next 10 years. However, without any intention of over-emphasising their importance, it is essential to remember the possible consequences of lowering overall birth rates rapidly in any country with a mixed ethnic, cultural and religious background. Imbalances will inevitably arise, so that those sections of the community accepting the limitation of family size will reduce their numbers in a few decades, at the expense of other sections that will increase. In the very long term this may not matter. Indeed it could be argued that it is a good thing, as immigrant populations would tend to merge with the native population, and often bring with them new ideas, new cultures and new ideologies, which may be for the good of the total community. In the short term however it is important to be aware of the consequences of a too rapid fall in the birth rate in some sections of any community.

From these experiences in Europe, one may draw some tentative conclusions which may be of help when we come to consider the problems of what is now often called the "third world". First, although not essential in all societies, liberalised abortion laws are the most rapid way of reducing the rate of population growth. There cannot be any argument about that, although there are plenty of arguments about abortion from other points of view. Secondly, whether to introduce such laws is a political rather than a medical decision. Thirdly, such alterations in the law are likely to lead in the long run to complications as well as benefits, and like many other political decisions, may require modification in the light of experience. Fourthly, experience shows that contraception and contraceptive services are a far preferable method of reducing birth rates, but they are slower in making their impact. This I think is particularly so when there are many cultural and traditional blocks in the population towards the acceptance of contraception.

The Family Planning Movement in the United Kingdom since the early part of this century, has been motivated more by the ideologies of Marie Stopes and her

Society for Constructive Birth Control and Racial Progress, than by those of the Malthusian League. The latter concentrated its propaganda more on the problem of over-population, whereas the former emphasised the advantages of family planning to the whole family—parents and children alike. The advantages of family size limitation and the spacing of births in relation to the health and welfare of the mother and the children, the educational and recreational opportunities for both, and the economic stability of the whole family and community are now so obvious that it is hard to imagine that opposition could ever have been so vehement, as in fact it was. But these ideologies, so firmly substantiated by experience, have proved the soundest possible foundation on to which to build the family planning structure throughout the country. Built up over the years on a largely charitable and voluntary basis, the whole service is now to be incorporated within the framework of a comprehensive health service, and should in due course form a pattern for some other countries with less well developed services to emulate.

How then, do the developing countries stand in relation to the problems of family planning and population expansion? Asia alone contributes over 60 per cent of the total annual increase in the world's births, whereas Oceania contributes less than 0.5 per cent. Add to this the contributions from South America and Africa, and there is little doubt where the major problem lies. It is a sad and tragic fact that the world is currently divided in regard to both numbers and wealth. Those countries which have the largest number of mankind are also those in which the economic resources are less able to support the ever increasing numbers. If nothing is done in 100 years, the present $3\frac{1}{2}$ thousand million could rise to 50 thousand million, and between 80 and 90 per cent of them would be in the poorer half of the world's surface. I quote here from H. C. Reville: "If birth rates throughout the world can be lowered to between 15 and 20 per thousand per year by about the end of the present century then to continue to decrease slowly for a while thereafter, the Earth's population could level off at less than 10 thousand million by the latter half of the 21st century. The foreseeable resources

and the life support capacity of the Earth, are probably sufficient to allow a moderately high standard of living for this number of people. About 85 per cent of this population would live in presently poorer countries, only 15 per cent would be in today's so called developed countries, the Soviet Union, Japan, the countries of Europe, North America and Oceania. This partition between the rich and the poor countries underlies the essential nature of the population problem in the world. The technological means to solve it exist or can be found. The real questions are political, social and moral. How can the necessary political will, social organisation and ethical concern of all men for each other be developed?"

I think that this statement fairly sets out the problem, and at the same time issues a challenge and sets a target. It is better to have a target modest but attainable, than to have no target at all, or alternatively, to have a target which is totally unrealisable. A recent paper argued in favour of a target aimed at reducing the population of Great Britain to 30 million by the end of the century—a mere 25 years away. This seems impossible of achievement, short of a few atomic bombs, and is likely to bring the whole idea of population limitation into disrepute if it were taken seriously.

Since the end of the Second World War, vast sums of money have been poured into the family planning projects in Asia and to a lesser extent in Africa and South America. This has come mostly from our very generous friends in the United States, and to a smaller extent from other developed countries. In addition, the volume of research into and development of new and better methods of contraception has been quite remarkable throughout the world. Hence, from the technological point of view, we have almost reached the stage in which every unplanned or unwanted pregnancy should in theory be preventable. It was estimated that in India in 1969, a million and a half births were prevented by family planning procedures. This is a most impressive effort. But when set against the fact that in that year over 12 million additional births occurred, the enormous gap between the achievement and the desirable target is very obvious. The situation in

the other parts of Asia must be similar to that in India and in some areas facilities for family planning must be even less advanced. In the African continent the population problem is more variable, and the services in many areas are much less well developed. In some parts of that vast continent enormous areas of land are seriously underpopulated, but the economic development is far less able to sustain the increasing population. Because the numbers were so much smaller initially in the African countries, the problem is far less acute than in Asia, but population growth is at a similar rate and some, at least of the governments concerned, are becoming conscious of the need to provide a family planning service for the population.

Clearly the situation in most of the developing countries is urgent, and it is essential to face the fact that the policies which have been adopted for years in the developed countries, though they have been largely successful, have taken a long time to achieve results. Therefore the methods must be modified in those cases where the needs are far more urgent. Sterilisation and abortion require the services of trained medical personnel, but a great many contraceptive techniques can be taught and dispensed by para medical personnel and even non-medical people. What may be an unacceptable risk in London or New York may unfortunately have to be taken in places where trained doctors are few. A doctor-based service cannot hope to be successful in circumstances where there may be only one doctor in every 20 or 30 thousand of the population, and this is particularly so in areas predominantly rural. What then are the essentials for a successful family planning programme in the countries about which I am speaking? Firstly, to motivate the people to the acceptance and the conscientious and continuing use of whatever method of contraception is advised. Within this context the benefits to the individual and the family that are likely to accrue from limitation of family size, provides the strongest ammunition for motivation. We know that repeated pregnancies at short intervals result in high perinatal and infant mortality, deterioration in maternal health and impairment in the growth and development of surviving children. In the long term this means unemployment, drift from

the rural to urban areas in search of jobs, and emigration to more affluent societies. The consequences of these phenomena are more apparent today than ever before. In the United States the percentage of urbanised population grew from 6 per cent in 1880 to 73 per cent in 1968, with a corresponding reduction in the rural population from 94 to 27 per cent. A similar drift from rural to urbanised communities is happening throughout the world. There is evidence that this phenomenon is, at any rate in part, responsible for many of the social, economic and political problems which are current in many parts of the world. So I emphasise again, that improvement in the medical and nursing services is a first essential, and this can only be achieved in the developing countries by more economic growth or more economic aid from outside. "Transfer of capital rather than people in the reverse direction from rich countries to poor, would go much further towards bringing about economic and social development in the poor countries, and in creating one of the conditions that may be essential for solving the population problems." It is idle to imagine that they can be solved simply by trying to provide family planning services, especially if they are provided in isolation.

Secondly we have to look at the problem of who is to become involved in the motivation, the giving of instruction, and the providing of the services and the follow-up. It has long been my belief that most successful family planning is likely to be achieved when it is practised as an integral part of the maternity and child health services. Within these services the person who has been most ignored everywhere until comparatively recently is the midwife. But it is the midwife who comes most closely into contact with the mother during pregnancy, labour, and with the whole family during the postnatal period. Properly trained and motivated, she is in the best position by far to influence family attitudes, and usually has the full confidence of the mother herself. She can be trained, not only to motivate, educate and advise but also to act, to follow-up and be available for continuing consultation. It has been shown that, in rural areas particularly, the fall-off in all forms of contraceptive usage is high when continuing consultation ceases. There

is as yet no such thing as a "once-for-all" contraceptive which does not require some further consultation and advice, except in the case of those methods which are most unreliable. In many parts of Asia the traditional village midwife conducts 75 per cent of all deliveries, and though she may not be so well trained as her European colleague or those midwives working in the urban areas, she should be a valuable member of the family planning team, intermediate between the fully trained midwife and the traditional birth attendant in the villages; there is frequently the auxiliary nurse-midwife in many sub-centres, and she too can be integrated into the team. I understand that the Indian Government has already trained many thousands of such village midwives in techniques of family planning. The Joint Study Group established some years ago by the International Federation of Obstetricians and Gynaecologists and the International Federation of Midwives has been active in setting up working parties and educational conferences in a number of African, Central and South American countries. All of these have been designed to involve the midwife at all levels of family planning work, and in influencing government authorities into taking appropriate action at local level. It is surprising that this invaluable and ready made labour force has been neglected for so long in this area of the medical service. I think it will pay ample dividends during the next decade.

At present only trained medical personnel can carry out with safety sterilisation and pregnancy termination. There are those who believe that it should be possible to train technicians to perform some of these routine procedures. But if this were to be done, there can be little doubt that complications would increase, which could bring discredit to those ultimately responsible, and might well have an adverse effect upon the attitudes of the population. It is often better to proceed safely even if rather slowly. The possibilities of making skilled and trained medical staff more widely available to the population, especially in rural areas, have been explored, and practised to a limited extent by the establishment of mobile teams, and the setting up of camps in suitable places. In other words, bringing the services to the population rather than

the reverse. This is expensive in both time and money in the short term, but it could prove successful and therefore economic in the long term, and we await the results of these experiments with interest.

One of the many factors influencing national fertility rates is of course, the age of marriage. In Europe it has been estimated that those women marrying under the age of 20 are likely to have a family size of 2.88 on average. Those marrying between 20 and 25, 2.3, and those marrying between 25 and 30, 2.00. In many societies in the past late marriage has received official approval as the most effective means of reducing average family size, and so population growth. It is difficult at present to get reliable statistics from the Republic of China, with its 700 million inhabitants, but the recent account by a visitor to China published in the *Spectrum* makes interesting reading. The main features of this report suggest that now 85-90 per cent of Chinese couples practice some form of birth control, that marriage is illegal for women under the age of 18, that the average age of marriage for women is 25 in urban areas and 23 in rural areas. Further, there is reputedly no problem of pre-marital experience in China today, and figures quoted from the Commune of Tonwan, 40 Kilometers south west of Shanghai, which has a population of 23,000, the birth rate has fallen from 46 per 1,000 to 13.6 in 1971. Lastly this report states that the most popular form of birth control was female sterilisation. The official reasons given for such a vigorous family planning programme, apart from the political propaganda aimed at the need to create the socialist state are:

1. The need to plan births in order to have healthy children and mothers, - emphasis on health.
2. The need to create time during which the mother can study and work - social improvement of women.
3. The need to create the necessary conditions for the best possible education of the coming generation - education and cultural.
4. The need to regulate family size because of its impact upon the domestic economy - economic.

It would be difficult to fault these ideals and even if one accepts these figures with a grain of salt, and realises that it is hardly likely that they can apply to the entire population of China, they signify both the political will and the individual dedication to an ideology. Provided that such achievements can be reached without an unacceptable interference with personal freedom of choice and freedom of action, they seem wholly admirable. To reconcile personal freedom with national and international responsibility and obligation, is one of the dilemmas of the age in which we live. The personal freedom of the individual in relation to reproduction is one of the most prized freedoms in all societies, and interference with it will be resented most violently by all. Nevertheless, we have reached the stage in

the world's evolution in which we have seriously to ask the question whether any longer all individuals have an inalienable right to have an unlimited number of offspring, particularly when it is someone else, usually the state or the community, that will have to shoulder the responsibility of rearing, educating, training and finding employment for those children. The answer must surely lie in both education and persuasion, that what is in the best interest of the community within this context, is also in the best interests of the individual mother, her children, and the whole family unit. When these ideals are universally accepted, only then will parenthood become the really responsible, positive and rewarding experience that it ought to be throughout the peoples of the world.

THEME: WORLD FERTILITY PATTERNS

CHAIRMAN: Prof. D. A. Ranasinghe

**THEME: ROLE OF INTRA-UTERINE DEVICES
IN POPULATION LIMITATION**

CHAIRMAN: Prof. C. C. de Silva

Appropriate Technology Services
121, POINT-PEEPO ROAD
NALLUR, JAFFNA
No. _____

1. THEME: WORLD FERTILITY PATTERNS

WORLD POPULATION AND FERTILITY TRENDS

By

DR. L. SNAITH

Sir John Peel has already indicated the unreliability of population forecasts and fertility trend estimates, referring to experience in Great Britain where widely fluctuating forecasts were made, and some precipitate action took place, during the course of only a few years.

Speculation about the decline and fall of the Roman Empire has suggestions, based on no firm foundation, that as a civilisation develops it becomes effete, and its fertility declines: in the animal kingdom, and especially with regard to sheep, breeding of a selective variety tends to lower fertility. One curious phase in such lowering of fertility appears, in some species at any

number of female children born in Great Britain was the main factor in producing the marked variation in the estimates of population growth already referred to. A prolonged power cut in the U.S.A. some years ago is said to have resulted in a significant rise in the number of births nine months later.

The crude birth rate is not a reliable index of fertility. Even in relation to the crude death rate, it is an inaccurate means of deciding fertility trends, even over a short period, but it does give some assistance. The crude birth rates for certain Western countries between 1967 and 1971 are of interest (Table 1).

TABLE 1
CRUDE BIRTH RATE FOR WESTERN COUNTRIES

	1967	1971	
United Kingdom	17.7	15.1	Abortion Act + contraception.
France	17.0	17.1	Late effect of World War II and no Abortion Act.
Finland	16.6	13.1	Gross upswing in post-war years, now stabilising with contraception and sophistication.
Hungary	14.6	14.5	Abortion freely available. Reproduction rate below 1.0.
Germany	17.2	12.8	Similar reasons to those of Finland.
U. S. A.	17.8	17.3	Decrease slight, because of baby-boom children entering reproductive ages.

rate, to be accompanied by an increased tendency to multiple births, perhaps as an attempted biological correction of the decline in absolute fertility.

But other factors come into the picture apart from the incidence of starvation, wars and pestilence. Such factors directly affect both human and animal total populations: starvation tends to lower actual fertility, as do certain diseases. More important, human reaction, to war especially, alters breeding and therefore fertility rates. Failure to allow for the ultimate results of the sudden increase, in the post-war year or two, in the

The papers in the July 1973 issue of *Population Studies* give age specific fertility rates (ASFR) in Barbados and Malta over 10 years: in Barbados, age specific fertility rates show a decrease in all groups, three of which are shown in Table 2.

TABLE 2
AGE SPECIFIC FERTILITY RATES (BARBADOS)

Mean of years	Age 15-19	Age 25-29	Age 40-44
1961-65	110	181	35
1966-70	94	133	30

It is most unlikely that much of the decrease for ages 25-29 can be attributed to a decrease in the proportion married, though a more specific answer could be given if age specific marital fertility rates (ASMFR) were used. Barbados is not typical of a developing country as its Family Planning Programme has been particularly successful.

The age specific marital fertility rates for Malta are shown in Table 3.

TABLE 3

AGE	SPECIFIC MARITAL FERTILITY RATES (MALTA)	1948	1957	1967
Under	Age			
	20	529	524	528
	20 - 24	495	439	340
	25 - 29	400	324	224
	30 - 34	316	224	137
	35 - 39	233	152	75
	40 - 44	88	60	28

It is remarkable that there has been no decrease whatsoever for the under 20 group while there has been a substantial decrease for all the older age groups despite continued strong Church opposition to artificial contraception measures. The rates may have included illegitimate births in the numerator and only married women in the denominator. Interesting findings based on a 1971 Family Planning survey show that at ages 20-25, 67% of women were already practicing contraception, including 6% starting before any live birth, and 40% after only one birth.

In the Latin American countries where there has been a strong family planning effort, as in Costa Rica, a highly literate country, there has been a marked decline in fertility, whereas in backward countries, such as Haiti, Honduras and Bolivia there has probably been very little decline, though no firm data are available.

In the developed countries fertility has generally shown a steady downward trend. One exception is Romania, where the prohibition of abortion in 1966 after many years of permission, caused a marked increase in fertility in 1967, though fertility has subsequently decreased. In the U.S.A., Japan and most of Continental Europe,

fertility has declined to a point when the net reproduction rate is now around 1.0 or less. This does not mean that there are fewer births than deaths or that these countries are not displaying a natural population increase, but in the long run a continuance of the combination of age specific fertility rate and mortality rate resulting in a net reproduction rate of less than 1.0 must result in an actual population decrease, possibly in 50 or more years.

In the U.S.A. while fertility rates have declined steadily since 1957, it was believed that by the 1970s even with a continued decline in these rates, the crude birth rate would rise because of the baby boom children born in the 1950s moving into their reproductive ages. Actually, except for one year, nothing of this kind has occurred and not only the crude birth rate, but also the annual number of births are still decreasing.

One of the factors has been an increase in marriage age and possibly less marriages. A second factor is the legalisation of abortion, first by individual States, such as New York since 1970 and more recently a Supreme Court decision applying nationwide, that virtually assured abortion on demand in the first trimester. A third factor is the reported increase in vasectomies. The Association for Voluntary Sterilisation estimates that there are now, and have been for the last few years, about one million vasectomies a year in U.S.A. many prompted by fears about the pill.

The estimate may include a large backlog of vasectomies - so the figure cannot be assumed to remain constant. But if one can expect that there will be a steady stream of vasectomies amounting to only half a million a year, at an average age of 37, over 40% of all men will be having vasectomy while their wives are still in the reproductive age group. Add to this the number of women having sterilisation, contraceptive and therapeutic, and we see that a majority of American couples may be resorting to some form of sterilisation during their reproductive years.

Two recent papers compare the fertility of Taiwan, Korea and Sri Lanka. The first, by Freedman, Hermlin and Sun in the April-June 1972 issue of *Population*

Index compares the 1961-68 fertility declines of Taiwan and Korea, and the second, by Dallas Fernando in the November 1972 issue of *Population Studies*, compares the 1963-69 decline of Taiwan and Sri Lanka. Apparently, all three countries had fairly steady fertility declines in the 1960s, but early in the decade Sri Lanka had the lowest fertility. Taiwan the median and Korea the highest. Later in the decade, the total fertility rates were virtually identical in the three countries. This means that Korea had the most rapid decline, and Sri Lanka the slowest. Unfortunately, not all the figures are available for comparison but some comparison can usefully be made (Table 4).

TABLE 4
TOTAL FERTILITY RATES

Year	Korea	Taiwan	Sri Lanka
1961	6.05	5.61	n.a.
1963	n.a.	5.35	5.01
1968	4.24	4.33	n.a.
1969	n.a.	4.13	4.23

n.a. = not available.

Analysis of the components of fertility decline in the three countries indicates that in Sri Lanka, it was due primarily to a marked decrease in the proportion married at an early age, with an actual increase in marital fertility at ages under 25 and only a moderate decrease in marital fertility at the older ages. In Taiwan the same situation obtained at ages under 25, but the decline in marital fertility at the older ages was much greater. In Korea, however, not only was there a decrease in the proportion of married among the younger age group but also a decrease in marital fertility at all ages, particularly at ages under 20.

The low fertility rates at the younger ages in Korea are said to result to a considerable extent from a high rate of induced abortion. In Taiwan most of the reduction in fertility is due to the IUCD so that very little reduction would be expected for nulliparous women. In Sri Lanka, there has been an increasing, proportionate use of oral contraceptives, but so far as we have seen there has been very little acceptance of any method by nulliparous women, only 1% of new acceptors under the national programme being nulliparous though there may be a higher percentage, if consideration is given to coverage outside the programme.

CONTRACEPTION WITH INTRAUTERINE COPPER DEVICES

By

DR. J. ZIPPER

INTRODUCTION

General importance of copper as a physiological element

The presence of this trace element permits the adequate synthesis and function of at least seven well defined copper proteins with specific physiological properties that have been isolated from human tissues. These are: cerebro-suprein I, caeruloplasmin, cytochrome C oxidase, erythrocuprein, haemocuprein, copper protein of liver (CuLP) and tyrosinase¹.

The effects produced by copper deficiency have been demonstrated in animal species². In cattle and sheep a deficiency occurs through shortage of this element in the food ingested or through contamination with other trace elements that specifically compete with copper. The most important of these are molybdenum and zinc.³

Experimental copper deficiencies have been induced in several animal species. The pathology caused by these deficiencies includes.

1. Alterations in the haematopoietic system. Iron absorption and utilisation are altered. Anaemia and decrease of cytochrome oxidase activity have been described.^{4,5} There is evidence that caeruloplasmin, a plasma protein, is the link between copper and iron metabolism and is related to the rate of formation of Fe (III) transferrin and haemoglobin biosynthesis⁶.
2. Development of a demyelinating disease due to a defect in phospholipid synthesis biochemically manifested as an abnormally low capacity to couple coenzyme A - activated fatty acids to glycerophosphate.
3. Loss of wool, crimp and achromotrichia. The first due to a defect in the cross-linkages of keratin and the

second due to a low concentration of the copper containing tyrosinase. None of these alterations described in animals have been observed in the human, although it is known that in certain conditions there appears a decrease in the serum copper^{7,8}.

On the other hand copper toxicity has also been studied.

Natural chronic toxicity in sheep produces anaemia with haemolytic crises and marked hepatic alterations⁹. Fish, experimentally intoxicated with copper, show neural and renal degeneration¹⁰. In humans, the only pathological condition associated with copper intoxication through excessive tissue deposit is an autosomal and recessively inherited disease called Wilson's disease, in which the copper concentration in some tissues reaches much higher levels than normal. Caeruloplasmin synthesis is also altered in this illness, although all the other cupro-proteins remain normal. The function of this protein is to bind the copper of CuLP and then excrete it principally in the faeces. Lack of this protein makes copper penetration into the cells easier, which after some years, produces the excess of tissue copper and therefore the characteristic pathology of Wilson's disease.

Known physiological mechanisms that regulate the concentration of copper and other related trace elements

Plasma and hepatic copper are regulated by the hormones of the pituitary-adrenal system. Both values seem to be increased after hypophysectomy or adrenalectomy⁶.

Experiments performed in monkeys indicate that low doses of copper, 1 mg/kg body weight, stimulate caeruloplasmin synthesis while higher doses depress this. Oestrogenic and progestational action has been investigated in relation to copper metabolism.

The phenomenon of plasma copper increase during pregnancy has been known since 1928¹². In 1961, zinc was found to be depressed in this physiological state¹³. This increase in plasma copper and depression of zinc is also found in women taking oral contraceptive pills. Experimental studies in rats indicate that the oestrogenic compound mestranol produces plasma zinc depression. Norethindrone, the progestational compound does not produce this change¹⁴. Zinc uptake is increased in the liver, spleen, adrenals and uterus in rats treated with mestranol.

Experimental zinc intoxication in the rat, causes a sudden decrease in plasma caeruloplasmin that precedes the appearance of anaemia. Ceruloplasmin values can be partially restored by injecting copper¹⁵.

Biological action of intrauterine copper

The importance of the role described for the ovarian hormones, oestrogen and progesterone in the metabolism of plasma and tissue copper and zinc suggests that the excess of some of these metals might play a role in the normal physiology of the target organs of these hormones. In fact, ovulation has been experimentally produced in some animal species^{17,18} by injection of copper. In all the animal species studied up to now, the presence of copper cations in the uterine cavity produces marked effects on fertility^{19,20}. Even metals of high toxicity produce less contraceptive effectiveness than copper²¹, suggesting that the effect induced by this metal is highly specific. Studies performed by Hagenfeldt *et al*⁵ to determine the concentration and variation of certain trace elements in the normal human endometrium during the menstrual cycle, demonstrated that the zinc concentration is increased in the late secretory period and that copper concentration is increased in the whole secretory period. Manganese concentration is very high in the early proliferative, exceeding that of all the other phases, and sodium and potassium cations are in a higher concentration in the proliferative than in the secretory periods.

The concentration of copper and zinc cations in the endometrium, cervical mucus and serum in women users of a copper contraceptive device has also been investigated during the menstrual cycle and for a

period of one year of use. The conclusions can be summarised as follows: "The endometrial copper concentration was increased during the time with the Cu-T *in situ*: the maximal concentration in the proliferative phase was found 2-3 months after the insertion of the Cu-T."

Values became normal after the extraction of the device. The endometrial zinc levels showed a significant decrease (16.9 $\mu\text{g/g}$) from the pre-insertion values (21.3 $\mu\text{g/g}$) when biopsies were taken following 11-12 months of continuous use of the Cu-T device. No significant changes were found in plasma copper and zinc levels or in the zinc concentration of the cervical mucus during one year of intrauterine contraception with Cu-T.

Histochemical copper determination in the uterine mucosa and its location in the different morphological components in intrauterine device users has been investigated in our laboratory by Salaverry *et al*² using the rubeanic acid technique. Conclusions are that:

1. With this technique it is impossible to detect copper in the uterine mucosa of non-users of intrauterine copper devices or users of plastic devices.
2. Copper was not detected in the proliferative phase of the menstrual cycle in users of Cu devices, yet it was always present in the secretory phase.
3. The highest quantities of copper were observed in the cells of the glandular epithelium and, in a descending order, in the haemopoietic tissue and chorion.
4. Copper was no longer present in the uterine mucosa seven or more days after the extraction of the copper device, which was performed on the 14-16 day of the cycle. This demonstrated the rapidity with which this metal is eliminated from the mucosa.

Experiments aimed at determining the reversibility of the contraceptive action of copper, zinc and nylon in the rat and rabbit, performed by our group are consistent with this last finding¹. The device was removed 1-3 months after insertion in the second

day of pregnancy in the rat and in the third in the rabbit. No differences were found among the three types of devices studied as regards fertility recovery. The conclusion was that a permanent release of the cations was necessary to maintain the contraceptive action.

Aedo and Zipper¹² studied the effect of copper or nylon devices on radioactive oestrogen or progesterone uptake by the uterus of spayed rats. Results indicate that the uptake of oestradiol 17B-6, 7-H³ in tracer doses is significantly increased in rats inserted with a copper device in one of the horns, when compared with groups of rats, inserted with a nylon device in one of the horns, or in controls without any device. Progesterone 1, 2-H³ uptake, however, does not show significant differences in similar experimental groups, both in animals previously stimulated with oestrogen and in non-stimulated animals. In all the groups previously treated with subcutaneous oestrogen, 5 µg for three days, progesterone uptake is significantly increased when compared with those not treated with oestrogen. The fact that progesterone uptake is not increased in animals wearing an intrauterine copper device and not stimulated with oestrogen, indicates that in spite of the fact that copper facilitates oestrogen uptake (in tracer doses), it does not facilitate progesterone uptake, so it cannot be considered as an oestrogen *per se*.

The role of intrauterine copper in the development of improved intrauterine devices

It has become obvious from extensive clinical studies sponsored by the Population Council, that it is no longer as promising as was once thought, to make intrauterine devices of biologically inert materials using different shapes to improve clinical performance. In fact, it is questionable whether any of the new plastic devices, beginning with the Lippes Loop, have offered better continuation rates than the original Grafenberg device. Wheeler and his colleagues, analysing the physical characteristics of many devices and comparing them to the biological results, demonstrated clearly that removals for medical reasons, pregnancies and expulsion were dependent on the physical properties of the inert materials used. Size, surface area and stiffness of the device were of the utmost importance.

A device with a greater surface area would always offer a lower pregnancy rate and a higher removal rate because metrorrhagia, and the expulsion rate of every device developed until then was inversely related to its stiffness. Further, if stiffness was increased, expulsion decreased but metrorrhagia increased. Thus, the physical and biological properties required to obtain an optimal contraceptive result with low metrorrhagia and low expulsion rates were intrinsically opposed. The "inert" intrauterine devices, because of these limitations, have failed to give continuation rates which differ significantly.

The deficiencies of the "inert" IUD led us to formulate a new system of intrauterine contraception. This method depends upon a material which would act locally within the uterine cavity, and a carrier for the material, which in itself would minimally disturb the uterus. We have considered a number of agents which could inhibit fertility when used locally in the uterine cavity. These included cytotoxic agents, hormones and most important, compounds which might interfere with endometrial enzyme systems. In this last group, trace elements were thought to be of great interest. Of these, our animal studies showed that metallic copper had the highest activity and would provide a reservoir for prolonged effectiveness.

Intrauterine contraception is equivalent in concept to topical therapy in other parts of the body such as on the skin or the eye, in that the desired therapeutic effect, in this case fertility control, is accomplished using a drug by local application to the site where maximum drug concentration is needed to produce an optimal effect. Topical therapy permits overdosage at the site of treatment with a reduced chance of involving other structures. Topical therapy in the endometrium has another advantage as it is a naturally cycling tissue which sloughs and regenerates on an approximately monthly basis.

The introduction of this concept of intrauterine contraception by our group has shown that it is possible to separate the effectiveness of an IUD from its size and surface area. Since certain adverse effects such as uterine cramping and pain,

spontaneous expulsion of the device and in some cases, vaginal bleeding are also directly related to intrauterine device size, it has also become possible to decrease the incidence of adverse effects while maintaining high contraceptive effectiveness.

In our first clinical trials²² we inserted into the uterine cavity of women, various amounts of copper wire wound upon a small plastic "T" shaped carrier, which by itself afforded very little fertility protection (about 20% failure in one year). We found that the antifertility effect of the metallic copper ions being released from the metal surface and from oxidative products of copper thereon were responsible for the antifertility action. This was brought out further by experiments using metallic copper and zinc closely wound together on the same carrier.

We have shown that intrauterine copper contraception can achieve a high order of effectiveness, approaching a 1% failure annual rate. In addition, because of the smallness of the carrier, minimal distortion of the uterine cavity is produced, resulting in a decrease in the incidence of spontaneous expulsion, bleeding and pain.

Despite these benefits in patients acceptability, clinical experience has shown that this contraceptive system using metallic copper could be improved. In the first place, the T-shaped device (the carrier) has a cross sectional diameter when folded for insertion into the uterus, which can make introduction through the cervix sometimes difficult. This is not an uncommon situation in nulliparous women, in whom local intrauterine contraception would be particularly indicated. This has led to the development of the "7" shaped device, which has at least a 50% reduction in cross sectional diameter when folded for insertion as compared to the 'T' carrier.

The clinical contraceptive effectiveness two copper carrying IUDs, the T and the 7, with comparable plastic composition and surfaces, to which copper was added by means of a wire wound to the vertical arm, have been extensively analysed in several publications^{20,22,23}. These studies have shown that by increasing the copper

surface the pregnancy rate decreases. Nevertheless, 100% effectiveness has not been achieved.

Using our clinical data Gibor *et al*⁴ developed a mathematical model to predict the theoretical contraceptive efficacy of even larger copper surfaces. In their work they concluded that above 200 mm² of intrauterine copper, larger copper surfaces result only in slight decreases in pregnancy rate.

In this communication we will discuss the limiting factors of copper as an intrauterine contraceptive as we did before with inert IUDs. We will focus our attention on the following clinical parameters; pregnancy, expulsions and bleeding. The duration of the contraceptive activity of the wire will also be considered.

MATERIAL AND METHODS

The women studied were of proven fertility and belonged to the Northern and Southern Health Areas of Santiago, Chile. Two vectors were used, the T and the 7. Both have been previously described. Insertions were made post-menstrually according to the general rules for IUD insertion. As usual, copper was added as a copper wire of 0.2 mm in diameter wound around the vectors. The total copper surface added was carefully calculated in each experiment. In the case of the T, the winding always started at the union of both arms and then downward on the vertical arm. Winding on the 7 was done either on the vertical, the horizontal or on both arms.

The following groups of women were studied with the T vector:

1. T alone 611 women. Referred to hereafter as T alone.
2. T plus copper 30 mm², 279 women. Hereafter T 30.
3. T plus copper 120 mm², 362 women. Hereafter T 120.
4. T plus copper 200 mm², 846 women. Hereafter T 200.
5. T plus copper 340 mm², 345 women. Hereafter T 340.

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The following groups of women wearing the 7 vector were studied:

1. 7 plus copper 200 mm² wound on the vertical arm, 554 women. Hereafter 7-200v.
2. 7 plus copper 200 mm² wound on the horizontal arm, 789 women. Hereafter 7-200h.
3. 7 plus copper 250 mm², 200 mm² on the vertical arm and 50 mm² on the horizontal one, 227 women. Hereafter 7-250.
4. 7 plus copper 300 mm², 200 mm² on the vertical arm and 100 mm² on the horizontal one, 330 women. Hereafter 7-300.

Studies with the T vector allowed us to determine the influence of increasing intrauterine copper surfaces upon fertility, expulsion of the vector, and relevant adverse effects such as bleeding and pain. Studies with the 7 vector allowed us to study the influence of similar parameters when the copper wire was placed near the area of implantation, that is in the upper portion of the uterus.

Clinical data obtained on different groups have been analysed by the life table method following the indications of Tietze. We now have data after three years of experience with the T 200 and the 7-200v devices.

Our results seem to confirm the theoretical analysis made by Gibor *et al*⁴. The contraceptive effectiveness of intrauterine copper added to a vector is optimal around 200 mm². When the copper surface area was increased further, no significant decrease of pregnancy rate was observed.

Expulsion rates for a given vector change in relation to the copper surface and the localization of the metal inside the uterus. A minimum expulsion rate was observed when the copper was located in the medial, vertical region of the uterine cavity. As copper gets near the implantation area, as in the case of the 7-250 and 7-300, the rates of expulsion increase when compared to the 7-200v, suggesting a change in the uterine motility pattern. When copper is wound on the vertical arm, the optimal

surface to minimise expulsions in a specific vector is 120 mm² (T120). The unpublished experiments with rat uterus in vitro by Verdugo and his colleagues demonstrated that the copper and the zinc have a clear effect on the uterine motility: copper activates it and zinc inhibits.

The analysis of three years of use of the T 200 and the 7-200v devices clearly demonstrates that the contraceptive activity of copper continues over the entire observation period. Rates of expulsion and bleeding tend to decrease gradually during the second and third year.

The limiting factors described may perhaps also be applied to other pharmacological agents used as intrauterine contraceptives carried by intrauterine vectors.

Both T 200 and 7-200v devices have shown identical clinical performance.

Although this experimental series delimits precisely the clinical effectiveness of copper-carrying IUDs, new pharmacological possibilities could be open in the future to improve intrauterine contraception. At the present time, we are experimenting with new types of metals.

In relation to time-effectiveness of intrauterine copper, Hagenfeldt²⁴ and the Battelle group²⁵ have performed important studies in this line, essentially with a copper wire, 0.2 mm in diameter. The conclusions of the Battelle group for the Cu 7-200 are:

"Average corrosion rate: 14.5 ± 5.3 microns/year and 55 ± 18 μ g/device/day. A linear extrapolation leads to the prediction of 50% penetration in three years. This assumption is conservative in regard to the penetration rate, since the rate decreases with time²⁵."

The clinical data obtained with our experience in 36 months of the Cu 7-200 use, indicate that the pregnancy rate for the first year is 2.2, the same as for the third year. So, it is likely that the device will maintain its total effectiveness for at least 4 to 5 years. A slight increase in the diameter of the wire from 0.2 to 0.25 mm will provide us with a device that will surpass 10 years use with total effectiveness.

With the available data on T Cu and Cu 7 published up to now in regard to the quantity of copper and its contraceptive effectiveness, Gibor *et al*⁴ have developed a mathematical formula that shows that the active surface of the 200 mm² of copper would have to be considerably increased to obtain a slight decrease in the pregnancy rate of the first year. These data were obtained using copper in the vertical arm. Our experimental evidence, that the location of copper and other active materials is fundamental in its performance, can modify this hypothesis.

MECHANISM OF ACTION

All the evidence indicates that the mechanism of action might be centred on the modification of the uterine mucosal and sperm physiology^{1,11}. Unpublished results of Medel and his colleagues indicate that no sperms are found in the tubes of women wearers of copper devices. This phenomenon is not observed in the rat or rabbit. Blastocysts do not seem to be affected by the released copper since they

can be recovered and transplanted following a normal embryological development. In human pregnancies that reached term with the device *in situ*, no pathological alterations were observed in the newborn.

We can conclude that the mechanism of action of intrauterine copper is a biochemical change in the endometrial physiology, since no morphological changes have been found in the uterine muosa. These biochemical changes could be the following:

- (a) Partial inhibition of the zinc dependent enzymatic systems of the uterine mucosa.
- (b) Active uptake of the copper released by the device during the secretory phase of the menstrual cycle and its concentration and excretion through the secretory vacuole, producing an inhibition of the enzymatic systems present in the uterine milieu and necessary for implantation.

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IUD PERFORMANCE PATTERNS: LIPPES LOOP D, COPPER-T AND M-DEVICE

By

DRS. ROGER P. BERNARD *and* ELTON KESSEL

INTRODUCTION

Several years of research and testing have now elapsed since the beginning of the era of the "second generation IUDs" in the late 1960's. At that time it had become increasingly clear that optimal performance of conventional, inert "first generation IUDs" is impaired by three major problems pertinent to IUD performance. These problems are:

1. failure in pregnancy prevention,
2. failure in retention, and
3. the necessity for removal as a consequence of bleeding and pain.

During that time, two major thrusts in IUD experimentation could be observed. One was research to improve the mechanical characteristics of inert devices which would affect such parameters as surface, rigidity, thickness and position assumed in the uterus, anticipating that characteristics of the device might affect one or more of the three pertinent events. Another was research pertaining to certain elements and compounds capable of possible interference with implantation of the fertilized ovum or sperm migration. In sum, to optimize the inert device was one goal; experimentation with bioactive adjuncts was the other.

Methods

This report compares the performance of two second generation IUDs—the Copper-T and the M device—to the Lippes Loop, considered a standard for inert devices. Loop D baseline data are drawn from the Cooperative Statistical Program (CSP) of the Population Council, New York¹ and the International IUD Program (I-IUD-P) of the Pathfinder Fund, Boston². The CSP baseline data are pooled from many clinics. By contrast, the I-IUD-P data

comprise the Ljubljana baseline data from the Family Planning Institute in Ljubljana, Yugoslavia. The Copper-T data are from the Population Council and the M-device data are from the Family Planning Institute, most recently computed by the International Fertility Research Program (IFRP) of the University of North Carolina at Chapel Hill.

Comparisons are based on rates of the three pertinent events³ significant for evaluation of new IUD designs:

1. pregnancy,
2. first expulsion, and
3. removal for pain and bleeding.

The rates are computed according to the multi-decrement life table approach⁴ for first segment only, which restricts analysis to the first intervening event. Gross cumulative rates are used, as they permit evaluation of each pertinent event irrespective of other competing risks. Net rates are more appropriate for deriving program performance, as they are additive, enabling the calculation of event rates that determine continued use of a given IUD.

The Devices

The development of each of the experimental devices—Copper-T and M-device—started with different hypotheses. The Copper-T⁵ focused on the effect of copper ions on pregnancy prevention, and the M-device⁶ focused on a "fundal seeking" design to reduce expulsions.

The Lippes loop is formed in a double-S shape of polyethylene containing barium sulphate. It is the present standard used in most family planning programs around the world.

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The Copper-T is a T-shaped polyethylene device containing barium sulphate for X-ray visualization. Secondary hypotheses in its design were that its transverse arm would fit the fundus of the uterus and be held in place there, and that its low mass would cause minimal irritation to the endometrium and result in fewer symptoms of pain and bleeding. The plain-T was an excellent choice to test the effect of copper because the device had a remarkably high pregnancy rate. Early and small clinical trials quickly demonstrated that copper reduced pregnancy rates—the rate dropping with increasing surface area of copper to 200 mm². Trials of the plain-T were discontinued before the effect of copper on expulsion and removal rates could be definitely evaluated. Zipper⁷ has shown some effects on these two pertinent events by varying the amount of copper and by varying the copper placement on the T-device.

The M-device is a medical grade stainless steel band formed in the shape of an M. Its fundal seeking principle was based on the hypothesis that a uterine contraction at the fundus would cause the legs of the M to spread and thereby resist expulsion. A contraction of the lower uterine segment would tend to push the device toward the fundus of the uterus.

The pregnancy rate of the device was thought to be possibly related to the width of the steel band. Increased bleeding was not anticipated, despite the narrow metal band, because the lateral spring action of the device would "give" with uterine contractions; little pressure would be exerted in the anterior-posterior plane of the uterus to cause embedding of the device in the endometrium⁸.

All three devices are inserted using plastic tubular inserters. For the Copper-T and M-device, the inserter is passed to the fundus of the uterus like a sound and the tubular outer sheath then withdrawn to release the device at the fundus. The Lippes loop is pushed out of the inserter after it has passed the internal os of the uterus.

Analysis of data

Table I gives an overview of one year rates for the three devices, including blind controlled comparisons of 200 mm² (TCu-200) and 300 mm² (TCu-300) surface areas of copper on the Copper-T, and two widths of the steel band of the M-device—M-211 being broad (2.67 mm) and M-213 being narrow (2.36 mm).

Rates of removal for pain and bleeding vary between centres in the loop D data.

TABLE I

ONE YEAR GROSS CUMULATIVE RATES OF PERTINENT EVENTS PER 100 WOMEN, BY PLACE and DEVICE
1964 - 1973

1 YEAR	USA-CANADA [multi-center]			YUGOSLAVIA [single-center]					
	BIOACTIVE DEVICES			INERT DEVICES					
	TCu-200		TCu-300	LOOP D				M-211	M-213
	BLIND CONTROLLED			AGE PARITY				BLIND CONTROLLED	
					AGE 25 or 0-1	26+ and 2+			
				low	high				
PREGNANCY	3.2	3.1	2.4	2.9	4.1	5.0	3.6	2.4	3.4
EXPULSION	9.8	12.3	10.7	9.9	16.6	25.7	> 10.4	0.5	0.6
BL/Pn REMOVAL	8.8	11.9	10.7	12.1	4.3	6.3	> 3.0	5.4	5.2
Women	6,733	1,848	1,931	7,553	506	= 213	+ 293	457	384
Woman Months	71,812	10,542	11,102	66,777	5,120	= 1,959	+ 3,161	4,501	3,873
	1971-1973			1964-1970	1964-1969			1968-1973	
								CH 18 11 73	
IUD Generation	SECOND			FIRST				SECOND	
Reference:	17	17	17	1	2	2	2	6	6
Release Place:	Seattle			New York	Dubrovnik			San Francisco	
Release Date:	10-1973			7-1970	10-1969			11-1973	
Source:	C. Tietze			C. Tietze	R.P. Bernard			L. Andolsek	

The aggregate data of the Cooperative Statistical Program (CSP) are similar to the high age/parity group (women aged 26 and over with 2 or more live births) of the Ljubljana baseline data, with which they are more appropriately compared. The markedly lower removal rate for pain and bleeding is characteristic of this centre for nearly any device tested. These centre effects stress the need for carefully conducted blind controlled trials as well as the need for age and parity adjustment in comparing uncontrolled studies.

For the Copper-T, the two areas of copper give similar results and these are also similar to results of loop D in the CSP. A slight improvement in pregnancy rate is suggested for TCu-300.

with the M-211 is confirmed. The low expulsion rate of both variants of the M-device still holds. Removals for the M-device are now slightly increased over loop D in the Ljubljana baseline data.

The available data on performance patterns of the three devices up to four years are summarized in Figure 1, which compares the two second generation devices' performance with the U.S. loop D standard. Pregnancy rates are similar for all three devices. By contrast, a marked device effect^{9,6} is associated with expulsion rates. The risk of expulsion for either Copper-T or loop D is in excess of 20 times that for the M-device. Although the removals of the M-device appear to be only half the rate for the Copper-T and loop D, these differentials

TABLE 11

TWO YEAR GROSS CUMULATIVE RATES OF PERTINENT EVENTS PER 100 WOMEN, BY PLACE and DEVICE
1964 - 1973

2 YEARS	USA-CANADA [multi-center]				YUGOSLAVIA [single-center]			
	BIOACTIVE DEVICES		INERT DEVICES					
	TCu-200		LOOP D				M-211	M-213
	AGE-PARITY ADJUSTMENT		AGE-PARITY				BLIND CONTROLLED	
PREGNANCY	5.7	6.1	5.5	4.9	6.3	5.7 * 6.5	4.7	7.8
EXPULSION	12.9	13.0	14.3	12.1	20.6	31.6 > 13.3	0.5	0.6
BI/Pn REMOVAL	17.8	17.1	20.5	19.0	6.4	9.1 > 4.7	9.3	8.2
Women	6,733	6,801	7,419	7,553	506	= 213 + 293	457	384
Woman Months	85,113	52,133	105,199		9,455	= 3,464 + 5,991	8,510	7,237
	1971-1973		1964-1970		1964-1969		1968-1973	
IUD Generation	SECOND		FIRST				SECOND	

Reference:	17	17	17	1	2	2	2	6	6
Release Place:	Seattle		New York		Dubrovnik		San Francisco		
Release Date	10-1973		7-1970		10-1969		11-1973		
Source:	C. Tietze		C. Tietze		R.P. Bernard		L. Andolsek		

For the M-device, the M-211 appears to have a lower pregnancy rate than the M-213. The expulsion rate of the M-device is considerably lower than that for the Copper-T or loop D. Removals for bleeding/pain of the M-device are similar to those of the loop D in the Ljubljana baseline data.

are assumed to be mainly due to the centre-effect associated with the Ljubljana centre.

In sum, the only significant gain demonstrated in this comparative analysis is the M-device's superior retention.

Discussion

The contraceptive effect of copper ions was well documented in early trials comparing plain and Copper-T devices¹⁰. It appears, however, that the low contraceptive performance of the plain T cannot be

Two year rates for the three devices are shown in Table 2. The similarity of the TCu-200 to loop D is confirmed in this age/parity adjusted analysis. The higher pregnancy rate of the M-213 as compared

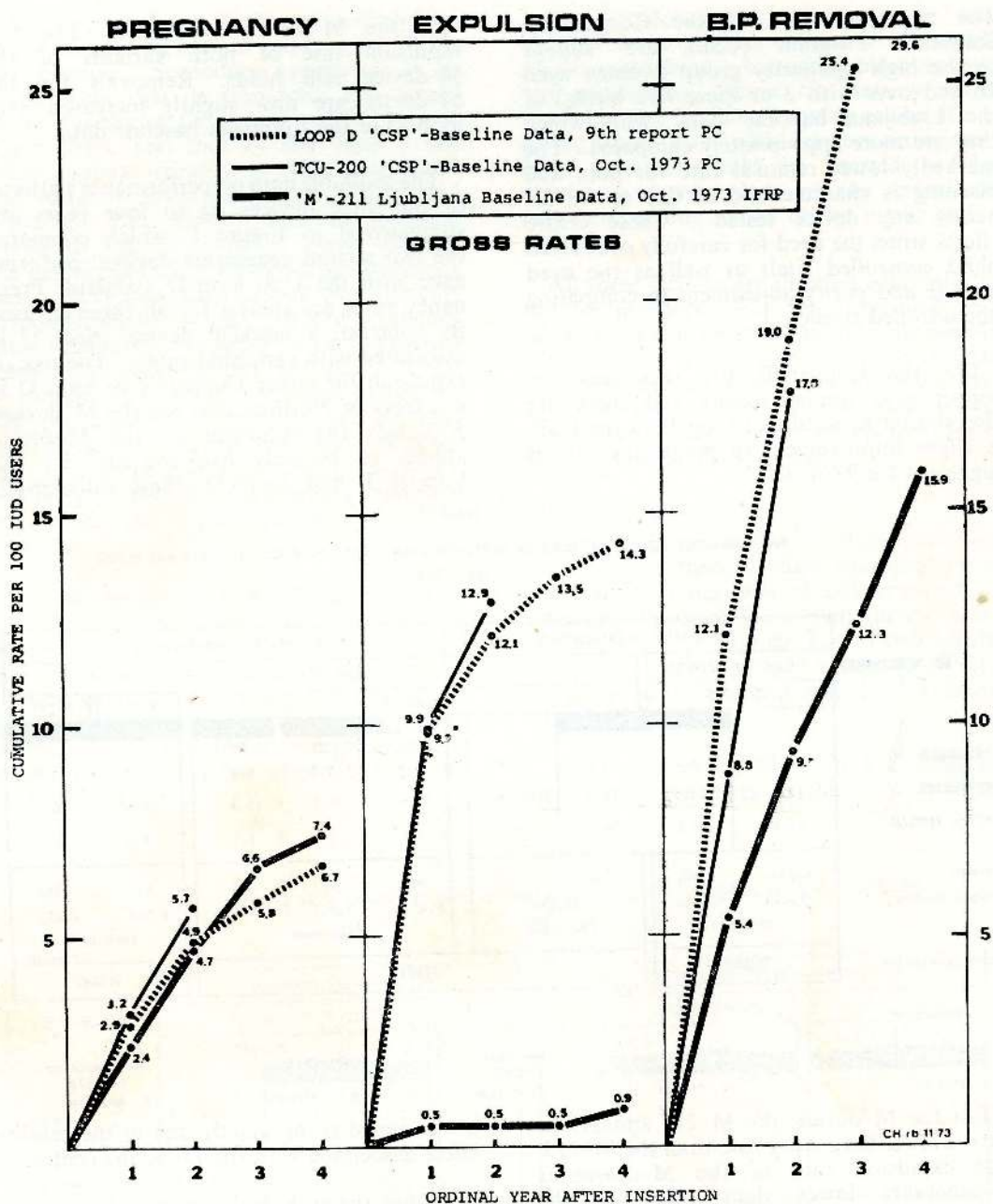


FIG. 1. Performance Patterns of Three Selected Intrauterine Devices, by Pertinent Event. Loop D (Ref. 1) TCU-200 (Ref. 17), and M-211 (Ref. 6). Gross Cumulative Rates per 100 IUD Users. USA and Yugoslavia, 1964-1973.

entirely overcome by addition of copper to this carrier. The TCu-200 performance is similar to that of loop D. The recommendation that copper devices be surgically removed in the occasional perforations of the device¹¹ is one disadvantage compared to loop D.

The rate of dissolution of copper¹² decreases over time, while pregnancy rates appear to be constant over the first two years of use. The exact duration of efficacy of the original load of 200 mm² copper surface of the TCu-200 is not yet known. The effect of fragmentation of copper wire has not been evaluated.

The hypothesis concerning adaptation of the T-device to the uterine cavity may only partially account for its retention. Part of its retention may be related to embedding of the transverse member of the T into the endometrium and myometrium¹³. The low mass of the device has not improved bleeding and pain removal rates as compared to loop D.

There is increasing evidence to support the "fundal seeking" hypothesis given for retention of the M-device. Reports of difficult removals in some centres using earlier prototypes suggested that the mechanism of retention might be embedding, but this has only occasionally been a problem in the Ljubljana study.

The width of an IUD as a hypothesis to explain efficacy gains support from the different results of the two M-device variants. This width-effect may be more important than an increase in surface area *per se*, although both factors may be important. Certainly, the surface area of a device does not have to be in contact with the endometrium to play a role in efficacy, as has been suggested¹⁴.

The hypothesis that a device may be quite thin, as is the M-device, without increasing bleeding, if there is no pressure by the device to make it embed, seems to be borne out.

While there were no perforations in the Ljubljana M-device series, this has been a problem at other trial centres¹⁵. The few

perforations which did occur at other centres were symptomatic and were managed surgically.

Summary and Outlook

Rigorous analysis of data accumulated from clinical trials of the Lippes loop D, Copper-T and M-device in North America and Yugoslavia during the last five years provides new insight into the performance of these very different devices.

Despite the great variety of devices introduced into clinical trials during the last decade, the Lippes loop has remained the standard. And despite its limitations, it has proved remarkably difficult to surpass in its overall performance.

It appeared from preliminary reports of Copper-T performance^{5,10} that this device was more effective with fewer complications than other devices. Analyses of composite age and parity adjusted data from multiple trials, and a double blind trial of TCu-200 and -300¹⁷, do not demonstrate that the Copper-T has any better performance than the Lippes loop D. The risk of expulsion with the Copper-T, like that of the Lippes loop, is inversely related to age and parity. Young nullipara and primipara might experience fewer expulsions and bleeding/pain removals with the Copper-T than with the loop D. Results of additional testing are needed to determine this.

Analysis of long term follow-up data on a double-blind trial of two variants of the M-family of devices documents one unique performance characteristic for this experimental device^{6,8}. The 99.5% retention rate at 4 years after insertion with few cases of embedding and no perforations for 841 devices is an important finding. The overall continuation rate for this device after 4 years was 62 per cent.

Further modification of the Copper-T and the M-device may further improve the performance patterns of these early second-generation devices, one bioactive, the other inert. The combination of optimal characteristics from both devices might lead to a third generation of IUDs.

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COPPER T-200: COMBINED BANGKOK HOSPITAL CLINICAL EVALUATION

By

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PRAYOON KLINCHOM and SOMSAK VARAKAMIN

Introduction

The development and rationale of the Copper T intra-uterine device and the biologic aspects of copper have been described by Tatum ^{1,2}. Several investigators have reported clinical and field studies on the use-effectiveness of the Copper T-200, a version of the plastic T-shaped device with 200 mm² of exposed copper surface ^{3,4,5,6,7}. This report presents and analyses briefly the findings of a collaborative Copper T-200 clinical trial in five large Bangkok hospitals.

Material and Method

Clinicians from the five hospitals agreed to recruit between 250-500 non-puerperal fertile women over a three-month period beginning in late 1971 and early 1972. Acceptors were chosen from among those women who agreed to the use of the new device and fulfilled the following two criteria: (a) whether the acceptor was likely to cooperate with the clinic follow-up schedule at 1, 6 and 12 months, and (b) whether the acceptor could be located for follow-up at home, i.e. stable address reasonably close to clinic. Insertions were carried out by physicians, nurses, or, at one hospital, nurse midwives undergoing a training course in IUD insertion technique. A home follow-up visit was attempted at one year for all acceptors, and successfully completed for 67 per cent. Clinic data was available on 90 per cent of the 1,180 acceptors, however, and was used to complete the experience of acceptors lost to follow-up. The study used a standard form developed by the Population Council. One of the five original hospitals was unable to participate in the home follow-up phase. Thus, only data from the four hospitals attempting home follow-up is included in this report. To lessen possible bias in estimating continuation rates, women with post-acceptance data were weighted by hospital of acceptance, number of living

children, and number of additional children desired to represent all Copper T acceptors in the same group.

TABLE 1

COMBINED BANGKOK HOSPITAL STUDY:
SELECTED COPPER T-200 ACCEPTOR CHARACTERISTICS (N = 1,180)

Characteristics	No.	Per cent
Age		
under 20	48	4
20-24	308	26
25-29	376	32
30-34	275	23
35-39	126	11
40 and over	47	4
Living Children		
0	23	2
1	368	31
2	374	32
3	196	17
4	96	8
5 or more	123	10
Additional Children Desired		
None	476	40
One more	286	24
Two more	176	15
At least three more	27	2
More, number uncertain	107	9
Unknown, Not sure	108	9
Outcome of Last Pregnancy		
Live birth	1,097	93
Stillbirth	9	1
Induced Abortion	13	1
Spontaneous Abortion	48	4
Never Pregnant	13	1
Ever Use Contraception?		
Yes	761	64
No	419	36
Ever Use IUD?		
Yes	369	31
No	811	69
Ever Use Pills?		
Yes	495	42
No	685	58

RESULTS

Basic acceptor characteristics appear in Table 1. Copper T-200 acceptors in Bangkok were young (62 per cent under 30), of low parity (65 per cent with 2 or fewer living children), likely to want more children (only 40 per cent said they wanted no more children), fertile (99 per cent previously pregnant), and likely to have used contraception before (64 per cent). Forty-two per cent had used the pills and 31 per cent the IUD.

The overall 12-month first segment continuation rate per 100 acceptors was 77.3. Table 2 presents data for interviewed acceptors and from clinic records for non-interviewed acceptors. The pregnancy rate was low, as was the termination rate for expulsion. At 16.7 per 100 acceptors, the total removal rate was relatively high. The main causes for removal were pain, bleeding, and other medical reasons, 6.1; desired pregnancy, 4.6; and other reasons, 6.0. Continuation at 12 months was directly related to age. Women over 30 had continuation rates of 84.0 or more, while only 56.9 per 100 acceptors under 20 continued use for one year. Pregnancy

rates show no important variation by age. With the exception of the 35-39 age group, termination rates for expulsion decline with age. The expulsion rate for the 35-39 age group, however, is not significantly different from surrounding age groups. Removal rates decline with age. As might be expected, younger women are more likely to ask for removal to become pregnant.

In Table 2, continuation rates tend to increase with increasing parity. The trend is broken by women with four living children, but their rate is not significantly different from women with three living children. The overall range is 69.6 for women with 0 or 1 child to 86.9 for women with 5 or more living children. Removal rates tend to fall with increasing parity, but again, women with four children break the trend. Women with the least number of children are more likely to request removal to become pregnant.

Two cervical perforations were reported in this series, neither case requiring hospitalization. There were no cases of bleeding, pelvic infection, or other complications serious enough to require hospitalization.

TABLE 2

COMBINED BANGKOK HOSPITAL STUDY:

NET FIRST SEGMENT CONTINUATION AND TERMINATION RATES OF COPPER T-200 AT 12 MONTHS BY AGE AND LIVING CHILDREN (INTERVIEWED ACCEPTORS AND CLINIC RECORDS WEIGHTED FOR NON-RESPONSE)

	<i>Termination Rates By Reason</i>							
	<i>Continuation Rate</i>	<i>Pregnant While Using</i>	<i>Expulsion</i>	<i>All Removals</i>	<i>Pain and Bleeding</i>	<i>Other Medical Reasons</i>	<i>Wanted a Child</i>	<i>Other Reasons</i>
All Acceptors	77.3	1.1	4.9	16.7	4.6	1.5	4.6	6.0
Age								
under 20	56.9	0.0	13.6	29.4	6.0	0.0	7.0	16.5
20-24	68.8	1.2	7.1	22.9	4.8	2.8	6.6	8.7
25-29	76.4	1.8	4.5	17.3	5.1	1.5	4.9	5.9
30-34	84.0	0.8	2.0	13.2	3.9	1.4	3.0	5.0
35-39	86.1	0.0	6.0	7.8	3.6	0.0	3.2	1.0
40 and over	90.8	0.0	0.0	9.2	6.0	0.0	0.0	3.2
Living Children								
0 or 1	69.6	1.0	7.4	22.1	3.5	2.3	8.5	7.8
2	78.1	2.1	3.9	15.9	4.7	1.3	4.0	5.9
3	82.5	0.0	.9	13.6	2.4	1.7	1.8	6.5
4	80.2	1.2	0.0	18.6	13.6	0.0	1.1	3.8
5 and over	86.9	0.0	5.8	7.4	2.5	1.0	1.3	2.6

The participating hospitals had quite different results when compared to each other. The range in the overall 12-month continuation rate in Table 3 is striking, from 71.7 to 90.5 per 100 acceptors. Three of the four had reasonably comparable 12-month continuation rates, however, ranging from 71.7 to 76.6. Save for hospital B, total removal rates fall within a narrow band, although removal rates by reason were very different. Hospitals A and D had higher termination rates for expulsion. There were noteworthy differences among the hospitals in the median parity of Copper T-200 acceptors.

13.1, at 12 months⁴. Removal rates were higher in Bangkok for planning pregnancy and for other personal reasons, perhaps reflecting a younger population of acceptors than in the U.S. clinical study.

The data on continuation rate by hospital in Table III suggests the strength of collaborative studies in providing a balanced picture of the effectiveness of a contraceptive method. Had the study been conducted only at hospital B, a too optimistic judgment of Copper T-200 performance might have been made. Although some of the difference is explained by a higher median parity of

TABLE 3
COMBINED BANGKOK HOSPITAL STUDY:
NET FIRST SEGMENT CONTINUATION AND TERMINATION
RATES OF COPPER T-200 AT 12 MONTHS BY PARTICIPATING HOSPITAL

Hospital	No.	Median Parity	Continuation Rate	Termination Rates By Reason					
				Pregnant While Using	Expulsion	All Removal	Pain and Bleeding	Wanted a Child	Other Reasons
A	367	2.16	71.7	1.7	8.9	17.8	9.3	4.7	3.1
B	200	3.17	90.5	0.0	1.2	8.4	1.7	3.8	1.1
C	331	1.97	76.6	1.1	2.4	20.0	6.4	3.0	10.2
D	282	1.44	75.3	1.2	5.3	18.3	5.0	7.5	5.3

Comment

The findings of the Combined Bangkok Hospital Copper T-200 trial are not dissimilar to other published clinical findings. At 12 months, a study of the Copper T-200 in the U.S. involving 27 clinical investigators reported a first segment continuation rate of 76.4⁴. Another study reports a comparable 12-month continuation rate of 75.9². Ours was 77.3. The relationship of continuation rates with age seen in the Bangkok data has been observed in the large U.S. clinical study cited above⁴. It is also seen in a field study of the Copper T-200 in Thailand and Columbia, but the relationship is less clear in 3 other participating countries³. Although continuation rates with the Copper T-200 tend to rise with increasing parity, the relationship is an irregular one (^{3,4}). Comparing our data on termination rates with those from the U.S. clinical study, Combined Bangkok termination rates for expulsion are lower 4.9 to 8.3, but termination rates for removal are higher, 16.7 to

acceptors, performance at hospital B is significantly better than the other hospitals in the study. The differences in results of contraceptive trials among hospitals using the same protocol reflect many factors, among them other demographic characteristics of acceptors, client selection procedures, staff attitudes, as well as still others more difficult to identify. In the case of one hospital, the need for cases in a Copper T insertion training course for nurse-midwives led to the selection of almost all interested women. It is thus understandable that the criterion of whether the acceptor could be followed later was not as high a priority at this institution as at the others. All insertions were six weeks or later after delivery or abortion, however, and a common revisit schedule was followed.

Table IV compares the first *segment* results of the Copper T-200 in the four Bangkok hospitals with first *method* rates from a follow-up study of a sample of over 2,200

TABLE 4

COMBINED BANGKOK HOSPITAL STUDY:

COMPARISON OF FIRST SEGMENT COPPER T-200
AND FIRST METHOD LIPPE'S LOOP CONTINUATION
RATES AT 12 MONTHS BY AGE AND LIVING
CHILDREN (INTERVIEW AND CLINIC DATA)

Age	Copper T-200 (1973)		Lippes Loop Postpartum Study (1970)	
	No	Rate	No	Rate
under 20	48	56.9	99	61.1
20-24	308	68.8	561	68.7
25-29	376	76.4	773	73.5
30-34	275	84.0	416	81.9
35-39	126	86.1	295	85.3
40 and over	47	90.8	102	76.5
Living Children				
0 or 1	391	69.6	243	60.3
2	374	78.1	512	69.5
3	196	82.5	462	75.8
4	96	80.2	372	79.3
5	54	89.8	256	78.8
6	28	83.4	446	84.9
7 or more	41	89.3	(6 or more)	

Lippes loop acceptors in the Thai postpartum program⁸. The comparative loop data largely represents the experience of 1966-1969 acceptors at 3 of the 4 hospitals participating in the Copper T-200 study in 1971-1972. Unlike the Copper T-200 sample, a small percentage of loop acceptors were inserted early in the postpartum period. The continuation rates for early and delayed postpartum loop acceptors in the sample were very similar however³.

Despite the fact that the loop rates include all segments of use, the first segment Copper T-200 continuation rates in Table IV are higher for women with 3 or fewer children and about the same for women of higher parity. This finding confirms the results of

the Thailand field study³. The comparisons are more even by age, especially for women under 30. A much larger proportion of Copper T-200 acceptors had 0-2 children (65 per cent) than did acceptors in the earlier loop acceptor cohort (33 per cent), however. Since lower parity is associated with lower continuation, this difference between the two groups would tend to mask real differences in continuation rates by age.

Summary

In a group of 1,180 Copper T acceptors at 4 Bangkok Hospitals, the 12-month first segment, net continuation rate, established by home interview and clinic records, was 77.3. Continuation was directly related to age, older acceptors generally having lower expulsion and removal rates. Lower parity acceptors tended to have lower continuation rates, but the relationship was not completely regular. Overall, the removal rate was high, principally because of desire for another child and other personal reasons. A high proportion of acceptors were young and of low parity. Pregnancy rates were low. Two cervical perforations were reported in this series. These did not require hospitalization and there were no other serious complications.

The variation in continuation rates among the four participating hospitals suggested the strength of a combined trial in providing a reliable evaluation base. A clinical IUD trial in a single hospital may not anticipate or successfully predict later experience. In this case, the risk, successfully avoided, was a misleadingly favourable continuation rate. On the other hand, study of the procedures at hospitals with higher continuation in this study reveal clues to better management of family planning service programs.

When compared to Thai data on the Lippes loop, the Copper T-200 appears to be superior among low parity women, a result found in other studies. This advantage must be weighed against the need to replace copper-bearing devices at periodic intervals, usually three years. Newer copper-bearing devices may extend wearing time and substantially reduce the burden of three-year replacement.

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THE SIGNIFICANCE OF ALTERATIONS IN MORPHOLOGY AND DISPOSITION OF INTRAUTERINE CONTRACEPTIVE DEVICES

By

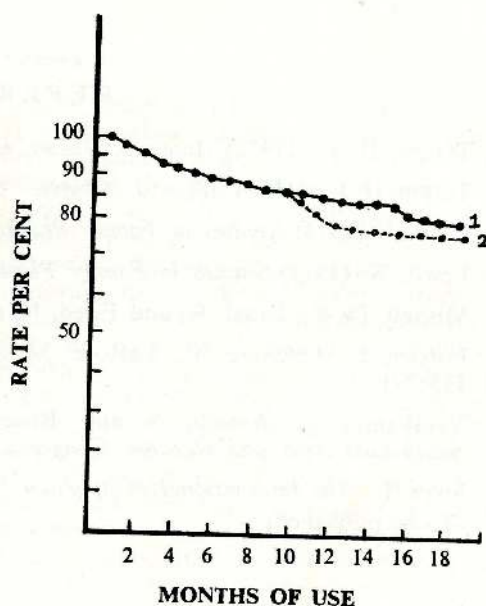
DR. MAHASARA GUNARATNE

In the early part of this century (1909), Richard Richter of Breslau successfully prevented pregnancy by introducing a strand of silkworm gut into the uterus. Shortly afterwards Grafenberg (1929) whose name is more familiar to students of contraception used a silver wire ring now named after him. Since then no other contraceptive method has undergone so rapid and thorough a change as that experienced by the intrauterine device (IUD). Today, intrauterine contraception has received the explicit approval of leaders of the medical profession and is the subject of active research. The work of multidisciplinary teams has resulted in the evolution of a number of 'second-generation' devices. We thus find ourselves in a period of what can be termed the 'Renaissance of intrauterine contraception'. Modification of the IUD have resulted in the use of new material, designs to suit uterine size and shape, and the recent incorporation of antifertility substances.

The acceptability of the IUD would depend on its use-effectiveness in preventing unwanted pregnancy and the incidence of complications. The acceptability of the numerous devices in use have been systematically evaluated by the Life-table method and there is little doubt that this is largely dependent on IUD design evolving from a thorough scientific background.

Recent research on the IUD has broadened our knowledge on its mode of action while claims of excellent use-effectiveness with the shield type device have been made (Davis, 1970). The continuation rate for the Lippes loop at our clinic is high - 82.5 per cent as deduced by the Life-table method (Gunaratne, 1974). Fig. 1.

However, reports of translocation with all types of devices continue to appear in the literature. Although IUD translocation is an insidious and asymptomatic process, attention has been drawn to changes in



Acceptability Rate - Life-Table Method

1 - Best Estimate 2 - Worst Estimate

FIG. 1.

attitude of devices which herald this process (Gunaratne, 1973). It is believed that changes in morphology of devices in use reflect defects in design but research in this field has been neglected. Information of this nature could prove invaluable to multidisciplinary teams in producing a more acceptable IUD.

By changes in IUD morphology one recognises those due to loss of compliance, device distortion and fracture. Often alteration of disposition independent of morphological changes bear clinical significance, a particular change or attitude being characteristic for a particular device. These aspects reflect a new dimension in intrauterine contraception viz. defects of IUD design in relation to uterine accommodation producing clinical problems.

Changes in morphology and disposition are often recognised by diagnostic radiology, but close study of translocated devices and those devices recovered after prolonged use could reveal the intricate mechanism of these changes.

Patients and Methods

This paper is based on acceptors of the Lippes loop and SAF-T-Coil (33s) device at the Family Planning Clinic, Buwelikada, Kandy. Those acceptors with complications requiring further investigation and surgery are admitted to the University Gynaecological Unit of the Kandy General Hospital.

A prospective study of translocated devices and those removed for personal and medical reasons between the period 1st June, 1971 to 1st October, 1973 was made. The patient being familiar with the type of the IUD inserted was instructed to recover and produce expelled devices for inspection. The IUDs suspected of translocation were first subjected to diagnostic radiology and vaginal exploration attempted whenever relevant. Laparotomy was carried out to remove devices from the peritoneum. In a few instances hysterectomy with the device in place was done and observations made. Experimental work to determine the behaviour of the IUD at the time of insertion is presented. The changes in morphology and disposition are analysed and the clinical significance stated.

RESULTS

Changes in compliance

The concept of loop compliance is of outstanding importance in the use-effectiveness of linear devices. Loading and insertion causes changes in appearance, which are brief and the normal shape is regained within the uterus. Occasionally an expelled Lippes loop shows minor changes in appearance (Fig. 2) due to changes in compliance. Resulting from defects in manufacture they possess a dual significance. On the one hand, the more linear the device the greater the tendency to expulsion. On the other, the wide separation of the limbs of the device leaves larger areas of endometrium exposed to nidation. Commercially, changes in compliance can be verified by the deflection test (Peel & Potts, 1969).

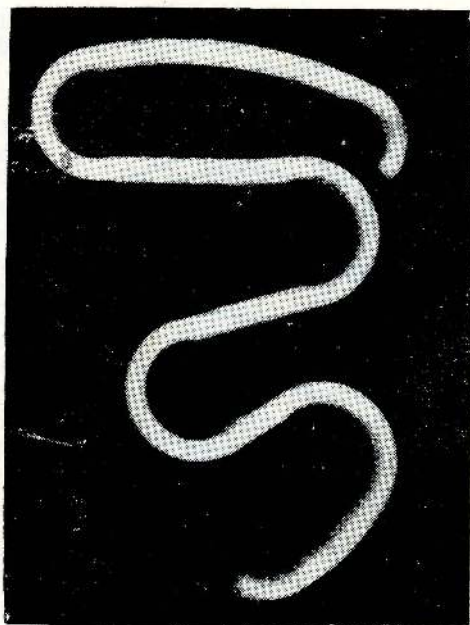


FIG. 2. Altered appearance due to change in compliance.

Lippes loop fracture

Disintegration of plastic devices in utero due to prolonged use is possible. However, this does not appear to be the basis of loop fracture with spontaneous expulsion taking place a few weeks after insertion. Examination of fractured loops in this series showed a characteristic pattern, a feature confirmed by others as well (Last, 1972).

Often the fracture occurs at a 'bend' in the loop (Fig. 3) suggesting that it results during loading of the device into the applicator. Once again a result of a defect in manufacture this could be spotted before insertion by viewing the applicator with the device against a source of light (Gunaratne, 1972). Fracture may also take place during the attempted removal of a loop embedded in the uterine muscle (Fig. 4). Here too the site of fracture is located at a 'bend'.

Accommodation of the IUD

The manner in which the uterus accommodated the IUD plays an important part in the subsequent behaviour. The question of accommodation should be considered in two aspects, the disposition of the device and the reaction of the uterus. Clinical and

experimental evidence suggest a relationship between changes in morphology and attitude with uterine accommodation.

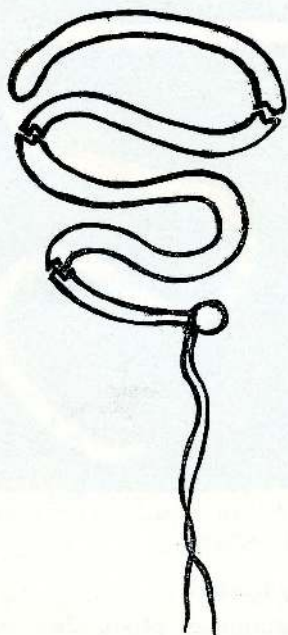


FIG. 3. Common sites of fracture.



FIG. 4. Fracture resulting in removal of an embedded loop.

The behaviour of the Lippes loop at the time of insertion was determined experimentally. For convenience of description and reference (Fig. 5) upper and lower poles are

recognised in relation to the normal position in utero. The terminal portion of the upper pole is curved, spoken of as the 'tip' and denoted T. AB will be the proximal limb of the upper pole. The first and second bends in the upper pole are B and C – the portion between them denoted BC. Most observations and comments are confined to AB, BC and T.

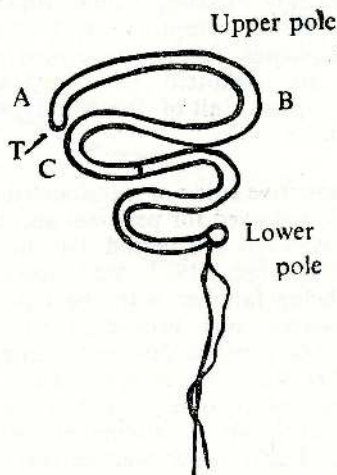


FIG. 5. Labelling of the Lippes loop.

The importance of performing experiments with fresh specimens of uteri is emphasized. Those that have been immersed in preservatives lose their natural suppleness and any conclusions may be invalid. In this series fresh specimens of uteri removed at hysterectomy were used. Photographs of the behaviour of the loop at the time of insertion were obtained. The specimen was held in the palm and the loop was introduced in a deliberate but gentle manner so that observations could be made (Fig. 6). Practically every insertion showed uterine distortion confined mainly to the fundus which was best appreciated by the palm of the investigator. Maximum distortion was with size D and minimal with B and C. Upon entry of the loop, the fundal impact was followed by an elongation of the corpus relative to the cervix. A further observation was that uterine distortion was clearly amplified with positioning in the incorrect uterine plane. With supravaginal elongation of the cervix distortion was confined to the isthmus and on one occasion perforation with lateral expulsion resulted.

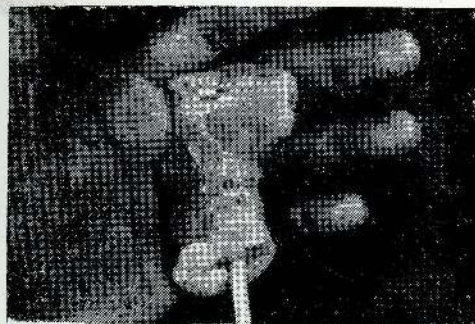


FIG. 6. Position of uterus in palm prior to loop insertion.

Investigations were next carried out so that the positioning of the loop could be directly observed by creating a small aperture or 'window' in the anterior wall.

The tip of the introducer is seen in the cavity (Fig. 7). The entry of the loop is by short irregular or 'jerky' movements. The limb AB is initially directed towards the fundus, displacing the cornu upwards (Fig. 8). This is followed by a rapid downward displacement of AB bringing the tip T into contact with the endometrium (Fig. 9). Sometimes it was noticed that AB, particularly A tends to remain at a lower level than B producing a more intimate contact of T with the endometrium. The significance of this translocation will be discussed. With gradual entry of the loop, limb AB tends to rise towards the fundus assuming the normal disposition (Figs. 10-12). These specimens also demonstrate the distortion of the corpus at the time of entry of the device. With a large or 'roomy' cavity, a normal disposition of the loop resulted but when the cavity was restricted abnormal attitudes were seen. These experiments suggest that besides proper positioning of devices, uterine size and shape play a significant role in its subsequent behaviour.

It has never been conclusively proved that partial penetration at the time of insertion occurs due to the impracticability of such a demonstration. For the Lippes loop minimal perforation at the time of insertion could well be the commencement of translocation, that this is the basis of the mechanism of translocation is supported by this case report. A rare instance of early perforation with a Lippes Loop, an incidental

finding in a hysterectomy specimen is presented.

SZ, a 45-year-old patient with five children had used the Lippes loop for the past four years. She was admitted on 13th April 1972 with irregular bleeding of two months, duration. On pelvic examination, the cervix was healthy and the threads of an IUD were issuing from the os. The body of uterus was anteverted and of normal size. The adnexae were not palpable. Papanicolaou smear was Class I. In view of the patient's age and parity, total hysterectomy was considered suitable. It was decided to examine the IUD in the post-hysterectomy specimen.

The uterus when cut along its anterior wall (Fig. 13) showed a Lippes loop. Close examination showed that the tip of the upper pole was embedded in the upper part of the posterior wall. The loop was removed and an orange stick used to gauge the depth and direction of perforation (Fig. 14). Penetration had taken place in a downward direction to a depth of 6mm. The nature of the injury would not conform to instrumentation at insertion. The tip of the upper pole of the loop, is the incriminating agent in translocation.

Morphological changes as determined by radiology

The clinical and experimental evidence leading to translocation is substantiated by radiological appearances. The radiological features of translocation were essentially of two types, reversal of polarity and loop distortion.

Reversal of polarity

With commencing translocation changes in polarity were observed ranging from minor degrees (Figs. 15,16) to complete reversal of polarity (Figs. 17,18). These changes present similarities of appearance in that reversal of polarity is accompanied by loop distortion.

Lippes loop distortion

Distortion affects limb AB and BC resulting from a downward displacement of T. The appearance of the lower pole is unaltered. However, Lippes loop incarceration produces extreme degrees of distortion

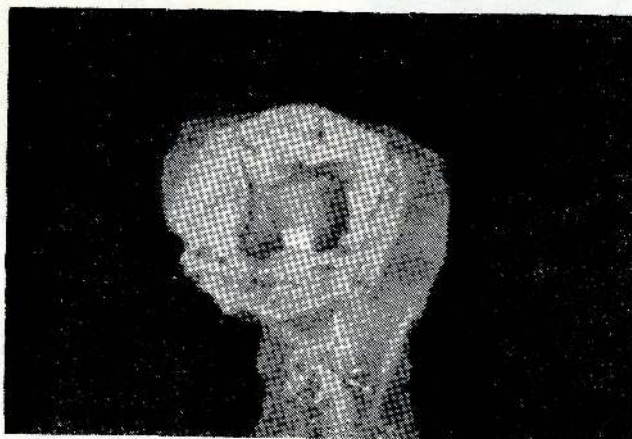


FIG. 7



FIG. 8

FIGS. 7 - 12

Direct observation of the behaviour of the loop at insertion.

FIG. 7. 'Window' in uterus with introducer in cavity.

FIG. 8. Displacement of cornu by limb AB.



FIG. 9

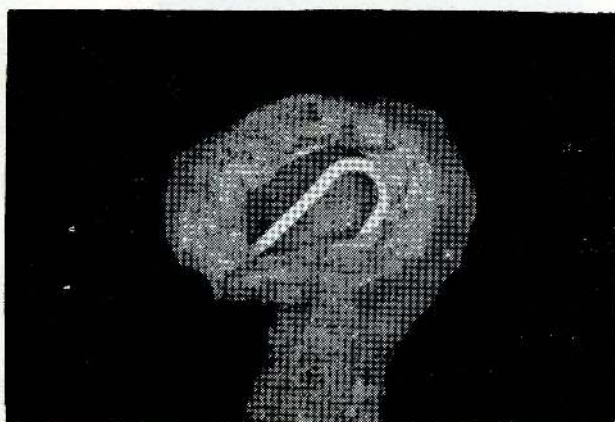


FIG. 10

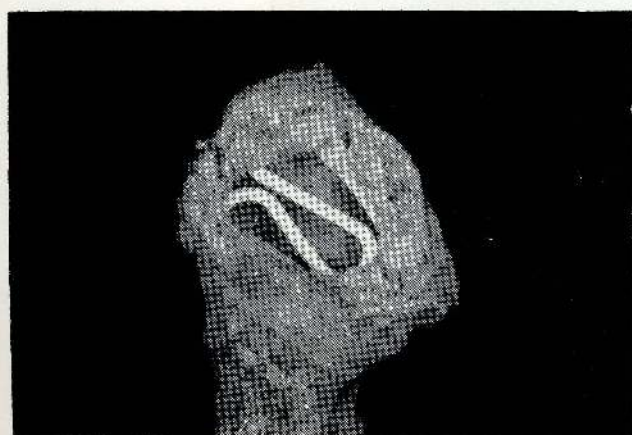


FIG. 11

FIGS. 9 - 11. Show gradual entry of loop.

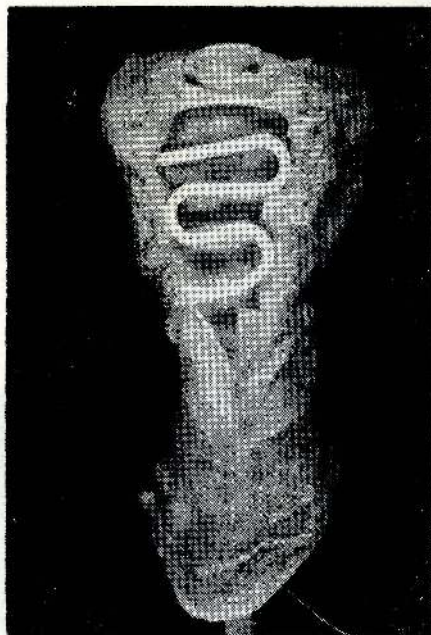


FIG. 12. Loop in normal position.

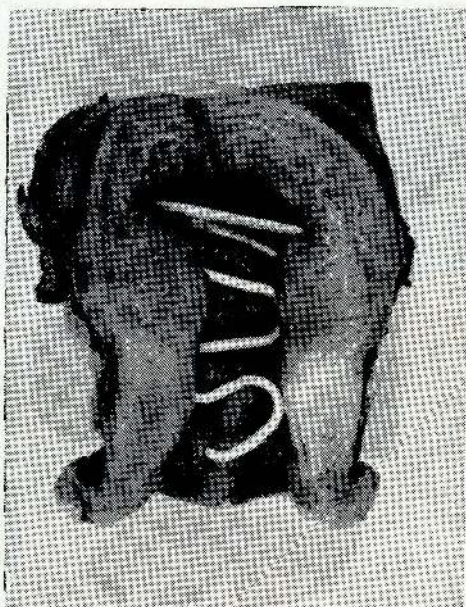


FIG. 13. Uterus cut open to show embedding of tip of loop.

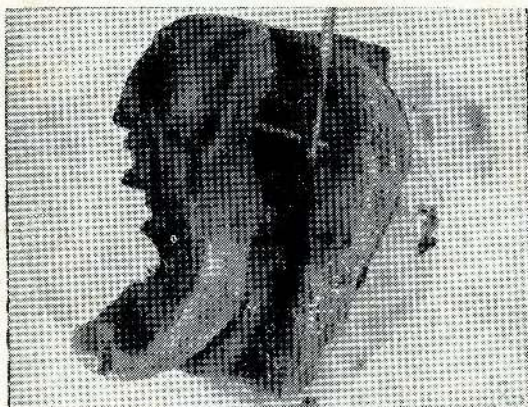


FIG. 14. Orange stick used to show direction of perforation.

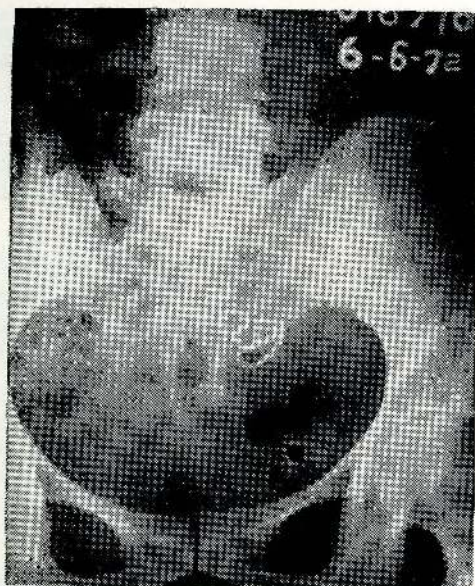


FIG. 15

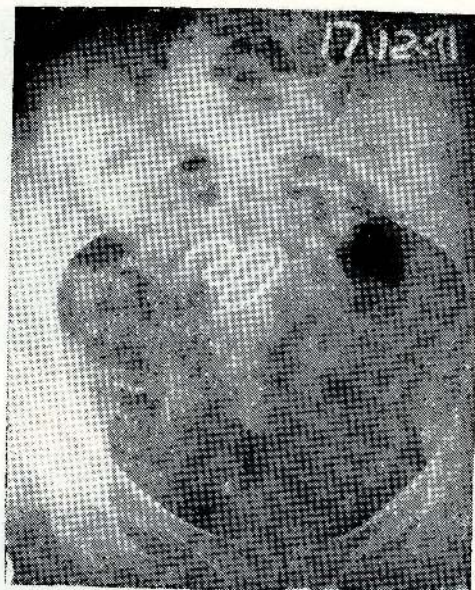


FIG. 16

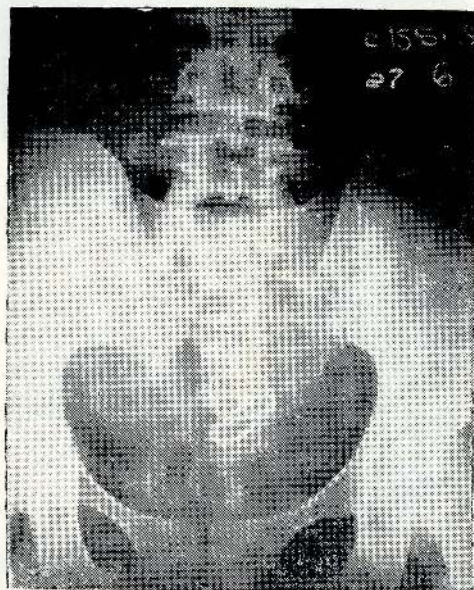


FIG. 17

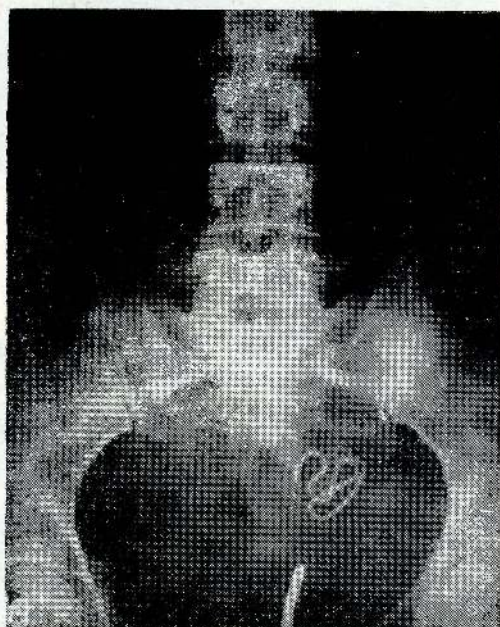


FIG. 18

FIGS. 15 - 18
Shows changes in polarity.

FIG. 15 - 16 minor degrees.

FIG. 17 - 18 complete reversal of polarity.

(Figs. 19, 20, 21). These appearances resemble that seen on radiology and the changes in morphology bear a constant pattern with reference to AB, BC and T. The 'worm-like' appearance during translocation is characteristic, and results from uterine contractions and the permanency of the change suggests an insidious process.

Not all devices translocate. The majority are retained. However, recurrent IUD expulsion points to some inability of the uterus to accommodate the device. Our

experience is that those showing recurrent expulsion of the Lippes loop expelled the SAF-T-COIL as well.

Is proper positioning a factor which contributes largely to IUD retention? The case that is next presented could add weight to this hypothesis.

MGN had a Lippes loop inserted on 29th March, 1969. At follow-up three months later, the threads were not felt at the os but on bimanual examination the

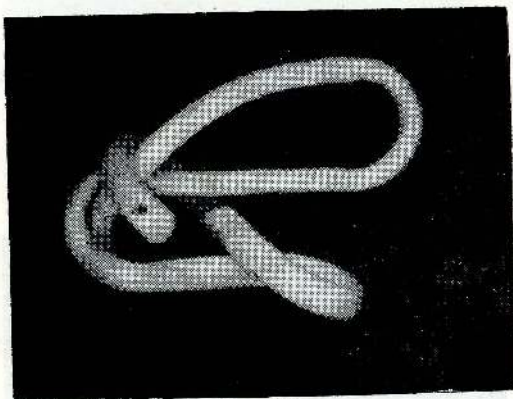


FIG. 19

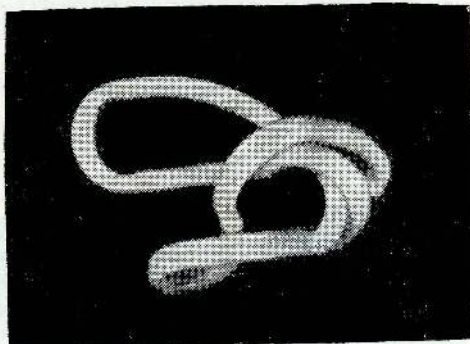


FIG. 20

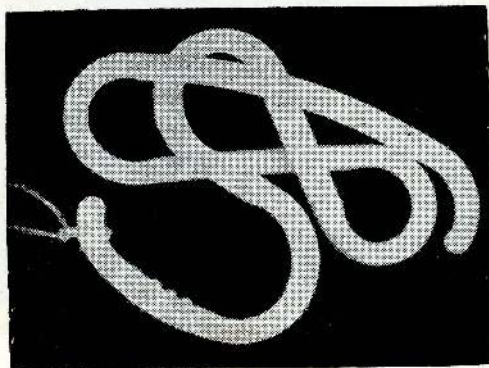


FIG. 21

FIGS. 19 - 21
Appearances of incarcerated Lippes loops.

loop was palpable in the pouch of Douglas. Removal of the loop was recommended but she was reluctant to come in due to domestic difficulties and a second Lippes loop was inserted to prevent conception. Being symptom-free she defaulted follow-up until four years later when she came to the clinic.

On pelvic examination the threads of an IUD were felt at the os while another device could be palpated in the pouch of Douglas. An X-ray in the lateral position confirmed the presence of two Lippes loops (Fig. 22). The translocated loop is seen in the sagittal plane with the second loop occupying the normal or coronal plane of the uterus. The latter had been retained for four years in a uterus which has been the site of recent translocation probably as a result of improper positioning.



FIG. 22. Two loops, one translocated and lying in the sagittal plane and the other within the uterus in the coronal plane.

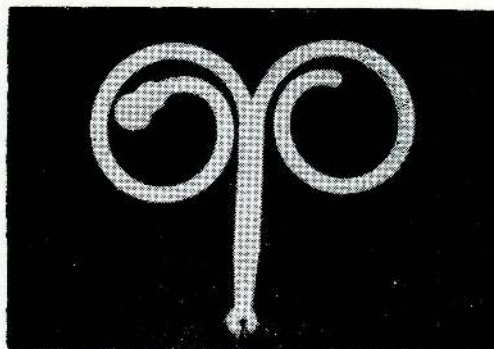


FIG. 23. The Saf-T-coil 33S.

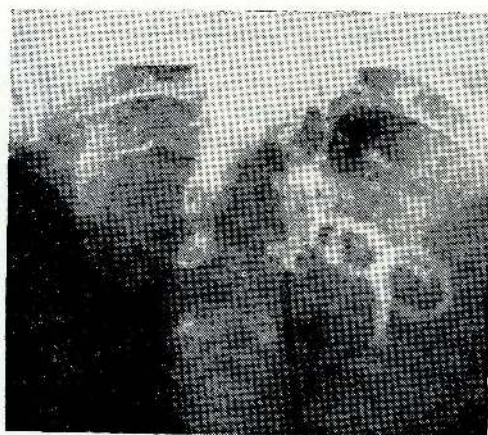


FIG. 24. Distortion of coiled portions.

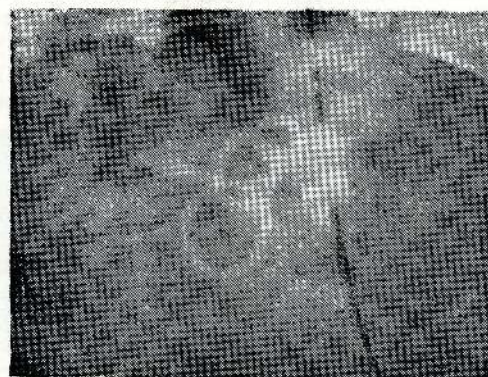


FIG. 25. Change in altitude showing horizontal disposition.

The SAF-T-COIL

The SAF-T-COIL 33 S (Fig. 23) was introduced at our clinic in October 1972 and up to the time of writing there have been 177 acceptors. The radiological changes observed with use were distortion (Fig. 24), and changes in disposition when the device assumed a horizontal attitude in

utero (Fig. 25). The horizontal disposition resembles early reversal of polarity as with Lippes loops, posing problems to acceptor and clinician alike. Due to the change in

disposition the threads were drawn into the uterus making it difficult to ascertain the presence of the device except by sounding the uterus or by radiology. The change of disposition is probably a result of defective uterine accommodation in certain instances.

The clinical significance of uterine accommodation of this type of device is shown in this case report. Patient P.L. complained of cramping lower abdominal pain for two months from the time of insertion of SAF-T-COIL. The device threads were palpable vaginally but removal was indicated on account of pain. On removal, the coil was distorted (Fig. 26). In such a manner indicating positioning in an incorrect plane. She was free of pain thereafter. Close examination shows that with this type of deformity a significantly large endometrial area is left exposed to nidation.

Potential hazards due to a 'closed-loop' effect

In contrast to 'closed' devices of the Grafenberg and Birnberg types the Lippes and SAF-T-COIL devices are termed 'open'. If the latter should translocate the risks of bowel obstruction are minimal. Consequently such devices may be indefinitely left in the peritoneum whereas the removal of 'closed' devices is mandatory. Evidence is now presented that gross distortion in morphology among translocated Lippes loop converts them into 'closed' devices (Figs. 19, 20 & 21). The 'closed-loop' effect was also observed with the SAF-T-COILS removed for medical reasons (Figs. 27 & 28). A claim is therefore made for early removal of all types of translocated devices.

A case encountered recently exhibited an unusual variety of morphological change (Gunaratne, 1973). At laparotomy a translocated Lippes loop (Fig. 29) was extruding into the peritoneum from the back of the broad ligament acquiring adhesions during the process. Adhesions between two Lippes loops simulating the conditions described have been reported (Ratnam & Yin, 1968).

Conclusions

In the field of intrauterine contraception innovation in design is aimed at producing an IUD more acceptable than the ones originally introduced and possibly to achieve

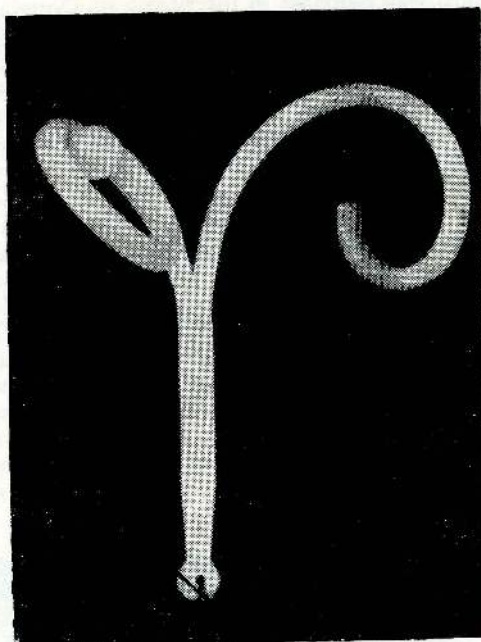


FIG. 26. Distortion causing abdominal pain.

the same degree of use-effectiveness as oral contraceptives. The morphological changes of Lippes loop and SAF-T-COIL during use have been analysed and these together with changes in disposition bear a rather constant pattern with clinical significance.

The changes in morphology and disposition of devices reflects defects in design, which information is useful to multidisciplinary teams engaged in bringing out new devices.

That uterine accommodation is of paramount importance in the subsequent behaviour of devices is supported by clinical and experimental evidence.

There is no doubt that uterine forces play a significant role in changes of morphology and disposition and the designing of devices must conform to this aspect as well. Myometrial function with an IUD in place as determined by linear displacement analysis (Berhman & Burchfield, 1968) revealed two types of propagating waves, not only from the fundus downwards but from the cervix upwards as well. The tolerance of an IUD design may well depend on myometrial function, but proper positioning at insertion is equally important.

FIG. 27

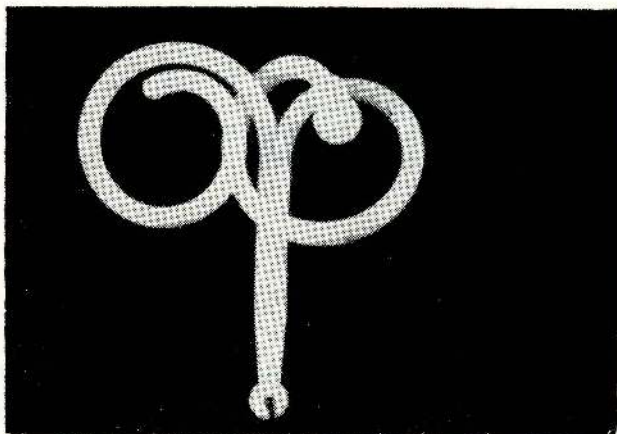


FIG. 28

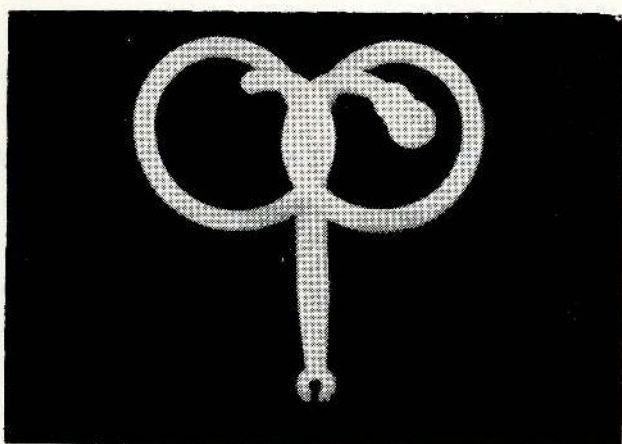


FIG. 27 - 28
'Closed-loop' effect.

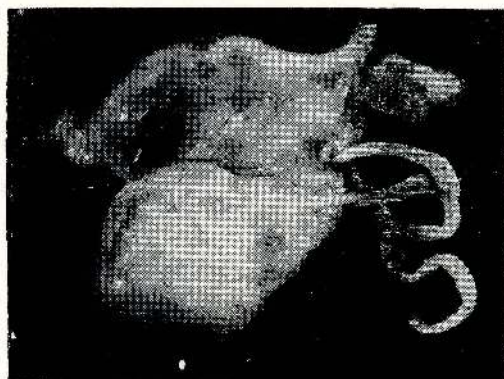


FIG. 29. Extension of translocated loop showing adhesions.

Acknowledgement

Appreciation is expressed to the President, Family Planning Association of Sri Lanka, Head of the Department of Obstetrics & Gynaecology of the Peradeniya Campus, International Planned Parenthood Federation

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THEME: HORMONAL CONTRACEPTION

CHAIRMAN: Dr. Edward Tyler

DESIGN AND ASSESSMENT OF CLINICAL TRIALS OF STEROID CONTRACEPTIVES

By

DR. A. HERXHEIMER

Clinical trials are performed to answer questions about particular treatments. The questions concern effectiveness, in our context in preventing pregnancy, the nature and frequency of unwanted effects, and acceptability. The results of trials should enable the clinician to choose the suitable preparation for a particular purpose.

In the measurement of effectiveness in the prevention of pregnancy, the great difficulty arises from incomplete follow-up. If, for example, 100 women have been given a certain pill for one year, and 80 of them have been seen after using it for one year, then one can state the pregnancy rate for these 80 women. If one became pregnant, the rate would be 1.25%. But it is possible that some of the 20 women not followed up also became pregnant. To take the most extreme view, if all of them had become pregnant, then the true pregnancy rate for the whole group would be 21%. There is some evidence that the risk of pregnancy tends to be greater in women lost to follow-up than in those who are followed up. The incidence of unwanted effects also tends to be higher among those lost to follow-up. For these reasons the loss to follow-up must be minimised. Wallace Fox (1971) has described methods for doing this particularly in relation to trials of chemotherapy of tuberculosis. These can be applied in trials of contraceptives. Every design of a trial of a contraceptive should include a description of the methods used to minimise loss to follow-up.

In the assessment of unwanted effects, one wants to know their frequency and their severity. Here the main problem is one of communication. If the patient is asked a non-specific question, e.g. "Have you noticed any change in how you feel since you started taking the tablets?" many effects will be missed. Asking specific questions, for example about the amount of blood lost at

menstruation, or the occurrence of nausea, will yield a higher proportion of positive answers.

But how realistic the estimate is depends greatly on the way in which the question is asked, the exact words used, the tone, and by whom it is asked, for example by a doctor or a nurse. In clinical trials therefore, it is important to standardise the way in which questions are asked, and by whom, and when the results are reported this information should be included.

Serious unwanted effects that are rare are important and need to be detected, but if the incidence is of the order of 1 in 1000 or less, very large numbers of patients will be needed. By far the most practical way of approaching this problem is to use the case control method. This requires a more specialised organisation and is practicable only at regional or national level.

Efficacy and the incidence and importance of unwanted effects are well known to vary in different groups of women. These variations may relate to genetic make-up, age, parity, education, religion, social class, the climate of public opinion, or other factors. The results of a clinical trial must as far as possible be interpreted bearing in mind the characteristics of the women from the same community who did not take part, because the conclusions of the trial may not apply to these. In any trial report, therefore, some description of the sample, and of its relation to the local population is desirable.

Finally we come to what is probably the most important point about any clinical trial, and that is, that it involves a comparison between two or more different treatments. When a clinician gives a new pill to a series of women and reports the results, he is implicitly comparing those results with his earlier experiences using other preparations.

He thus has an impression of the relative value of the new one. But impressions are unreliable, and he will do better to use carefully recorded data from his previous work, or from the work of others. But even such comparisons are unreliable, because there may be many differences between the series of patients that are being compared. They were seen in different years, by different medical and auxiliary staff, probably with a different amount and type of experience; the state of medical opinion, and of lay opinion about family planning and the pill probably differed at the two times and in different places. So any difference in results might be due to any combination of such factors, as well as to a difference in the actual preparations used. There is only one satisfactory way round these difficulties, namely, to perform trials in which the two or more treatments

that are to be compared are given concurrently to the same population of women. Which particular preparation a woman receives is decided at random, and this is best done by the use of a table of random numbers. With reasonably large numbers, the different treatment groups will usually be comparable in all important respects, but of course, this needs to be checked.

Such comparative trials are no more difficult to perform than trials of a single preparation, and they give much more useful results. Only few such trials with oral contraceptives have so far been reported, but their adoption will greatly clarify the important questions about the relative merits of different preparations, questions that concern every clinician who works in family planning.

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EXPERIENCE WITH ORAL CONTRACEPTIVES IN SRI LANKA

By

DR. HIRANTHI WIJEMANNE

Ever since the Family Planning Movement gathered momentum, Man has been searching for the ideal contraceptive. One of the most exciting medical advances in this direction was the synthesis of hormone-like compounds which were capable of temporarily suppressing ovulation in normally fertile women. The whole picture of contraception was changed by this important discovery. Although the ovulation-inhibiting effects of the corpus luteum have been known since the beginning of the century, the first oral contraceptive field trials began in Puerto Rico in April 1956, under Pincus and Rice-Wray, and it was in the following year, that the first oral contraceptives were available for general use. The current estimate is that about 50 million women all over the world are taking oral contraceptives. It was the first contraceptive method which was capable of giving nearly 100% fertility control, aesthetically acceptable, unrelated to the time of intercourse and which had reversible effects.

The origin of the first Family Planning Clinic in Sri Lanka dates back to the year 1937. Opened by Dr. Mary Rutnam, it was one of the first Family Planning Clinics in the East. With the inauguration of the Family Planning Association in 1953, the next Family Planning Clinic was opened at the De Soysa Maternity Home. All the methods available then were conventional and traditional ones.

It was at the 6th International Conference of the I.P.P.F. held in New Delhi in 1959, that the oral contraceptive was spotlighted as being an acceptable method for women of low income groups in Puerto Rico and Haiti. Following this, plans were made by Dr. Siva Chinnatamby to conduct the first trials in Sri Lanka in October 1960. Ours was one of the first countries in South East Asia to embark upon a trial of the oral contraceptive. The chief strength and support for this project was given by

Dr. Gregory Pincus - the "Father of the Pill". He visited Sri Lanka six months after the initiation of the trials. The oral contraceptive used was "Conovid E" 2.5 mg. During the first six months only a total of 50 cases was obtained. After this initial phase, there was a swift increase in the popularity of the pill, and in October 1962, further trials were done using "Anovlar" and "Lyndiol" and Ethynodiol diacetate in doses of 1 mg and 5 mg.

This initial trial which lasted for 3 years brought to focus the interesting fact, that this method of contraception was acceptable to Ceylonese women with little or no education and of a low socio-economic level. The reasons were mainly that all the previous methods were mechanical and related to the act of sex union, and this method was therefore aesthetically more acceptable. It was also demonstrated that the strict regime involved in the daily ritual of taking a tablet, was no barrier to its acceptance by this group of women.

In this trial conducted by the Association, 1,118 women participated. They were under 45 and over 16 years, the average age being 28.2. The average number of pregnancies was 4.8. A significant point was that 67.1% were below 100 lb in weight. 80% had never attended school but only 30% needed greater and more extensive explanation as regards learning and understanding the pill regime.

In all these women, a routine pelvic and speculum examination was done. In addition vaginal and cervical smears were taken at six monthly intervals. They were all given a chart with written instructions, and individually taught how to maintain it. The types of oral contraceptives used at this time were "Conovid", "Lyndiol", "Conovid E", "Anovlar" and Ethynodiol diacetate 0.5 mg. and 1 mg.

It was interesting that in this trial, only 10-12% discontinued use, due to adverse effects or the fear of adverse effects. As many as 22% did not return for supplies as they 'had no time' or 'had no money for transport'.

The adverse effects most commonly prevalent among these women were nausea and vomiting, headache, menstrual irregularities, changes in body weight and effects on lactation. In this group there were 350 lactating women and 70% of the lactating mothers experienced no suppression of lactation. However they were all mothers who had breast fed their babies in previous pregnancies, up to periods of one year.

The next trial was in 1966, by which time the number of oral contraceptive acceptors in the Family Planning Association clinics had risen to 3,000. They were between the ages of 16 and 43 years. Significantly, 80% were between the ages of 21 and 31 years.

The commonest adverse effects were nausea and vomiting. Education regarding the cause of the symptoms and reassurance reduced the incidence of "drop-outs". Of the women complaining of headaches, only two discontinued because they felt it interfered with their daily routine. Those who complained of giddiness during the first cycle, when persuaded to continue, admitted that this effect disappeared with continued use. A few women complained of abdominal cramps, more obvious during the premenstrual phase. A few complained of breast discomfort. A true picture of changes in libido was difficult to ascertain, due to an inherent shyness in these women. Nearly 70% of the women were under 100 lbs. in weight. Therefore a gain in weight was usually welcomed.

350 lactating women were given the oral contraceptive from six weeks after partus. In 10% lactation was suppressed to an extent that the babies had to be given supplementary feeds. 30% continued to lactate for more than nine months, needing no supplements, and the babies gained weight normally. Women who were able to lactate for long periods gave a history of having previously lactated for a period of at least one year.

Three women developed rashes which disappeared after they persisted with the tablet. One woman developed a herpetic rash on the chest which disappeared within a fortnight.

In our series, no cases of thrombophlebitis or embolism were detected. However, it is important to bear in mind that thrombo-embolic disease is relatively rare in Sri Lanka, for reasons not yet fully understood. Even in the developed countries where the natural mortality is low, the proven risk of death from thrombosis associated with one year's use of oral contraceptive is only 1/10th of the risk of dying associated with pregnancy, excluding the risks associated with illegal abortion.

One woman had severe pain in one arm. They were symptoms caused by filariasis which was prevalent in her area, but medication was discontinued. No cases of cancer of the genital tract or of foetal masculinization in pregnancies following the discontinuance of the oral contraceptive have been recorded in our series.

In this trial too, which included women from urban, semi-urban, rural and estate areas, it was evident that the level of education and the socio-economic level were no barriers to the acceptance of the oral contraceptive.

Control of fertility was nearly 100% and only two first-cycle failures were detected. Three women who failed to take the tablet regularly became pregnant. All three had omitted more than 3 consecutive tablets in the cycle.

When subsequent fertility was examined, in the first post-therapy cycle, 62% became pregnant. In the 2nd cycle 84% and in the 3rd cycle 92% became pregnant.

An interesting study was carried out in 1970, when 100 women were collected, all of whom had taken oral contraceptives continuously from 3-9 years. Ten had taken it for 36-40 cycles, ten for 41-45 cycles, eleven for 46-50 cycles, 50 between 50 and 81 cycles, ten for 81-85 cycles and seven for 86-90 cycles. There was one woman who had used it continuously for 115 cycles since the original trial.

This proved that Ceylonese women are capable of sustained motivation and following a strict regime, when they are satisfied with a particular type of contraceptive.

When parity was examined, 21 had 2 children, 19 had 3 children, 16 had 4 children and 14 had 5 children. The rest had over 5 children. The largest number of children was 13.

As regards weight, 76 had a stationary weight, 20 had increased and 4 had lost weight.

For this study, routine pelvic and speculum examinations were done. Cervical and vaginal smears were examined. A complete physical examination was done including an ophthalmological examination and examination of the blood pressure. Other investigations included blood glucose estimation and glucose tolerance tests, liver function tests, bleeding time, clotting time, prothrombin time and the platelet count.

One woman was found to have a blood pressure of 200/130 mmHg. with grade 1 retinopathy and she was referred for treatment. She had been on the oral contraceptive for 6 years. One woman had an elevated blood glucose level and an abnormal glucose tolerance curve, but gave a family history of diabetes mellitus. No other abnormalities were detected.

Since 1970, no regular trials have been carried out. The types of combined oral contraceptives used have changed to "Nordiol", "Norlestrin", "Ovral", "Eugynon", "Ovulen 50" and "Norinyl". Since 1968, until the present time the total number of users has increased to 4,424; 8% are below the age of 20; 66% are between 21 years and 30 years, while 18% are between 31 and 35 years. It was noted that in our earlier trials that the largest percentage of

acceptors were in the age group 31-35 years, and the pattern of menstruation remains unchanged with the passage of time. Compared with the earlier trials, more young nulliparous women are finding spontaneous sexual expression especially in early married life. In our group 8% had no children, 18% had one child, 21% had 2 children and 18% had 3 children. With more and more women going out to work, the number of newly married women wanting to postpone a pregnancy is increasing.

The adverse effects have become minimal in the last few years with the development and availability of newer, lower dosage oral contraceptives. In addition, the 28 tablet cycles containing 7 iron and vitamin tablets, makes usage much easier for our women, as the continuity of tablet taking is uninterrupted. Also in Sri Lanka, where anaemia is often a problem, the iron and vitamins are especially beneficial.

Though nausea, vomiting and giddiness are still the commonest adverse effects during the first 3 cycles, few give up use once they are reassured and the symptoms explained to them. Out of our group 11 changed over to sterilisation, 12 changed to the intra-uterine device and 22 changed over to depot medroxyprogesterone acetate injections, as they found daily pill-taking troublesome and inconvenient.

There was 100% fertility control, but there were 3 patient failures. These women had missed more than 3 consecutive pills in the cycles.

In the years 1971, 1972 and 1973, when the different methods of contraception accepted by new acceptors in family planning clinics conducted by the Government, Municipality and Family Planning Association are examined the trends observed are depicted in Table 1.

TABLE 1
ACCEPTANCE OF DIFFERENT METHODS OF CONTRACEPTION

Year	I.U.D.	Oral Contraceptives	Condoms	Foam tablets	Male & Female Sterilisation	Others
1971	13,980 24%	28,479 50%	7,952 14%	407 0.7%	6,081 6%	408 0.8%
1972	18,599 26.2%	32,300 45.5%	9,290 13.1%	370 0.5%	9,576 12.1%	907 1.3%
1973 1st 3 quarters	21,511 29.9%	26,662 37.6%	9,658 12.9%	279 0.4%	10,952 17.8%	485 0.6%

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No.

The trend in acceptance of the oral contraceptive shows a decrease; the intra-uterine device and male and female sterilisation have shown a significant increase. The popularity of sterilisation is a desirable trend. This would be of great advantage to our national programme as 50% of women in the fertile age span have more than 6 children, and a method of limitation should be their method of choice.

Comparing the number of cycles, where the oral contraceptive distributed by the Association was used in relation to other methods, the acceptance of the oral contraceptive has remained fairly constant, though newer methods are available and sterilisation is gaining popularity. (Table 2)

TABLE 2

NO. OF CYCLES OF USE WITH DIFFERENT CONTRACEPTIVE METHODS

Year	Oral Contraceptives	Depot Med-roxy Pro-gesterone acetate injection	Condoms
1971	57,326	1,080	79,900
1972	53,570	12,179	65,548
1973	63,868	10,335	214,998

Women who attend our Family Planning Clinics, and are motivated towards accepting

the oral contraceptive, are first checked to exclude any specific contraindications like a history of thrombosis, serious heart disease, jaundice in pregnancy and breast cancer. Their blood pressure is checked and a routine pelvic and speculum examination done. Vaginal and cervical smears are taken at the first visit, and once a year thereafter. At the first visit, one cycle is usually given, and from then on up to 3 months' supply is issued at a time. "Drop-outs" are first sent a letter, and then visited in their homes. Acceptability has to be gauged in terms of initial adoption as well as continuation of use. Therefore there is a need to follow up the "drop-outs" with early home visiting and systematic counselling, for this is a crucial stage when the woman is about to become a continuous user.

Although the pattern of contraception has undergone many changes, and newer methods are coming into focus, the original position occupied by the oral contraceptive has still been maintained.

In any method of contraception, psychological factors play a significant role. Ultimately therefore, the choice of the individual plays a more important role than the method of choice mass-programme planners would like to emphasize in family planning programmes. The preference of the user must be considered for the family planning effort to bear fruit.

ETHINYLOESTRADIOL FOR POSTCOITAL CONTRACEPTION

By

DR. HANS LEHFELDT

This lecture deals with a method to prevent pregnancy as an emergency measure after unprotected intercourse. It is not a technique to be used routinely or frequently.

The experimental and clinical pioneer studies by John McLean Morris and Gertrude Van Wagenen in this field have been called "the most important advance in anti-fertility research in the human being since the pathfinding work by Rock and Pincus".

Animal Experiments

Morris and Van Wagenen² first studied the effect of oestrogens and various other compounds on the inhibition of ovum implantation in rabbits. They found oestrogens to be extremely effective and then did the same experiment on Rhesus monkeys. They found that certain oestrogens given after coitus prevent implantation of the ovum in the primate.

Evaluation of a compound in the primate requires approximately 3 years, according to Morris and Van Wagenen². This testing also includes the effect on subsequent fertility and on the foetuses.

Post-coital oestrogens at mid-cycle matings in the primate produced 11 pregnancies in 658 cycles, i.e. 1.7% compared to 20.7% in the control series. The various oestrogens tested included stilboestrol, ethinyl oestradiol, oestradiol, and conjugated oestrogens. Oestradiol was discontinued because of a high pregnancy rate. The other oestrogens showed a low pregnancy rate.

Oestrogens are not 100% effective in preventing pregnancy, neither do they produce abortion when implantation has taken place, but they seem to prevent implantation.

The exact mechanism by which oestrogens interfere with implantation is unknown. In order to learn something about the mode of action, plasma progesterone and prostaglandin F levels were studied in primates by Aulletta *et al.*,³ of the Yale U group. They found that oestrogens produced a rapid decline of progesterone levels in 13 out of 16 monkeys. In more than 50% of the animals there was also a rise in prostaglandin F, determined by radioimmunoassay.

Clinical Experience

Morris and Van Wagenen² then started using oestrogens in clinical trials in humans, using volunteers and women who had been raped. 50 mg/day of stilboestrol was prescribed for 4 to 6 days; in another series ethinyl oestradiol in dosages of 0.5 mg. to 2 mg/day was given 4 to 5 days after coitus. They found that oestrogen administered in such high dosages at mid-cycle counteracted the thermogenic effect of progesterone on the basal body temperature curve, lowering the temperature during the luteal phase of the cycle. Endometrial biopsies taken during this phase usually showed a secretory endometrium with signs of "retardation", basal vacuoles, which are ordinarily not seen after the fourth post-ovulatory day, persisted for six to 12 days after ovulation. No pregnancies occurred when the oestrogen dosage was adequate and the timing correct.

More than 6,000 cycles have by now been observed by various investigators using this method. 26 pregnancies occurred, of which 25 can be attributed to wrong timing or wrong dosage, and only one to method failure. The technique is therefore highly effective although not 100%. Tietze⁴ states that the probability of conception from a single unprotected intercourse is between one in 50 and one in 25. The two largest published series are by Kuchera⁵ who used

stilboestrol in more than 1000 women, and by Haspels⁶, who used both ethinyl oestradiol and stilboestrol in 2,000 women. Nausea and vomiting were the most common side effects. In Kucher's series vomiting occurred in 16%; in Haspel's series in 25%. Haspels found vomiting slightly more frequent in women using ethinyloestradiol than in stilboestrol users. Other adverse effects were tender breasts, menorrhagia, headaches, and dizziness.

My own experience⁷ consists now of 150 observations, all with complete follow-up. Ethinyloestradiol was used exclusively. The series was started in February, 1967.

In the beginning, I used small dosages of ethinyloestradiol or a total of 6-10mg. for three days only. Since December, 1970, I have increased the dosage to 5 mg. of ethinyloestradiol daily, or a total of 25mg. This dosage was administered as 10 tablets of 0.5mg. "Estinyl" (Schering U.S.) with the recommendation to be taken after meals. This method of administration has the advantage that it reduces the incidence and intensity of adverse effects. Only 10% of the women in my series complained of headaches, 10% of nausea and 2% of vomiting.

One pregnancy was observed in the early stages of this investigation. It occurred in a woman who had started treatment 8 days after exposure. More recently, with the 25 mg. regimen, an instance of possible left ectopic pregnancy was seen in a woman who had started ethinyloestradiol medication 24 hours after exposure. When the usually regular period of this woman was delayed for 5 days and I found the left adnexa were enlarged, I did an endometrial aspiration which revealed decidua. The pregnancy test was negative. Since then, the patient has had three normal menstruations.

Ectopic pregnancies after postcoital medication failure have also been observed by others. Morris and Van Wageningen² have emphasized that the relatively increased frequency of ectopic pregnancy is similar to the relatively high incidence of tubal and ovarian pregnancy observed with intrauterine devices⁸.

The I.U.D. as well as the postcoital pill may be described as methods of "interception" which are not preventing impregnation but implantation. Oestrogens and I.U.D.s both decrease carbonic anhydrase in the endometrium⁹.

In May, 1973 the American Food and Drug Administration approved, under restricted conditions, the postcoital use of stilboestrol. According to the FDA, "There is at present no positive evidence that the restricted postcoital use of stilboestrol carries a significant carcinogenic risk either to the mother or foetus. However, because existing data supports the possibility of delayed appearance of carcinoma in females whose mothers have been given stilboestrol later in pregnancy, and because teratogenic and other adverse effects on the foetus with the very early administration recommended are ill understood, failure of postcoital treatment with stilboestrol deserves serious consideration of voluntary termination of pregnancy."

Another important suggestion by the FDA is that pregnancy should be ruled out by appropriate tests, prior to instituting postcoital therapy.

In view of the suspected risk associated with stilboestrol it seems preferable to substitute ethinyloestradiol which is apparently quite as effective for interception while it differs chemically from stilboestrol and has a different biological effect. No foetal abnormalities were found in infant macaque monkeys whose mothers had been treated with small doses of various oestrogens, including stilboestrol and ethinyloestradiol. In human subjects, no instance of the adenosis-carcinoma syndrome was observed in the offspring of mothers treated with ethinyloestradiol during pregnancy.

In summary, then, the use of ethinyloestradiol as a postcoital pill, in a dose of 5 mg. per day for 5 days, is suggested in preference to stilboestrol.

Continued investigation of this method is indicated.

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ALLEGED THROMBOEMBOLIC AND CARCINOGENIC HAZARDS OF CONTRACEPTIVE STEROIDS

By

DR. J. W. GOLDZIEHER

Ladies and Gentlemen, I would like first to thank you all for the very cordial invitation to speak here.

It is my privilege to speak on thromboembolic and carcinogenic hazards which have been attributed to the oral contraceptives, even though, at worst, they would be rare complications. Since they have had a great deal of impact on the thinking of regulatory agencies, which determine in any country whether the drug will be permitted, they certainly deserve your attention. Hazards, real or alleged, will differ from one country to another, from one ethnic group to another and from one nutritional status to another. Thus, thromboembolic disease appears to be a disease characteristic of sedentary, urbanised, populations and is rarely found in rural, physically active people. Therefore, it is extremely important in the world view of these things, not to assume that data which are generated in one environment, in one culture, are necessarily applicable to another environment and another culture. The cautions invoked by the Food and Drug Administration of the U.S. are not necessarily justified in some other country, whose entire way of life, nutrition, ethnic background, etc. may be quite different; *and yet that has been done*. We know for a fact that the Food and Drug Administration in the U.S. has such an international impact that they have had to create an international division, because of the constant interchange of inquiries. Unfortunately, many people tend to skip over the fact that findings in the U.S.A., Great Britain and Sweden may not be applicable to S.E. Asia, and one of the reasons that I am happy to speak here is to call this to your attention, so that you will keep the findings which you read in the foreign literature in proper perspective.

Let us now turn to the question of carcinogenesis. Carcinogenesis has had an interesting history: the first intimation that

oestrogens produced breast cancer was obtained by a Frenchman in 1933, who injected very large doses of oestrogen continuously into one special strain of *male* mice. There are other strains of mice in which you can inject all the oestrogen you want and you never get breast cancer. However, there is no experimental animal in which a breast cancer has been produced by cyclic oestrogen administration. It always has required continuous, high level, long term oestrogen administration. Usually the tumour is initiated by carcinogens such as dimethylbenzanthracene (DMBA) and the oestrogen has accelerated the mammary carcinoma. In what respects this animal model has a relationship to human mammary carcinoma is a big question, to which no one has the answer today. Certainly it is not justified to assume that what is found in a male mouse given DMBA and loaded with oestradiol benzoate for half its life, may have any relationship to the carcinogenicity of oestrogens in oral contraceptives.

In fact, the tumours produced in mice have some very peculiar characteristics. If you give oestrogen, the tumour grows, if you take away the oestrogen, the tumour disappears. This certainly is not characteristic of human mammary carcinoma. If one induces such a tumour with DMBA and oestrogen and then does a hypophysectomy the tumour disappears in spite of the oestrogen. This means according to our present concept, that the oestrogen is, in these cases, a co-carcinogen which probably works by stimulating the production of prolactin from the pituitary: prolactin has a carcinogenic action under certain conditions in the mouse.

These findings cannot be reproduced in monkeys. This is very important, because the primate is obviously a much better model of the human disease than the mouse or the rat or the guinea pig, and *no monkey*

experiment of any duration has ever produced mammary carcinoma by oestrogen alone.

So much for the animal data except one further point. Very recently, the British conducted a large scale study on the oestrogen relationship to carcinoma in mice and rats, and their conclusion, in a nutshell, was that *no causal relationship could be demonstrated*. Scientifically, the problem of oestrogen effects on mammary tumours is a very important one, but in pragmatic terms, for those of you who are involved in the question of whether to use oral contraceptive pills or not, the experimental evidence does not constitute the demonstration of a human hazard.

When we come to clinical data, though oral contraceptives have been used for 15 or 16 years, very few people have used them continuously for 15 or 16 years. Therefore, the population at risk has not been large enough to say that the latent period of cancer has elapsed. One can do what is called a "case-control study" (of which I will have more to say later), where people who take these pills and those who do not are compared as to the incidence of breast nodules. I do not believe in case-control studies as a reliable scientific method, but there are those who do and who have used it. A group in Britain and a group in

the U.S.A. found no association between the oral contraceptive users and breast nodules. Actually, after two years, there were fewer nodules in pill users than in non-pill users, suggesting that the oral contraceptives have a preventive effect against the development of benign breast nodules. There is, however, a group of people who have been taking oestrogens for very long periods of time and who provide an excellent source of information regarding the incidence of mammary carcinoma, menopausal women who have been given cyclic oestrogen for long periods of time.

I summarise for you on Table 1, major series that have been collected on women who have used cyclic oestrogen therapy for long periods of time. In the last vertical column is the actual number of mammary carcinomas which were found. It is, as you will see less than the expected figure. Now, the difference is not statistically significant. This is not a conclusive experiment because there are many technical problems with this kind of study. However, the data available today from this sort of study do not bear out any carcinogenic potential of oestrogens.

A better example is to look at the morbidity and mortality data. We know when oestrogens were first marketed; we know

TABLE 1

CUMULATED EVIDENCE ATTESTS TO SAFETY OF ESTROGEN THERAPY†

† Adapted from Bakke, J. L., *West. J. Surg.*, 71 : 241 (Nov. - Dec.) 1963.

		Pt. yrs.	No. pts.	Duration (yrs.)	Expected cancers	Actual cancers
Gordan ^{1,2}	..	1,200	120	14	12-15	0
Wilson ^{3,4}	..	2,604	304	17	20	0
Wallach ⁵	..	1,480	292	25	22*	5**
Schelyer-Saunders ⁶	..	—	500	15	30*	0
Geist ⁷	..	—	206	5.5	12*	
Totals	..		1,422		96	5**
* Investigator's estimate.						
** Uterine cancers - only one of these occurred after 1945.						

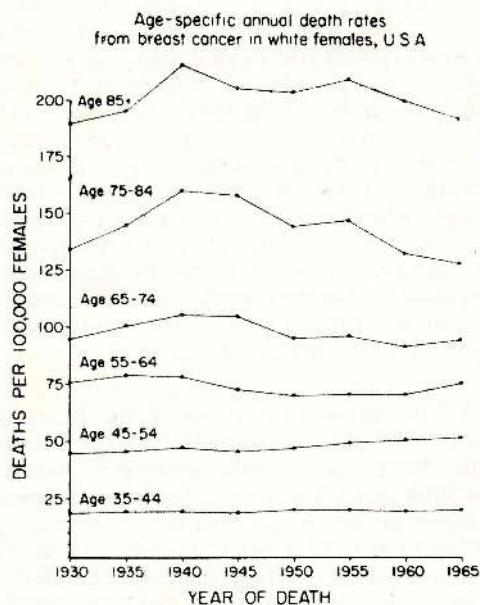


FIG. 1.

when they came into widespread use for menopausal therapy; and we know that many of those women have now taken for 20 or 30 years menopausal oestrogen therapy. So, the necessary time has lapsed. In Connecticut and certain other States in the U.S.A. there is an excellent Breast Cancer Registry. Fig. 1 shows some of the data. In the relevant age groups 55 to 64 and 65 to 74, there is no increase in the morbidity and mortality from breast cancer assuming a latent period of about 20 years.

Finally, a very interesting U.S.A. study in 1969 reported incidence of *various* cancers among women who received oestrogen therapy. It appeared that the incidence of breast cancer was not reduced in women who have been taking oestrogens but begins to occur approximately 10 years later. Oestrogens may have a *postponing* effect on the onset of breast carcinoma in American women taking cyclic oestrogen therapy. This observation applied not only to breast cancer, but to all cancers reported. I have no explanation for this, nor is this the time to go into it, but these data reflect the available clinical evidence relating oestrogens to cancer.

We have one more question on carcinogenesis, and that concerns certain

progestational compounds like chlormadinone and medroxyprogesterone. Given to beagle dogs in very large doses, they produce mammary tumours. The question is, what relevance have beagle dogs to humans? The beagle, like any other dog, comes into heat only twice a year; therefore the superimposition of a menstrual cycle is quite foreign to the physiology of the dog. Moreover, the metabolism of steroids, and particularly progestational steroids in the dog is entirely different from that of man. Since the animal is not used to this kind of hormonal exposure, and since it does not handle these hormones the way human beings do, one can legitimately question whether beagle breast tumours have similarity to human breast tumours. The probability is that they do not, but they have nevertheless produced considerable disturbance among the regulatory agencies who are under all sorts of pressures to make "prudent" decisions. On that note, we can leave the question of carcinogenicity and turn to the question of thromboembolism.

Thromboembolism is an admittedly rare condition when it is idiopathic and not following surgery, delivery, accidents, hypertension and so on. In spite of its great rarity, it has created an enormous amount of discussion and has in many ways obstructed the widespread use of oral contraceptives. In 1961 in Los Angeles, California, one of the newspapers found that two young women on oral contraceptive pills happened to get thromboembolism at the same time. This was enough for front-page headlines. After that it became a public issue. Now it is quite obvious that if millions of women are taking a particular drug, whether it is an oral contraceptive or aspirin, some of them will get appendicitis, some of them will be hit by automobiles, and some of them will develop thrombophlebitis.

The important question here is whether it is causally related to the drug in question. Now when a rare event like phocomelia occurs with thalidomide, there is very little difficulty in establishing a causal relationship. When the event is common and the causal relationships are not immediately apparent, it becomes difficult and sometimes almost impossible to establish a causal relationship.

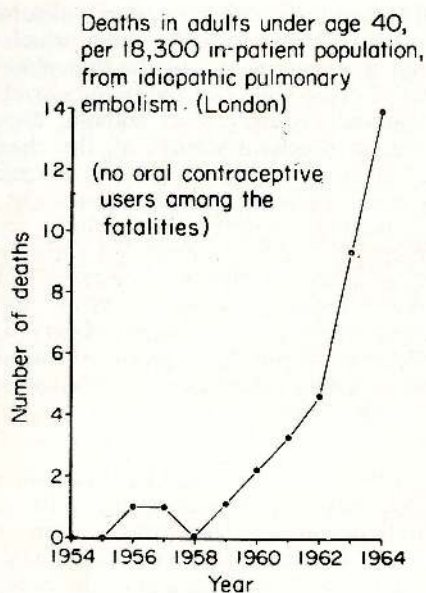


FIG. 2.

You will see in Fig. 2 the incidence of pulmonary embolism. In a particular hospital in London there was an enormous rise in pulmonary embolism which co-relates exactly with the time that the oral contraceptives were first introduced in England. There is only one problem—none were pill users. So the disease itself was changing and had these been pill users, it would have been very easy to say that with more use of oral contraceptives, there is more pulmonary embolism, there must be a causal relationship.

To find out what the facts of this matter are, we first have to find out what the incidence of idiopathic thromboembolic disease is in the population at large. This is very difficult to do, but by and large the incidence is of the order of 1 per 1000 women per year. You may remember, in the very early days of the thromboembolism scare, that one reason people were scared was that the pill produced a "pseudopregnant"

state, and thromboembolism is one of the complications of pregnancy. a matter of fact, thromboembolism is not a complication of pregnancy at all. It is a complication of delivery and the post partum state. Our estimate of the incidence in 350,000 women during pregnancy was about 0.5. In the post partum state, the incidence is about 10. Thromboembolism is not associated with the high levels of hormones in pregnancy: thromboembolism is associated with the trauma of labour and delivery and the post partum state. Given those preliminaries let us look at the data from clinical trials in family planning clinics. In over a million cycles the incidence is about 0.9—in other words, of the same order of 1 per 1000 women per year, which is our best estimate for the normal incidence. In a particular trial we carried out in San Antonio where the supervision was much better we found an incidence of 0.6. Certainly, there was no more thromboembolic disease in that group than in others. So from clinical trials on huge samples, there is, to date, no evidence of increased thromboembolic disease.

These clinical trials are open to criticism: one may lose patients, one may not hear of the thromboembolic disease, and so on. There is an epidemiological approach called a "case-control" study. The case control study is where you look at all patients who enter a hospital with thrombophlebitis, reject the ones with thrombophlebitis with known causes, and look at the rest to see how many of them took oral contraceptive pills. Then you try to match the patients against other patients who do not have thrombophlebitis and see how many of *them* are taking pills. If those who have thrombophlebitis use pills much more than those who did not have thrombophlebitis, one is entitled to say, that there is some kind of an association here. If you look at one case control study and its relative risks some peculiar things emerge (Table 2). In

TABLE 2
RELATIVE RISK OF USING ORAL CONTRACEPTIVES, BY CITY (SARTWELL STUDY, 1969)

City	No. matched pairs	Relative risk of thrombophlebitis (User/Non-user)	Statistical Significance
Baltimore & Washington, D.C.	26	2.2	N.S.
Pittsburg	25	3.0	N.S.
New York	83	4.2	P<01
Philadelphia	41	17.0	P<.001

Baltimore and Washington, no increased risk could be established. In the data from Pittsburgh, no increased risk was established. In New York there was some risk, and in Philadelphia there was a very large risk. Now what are we supposed to assume? Girls in Philadelphia shouldn't take pills? What is done is to lump all the figures together to make a nice average and then you say there is a risk. Such data are open to a good deal of criticism.

In the U.S. we have a lot of automobile accidents. You will find that 95% of people who have an automobile accident before noon, drank coffee that morning. On the other hand, two thirds of the people who have automobile accidents after 6 p.m. drank alcohol. Now we know that alcohol is related to automobile accidents because we know that it disturbs co-ordination and sensorium. Experiments tell us that alcohol is bad, not the association; the association with coffee is stronger but only experiments can tell us what is the cause and effect. If one sees an epidemiological association less obvious than coffee, alcohol and automobile accidents, you must be very careful not to assume that an association is the same as cause the effect. Yet this is what has been done by many of the regulatory agencies and by many scientists. The interesting thing is that if the birth control pills were an initiator of thromboembolic disease, it ought to increase the incidence of thromboembolic disease. But even the British data do not bear this out. This is very difficult to explain. There is also the argument that because oestrogen produces changes in

clotting factors this causes thromboembolism. There are two facts which go against that argument. In the first place no test of clotting ability of the blood correlates with actual occurrence of embolic disease. Second, in pregnant women all the changes which occur in the blood with oral contraceptives occur to a far greater extent (and for nine months continuously without cyclic interruption every month) and there is no increase in the incidence of embolic disease in the pregnant woman. Why should changes that produce thrombophlebitis when caused by a pill not produce thrombophlebitis when they occur in association with pregnancy?

One further relationship has been adduced to say that oral contraceptive pills cause thrombophlebitis. There was a joint study in U.K. and Sweden which claimed a relationship with the dose – the higher the dose, the higher the incidence of thrombophlebitis. From other U.S. data, we see no association with dosage. The figures are well within the normal range of about 1 to 3 per 1000 women per year. The U.S.A. data do not bear out the original dose-response association.

So much for thrombophlebitis. Let us assume that everything I have said is wrong. Let us assume that everything that has been said by the alarmists about thromboembolic disease is true. Let us say the worst risk they have calculated is correct. Then we have one more question. How important is it? (Table 3) The mortality

TABLE 3
PREGNANCY, CONTRACEPTION AND DEATH RATES
(Annual rates per million users)

Method	No. of pregnancies	No. of deaths due to		Total
		(1) Pregnancy	(2) Method	
Unprotected exposure	800,000	200-1,000	—	200-1,000
Rhythm	230,000	64	—	64
Criminal abortion	800,000	—	150-400	150-400
Diaphragm	200,000	56	—	56
Condom	100,000	38	—	28
IUD	50,000	12	24	36
Oral contraceptive (max.)	10,000	3	24	27
Annual Deaths from other causes, per million (United Kingdom 1957-1961)				
Lung cancer related to smoking				900
Road accidents (women only)				59
Suicide (women only)				33

from pregnancy and delivery varies from one society to another. In Sweden it is extremely low; elsewhere it is much higher. There is a range. If we take a million women exposed to pregnancy per year, we expect to get 100,000 pregnancies and in the U.S.A. we would get about 200 deaths. With the condom, in a million users we would expect to find about 100,000 pregnancies and we would expect about 28 deaths. In a million women using the I.U.D. we would get only 50,000 pregnancies and about 12 deaths from the pregnancies plus perhaps a couple of dozen deaths associated with infection, perforation etc. with the IUD giving a total of 36 deaths.

With oral contraceptives, properly used, we would expect a maximum of about 10,000 pregnancies per million women; we would expect 3 deaths due to pregnancy, and if the alarmists on thromboembolism are right, we would expect 24 deaths from thromboembolism, adding up to 27. 27 is still the lowest number of deaths on the list. So, if we accept the thromboembolic risk as real, we are still going to save more lives by putting women on the pill, if they use it properly, than by offering them any other alternative. That is the perspective in which a family planning group, concerned with the welfare of women who go to a clinic, must have. Those are the statistics which really count.

EXPERIENCES WITH AN INJECTABLE CONTRACEPTIVE IN THAI WOMEN

By

DRS. SUPORN KOETSAWANG, SUWANEE SRISUPHANDIT, SABIANG SRIVANABOON,
PRAPAS BHIRALEUS, DAUNGDAO RACHAWAT, ORAWAN KIRIWAT
and AMORN KOETSAWANG

Although the long-acting injectable contraceptive has been studied for over 10 years, the feasibility of introducing this method into mass family planning programmes is still debatable.

In Thailand, the long-acting injectable contraceptive has been extensively used in the northern rural area with satisfactory results by McDaniel *et al.*,^{1,2}. However, from their recent study, despite a high level of initial acceptability, there was a relatively rapid drop-out rate among users.³ This method has also been used considerably in private practice, in some instances unfortunately, without informing the patients about the possibility of abnormal bleeding patterns and delayed return of ovulation after cessation of the medication. Lack of proper selection of patients and inadequate education of the acceptors has added more debatable opinion regarding the use and acceptability of this method.

It is repeatedly asked whether or not this method should be used in the national family planning programme of Thailand.

This study aims to assess the feasibility of the long-acting injectable contraceptive, depotmedroxyprogesterone acetate* (DMPA) for mass family planning programme by assessing its effectiveness, adverse effects, patients' tolerance and acceptability.

Material and methods

The study is of 886 women enrolled as DMPA acceptors between mid 1967 through December 31, 1971 and observed up to September 30, 1973. The total months of use was 24,399.

DMPA 150 mg. was given intramuscularly every 90 days. The first injection was given within the first 5 days of the menstrual cycle. A number of other injectable preparations were tried previously but abandoned because of high pregnancy rates.

The following criteria were used for selection of patients:

- (1) Age 25 years and over
- (2) Women with 2 or more living children
- (3) Healthy woman with none of the following contraindications:

- Liver disease
- Known or suspected breast or genital malignancy
- Undiagnosed vaginal bleeding
- History of thromboembolic disorders
- Diabetes mellitus

- (4) Acceptance of the unpredictable bleeding pattern during medication

After having used this preparation for 2 years, with evidence of better return of ovulation after stopping the injections than anticipated, women under 25 years with one living child were also accepted.

On admission, the patient had a full medical history taken, and a complete medical and gynaecological examination, breast examination and Papanicolaou smear. The patient was given a menstrual diary card and instructed on its use.

The possibility of a changing menstrual pattern without any harm to her health was clearly explained.

*"Depo Provera" 50 mg./ml Upjohn Co., Kalamazoo, Michigan, USA.

At the follow-up and before the next injection, the patient's menstrual history was recorded. Non-specific questions concerning adverse effects were asked. Vaginal examination, Papanicolaou smear and breast examination were repeated every 12 months, or more frequently, if indicated.

Certain patients were agreeable to special studies: endometrial histology, liver function tests, renal function tests, oral glucose tolerance test, etc. prior to medication and at later intervals.

Ovarian biopsy was also done for histological study, if culdoscopic sterilisation or laparotomy for any reason was performed.

RESULTS

Patient Characteristics

The characteristics of the 886 women under study are shown in Table 1.

The majority were between 25–34 years old (75.9%) and had 3 or more living children (86.8%) with one or more sons (92.4%). Most of them had reached a primary or secondary educational level (90.4%). Over 90 per cent were Thai and Buddhist; 83 per cent lived in the Bangkok metropolis. The majority had relatively low incomes. Half of them were housewives.

Only 38 per cent of these women had previously practised contraception (Table 2).

TABLE 1
CHARACTERISTICS OF 886 DMPA USERS IN PER CENT

Age group	20 – 24 9.8	25 – 29 40.5	30 – 34 35.4	35 – 39 13.8	40 0.5	
Living children	0*	1	2	3	4	5
Total	0.1	0.1	13.0	34.9	22.0	29.9
Son	7.6	26.9	35.6	19.0	7.4	3.5
Race	Thai 95.0	Thai & Chinese 1.5		Chinese 3.5		
Religion	Buddhist 94.1	Confucious 2.6		Islamic 1.8		Christian 0.7
Education	None 7.1	Primary 79.2		Secondary 11.2		Vocational or higher 2.5
Occupation	House- wife 50.6	Farmer 12.3	Semi- skilled Worker 17.0	Sale worker 16.1	Clerk 2.5	Teacher 1.3
				None 0.1*		
Income (Baht)	500 8.0	500–999 37.8	1000–1499 29.6	1500–1999 11.0	2000 13.5	Dependent 0.1*

*one case of Down Syndrome.

TABLE 2
PREVIOUS CONTRACEPTIVE PRACTICE OF 886 DMPA USERS IN PER CENT

<i>Practice</i>	<i>None</i>	<i>Regular</i>	<i>Occasional</i>	<i>Total</i>	
No.	594	222	115	886	
Per cent	62.0	25.0	12.0	100	
<hr/>					
<i>Previous method*</i>	<i>Oral pill</i>	<i>IUD</i>	<i>Injectable</i>	<i>Conventional</i>	<i>Total</i>
No.	247	60	34	12	353
Per cent	70.0	17.0	9.6	3.4	100

*Method used by 337 women – (one woman might use more than one method).

The first three most commonly used methods were oral contraceptive (70%), IUD (17%) and injectable contraceptive (9.6%). Women who previously used injectable contraceptives had discontinued this method for some time.

TABLE 3

REASONS FOR CONTRACEPTION IN 886 DMPA USERS

Reasons	No.	%
Enough	698	78.7
Spacing	138	15.6
Financial	42	4.7
Medical and eugenic	8	0.9
Total	886	100

Most of these women (78.8%) practised contraception for family limitation (Table 3). As shown in Table 4, the two big sources of information which brought them to the family planning clinic were the post-partum family planning motivation and education programme (62.9%) or were patients from our clinic (32%).

TABLE 4

SOURCE OF INFORMATION ABOUT DMPA

Source	No.	%
Post-partum program	557	62.9
Patients of this clinic	284	32.0
Patients of other family planning clinic	2	0.2
Doctor or nurse not in the program	14	1.6
Mass media	15	1.7
Miscellaneous	14	1.6
Total	886	100

Terminal Status

At the cut-off date of the study, there were 513 dropped out cases and 373 women were still using the method. As shown in Table 5, after one year of use, 76 ± 1.1 per cent were still active.

The continuation rates after 2,3 and 4 years decreased to 60.2 ± 1.8 per cent, 46.4 ± 2.0 per cent and 37.6 ± 2.2 per cent respectively. The number of acceptors

continuing beyond 4 years is too small for statistical study.

TABLE 5

CUMULATIVE CONTINUATION RATES*

Period	Cumulative continuation Rates
After 6 m.	88.7 ± 1.1
After 1 yr.	76.2 ± 1.5
After 2 yrs.	60.2 ± 1.8
After 3 yrs.	46.4 ± 2.0
After 4 yrs.	37.6 ± 2.2

*Statistical technique used derived from Tietze's "Recommended Procedure for the Statistical Analysis of clinical data on Intrauterine Contraceptive Device."

Reasons for Drop-out

Of 513 dropped-out cases, 25 women (4.9%) became pregnant during medication (method failure), 5 women (1%) became pregnant because of delayed visits, 35 women (6.8%) discontinued the method for planned pregnancy, 20 women (4%) stopped practising contraception because protection was no longer needed. Thirty-six women (7%) discontinued the method, with continued exposure to the risk of unplanned pregnancy. A large group, 165 women (32.1%) changed the method. One woman changed to another clinic, using the same method. 226 (44.1%) were lost to follow-up.

TABLE 6

TERMINAL STATUS OF 886 DMPA USERS
(CUT-OFF DATE: SEPT. 30, 1973)

Terminal Status	No.	%
Terminated cases	25	4.9
Pregnancy before injection (delayed visit)	5	1.0
Planning pregnancy	35	6.8
Protection not needed	20	4.0
Discontinuation, other reasons	36	7.0
Changing method	165	32.1
Transferred to other clinic	1	0.2
Lost to follow up	226	44.0
Total	513	100
Continuing cases	373	

*Husband away 13, separated 5, husband died 2.

The reasons of discontinuation or change of the method are shown in Table 7. Abnormal menstrual patterns, including amenorrhoea (13.4%), prolonged and/or irregular bleeding (16.4%) were the most important medical reasons despite the previous warning of these effects and regular reassurance. These problems will be discussed later.

TABLE 7

REASONS FOR DISCONTINUATION AND CHANGE OF METHOD (DISCONTINUATION 36, CHANGING METHOD 165)

<i>Reason</i>	<i>No.</i>	<i>%</i>
Medical (130 = 64.7%)		
Amenorrhoea	27	13.4
Abnormal bleeding	33	16.4
Miscellaneous complaints	48	23.9
Medical condition not related to method	22	10.9
Personal (71 = 35.3%)		
Clinic staff's advice	19	9.4
Regular attending became difficult	19	9.4
Infrequent sex relation	14	7.0
Financial	4	2.0
Other personal reasons	15	7.5
Total	201	100

Another major reason was the large group of miscellaneous complaints (23.9%) such as general weakness, palpitation, dizziness, pelvic pain, etc. which were not the actual reasons of discontinuation. Behind these complaints were fear and anxiety caused by abnormal bleeding patterns. The occurrence of illness during medication not related to the method (10.9%) such as appendicitis, bronchial asthma, etc. was also a reason for discontinuation.

Nineteen women (9.4%) changed to interval tubal sterilisation because of the clinic staff's advice. Difficulty in regular attending the clinic was also an important reason (9.4%). Most women could attend the clinic, but to come exactly on the day of the next injection was hardly ever possible for some women. There were 14 women (7%) who changed to more simple methods such as the condom because their sexual relations were considered too infrequent to

use DMPA. The other personal reasons included objection to laboratory tests, shifting of residence, belief that one injection will offer protection up to one year and a forgotten appointed date.

Contraceptive Methods selected after DMPA

Various methods selected by 165 women after discontinuation of DMPA are shown in Table 8. As many of them had enough children, they were persuaded to change to interval tubal sterilisation (24.8%). In 6 cases, their husbands had vasectomy done. Oral contraceptive pills was the most frequent method chosen (40.6%). This was partly because of our advice, given in the hope that the oral contraceptive would mask the bleeding problems after discontinuing DMPA. The IUD though not so suitable in such cases, were used by 25 women (15.2%). Many women (15.8%) changed to other methods, mostly condom and vaginal spermicide³.

TABLE 8

METHOD SELECTED AFTER DMPA (165 CASES)

<i>Method</i>	<i>No.</i>	<i>%</i>
Interval sterilisation	41	24.8
Vasectomy	6	3.6
Oral pill	67	40.6
IUD	25	15.2
Conventional	26	15.8
Total	165	100

Method Failure

As shown in Table 9, 25 women became pregnant during therapy, giving a pregnancy rate of 1.2 per 100 women years. All were from a highly fertile group with a mean age of 29 years and an average para 4. In three, pregnancies occurred after the first injection, endometrial study performed before the injection, revealed early proliferative endometrium. Pregnancy before medication was, therefore, excluded. In 23 cases, conception dates were calculated from date of the delivery, together with other evidence, such as pregnancy tests, occurrence of morning sickness, etc. Most estimated conception dates were in the last 14 days of the 3 months post-injection period. In 15 cases, conception had occurred in the last 10 days. Regarding the bleeding patterns during the last 3 months before

TABLE 9
SOME FINDINGS IN 25 CASES OF FAILURE

Age No.	20 - 24 3	25 - 29 8	30 - 34 14	
Parity No.	2 5	3 6	4 5	5 9
<i>Failure occurred after ordinal injection</i>				
	Injection order	No.	Injection order	No.
	1st	3	8th	1
	2nd	3	9th	—
	3rd	3	10th	1
	4th	2	11th	2
	5th	3	12th	—
	6th	3	13th	1
	7th	2	14th	1
<i>Estimated conception day</i>				
Day after last injection	Uncertain	71 - 75	76 - 80	81 - 85
No.	2	4	4	9
<i>Bleeding patterns during last 3 months before conception</i>				
Acceptable		18		
Irregular or prolonged		7		
<i>Pregnancy outcome:</i>				
Full term delivery 23:		Abortion 1:		Still pregnant 1

conception, 18 women had acceptable bleeding and 7 women had irregular or prolonged bleeding.

Out of 24 women followed up to termination of pregnancy, 23 cases had full term delivery and healthy children. There were two large babies weighing 4100 g. and 3850 g. One woman aborted about the 6th week of pregnancy. One woman was still pregnant. All of these women received one additional injection after conception as pregnancy was not diagnosed at the time of the injection.

Effects on Bleeding Patterns

It is difficult to describe or classify the bleeding patterns in women using this method. A normal bleeding pattern was seldom observed in our 886 cases. In this study, the patterns in 3 months following each injection were divided into 3 types: (1) amenorrhoea, (2) acceptable bleeding pattern which was not normal but less than 7 days' duration and at intervals of 28 ± 10 days, and (3) irregular or continuous bleeding. As one might expect, there was some overlap between these types.

Detailed study of bleeding patterns in women not receiving additional hormonal treatment to correct the bleeding patterns are shown in Table 10. With continuation of injections, the incidence of amenorrhoea gradually increased from 12.6 per cent after the first injection to 46 per cent after the 16th injection. Prolonged and irregular bleeding tended to decrease after subsequent injections. The incidence of acceptable bleeding patterns remained approximately between 30-35 per cent for all periods.

In all bleeding patterns mentioned above, the bleeding was usually less than normal menstruation before therapy. Prolonged or continuous bleeding was usually light or only spotting. Heavy bleeding was rarely seen during medication.

The duration of bleeding or spotting after each DMPA injection is shown in Table 11. The incidence of bleeding lasting 1-7 days remained unchanged in approximately 25-30%. The percentage of women with longer bleeding periods tended to

TABLE 10
BLEEDING PATTERNS IN 3 MONTHS INTERVAL FOLLOWING EACH INJECTION

Injection order	Bleeding pattern						Total cases studied	
	Amenorrhoea		Acceptable		Prolonged or irregular			
	No.	%	No.	%	No.	%	No.	%
1	48	12.6	184	48.4	148	38.9	380	100
2	70	27.9	112	44.2	70	27.9	283	100
4	99	39.9	86	34.7	63	25.4	243	100
8	87	37.3	89	38.2	57	24.5	233	100
12	84	43.5	58	30.1	51	26.4	193	100
16	40	46.0	36	41.4	11	12.6	87	100

TABLE 11
DURATION OF BLEEDING IN 3 MONTHS INTERVAL

Number of bleeding in 3 months after each injection													
3 months post-injec.	(Amen)		1-7		8-14		15-21		22-28		28		Total
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	
1	48	12.6	109	28.7	96	25.3	64	16.8	20	5.3	43	11.3	380
2	79	27.9	77	27.2	71	25.1	22	7.8	14	4.9	20	7.1	283
4	99	39.9	64	25.8	46	18.6	13	5.2	13	5.2	13	5.2	248
8	87	37.3	62	26.6	36	15.5	22	9.4	19	8.2	7	3.0	233
12	84	43.5	46	23.8	28	14.5	18	9.3	8	4.1	9	4.7	193
16	40	46.0	26	30.0	13	14.9	3	3.4	1	1.1	4	4.6	87
Total	437	30.7	384	27.0	290	20.3	142	10.0	75	5.3	96	6.7	1424

decrease after subsequent injections. The longest bleeding period in this study was 81 days and occurred after the 4th injection. Fortunately, in this case, the bleeding was very light.

Management of Bleeding Problems

Regular reassurance was necessary to encourage the women to accept the abnormal bleeding or amenorrhoea. The patients were reminded about the pre-treatment instruction that abnormal but harmless bleeding patterns resulted from the injection. If the prolonged or irregular bleeding was not too frequent the patients usually accepted it. In fact, many women were satisfied with their amenorrhoea. Hormonal treatment was not routinely used for the treatment of bleeding problems but only in a few cases of continuous bleeding. For economic reasons, the already available oral contraceptive pills were used. One or two courses of oral contraceptive pills were given to correct continuous bleeding.

Body Weight Change

An increase in body weight 2.5 kg. or over from the control weight was found in 18.7 per cent of women at 3 months after the first injection and was increased to 62.8 per cent after 48 months of use (Table 12).

Other Complaints

Apart from the abnormal menstrual patterns, the majority of patients had no complaints. However, from some patients, there were so many subjective complaints that they could not be included in the illustrative table. The examples of these complaints were headache, dizziness, abdominal pain or discomfort, fatigue, palpitation, back pain, chest oppression, nausea, increase in libido, decrease in libido, loss of memory, insomnia, etc. These complaints were very difficult to evaluate and might be related to anxiety resulting from abnormal bleeding patterns.

TABLE 12
BODY WEIGHT CHANGE (2.5 KG. or more)*

Month of use	No. of cases	Gain		Loss		Unchanged	
		No.	%	No.	%	No.	%
3	400	75	18.7	33	8.3	292	73.0
6	274	32	11.7	5	1.8	237	86.5
12	229	55	24.0	12	5.2	262	70.7
24	228	127	55.7	12	5.2	89	39.0
36	189	124	65.6	3	1.6	62	32.8
48	86	54	62.8	1	1.2	31	36.0

*excluding post-partum cases

Effects on Breast and Lactation

Only two cases of fibroma of breast were found during the period of study. In our previous study it was found that this method promotes lactation and does not alter the milk composition.⁴

Laboratory Findings

The serum transaminases (SGOT, SGPT) and alkaline phosphatase performed in over 100 women before and during continued medication were all in the normal range. There were 3 per cent with slightly delayed BSP retention which returned to normal when repeated and might be only technical errors.

The values of blood urea nitrogen and fasting blood sugar in over 100 women before and during medication were all normal. The analysis of glucose tolerance studies are still not complete.

Abnormal Papanicolaou smears were found in 3 cases during medication. The final diagnoses were cervical dysplasia in 2 cases, and preinvasive carcinoma in one case. This seems nothing more than a coincidence.

Endometrial Change

The results of 163 endometrial biopsies performed after 3 months, is just before the next injection, are shown in Table 13.

Specimens which were inadequate for histological study were not included or interpreted as 'atrophic'. Some of these might be due to inadequate curettage because the surgeon tried to minimise the patient's pain and discomfort during the procedure. At 3 months after the first injection, 57.8 per cent of specimens showed a quiescent type of endometrium as described by Mishell *et al.*^{5,6}. The endometrial glands were narrow, non-tortuous and widely separated with oedematous and pseudodecidual stroma. Proliferative endometrium was found in 42.1 per cent at the same period.

After 6 months of use or just before the 3rd injection, the incidence of quiescent endometrium increased to 75.9 per cent and remained more or less the same up to 33 months of use. The incidence of proliferative endometrium dropped to 24.1% after 6 months of use but did not show a tendency to decrease after this period up to 33 months.

TABLE 13
ENDOMETRIAL CHANGE* IN DMP USERS

Duration of use (month)	Endometrial picture				Total Specimens	
	Quiescent		Proliferative			
	No.	%	No.	%	No.	%
3	48	57.8	35	42.1	83	100
6	22	75.9	7	24.1	29	100
9	10	76.9	3	23.1	13	100
12 - 33	27	71.1	11	28.9	38	100
Total	107	65.6	56	34.4	103	100

*Endometrial biopsy performed 3 months after 1st - 11th injection.

TABLE 14
ENDOMETRIAL TYPE AND BLEEDING PATTERNS

Endometrial picture	Bleeding patterns						Total Specimens	
	Acceptable		Prolonged or irregular		Amenorrhoea		No.	%
	No.	%	No.	%	No.	%		
Quiescent	33	30.8	26	24.3	48	44.9	107	100
Proliferative	34	60.7	12	21.4	10	17.9	56	100
Total	67	41.1	38	23.3	58	35.6	163	100

The bleeding pattern during the 3 month period before biopsies were obtained are shown in Table 14. Amenorrhoea was found in 44.9 per cent of women having a quiescent endometrium. The incidence of amenorrhoea in women having a proliferative type of endometrium was only 17.9 per cent.

Effects on Ovary

Ovarian biopsies were done on six women aged between 30-39 years, with 5-8 living children and receiving the 6th-9th injection of DMPA. All ovaries were rather small, fibrotic and less vascular. Microscopic examination showed thickened tunica albuginea in 2 cases. The thickest one was 33 microns. The cortical stroma was replaced by dense connective tissue in all cases. Only primordial follicles, early growing follicles, atretic follicles and cystic follicles were found. No corpora lutea were observed.

Return of fertility after discontinuation of DMPA

Twenty-nine out of 35 women discontinued DMPA for planned pregnancy. Twenty-eight women became pregnant within 2 - 11 months after discontinuation. Only one woman was still not pregnant after 18 months. Of these 28 pregnant women, 24 had delivered a full term healthy baby, 3 were still pregnant and one aborted at 8 weeks of pregnancy. The aborted woman was pregnant again a few months later and has delivered a healthy full term baby. The return of fertility in this group is quite favourable and there seems to be no correlation between the number of DMPA injections and the interval till pregnancy. However, the number of cases followed are not enough for statistical analysis.

Discussion

The use of DMPA 150 mg. given intramuscularly every 90 days, will provide an additional useful contraceptive method in family planning service. The acceptability of this method, as measured by continuation rates, is satisfactory.

The failure rates of 1.2 per 100 women-years in this study are higher than those reported from other Asian countries.^{7,8} There is no exact explanation for this except the high fertility of the Thai women. Age-specific birth rates for Thai women are relatively high at all ages⁹. In this study, the proliferative endometrium could be found even after the 10-11th injection. This may indicate the higher tendency to ovulation in this group of women. All 25 failures occurred during post-injection intervals with bleeding. Conception usually took place near or at the time of the next injection. Combining these facts together, it is apparent that the failure could be reduced by shortening the interval time between injections. Dodds has suggested that subsequent injection should be given no later than 12 weeks⁷. It is even safer to use an 80 days' interval between injections, especially in women still having bleeding during that particular post-injection interval.

There are two main problems in using this method; the unpredictable bleeding patterns and the question of delayed ovulation after discontinuation of therapy.

The possibility of a changing menstrual pattern without any harm to the woman's health should be clearly explained before hand. We found that many women accepted

the menstrual change well. Many are even happy with their amenorrhoea which will let them 'free for the whole month'. Prolonged and irregular bleeding can be better tolerated with additional hormonal treatment. McDaniel and Zelanik¹ put their patients on a cyclic oral oestrogen supplement every month (diethyl stilboestrol 0.5 mg. per day for 10 days) and reported more or less regular withdrawal bleeding and reduction in incidence of bleeding complications. We feel that little would be gained by routinely prescribing a cyclic oral oestrogen. But it will be useful in amenorrhoeic patients if they desired so. Prolonged bleeding can be successfully treated by giving ethinyl oestradiol 0.015 mg. once daily for 21 days or one cycle of oral contraceptive pills which contains at least 0.05 mg. of oestrogen⁶. Oral contraceptive pills are used for this additional therapy in our clinic. The necessity for such treatment should not be more than a few months.

How soon fertility would be restored after discontinuing DMPA is another problem. Though many pregnancies occurred relatively soon after stopping medication in our study, this is not statistically conclusive. Results of previous studies^{2,7,8,10,11} suggest that return of ovulation and fertility after discontinuing DMPA, usually occurred no later than 12 months after the last injection. Dodds suggested from her findings that DMPA can be used at all ages and all parities, excluding nulliparae⁶. However, as delayed ovulation may occur, it would be advisable for the DMPA users to switch to other contraceptives one year before planning another pregnancy.

In conclusion, this method is well accepted by women of low socio-economic groups. It is especially suitable for multiparous women who cannot tolerate the IUD and cannot correctly take the oral pill. Adding this method to the mass programme will offer one more choice of contraceptives and make the whole programme more acceptable.

Summary

1. The results of the study on long-acting injectable contraceptive, Depot medroxyprogesterone acetate (DMPA) given intramuscularly every 90 days in 886 patients with 24,399 months of use is presented.
2. The cumulative continuation rates after 1, 2, 3 and 4 years were 76 ± 1.1 per cent, 60.2 ± 1.8 per cent, 46.4 ± 2.0 per cent and 37.6 ± 2.2 per cent respectively.
3. The main adverse effects were prolonged or irregular bleeding and amenorrhoea. Prolonged or irregular bleeding tends to decrease after subsequent injections, but amenorrhoea tends to increase. These effects can be treated by additional oestrogen.
4. The incidence of other adverse effects was low and most were of a vague nature.
5. No serious adverse effects were found in any of the patients.
6. The method failure can be reduced by shortening the interval between injections to 80-84 days, especially in women still having bleeding during that particular post-injection interval.
7. The return of fertility after discontinuation of DMPA, proved by occurrence of pregnancy, is favourable. However, as delayed ovulation may also occur, it is advisable that women who plan a pregnancy switch from DMPA to another contraceptive method about 1 year before planning pregnancy.

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PRESENT STATUS OF CONTRACEPTIVE INJECTIONS

By

DR. EDWARD T. TYLER

Since the beginning of modern methods of contraception, the development of a birth control injection has been a major goal of those concerned with family planning. There are many reasons for this, among the foremost of which may be the fact that injections e.g. vaccines have long been considered acceptable in various countries as techniques in preventive medicine. It can be reasonably argued that cultures which will accept vaccines against endemic diseases would also accept the principle of injections against unwanted pregnancies, assuming of course that the importance of family planning was adequately comprehended and endorsed by the population involved.

Another major reason why contraceptive injections seem to be important to family planning experts is the fact that these can be administered at any reasonably required intervals by public health personnel who would need only minimal training. The administration of an injection by an individual other than the recipient, leads to a certain degree of confidence. The same of course, cannot be said for such methods as pills, condoms, jellies or even I.U.D.'s.

Another important advantage of injections as compared, for example, to I.U.D.'s is the fact that substantially more skill is required to insert an I.U.D. than to give any of the ordinary injections. In addition, depending on the frequency of the interval between injections and the cost of medication, the injection could be cheaper.

Unfortunately progress in the field of development and utilisation of contraceptive injections has been comparatively slow. The reasons for this are many, and differ in relation to the type of injection being considered. Until now there have been three types of birth control injections which have commanded most attention. These are (1) contraceptive vaccines based on typical antigen-antibody reactions, (2) long acting hormone injections similar to the

chemical used in oral birth control pills but designed to be effective when given at intervals of 12-24 weeks, and (3) short-term injections which are designed to be given once every 4 weeks and thereby maintain a reasonable degree of cyclic bleeding resembling menstruation. More recently, attention is being directed towards the possible use of anti-gonadotrophins and anti-releasing factors but these are still at a very early stage in development in a few research centres. In this article I would like to discuss each of the methods separately and not necessarily in order of importance.

Contraceptive Vaccines

Theoretically, the development of a contraceptive vaccine would offer a very intriguing method of family planning. If, for example, an injection could be given to immunise individuals and render them infertile for a period of time it would undoubtedly be a great step forward in helping to resolve our international population problems. It is not beyond possibility that a vaccine could be administered whose effects would persist for perhaps two or three years or more, and after this period of time the individual would again be fertile. I personally do not feel we are very much further along in the field of immuno-contraception than we were twenty years ago. Since I have had considerable interest in immuno-contraception from the standpoint of ultimate development of a birth control vaccine, I have had an opportunity to both participate and observe development in this area. On the basis of our experiences, I am not convinced that spontaneous infertility is caused by immunological reactions or that we have any substantial clues directing us toward the development of a method by which immunological infertility can be induced in humans on a safe and practical basis. This opinion acknowledges the fact that azoospermia, for example, can be induced in men by giving testicular injections

fortified with materials like Freund's adjuvant and that this lack of sperm production may persist for some time, but the damage to the testes evidenced by histological patterns is such, that one wonders whether further pursuit of this type of induction of sterility would offer much promise. There have also been suggestions that perhaps antibodies can be produced in the cervical mucus that would agglutinate sperms and thereby prevent them from reaching the tubes. Unfortunately, the evidence for the presence of sperm antibodies in cervical mucus is very flimsy and after many years of study, I am impressed with the lack of occurrence of agglutination in physically normal cervical mucus although theoretically antibody immobilisation of sperm in the cervix would be a good approach to contraception.

Another relatively widely popularised area of immuno-reproductive research involves detection of sperm antibodies in blood serum. Presumably when these occur, there is some immunological reaction with either the sperm or the egg which prevents normal fertility. We have studied several of these serum antibody tests and have not been able to find any correlation between positive tests and infertility. Furthermore, even if sperm antibodies in the serum were important, no one has clearly demonstrated the site of their action.

A major reason for my discouragement about the development of a contraceptive vaccine is the fact that probably twenty years ago there was more activity and research support in this area than there is today. Apparently most supporting agencies are also discouraged about the prospects of obtaining practical results from supporting immuno-reproductive research and to my knowledge there are only a few centres where any substantial research is currently being done in this field.

Once-every-four-week injection

As many family planning workers know, a hormonal contraceptive injection was available for research in the United States for a number of years and it has been marketed on a limited scale in other countries. The injection I refer to is "Deladroxate" which contains 10 mg. oestradiol-oenanthate, a long acting oestrogen, together with 150 mg.

of dihydroxyprogesterone acetophenide, which is a long acting progestogen presumably having a duration of action of about 3½ weeks. We evaluated in detail a series of patients on "Deladroxate" injections for several years, administering the injections on the same day each cycle on the assumption that ovulation would be inhibited just as it is with the pills, and that the endometrium would be maintained for the duration of the medication. The occurrence of withdrawal bleeding would be related to the lack of effective support of the endometrium after the injectable material had been completely absorbed. Since the company which manufactured "Deladroxate" decided to discontinue further research on this product that would be required for Food and Drug Administration approval in the United States, and its use is very limited, I will not spend too much time on it. Briefly, in our experience, there were two major difficulties with this type of injection (1) Breakthrough bleeding was excessive, and (2) there was not sufficient maintenance of regular cycles in an adequate percentage of women. Contraceptive effectiveness was very good but one can only conjecture that the sponsors felt that their product would not be competitive with the pills, since the interval between injections was relatively frequent and moreover there were cost considerations in the developed countries. Furthermore, it was obvious that the Food and Drug Administration would have required a much more substantial amount of study than the company felt was warranted. In general, therefore, it was a rather discouraging situation. Despite this, in countries where "Deladroxate" is available it has a certain degree of popularity.

Depot medroxy progesterone acetate injections

The injectable material that seems to show the most promise is the long-acting progestogen alone. We have utilised and studied injections given every 12 weeks of 150 mg. of depot medroxy progesterone acetate (DMPA) for about 9 years. While the total number of patients in our study series is not great, we have treated several hundred others, and those in the research programme have been studied in considerable detail, particularly with a view toward determining whether these injections might be associated with serious toxicity problems. The results of our toxicity studies failed to

reveal any serious metabolic problems and there was excellent effectiveness. Any patients missing the required time for injections were automatically dropped from our series, and if pregnancies *did* occur, these would have had to be medication failures. Such failures *did not* occur with this preparation if given at a 20 day interval in 150 mg. dosage.

While there are several mechanisms of action which may account for the contraceptive effect of DMPA, it is likely that inhibition of ovulation is the major one. In addition there are effects on the cervical mucus, the endometrium and presumably several other areas which have not been completely elucidated.

Although contraceptive effectiveness is excellent, there are some problems associated with the administration of DMPA. The major difficulty is the fact that cycle regularity is not maintained. In contrast to oral contraceptive pills where bleeding occurs at approximately 4-week intervals, cyclic regularity is not maintained. For this reason patients have to be told in advance that they will not have regular periods and may either have persistent spotting or heavier bleeding, or that they may have varying degrees of amenorrhoea. Percentages of these problems vary in different patient populations, and a portion of our series has been tabulated. Despite the fact that bleeding problems can be very disturbing, if patients are adequately forewarned about them, there is a greater chance that they will remain in the programme. As a matter of fact, there was a time in our study, when it appeared that it would be necessary to discontinue the use of DMPA because of Food and Drug Administration regulations and a number of patients who were told this were very disturbed because this was the one method of contraception that they preferred.

In relation to Food and Drug Administration regulatory matters, this agency in the United States at one point, was concerned about laboratory findings suggesting that DMPA produced mammary tumours in beagles. This situation had been noted with other progestational agents, and its significance has been obscure. A subsequent directive from the Food and Drug Administration indicated that DMPA could continue

to be used in research programmes provided certain findings relative to metabolic effects and other evidence of proof of safety were evaluated. Because of this we subsequently conducted a rather detailed study of a limited number of patients to determine whether hormonal balances were dangerously altered and whether DMPA could safely be used. There included radioimmunoassays for gonadotrophins and ovarian hormones, glucose tolerance studies and evaluation of other laboratory parameters.

As a result of many detailed studies, including our own, the Food and Drug Administration recently indicated that DMPA would be made commercially available (after a brief "announcement" period) specifically for those patients who could not tolerate oral contraceptives or were for one reason or another primary candidates for this type of injection. This has been a marked step forward and may encourage family planning people in other countries to utilise this medication to a greater extent than before.

Results of Original Study up to 1970

At one point in our study, when we had about 250 women enrolled actively in the research programme several years ago, we analysed the effects of DMPA on the cycle and evaluated side-effects. At that time 244 women between 15 and 40 years of age had been enrolled in the programme. The average age was 25.7 years and all had demonstrated prior fertility. About two thirds of the women had 3 or more full-term deliveries, and about two thirds had had a pregnancy within a year of starting the injection programme. None of them had hormonal therapy for about 90 days before being admitted to the study. While the numbers analysed at the time were small, our subsequent findings suggest that the general percentages are valid.

In this type of injection programme we cannot use the term "cycle" to describe events since cycles are disrupted intentionally. Therefore we employed the term "interval" which implied the duration of time between the beginning of one bleeding episode and the beginning of the next. We note that these intervals were extremely variable, from 3 to 146 days. The unusual bleeding pattern suggested that we estimate the

total amount of bleeding observed in the entire group, and obtain averages to better evaluate the lengths of time the women were bleeding. Therefore, each 90 day injection period was separately tabulated according to the number of women-days of bleeding relative to the number of woman-days in each injection period. This provides a general impression of the average percentage of each injection period during which bleeding occurred. It was readily observed that there is a definite trend toward lowered percentages of bleeding during the later injection periods. Since women with a regular 28-day menstrual cycles having a period of 4 - 5 days, bled on about 17% of the days, one may quickly conclude that during the first injection period the average bleeding duration is almost twice normal, but by the third injection period it is close to that of untreated women. By the fourth injection period it is definitely less although in the later injection periods the number of woman-days observed was relatively very small.

Since bleeding problems constitute the major adverse effect occurring with the use of this injection, these occurrences should be considered an inherent part of the method. As to the other symptoms patients complained of, and reasons for discontinuance, these are summarized in the tables 1-13.

With excellent effectiveness and demonstrable return to normal fertility, as reported by us and others, the use of DMPA at 90-day intervals merits a substantial place in virtually all well-balanced family planning programmes.

TABLE 1
DISTRIBUTION OF PATIENTS BY AGE AND RACE IN DMPA 90-DAY INJECTION PROGRAMME

Age	No.	Per cent
15 -	2	0.9
15 - 19	39	17.0
20 - 24	67	29.1
25 - 29	63	27.4
30 - 34	37	16.1
35 - 39	18	7.8
40 - 44	1	1.7
Total	230	100
Not reported	14	
Mean age	25.7	
Standard deviation	6.1	
Median age	25	
Race	No.	Per cent
Non white	155	63.8
White	88	36.2
Total	243	100

TABLE 2

DISTRIBUTION OF PATIENTS BY GRAVIDA, PARA, AND ABORTUS IN THE DMPA 90-DAY INJECTION PROGRAMME

Gravida patients			Para patients		Abortus patients	
		%		%		%
0	9	3.7	11	4.5	166	68.0
1	54	22.1	64	26.2	47	19.3
2	37	15.2	46	18.9	17	7.0
3	29	11.9	34	13.9	6	2.5
4	39	16.0	32	13.1	3	1.2
5	23	9.4	23	9.4	2	0.8
6	19	7.8	16	6.6	3	1.2
7 - 9	30	12.3	15	6.1	0	0
10 - 12	3	1.2	3	1.2	0	0
13	1	0.4	0	0	0	0
Total	244	100.0	244	100.0	244	100.0

TABLE 3

DISTRIBUTION OF PATIENTS BY NUMBER OF MONTHS SINCE LAST DELIVERY
OR ABORTION IN DMPA INJECTION PROGRAMME

<i>No. of months</i>	<i>No.</i>	<i>Per cent</i>
0 - 1.99	34	13.9
2 - 3.99	58	23.8
4 - 6	28	11.5
7 - 9	17	7.0
10 - 12	16	6.6
13	91	37.3
Total	244	100.0

TABLE 4

MEAN INTERVAL BETWEEN EPISODES OF BLEEDING AND MEAN DURATION OF BLEEDING WITHIN EPISODE
DURING DMPA 90-DAY INJECTABLE PROGRAMME (FOR ALL PATIENTS WITH MORE THAN TWO
EPISODES)

<i>Episode</i>	<i>Interval between episodes</i>		<i>Duration of bleeding</i>		<i>No. of patients</i>
	<i>Mean</i>	<i>Standard deviation</i>	<i>Mean</i>	<i>Standard deviation</i>	
	<i>days</i>		<i>days</i>		
1	35.8	29.3	12.5	17.0	131
2	37.0	34.5	10.9	13.1	131
3	42.3	42.6	9.9	10.3	131
4	39.7	43.9	10.2	13.8	109
5	43.1	49.1	8.7	11.5	96
6	54.6	76.3	8.3	7.8	79
7	36.1	31.3	7.4	7.8	57
8	36.1	35.9	8.5	10.6	46
9	38.1	52.8	7.2	6.8	40
10	42.2	62.8	4.9	5.6	34
11	29.9	38.4	5.3	4.2	28
12	33.0	32.7	7.7	6.4	22
13	30.2	29.9	5.5	6.4	21
14	62.6	84.1	6.4	4.0	18
15	34.5	40.4	4.5	3.2	14
16	23.7	24.7	5.4	5.8	12
17	28.9	13.9	6.7	7.2	10

TABLE 5
AMENORRHOEA DURING THE USE OF 90 DAY DMPA
INJECTABLE PROGRAMME

<i>Patient No.*</i>	<i>Time from initial injection that patient was amenorrheic months</i>
207	1
208	1
247	1
248	1
249	1
250	1
252	1
253	1
210	3
124	5
140	6
160	6
192	6
237	7
163	9

*All other patients had bleeding on at least 1 day during their follow-up period.

TABLE 6
BLEEDING EXPERIENCE PER INJECTION PERIOD (90 DAYS) IN DMPA 90-DAY INJECTION PROGRAMME

<i>Injection period +</i>	<i>No. of women</i>	<i>No. woman days/ injection period</i>	<i>No. woman days of bleeding/injec- tion period</i>	<i>Injection period during which bleeding occurs</i>
1	216	19,440	5,652	29.1%
2	172	15,480	3,234	20.9
3	121	10,890	1,760	16.2
4	82	7,380	934	12.7
5	65	5,850	407	7.0
6	50	4,500	322	7.2
7	43	3,870	225	5.8
8	36	3,240	171	5.3
9	29	2,610	95	3.6
10	18	1,620	77	4.8
11	5	450	11	2.4
12	1	90	0	0

*Only data for completed injection periods used in calculations.

+ An estimate of the proportion injection period during which a patient will bleed.

TABLE 7

ADVERSE EFFECTS NOTED DURING DMPA
90-DAY INJECTION PROGRAMME

<i>Adverse effect</i>	<i>No. of times side effect was reported</i>	<i>No. of women reporting side effect</i>	<i>Rate %</i>
Nervousness	23	11	4.6
Nausea	15	8	3.4
Headache	9	5	2.1
Bloated feeling	7	4	1.7
Breast swelling and tenderness	4	3	1.3
Swelling of abdomen	3	2	0.8
Oedema of feet	2	2	0.8
Vaginal discharge	2	2	0.8
Dizziness	3	2	0.8
Loss of libido	2	1	0.4
Alopecia	1	1	0.4
Chloasma	1	1	0.4
Back pain	1	1	0.4
Asthenia (Tiredness)	1	1	0.4
Dysmenorrhea	1	1	0.4
Abdominal discomfort	2	1	0.4
Pruritus vulvae	1	1	0.4
Hot flushes	2	1	0.4

No. of women reporting one side effect or more once or more than once = 35. Percentage of women reporting one side effect or more once or more than once = 14.3%.

TABLE 8

REASONS FOR DISCONTINUATION

<i>Reason</i>	<i>No.</i>	<i>Rate %</i>
Moved away	28	11.8
Lost to follow-up	18	4.6
Bleeding	11	7.6
Advice of private physician	4	1.7
Adverse effect	1	1.7
Weight gain	3	1.3
Personal reasons	3	1.3
To get pregnant	3	1.3
None stated	3	1.3
Husband objects	2	0.8
Cannot get to clinic	2	0.4
Depression	1	0.4
Committed to mental hospital	1	0.4
No contraceptive needed	1	0.4
Advice of clinic physician	1	0.4
Total	82	34.8

TABLE 9

BODY WEIGHT CHANGES (RELATIVE TO WEIGHT ON ENTRANCE INTO STUDY) IN DMPA 90-DAY
INJECTION PROGRAMME

<i>Follow-up month</i>	<i>Mean weight change</i>	<i>Standard deviation</i>	<i>No. of patients</i>	<i>Proportion of patients with change + 10 to -18*</i>
	<i>Lbs.</i>	<i>Lbs.</i>		<i>%</i>
3	0.6	3.9	209	95.6
6	1.9	7.5	165	87.2
9	3.0	8.2	123	78.8
12	5.5	9.2	82	70.8
15	7.0	9.2	59	69.5
18	7.9	9.3	45	7
21	9.1	9.0	42	59.5
24	10.1	8.8	37	54.0
27	8.8	10.0	27	59.3
30	6.5	15.9	19	57.9
33	1.5	28.0	6	33.3

* — decrease in weight + increase in weight

TABLE 10

BLOOD PRESSURE CHANGES (RELATIVE TO BLOOD PRESSURE ON ENTRANCE INTO STUDY IN DMPA 90-DAY INJECTION PROGRAMME)

<i>Follow up</i>	<i>No. of patients</i>	<i>Mean change</i>	<i>Standard deviation</i>	<i>Proportion patients with change +20 to -20</i>	<i>Mean change</i>	<i>Standard deviation</i>
		<i>mm.Hg.</i>		<i>%</i>	<i>mm.Hg.</i>	
3	208	0.02	5.5	99.0	0.4	4.8
6	168	- 0.2	8.6	98.8	0.2	7.3
9	121	- 0.02	11.3	96.6	2.0	10.5
12	83	2.4	14.4	96.5	2.5	9.8
15	60	0.4	10.4	98.5	2.4	9.8
18	46	0.04	13.9	95.6	4.8	10.8
21	42	2.0	12.7	100.0	6.3	10.8
24	36	1.3	11.4	100.0	8.2	10.1
27	27	2.5	11.2	100.0	6.9	9.7
30	16	10.0	12.4	100.0	8.2	9.9
33	6	15.0	11.6	100.0	11.2	5.1

* — Decrease in blood pressure + Increase in blood pressure

TABLE 11

FASTING BLOOD SUGAR IN DMPA 90-DAY INJECTION PROGRAMME

<i>Follow-up Month</i>	<i>Mean</i>	<i>Standard deviation</i>	<i>No. of patients</i>	<i>No. of patients</i>	
				<i>Normal</i>	<i>Abnormal</i>
	<i>mg. %</i>				
Initial	99.7	14.2	205	201	4*
3	102.4	8.3	133	133	0
6	105.7	12.8	87	84	3**
9	102.4	8.0	59	59	0
12	103.0	8.4	43	43	0
15	103.9	9.0	38	38	0
18	103.0	9.6	35	35	0
21	105.6	9.8	31	30	1†
24	104.9	6.7	24	24	0‡
27	108.7	10.9	14	13	1
30	105.2	10.1	5	5	0

* Three lower than 80, 1 higher than 120 (maximum value 131)

** Three higher than 120, (maximum value 180)

† One higher than 120, (maximum value 129)

‡ One higher than 120, (maximum value 130)

TABLE 12

BLOOD UREA NITROGEN IN DMPA 90-DAY INJECTION PROGRAMME

Follow-up month	Mean	Standard deviation	No. of Patients	No. of Patients	
				Normal	Abnormal
Initial	mg. %				
Initial	12.2	2.0	205	204	1*
3	12.5	1.8	133	132	1+
6	12.7	1.8	88	88	0
9	12.8	1.9	60	60	0
12	12.9	1.9	44	44	0
15	13.3	1.8	37	37	0
18	12.9	1.8	35	35	0
21	13.6	1.8	31	31	0
24	13.4	1.6	24	24	0
27	13.8	0.9	14	14	0
30	13.8	1.3	5	5	0

* Initial value of 4.2 mg. %

† Value of 20.0 mg. %

TABLE 13

PROTHROMBIN TIME IN THE DMPA 90-DAY INJECTION PROGRAMME

Follow-up month	Mean	Standard deviation	No. of Patients	No. of Patients	
				Normal	Abnormal
Initial	Sec.				
Initial	14	0*	204	204	0
3	14	0	131	131	0
6	14	0	88	88	0
9	13.03	0.2	60	60	0
12	14.02	0.2	43	43	0
15	14	0	38	38	0
18	14	0	35	35	0
21	14	0	30	30	0
24	14	0	24	24	0
27	14	0	14	14	0
30	14	0	5	5	0

ACCEPTABILITY OF LONG-ACTING INJECTABLE PREPARATIONS BY WOMEN IN SRI LANKA

By

DR. (MISS) SIVA CHINNATAMBY

Though the Family Planning Association has been in existence for 21 years, in the first eight years we had hardly any method of control of fertility which was acceptable to women of low socio-economic levels. The method of limitation was surgery, especially for females, while for spacing, the conventional methods like mechanical barriers and chemical spermicides were the only methods available. The female barrier methods were learnt easily but the continuation rate was low specially as the method was contemporaneous with sex union. Male protectives were hardly popular. The introduction of the oral contraceptive in 1960 made a dramatic change in the acceptability of a method of control of fertility. This was due to the simplicity of method, its 100% reliability and the fact that the time of administration had no relationship to the time of sex union.

This method was accepted even by women in the estates and by women who have never been to school at all, as proved by our trials.

The intra-uterine device was introduced in 1960. This led to an increased demand for this method, but within 2 years the women reverted to the oral contraceptive due to the following reasons:

1. The intra-uterine device was not 100% reliable.
2. Alarming side effects like excessive bleeding, spotting.
3. Severe lower abdominal pain.
4. Low back pain.
5. Spontaneous expulsion of the device.
6. Perforation or migration of the device into the pelvic cavity.

With the availability of long acting injectables we decided to study the effectiveness and acceptability of these preparations in women in Sri Lanka.

The long acting injectables that were used were:

- (a) Depot medroxy progesterone acetate (DMPA) "Depo Provera".
- (b) Norethisterone oenanthate.

This study includes 2,250 cases using DMPA and 500 cases using norethisterone oenanthate. The trial on norethisterone had to be stopped as the manufacturer requested us to stop the project till further notice as some adverse effects like nodules in the breasts had been reported in beagle dogs. This paper deals mainly with the acceptability of long acting injectable contraceptives in preference to other methods and the side effects are compared between the two products.

Administration

Depot medroxy progesterone acetate (DMPA) 150 mg. was administered once in 90 days while norethisterone oenanthate was administered once in 84 days (3 cycles). We have used DMPA for over 60 months and norethisterone for 30 months.

The total number of cycles of use for DMPA is 46,406 and for norethisterone 4391 cycles.

Up to 2 years of the trial the method was offered only to women with more than 4 children as there was a general belief that the return of ovulation is delayed after the cessation of the drug therapy, but the last 750 cases were administered even to women with one or two children as they demanded this method. The reasons for this demand were:

1. Simplicity of the method.
2. No strict regime of a pill a day. The oral dosage schedule is not followed carefully and women fail to renew prescriptions or call for supplies and therefore many unwanted pregnancies occurred.

3. Gastrointestinal symptoms were minimal.
4. The method was almost 100% reliable though not as reliable as the pill.
5. The predictability of results regardless of the user's attitude or socio-economic environments.
6. A routine regular examination of the user is possible which is vital for women who would never have visited a doctor otherwise.

The persistence of the hormonal activity of the long-acting injection beyond the 3 cycles interval between injections is a valuable safeguard against accidental conception. Women remain protected for an additional period even in cases of default occurring by not attending on the specified date. This additional period of safety is not made known to them as there is a risk of their failure to observe the specified schedule.

Contraindications

1. Hypertension.
2. History of cerebro vascular accidents.

3. Cases with vaginal cytology indicative of Stage III.

4. Past history of thrombosis.

Tables 1, 2 & 3 show the analysis of 2,250 cases who took DMPA and 500 cases using norethisterone.

Routine pretreatment

A physical examination including general pelvic and cytological examination was done in every case. Vaginal cytology and a study of cervical secretion was done in every case. The estimation of pregnanediol in urine was carried out in the first 500 cases, with the help of Prof. Shearman. Body weight and blood pressure were recorded at every visit. The injection was administered on the 4th to 7th day of the cycle, intramuscularly into the gluteal region.

Adverse effects

The main adverse effects were disturbances in the menstrual cycle - amenorrhoea and oligomenorrhoea. Nearly 40% of the cases using DMPA had amenorrhoea varying

TABLE 1

DISTRIBUTION OF WOMEN ACCORDING TO AGE

Age (in yrs)	19	20-24	25-29	30-34	35-39	40-44	45+
DMPA	7	269	789	663	423	88	11
Norethisterone	Nil	36	185	169	104	6	

TABLE 2

DISTRIBUTION OF WOMEN ACCORDING TO PARITY

Parity	1	2	3	4	5	6	7	8	9	10+
DMPA	10	84	143	331	509	309	295	203	151	25
Norethisterone	Nil	2	4	57	131	104	92	59	26	15

89% had more than 3 children while 11% had 3 children or less.

TABLE 3

DMPA	—	No. of months of use	55
		Total number of cycles after 5 years.....	46,406
		No. of drop outs.....	644 (28.3%)
Norethisterone	—	Total number of months of use	30
		Total number of cycles for norethisterone	4391

from 3 cycles to 36 cycles. But this was very much less (under 10%) in women using norethisterone oenanthate. No form of oestrogen was given to induce withdrawal bleeding unless the user was apprehensive about the long period of amenorrhoea. Continuous bleeding throughout the cycle was found in about 8% of the cases using DMPA and 2% of cases using norethisterone oenanthate. These were controlled successfully either by oral oestrogen therapy or recently by "Depo oestradiol benzoate" and the control of cycle was very satisfactory. Summarising the effects of menstrual cycles: there is a complete disruption of the menstrual cycle and a totally unpredictable pattern of bleeding, more marked with DMPA than with norethisterone oenanthate. But amenorrhoea and oligomenorrhoea were accepted by most of them provided they were warned of the possibility of these symptoms at the onset of medication.

Other adverse effects of significance were

1. Increase in weight which was not so marked as in pill users. Loss of weight or gain in weight was more marked in users of DMPA than in those using norethisterone oenanthate. In fact 219 of the 500 cases using norethisterone oenanthate had no change in weight at all in the first 3 months compared to 449 cases out of 2250 users of DMPA. The alteration in weight was not a reason for abandoning treatment as in the cases using oral contraceptives.
2. Symptoms like headache and giddiness were uncommon and medication was seldom stopped due to this reason.
3. Gastrointestinal symptoms were absent.
4. Slight increase in blood pressure occurred in some cases.
5. Cramps in the legs and abdomen.
6. Nausea, vomiting and abdominal discomfort.
7. Allergic rash and pruritus.
8. Leucorrhoea in few cases.

Effect on Lactation

There were 56 women who were administered the long acting injection 6 weeks after partus. Only one stopped lactating

in the 3rd cycle after the first injection. Four carried on for 3 cycles with supplementary feeds. Three others continued with supplementary feeds for 6 cycles; 48 continued to lactate for more than 9 cycles with no supplementary feeds. The milk composition was not studied.

The number of women was too small to draw any conclusion on the effect of the long acting injection on lactation, but there was definitely much less suppression of lactation than in users of oral contraceptives, and there was no difference in the effect on lactation between DMPA and norethisterone oenanthate.

Reasons for drop-out

1. Menstrual disturbances specially amenorrhoea and continuous bleeding.
2. Abdominal cramp.
3. Pain in the chest.
4. Husband against the use of the method.
5. Wished to change the method.
6. Planned pregnancy.

80 women abandoned therapy. Of these, 34 were due to symptoms directly due to the administration of the drug.

Failures

The failure rate with norethisterone oenanthate is about 2.3 per hundred women years. The failure rate for DMPA was 0.8 per 100 women years. Analysing the cases that became pregnant, it was found that:

1. Over 60% of the cases failed after the first injection.
2. 35% failed due to default.
3. 3% after the second injection.
4. 2% after the 10th injection.

These were considered as method failures.

Cancer

Recently there has been fear about increased incidence of cancer among the DMPA users. Every woman in our trial

using long acting injectable preparations had a vaginal cytological examination on the first visit and every year after that.

There were no cases of cancer in the norethisterone oenanthate users. There were two cases in the last 6 years among the DMPA users. There were six cases among the IUD users. Therefore it is difficult to attribute the incidence of cancer to the drug, especially as the drug has been administered mainly to multiparous women who are predisposed to cancer. The long acting injection continues to be a popular method. Recently DMPA was distributed to general practitioners who had a gynaecological training and they were requested to provide quarterly reports on the women using DMPA for the last 6 months. The long-acting injection continues to be popular for several reasons:

1. Ready acceptability by the user.
2. Reliability.
3. No strict regime involved.
4. Ideal for women who are lactating.
5. No thrombosis has been recorded in any one of the centres.

Even the menstrual disturbances caused no worry to the users as long as the possibility of the adverse effects had been explained.

Acknowledgement

My thanks are due to Messrs. Schering A. G. and Upjohn Ltd., who gave us assistance in conducting the clinical trials.

RETURN OF FERTILITY AFTER DISCONTINUATION OF USE OF A LONG ACTING INJECTABLE-MEDROXYPROGESTERONE ACETATE

By

DR. EDWIN B. MCDANIEL and TIENG PARDTHAISONG

Introduction

Depot medroxyprogesterone acetate DMPA also known as "Depo Provera", a synthetic progestogen, is now used in at least sixty countries as a long-acting, injectable contraceptive. It is officially approved for this purpose by the health authorities of Belgium, the Netherlands, W. Germany, S. Africa and New Zealand. The U.S. Food and Drug Administration has just granted limited approval for its use as a contraceptive. In the authors' experience in Northern Thailand, from 31 October, 1973, there have been 28,649 new acceptors of DMPA in the 8½ years of use of this method, with approximately 24,000 currently active users. These women had received 189,367 injections and experienced 46,297 women years of use. New users are being enrolled at the rate of about 850 each month, representing 77% of all new acceptors.

With increasing use of this method of contraception, it is not strange that the question is sometimes asked, "After a woman who has been using this method of contraception decides to have another baby, and stops her injections, how long must she wait to become pregnant?" In other words, what about her *return of fertility*? The next question is "Are periodic injections of DMPA a safe and satisfactory method of spacing children?"

In an effort to answer these questions with some degree of accuracy, a study was undertaken of all women in a large urban family planning clinic in the city of Chiang Mai, Thailand, who had discontinued injections of DMPA for planned pregnancies.

Selection of Study Population

In the total population of new family planning acceptors in this clinic, there were

6,748 women who had started 3-month contraceptive injections of DMPA between 1 April 1965, and the cut-off date of 31 August 1972. Of these, there were 214 (3%) who later discontinued injections with the stated reason that they wished to have another baby.

The group of users being studied for return of fertility, had to fulfil the following six criteria:

1. A desire to have another pregnancy was the only or principal reason given for discontinuation.
2. No other method of birth control was used after discontinuation of DMPA.
3. The woman was married and living with her husband during the period of observation.
4. Her age was not more than 40 at the time of discontinuing DMPA.
5. Fertility before starting DMPA had been proven.
6. The woman had been in essentially good health throughout the period of observation.

Only 152 women fulfilled these criteria. Of these, 17 were eventually lost to follow-up, leaving an actual number of 135 women for the present study.

Characteristics of Study Group

Approximately 60% of the study group were Thai, and farmer's wives. Most of the women had four years of elementary education and could read and write at least simple testing materials. They range in age from 18 to 37 years.

Duration of use of DMPA before discontinuation for planned pregnancy is shown in Table 1.

TABLE 1

DURATION OF USE OF DMPA BEFORE DISCONTINUATION FOR PLANNED PREGNANCY

Months of use	No. of women	% of Total
3-12	57	42.2
15-24	38	28.2
27-66	40	29.6
Total	135	100.0

Methods and Materials

Each of the women studied had consistently received a 150 mg. dose of DMPA in one or the other deltoid muscle every 12 weeks* without interruption. In addition, each woman was asked to take a monthly, oral oestrogen supplement of either stilboesterol 0.5 mg. or ethinyl oestradiol 0.04 mg. for 7-10 days of each lunar month. This was an effort on our part to reduce the incidence of menstrual bleeding problems previously seen in women getting only DMPA.

The criteria of proven clinical pregnancy were the presence of one or more of the following signs:

1. Foetal heart sounds could be heard by the physician.
2. Foetal parts could be felt by the physician.
3. Foetal movements could be felt by physician.
4. Foetal skeleton was seen on the X-ray film.
5. The urine test for pregnancy was positive, together with symptoms of pregnancy.

Findings

Estimated dates of conception were calculated in most cases from dates of delivery of full-term babies, or (in the minority of cases) from fundal heights measured in the clinic, or dates of unmistakable abortions. Cumulative pregnancy rates were then calculated by the life-table technique. Results are shown in Table 2 and Fig. 1.

TABLE 2

CUMULATIVE PREGNANCY RATES FOLLOWING DISCONTINUATION OF 2-MONTH DMPA INJECTIONS AND ORAL OESTROGEN SUPPLEMENT (N = 135)

Month after Discontinuation	Cumulative Pregnancy Rate
6	62.4
9	66.6
12	76.8
14	82.4

*In a few instances the patients did not return for a repeat injection until 13-15 weeks after the preceding dose, well within the clinically "safe period".

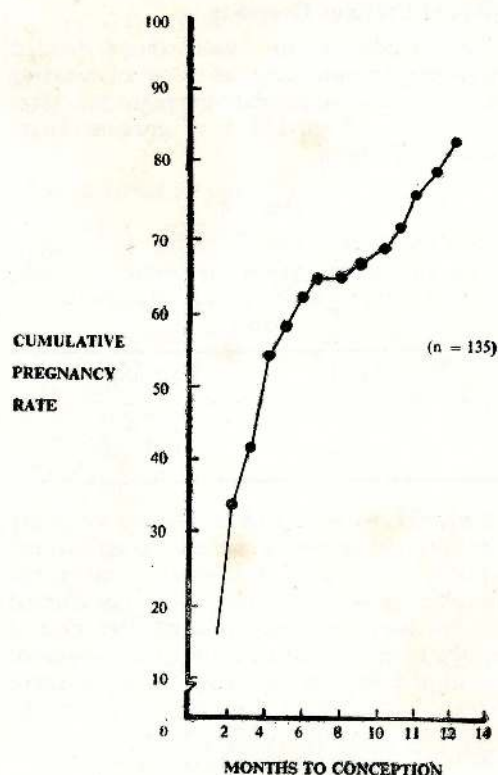


FIG. 1. Cumulative pregnancy rates after discontinuation of 3-month DMPA injections with oral oestrogen supplement.

Effect of Age

The study group was then divided into younger and older age groups, according to the age at discontinuation of the method.

The resulting cumulative pregnancy rates are shown in Table 3.

TABLE 3

CUMULATIVE PREGNANCY RATES 12 MONTHS AFTER DISCONTINUATION OF DMPA, BY AGE GROUPS

<i>Younger group</i> (18 = 25 yrs.) (mean = 22.4 yrs.)	<i>Older group</i> (26 = 37 yrs.) (mean = 30.7 yrs.)
78.4% (n = 80)	74.7% (n = 55)

The difference of only 3.7% was not statistically significant.

Effect of Previous Gravidity

The study group was then divided according to gravidity at time of starting the injections. Cumulative pregnancy rates for women of gravida 1 vs gravida 2 are shown in Table 4.

TABLE 4

CUMULATIVE PREGNANCY RATES 12 MONTHS AFTER DISCONTINUATION OF DMPA, ACCORDING TO GRAVIDITY AT START OF DMPA

<i>Gravida 1</i>	<i>Gravida 2</i>
68.0% (n = 66)	82.4% (n = 44)

Only 25 women had a history of more than two pregnancies at the start of the method. Because of their small number, the life-table analysis could only be carried out on these women through the first 3 months after discontinuation of the method. But at the end of this time 57% of these women had already become pregnant, as compared to only 37% of women with a history of one or two pregnancies.

Discussion

Among the 135 women who discontinued contraceptive injections of DMPA with oral oestrogen supplement in order to become pregnant, it was observed that in the cohort of 102 women followed for 12 months, 76.8% had become pregnant within one year of discontinuation. This compares

with a 12-month pregnancy rate of 88% reported by Tietze¹ after removal of IUD's for planned pregnancy. In a group of 99 DMPA injection women who could be followed for 14 months, 82.4% had become pregnant by the end of that time.

In this study, the return of fertility was not significantly affected by age at time of discontinuation. But those women of higher gravidity at the start of the method experienced a more rapid return of fertility.

Seymour and Powell² in a series of 752 women on 3-monthly injections of DMPA, found that the administration of an oral oestrogen supplement of ethinyl oestradiol for the first 7 days of each month tended to reduce spotting, and produced a definite pattern of bleeding.

Because of the great popularity and usefulness of the injection method of contraception and its increasing worldwide use, it is important to obtain reliable data on the return of fertility after discontinuation of the method, with a view toward its wider use as a means of spacing births, as well as for limiting family size.

Conclusions

The present study shows that the return of fertility after discontinuation of 3-month contraceptive injections of DMPA with oral oestrogen supplement, compares favourably with that seen after removal of IUD's.

Addendum

Practical aspects of the use of DMPA as an injectable, long-acting, contraceptive are as follows:

- (1) The cost of DMPA is about 63 cents (U.S.) per dose of 150 mg. when bought in lots of at least 100,000 doses. The IPPF can arrange such purchases.
- (2) The use of a six-month injection is as satisfactory as a three-month injection. The usual six-month dose is 450 mg. If six-month injections are contemplated, DMPA should be ordered in a special concentration of 150 mg/ml. This then is usable as a 1 ml. 150 mg. 3-month dose, or as a 3 ml. 450 mg. 6-month dose. Since

most method-failure pregnancies occur in the 3 months after the first injection, it may be expedient to double the dose for the initial injection. This can be done conveniently by using 2 ml. (300 mg.) of the special concentration.

- (3) *Oral oestrogen supplement.* There seems no general agreement that an oral oestrogen supplement should or should not be used routinely. Our clinical experience indicates that there should be such a routine supplement to reduce menstrual bleeding problems and promote an occasional withdrawal bleeding, psychologically important for many women on the injection method. Many women do not take the daily oestrogen pills for 7-10 days as directed. Reasons given by them are forgetfulness, nausea, headache, dizziness, and weakness, or a combination of these factors. Therefore, in an effort to simplify the taking of an oral oestrogen supplement, and to overcome the difficulties and side-effects just mentioned, we are now recommending the use of a single, 400 microgram capsule of the long-acting, oral oestrogen, "quinestrol", once a month.

No practitioner using DMPA injections should be without a long-acting injectable oestrogen to treat the rare case of really heavy bleeding. We use 2 ml. of oestradiol cypionate "*Depo Estradiol*" (Upjohn) intramuscularly. Bleeding usually stops within 24 hrs.

Adverse effects

Problems of irregular menstrual periods, amenorrhoea, spotting, and occasional heavy bleeding, seem to be directly related to the action of DMPA. These do not seem to be dose-related: As yet it is not possible to predict which women will have these adverse effects. Other complaints, seen in women on the combined DMPA - oral oestrogen regime, such as headache, dizziness, and nausea, seem to be directly related to the oestrogen, and usually disappear on withdrawal of the estrogen supplement. These symptoms appear to be less with the one-dose, oral oestrogen, quinestrol.

Continuation Rates

In a large series of women on DMPA injections, before the advent of easily

obtained contraceptive pills, the 12-month continuation rates were 75% for the 3-month injections and 82% for the 6-month injections. The 2 year continuation rates were 68% for 3-month injections and 72% for the 6-month injections. Continuation rates will vary greatly with local circumstances.

Method-failure rates

In our experience, we found a method-failure rate of 0.7 per 100 women years of usage, or roughly 1 woman in 142 using the method for a full year, can be expected to become pregnant sometime during that year.

Return of normal menstrual pattern

We have found that within 6 months after the first missed injection, 93% of women had resumed a normal menstrual pattern, a figure close to women not using contraception.

Use in lactating mothers

DMPA injections may be started at any time following delivery, and do not suppress lactation. The ethinyl oestradiol oral supplement is not given to nursing mothers, because of the risk of reducing their milk supply. However the 400 microgram oral dose of quinestrol seems to have little effect on lactation, and may be used in nursing mothers. The use of DMPA injections in the first two weeks of the post-partum period may sometimes prolong a moderate but annoying sero-sanguinous discharge for several months.

Women accepting a six-month injection of DMPA within a month of delivery, and a second injection 6 months later, can space their children at least two years apart.

Pregnancy and delivery of DMPA women

A large experience with women becoming pregnant just before, during and after DMPA injections shows no increased incidence of problems in pregnancy or delivery.

Offspring of DMPA women

There has been no demonstrably increased incidence of congenital anomalies or mental

retardation of any kind. Some of these children are now in grade school, and are said to be doing well.

"Ideal" Regime

Probably the ideal time to start is within the first 2-3 days of a menstrual period, to be followed in the in two weeks by a single dose of long-acting oral oestrogen, such as 400 micrograms of quinestrol. This will make for a simultaneous falling off of blood levels of both DMPA and quinestrol, hopefully promoting a withdrawal bleeding.

Summary

The convenience and psychological appeal of contraception by a long-acting injection are advantageous. But it must be borne in mind that DMPA is not the ideal contraceptive. It seems to be the best injectable

contraceptive available today, and certainly the one we know most about. Women who try DMPA and are unhappy with it for any reason should not be persuaded to continue the method. Rather, use can be made of her experience as an *introduction* to family planning (as it often is) to lead her on to another method, which may be more suitable for her.

Note: Except for the reference to the work of Seymour & Powell, this report is adapted and condensed from a fuller report of the same title and by the same authors, which appeared in the November, 1973 issue of *Contraception*. The reader is invited to refer to the original article for more details of text and methods of calculation (including a detailed life-table) and additional references. Reprints may be obtained from E. B. McDaniel at McCormick Hospital, Box 56, Chiang Mai, Thailand.

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**THEME: STERILISATION FOR LIMITATION OF
POPULATION**

CHAIRMAN: Prof. B. N. Purandare

**THEME: VASECTOMY FOR POPULATION
LIMITATION**

CHAIRMAN: Dr. Philip Alderman

THE STATE OF TEXAS,
COUNTY OF _____

IN WITNESS WHEREOF, I have hereunto set my hand and seal of office at the City of _____, this _____ day of _____, 19____.

FEMALE STERILISATION - A CRITICAL SURVEY AND PERSONAL EXPERIENCE

By

DRS. RAOUL and ELIZABETH PALMER

Female sterilisation is now, after vasectomy, the most important tool in the fight against population explosion.

We have published our laparoscopic technique of electro-coagulation and section of the tubes in 1962, but have, before and after that, tried most of the other methods, and participated in several meetings, where it was the major item, notably in Bombay, Geneva and New Orleans.

We think we can give a relatively unbiased review of the present status of the problem.

CRITERIA OF EVALUATION

I. Efficacy, safety, acceptability, reversibility

When sterilisation is considered as a problem of the individual or the couple, efficacy, safety and acceptability are important.

Until recently the total efficacy of a method of sterilisation was the best argument for its selection, because the motives for sterilisation were mostly serious medical indications. Many obstetricians, in order to have 100% efficacy, performed total or extensive salpingectomies.

In the last decade, with the extension of the use of sterilisation as a demographic tool against population explosion, reversibility is now a factor in the selection of a method, because a young woman can lose her children, or remarry.

The restorative operations for which valid statistical data exist are: tubal anastomosis (after mid-tubal resections) and tubal implantation (after proximal coagulation or resection). In specialised hands, one can expect a 60% pregnancy rate after re-anastomosis and a 40% after implantation.

II. Practicability and Costs

When sterilisation is considered as a demographic tool, practicability and costs become important items.

The practicability of a method includes:

- a. the necessity for hospitalisation and its duration.
- b. the type of anaesthesia required.
- c. the previous skills of the operator and duration of training.
- d. the number of assistants required and their qualifications.
- e. the time necessary for each case, and how many can be performed per day by the team.
- f. duration of convalescence.

The costs for each method include:

1. first investment.
2. maintenance of instruments
3. cost of each operation ($a + b + c + d$)
4. a balance of costs (e.g. for 100,000 cases).

SURGICAL TECHNIQUES

I. Operations performed on the tube

A. Total or distal tubectomy are to be used only when the sterilisation must be definitive.

B. Surgical ligature-resection of a tubal loop is by far the most popular method of sterilisation. Some 50 different techniques have been described, of which three are still in frequent use:

(a) The Medliner (1919) in which the loop is seized at the middle of the tube, crushed at its base, and ligated with some non-absorbable suture.

(b) The Pomeroy (1924) in which the loop, instead of being crushed, is ligated at its base with chromic catgut, and resected. The ligature is supposed to resorb slowly, and the two stumps to move progressively apart. These techniques have a 0.5% to 1.5% failure rate.

(c) The Labhardt (1911) which is our preference because it seems to give no failure: the tubal isthmus is seized with two Kocher forceps placed at 10 and 30 mm. from the uterine angle; longitudinal incision of the peritoneum between the two forceps; cautious liberation of the tubal segment from its peritoneal cover; resection of the tubal segment between two ligatures; a continuous suture will then obliterate the peritoneal bed.

The Uchida modification consists in injection of saline with adrenaline under the serosa to facilitate the bloodless dissection of the tubal segment.

C. Clamping the tubes with hemo-clips has been suggested as a rapid, and possibly reversible technique. When the method was proposed, it was hoped that fertility could be restored simply by removing the hemo-clips; if the tube is not completely crushed, there is a risk of tubal or even uterine pregnancy (see below). To have total efficacy, one should use the special Samuels forceps; the 523-170 hemo-clips have a good size for the proximal part of the ampulla. The route for surgical sterilisation depends upon the circumstances of the cases (puerperal, interval or associated with some other operation).

Vaginal routes

The vaginal route may be used either in combination with some other operation (for prolapse, urinary incontinence or fistula) or as an elective procedure for sterilisation alone.

In the first case, sterilisation may be done either by anterior or posterior colpotomy.

In the second case, it is generally done by posterior colpotomy. The vaginal operation through the posterior fornix is now used in India by 250 gynaecologists in sterilisation camps, where women are hospitalised for 2 or 3 days.

The operation, as described by Purandare and Soonawalla is performed under low spinal anaesthesia (or local anaesthesia with heavy premedication) in the lithotomy position. A bimanual examination is performed, and the uterus is pushed into retroversion. The posterior wall of the vagina is grasped, 1 and 3 cm from the cervix and cut through with the scissors

directed posteriorly, so as to enter immediately the peritoneal pouch. The opening is then widened by dilatation, until the vaginal retractor can be inserted. The ovaries are seen, and one tube is attracted into the vaginal opening with a Babcock forceps. The tubal sterilisation is then done – either by the Pomeroy technique on the middle third of the tube, if some chances of recanalisation are to be preserved, or by distal tubectomy, with ligature and resection of the distal part of the ampulla, if the operation is a definitive one. Then the vaginal wall is closed by a continuous O catgut suture, taking alternatively the whole wall with the peritoneum, or only the mucosa.

Laparoscopic techniques

In 1947, Anderson proposed the laparoscopic electro-coagulation of the tubal isthmus. Using this technique, Palmer found on two occasions, that one tube was not closed when salpingography was done 3 months later; it thus seemed difficult to be sure that the tubal mucosa is also coagulated when the surface is absolutely white.

To avoid this possible cause of failure. Palmer devised in 1960 and published in 1962 the electro-coagulation-section technique.

The first series was done with Guerin's laparoscopic punch-biopsy forceps. Ultimately, Steptoe (1967) proposed the use of Palmer's drill biopsy-forceps and most gynaecologists are now doing laparoscopic sterilisations with this instrument or a variant (the last and best is the Neuwirth-Palmer modification).

The instrument is generally introduced through a short cannula, at a point half way between the pubis and the umbilicus, or at the right or left Macburney site. The tubal isthmus is seized very selectively at 25 mm from the uterine angle, with the interior sugar tongs, lifted a good distance from bowel and bladder, and coagulation applied until the tube becomes white for about 1 cm in each direction; then, the cutting cylinder is screwed until it reaches the top of the tongs; a second coagulation is applied, the cutting cylinder is screwed back. The median segment is not removed, because there might be a danger of bleeding when tearing it away.

In our private practice, we use quite often the operative laparoscope of Jacobs and Palmer (manufactured by Richard Wolf) in which a double rectangular angulation of the endoscope allows the introduction, (in a canal situated in the axis of the endoscope) of a small biopsy forceps, with which one can seize, electro-coagulate, section and recoagulate the isthmus 2 cm. from the uterine angle. The biopsy-forceps is sometimes too small to seize and coagulate completely the isthmus at the first grasp; a second grasp is always successful. The procedure is more rapid, because there is only one entry, but necessitates more experience, because it is always easier to control an instrument viewed laterally than axially. Therefore, we do not recommend it for beginners.

In all those laparoscopic techniques, the operation is facilitated by the mobilisation of the uterus with an insufflation cannula, inserted into the uterus, and manipulated by an assistant.

These electro-surgical procedures are easy, rapid, elegant, safe and without danger in skilled hands. On the contrary, they may be catastrophic if used by operators ignoring the dangers of electro-surgery, as any contact of the bowel or bladder with the coagulating electrodes or with the tube under coagulation may bring about a necrosis and a secondary perforation and peritonitis.

It is therefore compulsory to have:

- (a) a perfectly insulated instrument.
- (b) a perfect pneumoperitoneum to work in a large controllable space, with a controlled pressure of 15 mm Hg in the peritoneum.
- (c) a good anaesthetist.
- (d) good illumination to identify with certitude the round ligament and the tubal isthmus.
- (e) an experienced laparoscopist who should have the command of the foot switch to release it instantly in case of any danger.

When all these conditions are present, then this electro-coagulation-section technique, is safe, rapid and elegant. We permit the patient to return home the next morning, and resume normal activity after 2 or 3 days, and

we have never encountered any trouble or complication.

We have had no method failure among 206 cases, but observed 2 cases of pregnancy, one because the woman was already pregnant at the time of sterilisation (done on the 12th day), the other because one tube was embedded in intestinal adhesions so that it was erroneously felt that the risk of fecundation was low.

Stephens has published a series of 1200 cases, with one tubal pregnancy.

An ambulatory variant has been advocated by Wheeler from Baltimore and has been used in sterilisation camps, notably by Kantha Giri, with apparently good acceptability and good immediate results, but strict follow-up is difficult in such areas.

The procedure is done under local anaesthesia (after premedication) and, therefore, the pressure for the pneumoperitoneum and the Trendelenburg inclination must be moderate. The one-entry method is used, with a variant of the Palmer-Jacobs operative laparoscope. The patient goes home three hours later. This technique may be valid in skilled hands, and for very motivated women. I would not recommend it for extensive use, because of the above mentioned dangers of electro-surgery, especially with a reduced pneumoperitoneum.

Nor would I recommend, for the same reason, the technique described by Soderstrom from Seattle of electro-resection of a loop of the tube by strangulation with a metallic wire, with simultaneous electro-coagulation.

Rioux has presented at the International Congress of Laparoscopists in New Orleans in November 1973 the prototype of a new electro-coagulating forceps, which is bipolar-biactive, with a plastic insulating cannula, which would suppress, or at least diminish considerably the risks of electro-surgery.

The Laparoscopic installation of clips on the tubes had been tried, as early as 1959, by Newman, but his apparatus was not practical.

We have personally done five such applications through the operative laparoscope, but

had a pregnancy in the 5th case, in spite of the fact that the two hemo-clips had remained in position on the isthmus at 1 cm. distance, and with apparently good compression of the tissues. Therefore we have abandoned the use of this method.

Recently Hulka has devised spring-loaded plastic clips, with a specially devised laparoscopic applicator. He claims excellent results, and the probability of reversibility, after laparoscopic removal of the clips, but this remains to be proved.

Frangenheim has presented a prolene snare (Ethicon) which could strangulate a loop of the tube, as well as the surgical Madlener technique.

Culdoscopic techniques

Gutierrez Najar has published in 1971 his technique of tubal sterilisation by the vaginal route, under culdoscopic control, following Clyman's culdotomy technique, with personally devised instruments.

The procedure is performed under local anaesthesia (after heavy premedication) in the knee-chest position, the thighs of the woman being firmly fixed to two vertical fixing rods.

An assistant lifts up the posterior peritoneum with a retractor; the cervix is seized with a curved vulsellum, and manipulated to visualise the retrocervical dimple; 3 ml. of lignocaine are injected, then the operator punctures the cul-de-sac with the trocar of the culdoscope, and allows the air to rush into the abdominal cavity. Then, he introduces the culdoscope into the cannula, to evaluate the condition and situation of the tubes, to be sure that no difficulties will arise for their mobilisation and perhaps exteriorisation.

Then, the operator takes away the endoscope and the cannula and widens the puncture orifice with a forceps until he can introduce into the window, the curved blade of his special retractor, which has its bearing surface on the sacro-coccygeal region.

The culdoscope is now introduced into the vaginal window to locate the tube, while, with the other hand he seizes with the specially designed curved forceps, the middle

portion of the tube, and draws it in the culdotomy opening.

Then, he applies, with another special curved forceps, two 523-170 hemo-clips at the proximal end of the ampulla, at 1 cm. distance.

After careful verification, the instruments are removed, a rubber tubing is placed in the peritoneal cavity to facilitate the expulsion of the air, and the tubing is removed, when the incision has been sutured and the air expelled.

A patient stays for some hours in the clinic, and may return to normal activities after 2 or 3 days.

The procedure takes approximately 15 minutes, and seems well tolerated, probably due to the heavy premedication.

In Gutierrez Najar's hands, it is elegant, rapid and seems without danger, but at least two uterine and one extra uterine pregnancies have occurred in his series and, in less skilled hands, failures may be frequent.

An extensive statistical survey is thus necessary to know if the procedure should be recommended.

Trans-uterine blind techniques

The blind electro-coagulation of the cornu had already been tried by Dickinson (1929) and Hyams (1934) in the U.S.A.

It has been used in a relatively large scale in Japan after the war, and quite often at the termination of a pregnancy, which may explain many cases of perforation and peritonitis, and a 36% failure rate.

At the last European Sterility Congress in Athens in October 1972, Ishikawa described his special Thermistor electrode and his latest technique, detailing current frequency (mega H 2) intensity (800 MA) time of passage (30 sec) and tissue temperatures (125°). A control hystero-graphy is performed after 3 months and, in most instances, the cornu are symphysized on both sides; in case of partial failure, a second coagulation can be done. He claims a 98% success rate in his last series of 136 cases done with this technique.

At the Ford Foundation Meeting in Venice (1966) Palmer presented a curved cannula, which, introduced into the uterus and pressed against the bottom of the cornu had permitted his selective salpingography, without uterine filling. He suggested that such a cannula could be used to inject, at the contact of the ostium 0.2 ml. of some caustic paste.

Neuwirth (1971) has studied with this same objective a special ointment with 10% silver nitrate, which he tried first on monkeys, then on women, demonstrating that it induced an elective occlusion of the interstitial portion of the tube, with relatively mild inflammatory reactions. He is now studying this method, by injection into the ostium, under hysteroscopic control.

In this connection, we must also mention the intrauterine injection of quinacrine (mepacrine) proposed by Zipper (1969). It induces a sclerosis predominating on the isthmic segment of the tubes, and occlusion is generally obtained after 2 or 3 monthly injections, without important complications. Large scale studies are under way in Chile, but Quinones, using the injection under hysteroscopic control, did not succeed in occluding the tubes.

Hysteroscopic Methods

Hysteroscopy had been used long ago, under moderate distension of the uterine cavity by tepid saline, with poor results, because of poor light, poor distension and frequent bleeding.

Recently, new instruments with cold light have been manufactured by Storz (Lindeman's hysteroscope) and by Richard Wolf (Sermant & Porto with a 170° foroblic; Serrn with a 140° oblique axis of vision).

Neuwirth uses a hyperviscous 30% solution of dextran to distend the cavity under pressures around 150 mm. Hg. which stops the bleeding, and allows excellent visibility, especially around the 8th day of the cycle, when the endometrium is low. Very little of the dextran comes to the peritoneum, and its resorption is without danger.

Lindeman, Porto and Semm use carbon dioxide to distend the uterine cavity. The

rate of flow should not exceed 60 ml/min to avoid any accident from vascular passage of the gas. The pressures obtained vary from 70 to 150 mm. Hg. but are enough to localise the tubal ostium in most cases.

A catheter or a cauterizing device may then be introduced, under visual control, 5 to 10 mm. into the interstitial portion of the tube, either for injection of some sclerosing agent, or for electro-coagulation of the interstitial portion of the tube.

The procedure can be done with parametrial or cervical anaesthesia, and is thus ambulatory.

The results obtained until now are around 90% bilateral occlusions, at controls done 3 months after the procedure. A second attempt, gives a 98% occlusion rate. Later controls are necessary to exclude secondary recanalisation.

Summary and Conclusions

It seems to us evident, from our critical study, that there is no technique of choice for all situations, and that the selection of a method depends on the circumstances of the women (peurperal or interval), of the doctors and of the equipment available.

Post partum surgical sterilisation under local anaesthesia should be encouraged, as safe and less expensive.

Laparoscopic or culdoscopic sterilisations should be restricted to a small number of units, in university or regional hospitals, where laparoscopy and/or culdoscopy should be taught as a tool in gynaecological diagnosis as well as a method of sterilisation. A few very skilled operators could also go with their team in sterilisation camps.

Vaginal surgical sterilisations should be taught to all qualified gynaecologists.

Abdominal surgical sterilisations could be done safely by any qualified surgeon. A variant under local anaesthesia has been described by us.

Hysteroscopic methods are still at the experimental stage, but may be the methods of the future.

Appropriate Technology Services
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ABDOMINAL STERILISATION IN SRI LANKA

By

DR. ASHLEY G. S. DASSENAIKE

Tubectomy forms an integral part of any Family Health Programme. Different authors have described various operations for female sterilisation. The commonest being:

1. Total tubal resection.
2. Irving procedure – excision of part of the tube and burying the cut ends.
3. Medliner procedure – ligation of the tube after crushing, but still in continuity.
4. Pomeroy's method.
5. Cornual resection.
6. Aldridge method of reversible tubal sterilisation where the ampullary end is buried in the mesosalpinx.
7. Modified Pomeroy's method of reversible tubal sterilisation where the loop of the tube is taken at the ampullary end.

I was one of the few obstetricians in Sri Lanka who advocated female sterilisation in early 1964. My experience in female sterilisation dates back to 1964 and covers over 4700 operations.

During this period I served as obstetrician in Anuradhapura and Badulla, both rural areas, till I was appointed to the Castle Street Hospital for Women in November 1972.

In remote areas the indigenous people were very illiterate, backward and timid. In the Badulla district, in addition to the indigenous rural folk, there was the Indian estate labour class. They had large families extending to more than 8–10 children. Small families were never heard of. They had no knowledge of family planning whatsoever. The ante-natal clinics were full of grand multiparae with haemoglobin levels usually less than 50%. Their reaction

to the word 'operation' was such that, if ever this word was used in talking to them they would disappear from the ward. At that time I had no one to motivate the mothers for operation. It is in this background that I had to do my pioneering work on female sterilisation. I had to adopt ways and means to motivate these mothers for the operation. I had to obtain the consent of their husbands too, for the operation. No patient was ever forced into the operation.

Having got their consent I devised an operation which gave the least amount of post-operative discomfort to the patient, and was convenient to the anaesthetist, theatre staff and the ward staff. We often come across the young patient who genuinely wants a sterilisation to limit her family, but who may want another child after sterilisation. Here is a problem we have created. In this type of patient we can perform the reversible type of sterilisation. Pomeroy's technique is carried out in these cases but the loop of the tube is taken at the fimbrial end. Non-absorbable sutures are used and the loop of tube is not divided. If she subsequently wanted a reversal there was sufficient length of tube for a salpingolysis. Here was an operation that could be offered to the younger patient who wanted to limit her family.

The operation also had to be made attractive to the patient. A small transverse skin incision was made in the line of a skin crease, the level being determined by the height of the fundus. The length of the incision is such that it admits the index finger. The skin closure was effected with 3 zero catgut subcuticular suture material which did not require removal. The scar was hardly visible and there were no sutures to be removed. The post operative discomfort was minimal. The patient was up and about on the day of the operation. All these features made the patient accept this

operation very readily. They were discharged on the 3rd post-operative day, but if required, were discharged on the 2nd post-operative day.

The next problem was delivery of the tube through such a tiny incision. Direct vision was poor due to the small incision. It was too small to introduce a retractor. The cornu and the tubes could be felt with the index finger. The cornu was brought anteriorly but the tube could not be delivered. The cornu was brought anteriorly and then rotated beyond the midline with the index finger. The finger was now taken outside the peritoneal cavity. As the tube passed the abdominal incision on its way to its original position, it could be easily got at. Very often this was difficult. If the abdominal incision was fixed on the uterus after the cornu had been rotated beyond the midline and the cornu allowed to rotate back, its speed could be controlled and the tube is seen to pop out through the abdominal incision. At times the tube did not pop out so easily. In these instances, the tube could easily be picked up as it rolled past the incision, the one landmark being the ovary. Here was a method of delivering the tube through a transverse skin incision just sufficient to introduce an index finger. It did not take time; only a couple of seconds.

Having got the tubes what operation was to be done? It had to be simple, devoid of any post-operative risks however remote they may be, reversible and successful. Pomeroy's technique was modified in that the mesosalpinx was transfixed and a loop of tube tied at the fimbrial end with No. 40 linen. The loop of tube was not cut divided as there was a risk of post-operative haemorrhage however slight it may be. This too took only a couple of seconds. This was done with a view to reversal of the operation later if occasion did arise. The peritoneal cavity was closed with one suture. The rectus sheath with a figure of eight suture; the skin with 3 zero catgut sub-cuticular suture. The wound was painted with collodion. The whole operation takes about $3\frac{1}{2}$ -4 minutes and about 8 to 10 operations can be done per hour.

Anaesthesia

A general anaesthetic is preferred to local anaesthesia. With a local anaesthetic a

bigger incision has to be made, resulting in more post-operative pain and longer post-operative stay in the ward.

My consultant anaesthetist uses 2 ml. of 2% lignocaine as a spinal anaesthetic. The effects last for about one hour and the patient is quite relaxed. This might help to solve the problem of shortage of anaesthetists, as one anaesthetist could look after 3 or 4 patients at the same time.

The general anaesthetic used, is intravenous thiopentone sodium with 25 mg. gallamine as a muscle relaxant. No endotracheal tubes are used.

Post Operative care

The bowel sounds return by the 3rd hour. The patients are now given oral fluids. They are given the babies to breast feed. By evening they are assisted to the toilet. On the 2nd day they are on a normal diet and are up and about.

During my post-operative ward round I make it a point to question them as to what they felt after the operation. They invariably say that it was much less painful than what they expected. They were advised to tell their friends and neighbours in the village how simple it was to get a suture put on to prevent anymore children. I firmly believe that a satisfied patient is the best motivator. I had ample proof of this in my practice.

The simple technique in the operating theatre and minimal post-operative care in the ward was not a burden to the theatre or ward staff.

Scope of the operation

The operation can be made available to the masses in any of the following ways:

1. By getting the patients into hospital, operating on them and looking after them in the hospital during the post-operative period. The number of available beds may determine the number of operations that could be performed. If the patients are sent home on the 2nd and 3rd post-operative day the situation should ease.
2. Teams consisting of the obstetrician, anaesthetist and nurses could visit district hospitals where a room is available for

operation and the operation performed there. The resident doctor at that hospital could look after the patients during the post-operative period. This was done by me at Badulla by visiting a neighbouring hospital at Passara. The patients like it, as they can stay close to their homes and it is convenient to the relations.

3. Bring the patient from the maternity home, operate on them and send them back to the maternity homes on the same day. A project of this nature is being carried on in my Unit in collaboration with the Colombo Municipal Maternity Homes.

If these methods are practised the number of beds in a Unit need not determine the number of sterilisations in each Unit.

Interval cases

These too can be done by a median suprapubic transverse incision which is closed with one sub-cuticular suture. Although this takes a little longer time than the post partum cases it is much less than the time taken by the vaginal route operation. The abdominal route is preferred as this is free of infection. No prophylactic antibiotics are used.

Recurrent pregnancies

I have had five in this series of cases and I was very fortunate in operating on these patients after delivery.

One was an interval case where the operation-delivery time was 260 days. Both tubes were blocked at operation. The patient would have been pregnant at the time of the operation.

Absorbable suture material had been used in the second case. The right tube was blocked and the left tube was patent.

There were two cases in which silk was used as suture material. The sutures were slack on one side and tight on the other in each of these cases. The assisting nurse

reminded me that silk suture slackens when moist and suggested the use of linen. Since then there was only one recurrent pregnancy.

The fifth was a post partum case. On the right side, there was a low grade abscess. On the left side the suture was loose. In post partum cases the tubes are swollen and oedematous. The inexperienced operator does not tighten the suture for fear of cutting through. This appears to be the reason for the failure in this instance.

Other complications

There has been an occasional case of sepsis; one in about 200 cases. No cases of incisional hernia were met with.

Advantages of the operation

1. The small transverse incision with minimal post-operative discomfort, discharge from hospital on the 3rd post-operative day or earlier with no sutures to be removed, is attractive to the patient and the patient turns out to be the best motivator.
2. Shortness of the operation does not necessitate intubation. Decreases the amount of anaesthetic and relaxant drugs used.
3. Eight operations can be done per hour, 24 in a 3 hour session.
4. Dressings are minimal.
5. As these patients feed the babies and walk to the toilets from the first day there is no increased burden placed on the ward staff.
6. Discharge of patients on the 3rd post-operative day or earlier, helps in a quick turn over of the ward beds.

Visiting teams and transferring of patients on the same day help to solve the problem of shortage of hospital beds.

7. Considerable saving of money to the Government.
8. The operation is simple and it can be done by a trained Senior House Officer.

TUBAL OCCLUSION BY INTRAUTERINE INSTILLATION OF CHEMICALS FORMULATIONS, DELIVERY SYSTEMS AND CLINICAL EXPERIENCES USING QUINACRINE (MEPACRINE)

By

DRS. J. ZIPPER, E. STACCHETTI and M. MEDEL

Introduction

Tubal occlusion with chemical substances can be performed transabdominally or transvaginally. We will only discuss the last method due to the technical difficulties implied in the first approach.

The injection of caustic agents was initiated by Froriep, in 1849, who applied silver nitrate to the cornual areas of the tubal ostia.¹ Kvater in 1926 described the use of an iodine solution with the same aim.² The practice of chemical sterilisation with sclerosing agents such as phenol and iodine seems to be widely prevalent in Brazil, illegally performed by para medical personnel. Salgado in 1941 published a study in regard to this.³ With this historical data we started to repeat these experiments using ethanol formaldehyde 2% as a non specific sclerosing agent. Our experience which appeared in two publications led us to the conclusion that any non specific sclerosing agent that reached the tubo-uterine junction could produce fibrosis of the ostium if it was applied several times.^{4,5,6} In the specific case of ethanol formaldehyde, we demonstrated that 6 instillations are required to obtain 94.7% of obstruction. The endometrial mucosa is slightly affected producing moderate oligomenorrhea and hypomenorrhea.

Simultaneously with other authors, although separately, we started to investigate the action of sclerosing or granulomatose cytotoxic agents in the different animal species. Those agents were applied (a) directly into the oviduct to observe a possible obstructive reaction or (b) infiltrating the uterine muscle with the same aim. Our works already published, studied first the agents that had a known specific biochemical action.⁵ We investigated loss of fertility produced by these agents in the rat uterus and their histological reaction. Cadmium,

iodacetate, thio-TEPA, podophyllin, colchicine and quinacrine (mepacrine) were used. Of all these specific agents only quinacrine produced an obstructive granulomatose reaction in the rats. Richart in 1968 published one of the most interesting experimental works in the search of sclerosing and granulomatose agents, using the rabbit tube and monkey myometrium as a model. His conclusions are the following: "The most striking conclusion derived from this series of experiments is the singular capacity of the Fallopian tube to repair itself after what can only be described as acute massive injury. With virtually all of the effective compounds (including zinc chloride, silver nitrate, salicylic acid and necrosis - producing agents) large sections of the Fallopian tubes appeared to be completely necrotic in the animals sacrificed during the early stages of reaction. Despite this massive necrosis, islands of tubal epithelium and submucosa and fields of smooth muscle apparently survived and as the necrotic tissues were cleared away, epithelial repair began. In many instances, a damaged but intact Fallopian tube with a patent lumen was found 6 to 8 weeks following the original injury. Both the monkey and the rabbit appeared to be capable of reconstituting the tubal lumen following severe injury, in the monkey, because of the more complex structure of the primate Fallopian tube, residual damage was more obvious than in the rabbit."

It is interesting to note that, although Zipper has reported that quinacrine (mepacrine) produces blockade upon lavage of the human uterus this substance produced no effect in rabbits or monkeys.⁵

Later, Falb⁹ published an interesting experimental study using a surgical adhesive, gelatin-resorcinol-formaldehyde (G. R. F.). This compound is used as a hemostatic

agent or an adjunct to sutures. This adhesive was injected into the tubes of rabbits. He succeeded in blocking the oviduct with preliminary evidence that this blocking can continue with an ingrowth of tissue causing permanent tubal occlusion.

Our studies with quinacrine (mepacrine) separately demonstrate that the action of this granulomatose obstructive agent is effective in the rat's uterus while it is ineffective in the rabbit tube.¹⁰ These effects can be potentiated in the rabbit and depotentiated in the rat with the use of different pharmacological agents whose presence permits or hinders the action of quinacrine (mepacrine) in these two species. (Table 1)

The basic conclusion of this experimental review of the effect of occlusive agents in the tube and uterus of different animal species, is that its effectivity cannot be simply extrapolated to the human species, but it is possible that attacking the tube-uterine junction systematically and repeatedly with these substances, will prove effective. The most important factor necessary to make this method practical is to discover a highly effective innocuous agent in the human species and a very simple delivery system for the release of this agent in the cornual region.

Delivery systems

Three essential methods have been developed with the aim of depositing the substance in the tube-uterine junction. Two of them try to deposit the granulomatose, sclerosing or obstructive agent directly into the tube uterine junction. The first method is based on the direct visualisation of the uterine ostium, which implies a detailed discussion of the whole subject of hysteroscopy. Newell extensively discussed this theme. An extensive bibliography appears in his article.¹¹ This concept seems promising in the sense that the required reaction could be perfectly quantified once the adequate chemical substance is discovered.

The second method has been developed by Thompson *et al*, using the contrast pressure technique.¹² The contrast pressure technique, whereby the uterine cavity is isolated from the Fallopian orifice by the use of a small balloon filled with carbon dioxide under pressure and the

agent to be introduced into the lumen is forced at a lesser pressure.

TABLE 1
EXPERIMENTAL POTENTIATION AND INHIBITION OF QUINACRINE OCCLUSIVE ACTION AFTER INTRALUMINAL INSTILLATION

	Rat uterus	Rabbit tubes
Quinacrine 50 mg/ml	—	—
Quinacrine 100mg/ml	+	—
Quinacrine 200mg/ml	++	—
Quinacrine plus chelating agents:		
Cysteine	O	+++
Dimercaprol (BAL)	O	+++
Penicillamine	O	+
Tetracycline	O	+
Versenate	O	+
Quinacrine plus cations:		
Cu	+	+
Zn	—	—
K	+	O
Na	—	O
Quinacrine plus other agents:		
Adrenaline (Epinephrine)	+	+
Noradrenaline (Norepinephrine)	+	+
Orciprenaline (Metaproterenol)	—	O
Propranolol	—	O
Pilocarpine	—	O
Oxytocin	—	O
Aminophylline	—	O
Lignocaine	—	±
Lignocaine + adrenaline	+	+
Quinacrine plus castration	—	O

— No action

+ Occlusion

++ Severe occlusion

O Non tested

This technique seems potentially dangerous since the substance is deposited at a relatively high pressure, into an expanded uterus. The balloon orifice will not always fit with the tubal ostium and the substance to be deposited can possibly penetrate between the uterine mucosa and the uterine

TABLE 2

EFFECT OF DIFFERENT POTENTIATING AGENTS ON TRANSVAGINAL CHEMICAL STERILISATION WITH QUINACRINE IN WOMEN

Groups ^a	Number of women	One instillation		%	Two Instillations		Cumulative ^b % of non-patency	Pregnan- cies during treatment	Months of observa- tion per woman
		Patent	Non Patent		Patent	Non patent			
I	39	13	26	66.6	4	5	55.5	4	35
II	54	18	36	66.6	1	2	66.6	0	17
III	41	12	29	70.7	2	3	60.0	0	9

^a Group I Quinacrine 1.5g. in 5ml. water.

Group II Quinacrine 1.5g. in lignocaine 2% 5 ml.

Group III Quinacrine 1.5g. in lignocaine 2% 5 ml. plus adrenaline 20 ug, per ml.

^b Cumulative rates calculated from non-patent women after the first instillation plus those that received the second instillation.^c Original month of the event: Group I: 12, 14, 22, Group II: 5, 7, 11, 14 and Group III: 3, 3

(Zipper, J., Stachetti, E. & Medel, M., 1972.)

muscle, with the possibility of expanding into the venous plexus of the uterus.

The third method used by our group is the simplest. It consists in introducing the chemical substance through a simple 3 mm cannula attached to a syringe into the uterus to produce the obstructive reaction in the ostium. The substance is deposited without pressure and passes on to the cornual zone impelled by the natural tube-uterine motility. Our experience with this simple technique has shown us that the pharmacological factor associated with the mechanism of action of the granulomatoso or sclerosing agent that potentiates or depotentiates the substance, would be the key to obtain a high obstruction rate with the first instillation, and not so the release system of the material, specially when the chemical agent is an aqueous solution or suspension that does not coagulate proteins of the intrauterine fluid or the uterine mucosa, thus permitting a passive entry into the uterine ostium, as is the case with quinacrine (mepacrine) which also has the advantage of a high selectivity on the epithelium of the tube-uterine junction and not on the human endometrium. Our experience with a quinacrine (mepacrine) suspension in water has already been presented.⁵

Besides the works already mentioned, we had a communication from Davidson.¹³ His conclusions agree with ours, although he has obtained higher percentages of obstruction with shorter experimental series.

We wish to communicate the continuation of our clinical experience with the use of potentiating agents. Various agents were added to a standard dose of quinacrine 1.5 g in 5 ml of water such as for example 5 ml lignocaine 2% and adrenaline 20 ug per ml. The latter combination was found to present clear advantages over the initial combination of quinacrine and water. The importance of these two potentiating drugs, is that although the percentage of obstruction after the first instillation does not increase significantly, there is an evident contraceptive protection to women not obstructed in the first 2 to 3 cycles through a possible inhibition in the functioning of the endometrium. This has been experimentally determined in rats and permits a margin of security between the first and second instillation.

In this work we will present our experience after 6 years of quinacrine (mepacrine) endo-uterine instillation.

Material and Methods

Due to the impossibility of extrapolating to the human species the results obtained in animals with quinacrine (mepacrine) and other adjuncts, we performed 18 series of different clinical experiments, using the combinations described in Table 1. The total number of patients was 724, of whom 428 were obstructed, 257 in the first instillation and 171 with the second, the instillation technique has been described. Non patency was diagnosed with a Rubin insufflator. Those patients that were still patent after the second instillation were submitted to other contraceptive techniques. As the rates of obstruction with the first instillation varied according to the chemical combination used, from 25% to 70% and the analysis of each group is not relevant, we will only present in the results, the evaluation of the patients diagnosed as obstructed. The follow-up period of these patients was from August 1967 to May 1973.

RESULTS

Table 2 sums up the results obtained with 3 combinations of quinacrine. Table 3 sums up the evaluation of 428 obstructed patients followed for 1212,596 months. 37 pregnancies occurred, all of them normotopic which gives us a Pearl index of 3.6 in that period of observation and an absolute pregnancy rate of 8.6%.

TABLE 3
Pregnancy Rate (Pearl's index)
NON PATENT WOMAN INSTILLED WITH QUINACRINE

Number of non patent patients	428
Number of pregnancies	37
Women - months of observation	12,596
Pearl's index	3.6

Comments

The clinical experimental studies presented lead us to the conclusion that endo-uterine quinacrine (mepacrine) instillation associated with potentiating drugs must be used in the human species to demonstrate its effectiveness since some combinations not

active in experimental animals proved highly effective in women, as for example the lignocaine - mepacrine combination resulting in a rate of 66.6% of obstruction with the first instillation. The technique is so simple that it can be performed by paramedical personnel and in its actual state of development 3 successive instillations with an interval of one month between instillation will offer rates of obstruction and patency comparable to those obtained by surgery. The actual experimental development of our clinical research is oriented towards the

real possibility of obstructing almost 100% of the patients with a single instillation.

Secondary effects

In all our series we have only observed two cases of cortical irritability possibly produced by the drug. Barbiturates were injected for calming effects and the patients became normal in a few hours. No modification of the menstrual cycles or pain was observed during the instillation period.

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LONG TERM EFFECTS OF FEMALE STERILISATION

By

PROFESSOR I. S. PUVAN and DR. V. SIVANESARATNAM

Introduction

The demand for female and male sterilisation as a form of permanent contraception has been on the increase in the last decade. This is because sterilisation is a very reliable form of contraception, and is free from unpleasant adverse effects. Also, there are now many young women requesting them after having 2 or 3 children. However there are a few reports reporting a high incidence of menstrual abnormality. The object of the present study, done in 1972 - 1973, was to investigate the incidence of gynaecological disorders and psychological upsets following female sterilisation in Malaysian women. The results presented are our preliminary findings of the follow-up study.

TABLE 1
FREQUENCY OF STERILISATION

	1972	1973
Total deliveries	2725	3047
Post partum sterilisation	335	330
Total interval sterilisation	135	292
Laparoscopic sterilisation	62	254
Vasectomy	153	151

TABLE 2

NO. OF PATIENTS AND THE FOLLOW-UP
(1968-1969)

Total number of cases done	286	
No. returned for follow-up	123	
Post partum cases	92	123
Interval cases	27	
At Caesarean section	4	
Not traceable	120	
Remainder	34	

The Obstetrics & Gynaecological Unit of the Faculty of Medicine, University of Malaya has been functioning for about 6 years. It is a small unit having about 3,000 deliveries a year now. Table 1 shows an increased frequency of sterilisation especially with the laparoscopic method. In our Unit any mother over the age of 25 years and having 4 or more children is advised a permanent form of contraception. If she is younger than 25 years and has 3 or less children, the request is treated on individual needs.

There were 286 cases of female sterilisation done in 1968 and 1969 (Table 2). Letters were sent out to these patients to return for a follow-up. 120 letters were returned because the addresses could not be traced. Out of the 166 cases to whose addresses the letters were delivered, 123 cases turned up for this follow-up study. Attempts are now being made to home-visit the remaining 43 cases.

Age Distribution

Table 3 shows that most of the cases were in 30-34 years age group as in many other series. In contrast, Table 4 shows the cases which had laparoscopic sterilisation last year. It is evident that the age at which sterilisation is now requested is getting less.

TABLE 3
AGE DISTRIBUTION

Age	No. of cases
25 and under	1
26 - 29	31
30 - 34	47
35 - 39	36
Over 40	8

TABLE 4
AGE DISTRIBUTION OF LAPAROSCOPIC
STERILISATION CASES

Age	Percentage	Number
Less than 20 years	0	0
20 - 24	13.4	19
25 - 29	37.6	54
30 - 34	29.6	41
35 - 39	16.9	24
40 years and over	2.5	4

TABLE 5
PARITY DISTRIBUTION

Parity	No. of cases
4 and under	36
5 - 8	63
Over 8	24

Parity Distribution

This is shown in Table 5. Here again as in many series from developing countries the largest group is the 5-8 parity group. The laparoscopic sterilisation group is present for contrast in Table 6.

TABLE 6

PARITY DISTRIBUTION IN CASES OF LAPAROSCOPIC STERILISATION

Parity	Number	Percentage
2	4	2.5
3	19	13.4
4 or more	119	84.1

RESULTS

Pregnancy Rate

There has been so far no failures in the group of patients who returned for the follow-up.

Effects on the Menstrual cycle

About 85% of the patients had no change in their menstrual cycle. Table 7. One patient with menorrhagia had this complaint even before the operation, but refused hysterectomy. The other case of menorrhagia, subsequently had a hysterectomy. This finding is in contrast

to that reported by Muldoon (1972), where the incidence of menorrhagia was about 20% and about two-thirds of this group required hysterectomy. His study showed that most patients requiring further major surgery were either multiparous or had either a Caesarean section or a hysterectomy.

TABLE 7
EFFECT ON THE MENSTRUAL CYCLE

	No. of cases	Percentage
Normal	104	84.55%
Oligomenorrhoea	6	4.87%
Menorrhagia	2	1.62%
Epimenorrhoea	7	5.69%
Dysmenorrhoea	2	1.62%

Pelvic Pathology

In about 90% of the cases no pelvic pathology was detected. Papanicolou smears done in all the cases at the follow-up were reported as negative for malignant cells. Only the 2 cases of adnexial tenderness were probably related to the operation. (Table 8).

Both the above findings suggest that routine hysterectomy is unnecessary for the purpose of sterilisation in our population. It also has a higher mortality and morbidity rate than simple tubal ligation. Also if routine hysterectomy is done, the turnover of cases would be much slower, especially when compared with laparoscopic sterilisation. However, if there is any uterine pathology, then probably hysterectomy is preferable, though it may not be acceptable to all couples because of different cultural beliefs.

TABLE 8
PELVIC PATHOLOGY

Nil	112	91%
Vaginitis	9	7.31%
Myoma	2	1.62%
Tender adenexae	2	1.62%
Cystocoele	2	1.62%
Rectocoele	1	0.81%
Cervical polyp	1	0.81%

Effect on Libido

Physiologically one would expect no change as shown in about 77% of the

cases (Table 9). About 14% showed an increase in libido probably because the previous methods of contraception were inadequate. Eleven cases (8.94%) reported a decrease in libido. One of these cases reported that she feared the sutures on the tubes may give way during sexual intercourse.

TABLE 9
EFFECT ON LIBIDO

Increased	17	13.82%
Same	95	77.23%
Decreased	11	8.94%

Adjustment to work

This was specially looked into because there was a common belief that a woman

could not do her household duties after a tubal ligation. In our series, 10 cases (8.1%) reported that they could not work as hard as before and this seemed to be related to the abdominal scar (Table 10). With the present laparoscopic method, the rubber tappers are able to return to full work in 2 weeks' time. As a result of this study we are now chiefly using the small infra umbilical incision for our cases of post partum tubal ligations.

TABLE 10
ADJUSTMENT TO WORK

Better	22	17.8 %
Same	91	73.98%
Worse	10	8.1%

A REVIEW OF 300 CASES OF VAGINAL STERILISATION

By

DR. C. L. JHAVERI

The present review of 300 cases of vaginal sterilisation covers a period of four years from 1st October 1969 to 30th September 1973. These were performed either at the Department of Obstetrics and Gynaecology, Dr. Balabhai Nanavati Hospital, or in private nursing homes.

History and Progress

The concept of this approach to family planning is hardly 30 to 35 years old. It is said that Duhursen was the first to describe this method of approach to the Fallopian tubes in the year 1895. However, the evolution and popularity of this method of surgery is as old as the intra-uterine device which was first described in 1930 by Von Grafenberg.

The progress in female sterilisation has made great strides due to the new approach to the Fallopian tubes by endoscopy. From the conventional approach by laparotomy to perform post partum sterilisation, greater and greater interest is evinced to do laparoscopic sterilisation and similarly many colleagues prefer to do culdoscopic sterilisation instead of vaginal tubal ligation.

Long before the over-publicised reports and targets to achieve competitive figures in the last three Five Year Plan periods, gynaecologists were concerned about convincing their patients to undergo sterilisation on grounds of multiparity, ill-health, medical diseases and bad obstetric history. Many of us, as early as 30 years ago, used to sterilise patients either while performing Caesarean section or a few days after a normal or morbid confinement. Similarly, we used to sterilise women by the vaginal route as a part of a gynaecological procedure like the Manchester operation. Thus female sterilisation is neither a new concept nor a new application to gynaecological practice. In fact about 25 years ago if I remember correctly, Dr. B. N. Purandare showed how to approach the Fallopian tubes via the anterior pouch.

Material and Methods

The present study has shown that female sterilisation is becoming more and more popular since the acceptance of Medical Termination of Pregnancy Bill was passed by Parliament in September 1971, and allowed as a legal procedure in April 1972.

The practice of vaginal sterilisation has been accepted as a method of choice since the Department was recognised by the Government of India for implementation of Family Planning Programmes since 1955. In 1966 we presented about 8 years ago a study of a series of 600 cases of intra-uterine device – the Lippes Loop and cautioned the Government against many problems it will have to face because of the reckless way the I.U.D. Programme was implemented with set targets.

We still believe that vaginal tubal ligation, interval or otherwise is the best method of population control, lasting in effect, and efficient in implementation. It is a cheap long term procedure, though not as cheap as vasectomy. Our country having reached a figure of more than two million sterilisations, about 40% are female sterilisation and it is possible that this figure will be exceeded if all the female sterilisations are recorded as practised at all levels of obstetric and gynaecological practice. Table 1 shows the number of vaginal sterilisations during the 4 year period.

TABLE 1
NUMBER OF VAGINAL STERILISATIONS DURING
A 4 YEAR PERIOD

Year	Number of Patients	Percentage
First Year	38	12.7%
Second Year	60	20%
Third Year	72	24%
Fourth Year	130	43.3%
Total	300	100%

It seems the number of vaginal sterilisations shows an abrupt increase since legalisation of abortions.

In Table 2 I have attempted to show the various indications for tubal ligation. It must be admitted that multiparity is a common reason to demand sterilisation and recommend the same as well.

TABLE 2

COMMON INDICATIONS FOR TUBAL LIGATION

1. Multiparity
2. Motivation
3. Socio economic reasons
4. Pregnancy
5. Medical diseases
 - (a) Persistent ill-health
 - (b) Cardiac diseases
 - (c) Pulmonary T.B.
 - (d) Chronic asthma
 - (e) Chronic nephritis
6. Psychological disorder

Motivation

Since 1960, the medical profession and social workers have become aware of the necessity to preach family planning and recommend the operative procedure as the best method with a lasting effect. I remember very well that in 1960 at one of the meetings organised by the Government to review Family Planning Programmes, the late Dr. G. M. Phadke presented a sterilisation programme and asked for top priority. A constant motivation of persons on Radio or Television or by theatrical art is the most convincing approach.

Socio-economic reasons

This is the most important reason to practise family planning and more so, sexual sterilisation. Today the world over, the family planning implementation programmes get top priority because of this single reason.

Pregnancy

A woman agrees to evacuation and sterilisation in the early months of pregnancy, more so when a conception follows soon after delivery during the lactation period. Hence we exploit this situation to convince her and the family members to

resort to a permanent procedure instead of repeated medical terminations of pregnancy. A pregnant woman is more vulnerable to our advice in this phase of mental set-up.

Medical diseases

The various diseases shown in Table 2 are definite indications for sterilisation, but this forms a very small percentage of genuine indications for tubal ligation in practice.

Psychological disorders

In the assessment of this indication, I always obtain psychiatric advice, as all of you know how difficult it is to decide on such an issue. The usual reasons for non-acceptance are given in Table 3.

TABLE 3

USUAL REASONS FOR NON-ACCEPTANCE OF STERILISATION

1. Desire for a male child
2. Religious convictions
3. Opposition from in-laws
4. Social beliefs and taboos
5. Indifference of either partner
6. Inability to stand operation risk and hazard
7. Living apart from the husband most of the time
8. Wants a large family
9. Opposition from husband
10. Wants a female child
11. Social security
12. Wants husband's attachment

Operative technology

Vaginal tubal ligation (V.T.L.) was performed in two categories of women. One series covers women who underwent sterilisation as the only procedure and other series where it was combined with vacuum aspiration. No woman in this series was more than 12 weeks pregnant. We believe that no attempts should be made to perform vaginal sterilisation when the women are more than 12 weeks pregnant as it is hazardous, complicated and difficult to manage technically. The optimum term to operate in a non-pregnant woman is between 8th and 12th day following menstruation which would obviate unsuspected pregnancy. Further it is better to avoid the vaginal route when there is evidence of gross sepsis in the

TABLE 4

AGE DISTRIBUTION IN 300 PATIENTS

Age	Number of Patients	Percentage
21-25	36	12%
26-30	148	49.3%
31-35	51	17%
36-40	54	18%
41 and above	11	3.7%
Total	300	100%

genital tract or history suggestive of adnexial inflammation or mass in pelvis or when the patient is very obese or uterine motility is poor. It is imperative to douche the vagina preoperatively and further clean the vagina before incising it in the Douglas's pouch. It is equally essential to nick the pouch with sharp scissors and not to dissect, and finally swab the opened peritoneal pouch free of blood and leave no oozing surface to cause complications.

The choice of anaesthesia is decided by the anaesthetist and surgeon. The patient is put in the lithotomy position and after necessary toileting we use the speculum as devised by Dr. R. P. Soonawalla and always prefer long "Babcocks" Forcep Size "8" to bring the tubes down in the vagina. We always resort to the Pomeroy modified technique. We use chrome cat gut No. 0 to ligate the tubes, and prefer to stitch the peritoneum and vaginal wall in one bite with either interrupted or continuous sutures.

Table 4 shows the percentage incidence of sterilisation in various age groups. It is not uncommon to find women below the age of 25 years having three and four children because of early marriage, and we had 36 women below the age of 25 years. Today, all over the country the maximum age

group undergoing sterilisation is between 26 and 30 years. Regarding age group 40 years and above, I may mention that this group belongs to women who were operated when either they had amenorrhoea or did not wish to take the risk of pregnancy and submitted voluntarily for the operation.

With constant slogans ringing in the ears on the radio or the visual image of hazards of having many children or posters or television more and more intelligent women desire the operation. The constant propaganda by social workers and leaders in the community, it is observed that women demand the operation or submit to operation when camps are organised. Table 5 shows that 26% of women who underwent sterilisation had less than three children. The national slogans have gone a long way to achieve these objectives in certain strata of society.

TABLE 6

INDICATIONS FOR TUBAL LIGATION

Indication	Number of Patients	Percentage
Multiparity	48	16%
Motivation	69	23%
Socioeconomic	112	37.3%
Pregnancy	60	20%
Medical disorders	8	2.7%
Psychological disorders	3	1%
Total	300	100%

Table 6 attempts to categorise the various factors which favoured vaginal sterilisation. Three groups stand out prominently - motivation, socio-economic factors and pregnancy which account for 80% of the cases. Thus it is possible that everyone can play a role to achieve these targets in our programmes by extended education.

TABLE 5

DISTRIBUTION ACCORDING TO PARITY

Parity	II	III	IV	V	VI	Total
Number of Patients	30	59	128	68	15	300
	10%	16.7%	42.7%	22.6%	5%	Cases

TABLE 7

	<i>Patients</i>	<i>Percentage</i>
(A) Sterilisation with pregnancy termination	168	56%
Interval tubal ligation	132	44%
Total	300	100%
(B) Distribution of the types of cases needing termination		
Below 12 weeks Pregnant		140
Inevitable or Incomplete abortion		25
Missed abortion	3	

Table 7 shows that 56% of cases were pregnant when they desired vaginal sterilisation. It has been confirmed beyond doubt that the best time to sell your ideas either in the practice of contraception or sterilisation, is when the woman is pregnant and desires termination. It is further believed that a woman who has a termination of pregnancy should either have an IUD if she has a child or two, and vaginal sterilisation if she has three or more children.

Further, Table 7 classifies the types of pregnancy encountered in these 168 cases. 140 (83.3%) were pregnant and desired termination while 25 (15%) had either inevitable or incomplete abortion while there were three cases of missed abortion.

It is the experience of most of us that requests for vaginal tubal ligation have increased since the legalisation of abortion.

TABLE 8

DISTRIBUTION OF 168 CASES OF TERMINATION OF PREGNANCY ACCORDING TO SIZE OF UTERUS

<i>Size</i>	<i>Number of Patients</i>	<i>Percentage</i>
Below 6 weeks	42	25%
Below 8 weeks	82	48.8%
Below 10 weeks	36	21.4%
Below 12 weeks	8	4.8%

Table 8 classifies the cases according to size of the uterus at termination and vaginal sterilisation as evaluated either by the Resident Staff or Operating Surgeon. We desist from using vacuum aspiration when the uterus is more than 10 weeks pregnant. In this series 96% of cases were less than 10 weeks pregnant.

TABLE 9

<i>Operative procedures</i>	<i>Number of patients</i>
Medical termination with vacuum aspiration & vaginal sterilisation	168
Vaginal sterilisation	132
Repair of rectocele and old perineal repair	8

As described earlier in my paper, vaginal sterilisation was sometimes a part of another gynaecological operative procedure. We nowadays repair a moderate sized rectocele or an old perineal tear demanding operation. We believe it is quite harmless and equally feasible. We had such 8 cases on whom we did such surgery without increasing the morbidity. (Table 9)

TABLE 10
ANAESTHESIA

	<i>Number of patients</i>	<i>Percentage</i>
General	48	16%
Spinal	252	84%
Local	Nil	
Total	300	100%

Table 10 analyses the type of anaesthesia employed for the operations. It is evident from the table that lignocaine 0.8 to 1 ml was the anaesthetic agent of choice (spinal) in 84% of cases. A large number of those who had general anaesthesia were private patients. We have seen that one of the biggest disadvantages of spinal anaesthesia is post operative headache and hence we insist on a qualified, experienced anaesthetist to give spinal anaesthesia and we employ accessory measures to avoid subsequent headache.

TABLE 11

BED OCCUPANCY IN 300 OPERATIONS

<i>Days</i>	<i>No. of Cases</i>	<i>Percentage</i>
Upto 3 days	242	80.7%
Upto 5 days	34	14.7%
Upto 9 days	8	2.6%
More than 10 days	6	2.0%
Total	300	100%

It is evident from Table 11 that 242 cases i.e. 80.7% had a postoperative stay of 3 days only, while 34 cases i.e. 14% had a stay of 5 days and the most common complication was spinal headache. The common cause for a longer stay was the onset of infection and complications like parametritis. Vigilance in preoperative preparation of a patient is important to prevent fulminating infections. It has been proved by various authors all over the world that there is always a higher incidence of infection in vaginal sterilisation compared to abdominal procedures.

Table 12 reviews the complications encountered with vaginal tubal ligation. I always say that the patient forgets the operating

surgeon but often remembers the anaesthetist, who gives spinal anaesthesia. Backache and headache are common sequelae of spinal anaesthesia. Further it is desirable that a disposable sterile catheter should be used as and when required to avoid post operative cystitis.

TABLE 12

<i>Complications</i>	<i>Number of Patients</i>	<i>Percentage</i>
1. Spinal Headache	34	11.7%
2. Pyrexia	18	6%
3. Parametritis	12	4%
4. Bladder trauma	Nil	—
5. Cystitis	8	2.8%
6. Rectal trauma	Nil	—
7. Inability to reach tubes	3	1%
8. Delayed infection	3	1%

Conclusions

We are convinced that for mass availability vaginal tubal ligation is the method of choice compared to the endoscopic sterilisation either laparoscopic or culdoscopic under the present economic conditions. It is desired that more and more young qualified medical men be trained and involved in this interval tubal ligation programmes.

LAPAROSCOPIC STERILIZATION WITH A SPRING LOADED CLIP:

A Report of the First Three Hundred Cases

By

DRS. THAMPU KUMARASAMY, JAROSLAV F. HULKA, JACK P. MERCER,
JOHN I. FISHBURNE and KHAIRIA F. OMRAN

I. Introduction

Because of the need for a simpler, quicker, and safer method of female sterilization, a spring loaded clip to be applied to the uterine tubes via a 10 mm. diameter laparoscope was developed. The clips are applied through a single abdominal wall puncture technique under local anaesthesia on an out-patient basis. The advantage of this technique over cautery sterilization is the elimination of the possibility of burns to abdominal contents resulting from the use of electric current. Between September 1972 and November 1973, 300 patients were sterilized with the spring loaded clip. To evaluate the effectiveness and complications of this spring loaded clip method, the data on 300 patients were analyzed. Their follow-up data through December 1973 are included in this report.

II. Materials and Methods

A. Patient Selection

Generally the patients were healthy, desiring sterilization for family planning indications. While patients with previous surgery, such as appendectomy, cholecystectomy, ovarian cystectomy, and lower segment Caesarean section, were not excluded, one patient who had three previous laparotomies, including a colostomy for ulcerative colitis was excluded. Patients with Class III or Class IV Pap smears were excluded.

Table 1 lists the subjects by their schedule hospital status and the month, surgery was performed. The in-patients are further divided into three categories. Eleven patients were admitted pre-operatively but were not kept post-operatively. Eight of these eleven were aborted with intra-amniotic saline or prostaglandin prior to sterilization

and three were admitted pre-operatively for medical evaluation. Four patients were admitted pre-operatively and kept post-operatively for medical reasons. Three patients were treated as out-patients until they had vasovagal reactions that were prolonged enough to require hospitalization overnight.

TABLE 1
DISTRIBUTION OF LAPAROSCOPIC CLIP STERILIZATION PATIENTS BY SCHEDULED STATUS AND MONTH OF SURGERY

Month/Year	Scheduled Status		Total
	Out-patient	In-patient	
Sept. /72	1	0	1
Oct. /72	1	1	2
Nov. /72	2	0	2
Dec. /72	4	0	4
Jan. /73	18	1	19
Feb. /73	21	3	24
March /73	33	1	34
April /73	22	3	25
May /73	33	1	34
June /73	33	4	37
July (18th)/73	17	1	18
Aug. /73	20	2	22
Sept. /73	22	0	22
Oct. /73	27	0	27
Nov. /73	19	1	20
Total	283	18	300

Note: Eleven patients were hospitalized pre-op only; 4 patients pre & post-op and 3 patients post-op only.

This work was supported in part by the International Fertility Research Program of the Carolina Population Center, University of North Carolina at Chapel Hill (HID/csd 2979).

B. Patient Characteristics

Eighty-five per cent of these patients were married and living together (Table 2). Their ages ranged from 19 to 49 years, and parities ranged from 0 to 9. Fifty-six per cent of these patients were between 25 and 35 years of age, and sixty-six per cent had 2 or 3 children (Table 3). Clip sterilization was performed in 271 patients as an elected procedure and in 29 for medical indications (Table 4).

TABLE 2

DISTRIBUTION OF LAPAROSCOPIC CLIP STERILIZATION PATIENTS BY MARITAL STATUS	Number
<i>Marital Status</i>	
Single	9
Married (living together)	254
Separated	13
Divorced	20
Widowed	4
Total	300

TABLE 3

DISTRIBUTION OF LAPAROSCOPIC CLIP STERILIZATION PATIENTS BY AGE & PARITY							Total
<i>Age Group (yrs.)</i>	<i>Parity</i>						
	0	1	2	3	4	5+	
20	0	0	2	0	0	0	2
20-24	3	8	12	8	3	0	34
25-29	2	14	41	17	6	5	85
30-34	1	7	35	26	9	5	83
35-39	3	8	17	18	8	9	63
40-44	1	2	4	11	4	4	26
45+	0	1	2	2	1	1	7
Total	10	40	113	82	31	15	300

C. Concurrent Operations

The majority of patients had interval sterilizations (Table 5). No one was sterilized immediately post-partum, but eleven patients were sterilized between four and eight weeks post-partum. Of the combined sterilizations and abortion cases, thirty-two were aborted with vacuum aspiration, five

with saline, and three with prostaglandin. One patient had clips applied under general anaesthesia through a subcostal incision following a cholecystectomy. In another patient, salpingectomy was performed under general anaesthesia, after an ectopic pregnancy was detected by laparoscopy and after application of the clips under local anaesthesia.

TABLE 4

DISTRIBUTION OF LAPAROSCOPIC CLIP STERILIZATION PATIENTS BY INDICATION

<i>Indication</i>	<i>Number</i>
Elective Procedure	271
Medical Indication	29
Hypertension	8
Cardiac	5
Respiratory	3
Gastro-Intestinal	3
Psychosis	1
Diabetes (Juvenile)	1
Muscular Dystrophy	1
Other	5
Total	300

TABLE 5

DISTRIBUTION OF LAPAROSCOPIC CLIP STERILIZATION PATIENTS BY TIME OF OPERATION

<i>Time of Procedure</i>	<i>Number of Cases</i>
Interval sterilization	247
Post-partum sterilization (4-8 wks.)	11
As a combined procedure:	
With vacuum aspiration abortion	32
Subsequent to saline induced abortion	5
Subsequent to prostaglandin induced abortion	3
With cholecystectomy	1
With right salpingectomy (Ectopic)	1
Total	300

D. Technique

A history and physical examination were performed on all patients. Routine laboratory work included hematocrit, urinalysis

and a Papanicolaous smear. A chest x-ray and EKG were performed on all patients over 40 years of age. After emptying her bladder, the patient was taken to the operating room without prior medication. Sedation, 5 to 15 milligrams of diazepam alone or with 0.05 to 0.1 milligrams of fentanyl, was administered intravenously while the patient was prepped and draped in the dorsal lithotomy position. A pelvic examination was performed to confirm the size and position of the uterus. Via a single-hinged speculum, the controlling tenaculum (a combined tenaculum and sound) was placed into the uterus. Ten to 20 ml. of lignocaine were used to infiltrate the subumbilical skin, the abdominal wall and the peritoneum. Through a 2 millimeter incision in the infraumbilical skin, a Verres needle was introduced into the peritoneal cavity and pneumoperitoneum created with approximately 3 to 5 liters of nitrous oxide. The patient was then placed in the Trendelenburg position and a 10 millimeter trocar was introduced through the abdominal wall and the operating laparoscope was inserted. Through manipulation of the uterus by means of the controlling tenaculum, the uterine tube on one side was brought under direct vision, sprayed with 2 cc. of lignocaine, and the clip was applied. The clip applicator was removed, reloaded, and the procedure repeated on the opposite side. Before removal of the laparoscope, the uterus and the tubes were inspected to confirm proper application of the clips. The clip cannot be removed once it has been applied. If a clip was not properly applied, another clip was applied in the proper position. In the first 300 patients, thirty had more than one clip on each side. When the physician was satisfied with clip application, the nitrous oxide and all instruments were removed and the incision closed with a single subcuticular polyglycolic acid suture. The patient was taken to a recovery room where she remained until she was able to walk unassisted and then to a clinic recovery room where she rested until she was ready to leave the hospital.

E. Anaesthesia

Laparoscopic clip sterilization was performed under local anaesthesia with infiltration of the abdominal wall along the insertion route for 297 cases. Only 3 cases were administered general anaesthesia.

Various other agents were used in conjunction with the local anaesthesia in an effort to determine the effectiveness of additional anaesthesia and analgesia. The first sixteen patients received paracervical block anaesthesia. Various combinations of diazepam and/or fentanyl were administered. To determine whether application of 1% lignocaine directly on to the uterine tubes would reduce patient discomfort, seventy-one patients had one tube sprayed, one-hundred eighty patients had both tubes sprayed and forty-six patients had no tubal spray. Patient reactions and the physicians' reactions indicated that the most effective combination was intravenous fentanyl, local infiltration of the abdominal wall along the insertion route, and 1% lignocaine sprayed on the uterine tubes before clip application.

III. Results

A. Technical Difficulties

Some technical difficulties occur as a direct result of obesity in the patient. One technical failure occurred in a 209 pound patient with a thick abdominal wall in whom a direct channel through the preperitoneal fat between the rectus muscle and the peritoneum could not be maintained, even though the pneumoperitoneum had been accomplished and abdominal contents clearly visualized. The operation was discontinued after attempting further visualization for 40 minutes. In another patient who weighed 210 pounds, pneumoperitoneum could not be induced in the usual manner, however, nitrous oxide was successfully introduced through the cul-de-sac, and clips were then applied through the laparoscope. Obesity, however, did not always cause technical difficulties. The procedure was easily performed in a 5'2" patient who weighed 259 pounds.

Sometimes difficulty was encountered in creating pneumoperitoneum without an obvious reason. In one patient who weighed 165 pounds, pneumoperitoneum could not be created after four attempts during the first clinic trial, but was easily accomplished when the patient returned six weeks later.

Another source of technical difficulty was the presence of adhesions in the area of the tubes. One patient, sterilized concurrent

to abortion with prostaglandins, could be clipped only on the right side because a mass of adhesion with omentum obscured vision on the left side. Seven weeks later she was relaparoscoped under general anaesthesia and the left tube clipped.

B. Pain

Patients were carefully questioned regarding the degree of discomfort felt during the procedure. Pain was graded on a 0 to 4 scale (none to very severe pain). Of the first 50 patients when the tubes were sprayed with lignocaine, only six thought that the pain of the clip application exceeded that of the insertion of the intravenous needle prior to operation. The pain of the clip application persisted for 48 hours after application in two of the six patients. Most patients rated the pain during the application of the clip to the tubes as 0 to 2 on the 0 to 4 scale, and as less than that of the insertion of the intravenous needle. Interestingly, the discomfort of the trocar insertion and the pneumoperitoneum was not rated very high and in many instances was zero. A rating of four was never reached in this series.

C. Time

The average total time spent in the hospital for this out-patient procedure was 4 hours 26 minutes. The longest stay was 7 hours 20 minutes and the shortest was 2 hours. Average operating time beginning with infiltration of the abdominal wall with local anaesthetic and ending with suture closing of the wound was 18 minutes, with 15 minutes lapsing from the time of the insertion of the Verres needle until the final skin suture was placed. The longest procedure lasted 45 minutes and the shortest 6 minutes. The average patient remained less than an hour in the recovery room, with the shortest stay being 15 minutes and longest being 2 hours and 45 minutes for operations done on an out-patient basis.

D. Immediate Complications

In twenty-five patients vasovagal reactions occurred secondary to excessive manipulation of the uterus while attempting to expose the tubes for proper application of the clips. Intravenous atropine was given and all but two patients improved rapidly. Three patients were hospitalized post-

operatively for problems related to this procedure – two for twenty-four hours secondary to vasovagal reactions and the third for one week for treatment of a pelvic inflammatory disease. No laparotomies were required for emergency complications.

E. Follow-up Complications

This study was designed to follow patients at one week, six months and one year intervals. Of the 300 patients in this series, 297 were contacted within one week. Although some patients reported resumption of household activities the day after the operation, most patients required an average of two days before resuming full household or work activities. Seven patients reported fever of one day's duration; two received antibiotics. Two patients had enough lower abdominal discomfort to return to the emergency room within the first 48 hours. In comparing these patients with patients who had cautery sterilizations performed at Memorial Hospital in 1971, some interesting differences were noted. In the cautery series, 19 per cent of the patients reported some pelvic pain or discomfort with an average duration of only 12 hours. In the clip series, 25 per cent of the patients reported lower quadrant pain or cramps with an average duration of 36 hours. Shoulder pain was reported by 50 per cent of the cautery patients when carbon dioxide was used, while only 12 per cent of the patients having clip applications with nitrous oxide reported shoulder pain.

Of the 150 patients who were six months post-operative, 95 per cent were contacted. Seven patients complained of pelvic pain. Pelvic examinations performed on the two who returned for the six months follow-up revealed no abnormalities. Sixty-six per cent of the patients reported no changes in their menstrual periods. Twenty-two per cent of the patients indicated changes in the amount and duration of menstrual flow. All of these patients had either stopped using oral contraceptives or had had an IUD removed just prior to sterilization. All patients indicated they were satisfied with the procedure. More than 90 per cent of the patients had recommended the procedure to a friend.

To date, four of the patients in this series have become pregnant subsequent to clip

application. The first case (no. 21) discovered pregnant was operated on January 19, 1973. She became pregnant in February, 1973 and spontaneously aborted in May, 1973 (Table 6).

TABLE 6

PREGNANCIES SUBSEQUENT TO CLIP APPLICATION

<i>Particulars of Case</i>	<i>Reason for Failure</i>
Case number 21 Initial surgery 1/19/73 Became pregnant 2/73 Spontaneous Abortion 5/73	Salpingogram revealed incomplete application to one tube at its ampullary portion.
Case number 113 Initial surgery 5/4/73 Became pregnant 7/73 Aborted and reclipped 9/14/73	Clip on round ligament.
Case number 15 Initial surgery 1/15/73 Became pregnant 8/73 Aborted and reclipped 10/1/73	Clip on mesosalpinx.
Case number 58 Initial surgery 3/2/73 Became pregnant 10/73 Menstrual extraction 11/5/73 Admitted for hysterectomy 11/12/73	Inadequate application of the clip on the ampullary portion of the tube.

A salpingogram done after abortion revealed the clip to be applied not at the isthmic portion but in the ampullary portion at an angle that did not completely encompass the tube. The second case, (no. 113) operated May 4, 1973, became pregnant in July of 1973 and was brought back to the hospital for an abortion on September 14, 1973. At that time a repeat laparoscopic exam

revealed the reason for failure to be a clip on the round ligament instead of the tube on one side. Another clip was then applied properly to the tube. The third failure, (no. 15) operated January 15, 1973, was the first procedure combined with a vacuum aspiration abortion. She became pregnant in August of 1973. She was aborted October 1, 1973 and repeat laparoscopy revealed one tube to be correctly clipped but on the other side, a fold of meso-salpinx had been clipped instead of the tube. A clip was correctly applied at that time. This case offered the first opportunity to view the clip after an extended period of application. The result was epithelialization with no evidence of adhesions or undue reaction to the clip. The fourth case (no. 58) had clips applied on March 2, 1973, and became pregnant in October, 1973. On November 5, 1973, she had a menstrual regulation and was admitted on November 12, 1973, for a hysterectomy. The reason for failure was application of the clip on to the ampullary portion of the tube resulting in incomplete occlusion.

Discussion

It appears that the spring loaded clip is effective and can be applied via laparoscopic technique with relative ease on an out-patient basis under local anaesthesia. There are, to date, no known failures of the clip *per se*, (i.e., recanalization) only failures as a result of improper application of the clip. The reaction of the body to this foreign object appears to be minimal. An obvious advantage of the clip in preference to cautery is the absence of risk of accidental bowel burns. The possibility of re-anastomosis may be studied in the future because of the small amount of tubal damage observed in one patient eight months after clip application.

Although a larger series of cases and longer follow-up times are needed to prove the effectiveness, sterilization with the spring loaded clip appears to be safe and should be placed in wider use.

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VASECTOMY

By

DR. A. P. R. ALUWIHARE

It is preferable to attempt to provoke you into thinking about certain aspects of vasectomy arising out of our experience, rather than to repeat here what can so much better be written by others, describe what can be found in the excellent IPPF booklets entitled 'Vasectomy' and 'Male and Female Sterilization', or trespass on ground that will be covered later by others.

General comments on the operation

Vasectomy must be done on people who are medically and psychologically suitable, and who are properly prepared. Most men are suitable. It used to be an operation done under general anaesthesia with a long incision. It is now a common operation, and done by us and most others under local anaesthesia on an out-patient basis. The patient must be properly cleaned, and the instruments and equipment adequately sterilized. The operation can be done almost anywhere, with simple equipment, in 10 to 15 minutes. It is very safe. Millions have been done. Most men can return to work immediately after vasectomy.

The 'patient' lies on his back, and the vas is palpated on both sides at the neck of the scrotum and then fixed on one side at a time. As we often have no assistant, we fix it either between the thumb and two fingers of the left hand or by picking it up in a fold of scrotal skin with the thumb and index finger of the left hand. A local anaesthetic, plain 2% lignocaine, is injected into the skin over the vas, and around the vas itself. The skin is divided, and the vas is picked up with a tissue forceps. The vas is isolated from its coverings and a 1 cm piece removed. The proximal end is ligated, and the testicular end turned back on itself and tied. The ends are released, the testis pulled down to separate the ends, and the skin sutured with catgut. At all stages, meticulous control of bleeding is essential. We usually use two incisions for the two sides. The patient is reminded about his

first twelve ejaculations, and the need for follow-up.

More controversial aspects of vasectomy

Female sterilization is more popular than vasectomy in our area, probably due to a lack of propaganda about the latter. This is unfortunate. We need to make every effort to capitalize on the low morbidity and high efficacy of vasectomy (a failure rate of less than 1%), and the ease with which it can be done with minimal facilities inside or out of a medical institution. We need to use the pool of easily trainable consultants and senior house staff working in Surgical and Gynaecological Units, and the much larger number of trainable medical officers, available if adequately motivated. We do not believe vasectomy should be done lightly and carelessly by inadequately trained people, not only because this will give the Family Planning Programme a bad name, but more important, it is immoral and unethical to carry out any surgical procedure lightly. Doctors with the basic surgical skills are easier to train than those who have to acquire these and the special skills of doing a vasectomy under local anaesthesia on a non-premedicated patient.

We do not routinely discuss the possibility of reversal with the patient, and choose only couples who for socio-economic or medical reasons do not wish to have any more children. If a direct enquiry is made, we admit the possibility of reversal, with an emphasis on the problems involved.

A lot of work is going on as regards the use of no ligature methods of occlusion, which will turn vasectomy into an easier procedure, and one that can be used both for limitation and spacing. We use chromic catgut to ligate the vas, because the existing histological and clinical evidence is compatible with the view that the type of suture material does not alter the success of the operation,

and because infection in the presence of catgut is likely to be self-limiting.

We do not use routine prophylactic antibiotics even when the operation is done in the field.

We carry out vasectomy on three groups of patients (a) in the clinics in Kandy (b) on field visits to small hospitals and other suitable places around Kandy, and on our surgical ward patients, their parents or husbands. In all groups we have found follow-up difficult. Virtually none come for post-vasectomy sperm count. This is a pity. We would like to be sure that we have satisfied customers, both for their propaganda value, and also to satisfy our surgical pride.

Vasectomy in surgeon motivation and student training

As a full time general surgeon and university teacher, I also look upon vasectomy as a useful device to increase surgeon, doctor and student participation in family planning work, and to help achieve the integration of community orientated and family health attitudes into my daily work and that of my students after they graduate in whatever branch of medicine they enter.

As a doctor, teacher and surgeon I must (a) be informed of the demographic situation in Sri Lanka, need for food production, economic growth and family planning, (b) practice family planning (c) be aware of health, socioeconomic and other benefits of family planning at international, national, regional, and individual family levels (d) realistically communicate these to students, medical and paramedical colleagues in service and training, and to patients. More important, by example and attitude, one should motivate colleagues and students to consider family planning as part of the routine care of their patients, assist in family planning teaching and service at levels of planning and implementation, and do and teach vasectomy (and even perhaps female sterilization) whenever possible. This is where vasectomy, particularly gives us the chance to be involved in 'delivering the goods' in addition to just counselling. It gives us the excitement of feeling we have participated actively in giving permanent benefit to a couple.

On our vasectomy field trips we take students and a trainee doctor. They talk to patients before and after operation, and read about vasectomy if they have a free moment. They participate at all levels and are motivated to talk freely to the patient, and learn from him what benefits he expects from vasectomy.

I would like to end by provoking you to think about something we do with our ordinary surgical patients. We have found by analysing our ward and clinic figures the value of using our patients as contact points for family planning work either as part of the community orientated approach to each patient or because management of the surgical condition demands concomitant sterilisation spacing. Of 50 new patients seen in a week in the clinics 1/3 have four or more children, and of these only 1/3 have had any family planning advice. Of the 23 other married patients only 25% have had any family planning advice. 100 new patients pass through our wards each week, 25% have four or more children, and only about 10% have had any family planning advice. Thus there is an excellent opportunity for contact with people who come to us. We enquire into the community and family planning background of the patients who come into our surgical wards. We ask the patients if they feel they have enough children, and discuss sterilization and other family planning procedures. Examples of patients in whom surgical sterilization was done where family size was large enough for the patient are (a) a man with a gunshot injury requiring a saphenous vein graft to replace his popliteal artery (vasectomy a week later) (b) a man with a liver abscess (c) a man with a fractured femur (d) the husband of a woman with a peptic ulcer (e) the mother of a child with tuberculous lymph nodes (f) a woman with an abscess of the foot. In other instances sterilisation/spacing is part of the surgical management. For example, a grossly malnourished child with an intussusception, one of seven in a family, where we almost compelled the father to have a vasectomy just as we had to use compulsion in operating on his child's intussusception; or the mother of a child with an imperforate anus or Hirschsprung's disease is advised not to have another child till the present one is completely well (which may take some years), and for this purpose

the appropriate family planning method is recommended.

We are one of four surgical units in Kandy. There are many others in Sri Lanka. If we all did this sort of thing, using vasectomy as our excuse for involvement, how wide could be the impact in motivating staff and patients. If every physician, allopathic or ayurvedic, and every paramedical worker, adopted a similar approach I believe the result in terms of family planning acceptors and change of attitude of medical and lay public could be gratifying.

I must at this stage acknowledge my gratitude to my colleagues in the Department of Surgery, notably to Professor C. B. Kumarakulasinghe, and Dr. B. Panagamuwa, and to the ward and theatre nurses for their physical and moral support which makes this sort of approach possible—a team effort.

Summary

Vasectomy is a safe and excellent procedure for family planning. It is also very good as a pivot for inducing attitudes and practices favourable to family planning work.

COMPLICATIONS OF VASECTOMY

By

DR. PHILIP M. ALDERMAN

Vasectomy is generally regarded as a safe and innocuous procedure but it is not without morbidity. Complications may be physical or psychological, and must include failure. The most frequently encountered complications in the experience of the author, in order of their appearance, are:

Syncope

It occurs in about 1 : 250 cases performed under local anaesthesia and is characterised by pallor, nausea, unconsciousness, apnoea and convulsions. It does not develop until two to three minutes after the administration of the local anaesthetic. Apprehensive patients are more prone to syncope, which can be quite disturbing to the surgeon. A vaso-vagal reaction is probably the cause.

Syncope may be prevented or modified by pre-operative sedation of susceptible patients. Amyobarbitone or pentobarbitone 100-200 mg. is effective, and the use of adrenaline 1 : 100,000 in the local anaesthetic appears to help prevent the problem. Rarely syncope may occur some hours after operation when the patient is standing or urinating.

The Trendelenberg position suffices for treatment, the unconscious patient coming round after a few minutes.

Haemorrhage

Haemorrhage is evident when marked scrotal swelling develops within a few hours of a vasectomy. The resulting haematoma may triple the size of the scrotum and has occurred in about 1 : 800 of the author's cases. As an undetected or untreated bleeding vessel is responsible in all cases, great care must be taken to ligate even tiny bleeding vessels as the operation proceeds.

Surgical exploration of the scrotum in an effort to find the bleeding vessel is usually fruitless as the blood tends to stratify in layers and the vessel impossible to locate.

Treatment is symptomatic and resolution tardy. Larger haematomas seldom resolve in less than a month.

External bleeding through the skin incision, as distinguished from haematoma, is not uncommon after a vasectomy and merely requires a few extra sutures deeply placed through skin and dartos.

Infection

Superficial infections around the incision occur occasionally and respond promptly to removal of any remaining skin sutures.

Abscesses

Abscesses develop some 3 - 7 days after the surgery as a painful, tender, usually unilateral scrotal mass. Fever may be present. Local skin infections, poor surgical technique or bad luck pre-dispose to abscess formation, which has occurred in about 1 : 800 of the author's series. The organisms most often found are *E. coli* and *Staph. aureus*. Appropriate antibiotics are indicated but the treatment must include incision and drainage.

Sperm Granuloma

A sperm granuloma is a hard, slightly tender mass at the site of interruption of the vas which occurs from two weeks to some years after vasectomy. It is smaller ($\frac{1}{2}$ - 2 cm. in diameter) occurs later and is less tender than an abscess and is unilateral. Leakage of sperm from the proximal (testicular) end of the divided vas is the cause of these tumours. Although self-limiting, phenylbutazone is of value in relieving pain and swelling.

Sperm granulomas occur in about 2% of vasectomies where silk or chromic sutures are used for vas ligation and appear to be less frequently encountered with "Dexon" (a synthetic, absorbable material made of

polyglycolic acid) and do not appear to occur when fulguration of the lumen replaces suturing for vas occlusion.¹

Foreign body granulomas

Foreign body granulomas may result from the use of silk ligatures within the scrotum. At least two dozen have been encountered by the author in 2000 vasectomies using this material.

The patient presents some months or several years after the vasectomy with tender scrotal masses. They are frequently bilateral and are present most often at the site of interruption of the vas or between this point and the skin. Occasionally they appear at the top of the scrotum, near the external inguinal ring. Response to antibiotics or anti-inflammatory drugs such as phenylbutazone is disappointing.

Left alone, foreign body granulomas commonly erupt through the skin, discharging sterile pus and silk sutures until all the intra-scrotal silk is accounted for. Sometimes surgical excision is necessary.

Silk is not recommended in the scrotum.

Non-specific post vasectomy inflammation

About 1% of men who have had a vasectomy subsequently complain of intermittent scrotal, inguinal or lower abdominal pain. It occurs from some weeks to several years after the operation and is often related to exercise, position or sexual activity. Physical signs are minimal, but usually demonstrate at least some degree of inflammation of testicle, epididymis or vasectomy site on one side or the other.

While the aetiology of these problems is unclear, even well-established cases respond strikingly to phenylbutazone (200 mg. t.i.d. for 2 days, then 100 mg. t.i.d. for 2 days, then 100 mg. b.i.d. for a total of about 10 days).

Psychological complications

Psychological complications are an infrequent (less than 0.3% in the author's experience) sequel to vasectomy. Fatigue, marital disharmony or relative impotency may be complained of, most often by men with a previous history of unresolved

marital or psycho-sexual difficulties. The treatment, psychotherapy, is usually disappointing. Careful selection of candidates should minimize the risk of such problems.

Sperm antibodies

Obstruction of the vas results in marked distension of the ductuli efferentes by sperms while sperm agglutinating and sperm immobilizing antibodies subsequently develop in a high percentage of cases.²

The induction of an autoimmune response following vasectomy must be attributed to the autoantigenic properties of spermatozoa, and might constitute an unexpected factor of infertility after vasectomy reversal.³

No evidence has yet appeared to link these antibodies with disease.⁴

Failure and success

What is failure? What is success? A vasectomy may be considered successful if it is followed, three months or more later, by at least two negative and consecutive sperm tests at least one month apart. (A negative test is the complete absence of sperm in a specimen of undiluted ejaculate examined microscopically over 50 high power field.)

Two negative consecutive tests are required because the author has found that 4% of initially negative samples are followed by a positive one. Most of these positive tests do not show normal numbers of sperm, but merely an occasional sperm in an occasional field, i.e. less than 100,000/ml. Considering that normal sperm concentrations average at least 50 million per ml an occasional sperm in an occasional field represents only 1/5th of 1% of normal numbers. Are sperm numbers in this range significant? The author believes so, having seen three such cases causing pregnancy in circumstances having all the characteristics of legitimacy. One should therefore respect the "lurking sperm".

Failure

A vasectomy can be considered a failure if, after at least 12 ejaculations, samples of seminal fluid show (a) sperms in *normal* numbers six months after the operation, or (b) sperms in *any* numbers one year after

the vasectomy. What happens to sperm concentrations after a vasectomy? Freund and Davis⁵ report that about 65% of sperm remaining in the ductal reservoirs are expelled with each ejaculate, so that no *significant* number of sperm remain after 6-10 ejaculations. The question of the significance of very small sperm concentrations, has been discussed above. Relevant too, is the frequency with which small numbers of sperm are found in the post-vasectomy ejaculate. Thus with 1-3 cm. of vas removed and the ends tied with silk or chromic suture a review of 4,040 cases revealed the following:

(a) Two months after vasectomy 30% of samples demonstrated at least a few sperms;

(b) At three months, 20% of samples remained positive for sperm;

(c) At one year, about 1% contained sperms. These are the failures, and this 1% represents the failure rate of this series.

A review of the literature indicates that the incidence of failure ranges from zero⁶ to 1%⁷ or greater, the differences evidently depending upon the surgical technique and definition of failure.

Classification of Failures

Vasectomy failures may be divided into *overt*, *indeterminate*, and those which follow *proof of success*.

Overt failures are recognised by the presence of sperm in normal or near normal numbers six months or more after vasectomy. Forty per cent of the author's failures fall into this group.

Indeterminate failures involve the persistence of small (less than 100,000/ml) numbers of sperm one year or more after the operation. Approximately 60% of failures fell into this category.

Failures following "proof of success" (i.e. after at least two negative and consecutive sperm tests one month apart) have been seen in four of the author's 6,478 cases to date and represent a spontaneous reversal

of the vasectomy. In each of these four cases pregnancy resulted and normal or near normal numbers of sperm were found some years after assurance of success was given.

Possible causes of failure

1. *Accessory vas*

This has not been seen or at least recognised in almost 6,500 cases, nor have any such cases been noted in the literature.

2. *Missed vas*

If a vas has been inadequately identified or treated, failure would result with sperms present in virtually normal numbers. (It is of interest that 14 of the author's 6,500 cases were found at operation to have a unilaterally absent vas. Treatment of the remaining vas was followed by azoospermia in all 14 cases).

3. *Spontaneous Re-anastomosis*

This is the cause of most failures. Pressure behind the testicular end of the divided vas predisposes to the development of endothelial lined ductules. These new ductules span the gap, following the path of least tissue resistance.

Caveats

Although a generally safe and effective procedure, vasectomy is not without risks. Persons counselling or performing the procedure might keep the following points in mind.

1. Before operating, be sure your patient is well adjusted, well motivated, and well informed.

2. Careful antiseptic technique and meticulous haemostasis are especially important in scrotal surgery, where the area may be regarded as especially contaminated and tissue resistance to haematomata minimal.

3. While post-vasectomy sperm tests remain a reasonably reliable indication of failure or success, they are not infallible.

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VASECTOMY FOR POPULATION LIMITATION

By

DR. A. PURAVIAPPAN and PROFESSOR I. S. PUVAN

In the last few months, it has become obvious that it is not standing room that we are going to be short of, but essential commodities. World shortage of grain, spiralling prices of commodities and the widening gap between the developed and the under-developed countries are frequent headlines in our daily newspapers. Hence if there is going to be any future for our grand children, all family planning programmes should push the idea of a two child family.

There are approximately three and one half billion people in the world today. Based on the current 2 per cent growth rate in population there will be eight billion by 2005 and sixteen billion by 2025. Many authorities feel that the earth will not support more than ten billion lives which at current growth rates will be the population fifty years from now. Hence there is an urgent and pressing need to control this benign situation which already has a tendency to become malignant.

2000-2005 A.D., the population would be stabilised at about 35 million by 2060. If the present trend of five child family continues, the population would reach an unimaginable 370 million by 2070. (Fig. 1)

If one accepts the idea of a two child family, most women would have completed their childbearing by the age of 25-30 years. Probably a reversible method should be advised till the children are over 5 years of age because of the high infant mortality in many countries. During these 5 years there would probably be a few unplanned pregnancies due to contraceptive failures. Hence the importance of the need of legal abortions as a back-up procedure for these cases. Once the children are grown up, a permanent method of contraception is advisable. For the woman or man involved, it is a welcome release from further efforts to control fertility. They also have the advantage of a low failure rate.

Whether one should advise vasectomy or tubal ligation would depend on a number of factors. As things stand in most developing countries post-partum tubal ligation would be the first choice. However if one accepts the idea of a two child family, then probably vasectomy has obvious advantages over interval tubal ligation.

Some of these advantages are that it could be done as an out-patient procedure, with simple instruments and the recovery period is shorter. Also the number of vasectomies that can be done in a crash programme are much more than the number of tubal ligations that can be done over a similar period. However there are other social and cultural factors which may favour either vasectomy or tubal ligation.

In countries which do not already have a large vasectomy programme, an organised plan would help the vasectomy campaign.

(A) Training of Surgeon

This is a very important aspect. Surgical qualifications are alone inadequate. At

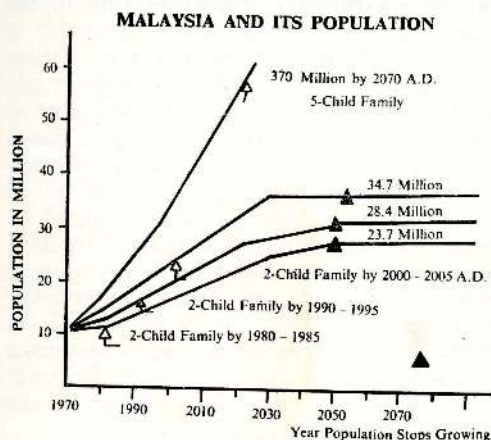


FIG. 1.

In Malaysia the population now is just over ten million. If a two child family is attained, by the year 1980 to 1985, the population would reach a plateau of about 24 million in 2025. However if this two child family is only attained by the year

the Intra-Governmental Co-ordinating Committee for Family Planning Activities last April in Malaysia, it was decided that the trainee surgeon should assist in 5 vasectomies and be assisted in at least 5 vasectomies before he is accepted as a competent vasectomy surgeon.

Vasectomy is a very simple out-patient surgical procedure done under local anaesthesia. Fortunately mortality is very rare from it. However minor complications such as infection and haematoma are not uncommon. Rarely orchitis, epididymitis and spermatic granuloma are seen as long term complications.

It is with respect to these points that special surgical care is important.

To prevent spontaneous re-anastomosis either the ends should be cauterised, turned back, or buried in different fascial planes, as done in our hospital. If a vasectomy is done on a relatively young man, a shorter segment of the vas should be excised. This helps re-anastomosis, if required later.

The surgeons should also be taught, that cases with a varicocoele, scar tissue from previous operations or a inguinal hernia are better done under a general anaesthesia.

(B) Nurses and Para Medical Staff

They form a very important part of the vasectomy team. All of them should be

given a good grounding in male reproductive physiology. This would enable them to explain the effects of the operation to the patients and their wives. As in other family planning services these staff can take the role of education and motivation. In the vasectomy team, they would:

1. Interview and book patients for vasectomy. In this connection, the exclusion of patients with sexual problems should be stressed.
2. Give pre and post-operative instructions.
3. Arrange for semen analysis to be done after a given interval.

During the initial period of a vasectomy campaign, it is important to aim at perfection. With satisfied individuals, the news spreads round by word of mouth, and the campaign would have started out on a sound footing. Most vasectomy reports have mentioned over 90% of satisfied patients.

In conclusion I would say that with the rising medical costs and the urgent need to control population growth, vasectomy would play an increasingly important role in the future.

ACCEPTABILITY OF VASECTOMY AS A METHOD OF CONTROL OF FERTILITY

By

DR. M. S. GHOUSE

My acquaintance with the subject of vasectomy goes back to 1949. Then, vasectomy was treated with great reserve and a good deal of suspicion. Now however, the climate of popular opinion has changed vastly. I propose to deal with the nature of, and some of the reasons for this change.

Even as recently as the 1960's, persons seeking vasectomy were comparatively few. The technique commonly practised then, was the two incision method which took, according to my experience, about 30 to 45 minutes for each patient. Publicity was conspicuous by its absence, and the weight of social pressures, such as tradition and religion, proved a very real brake on the progress of our campaign.

We must have regard first of all to the conditions that exist and the changes that are taking place in Sri Lanka, before we go on to examine the problem. It is a mistake, I think, to consider the conditions of a society in a country such as Sri Lanka by the criteria suitable for conditions in more or even less developed countries in the world. Until comparatively recent times, women in the Orient were regarded by their sisters in the West with pity, as being mere chattels, or drudges. They would find it inexplicable, I suppose, that Sri Lanka has not only a woman Prime Minister, and woman Deputy Minister of Health, but also a large number of women doctors, many of whom are enthusiastic promoters of Family Planning. All this, with the active co-operation of the men folk.

It is an accepted fact that in Sri Lanka today, resistance to many things is crumbling fast. Economic pressures are a very powerful factor in this process. People are realising quickly that in a country where so many public services are subsidised by Government, the unfettered increase of population makes large families a crippling

responsibility for themselves and the Government. They owe it to themselves and the society in which they live to limit their families so that all members of society can have a reasonable place in it.

This realisation is brought about to a considerable extent by propaganda on the part of the F.P.A. and by governmental concern. Our increasing economic hardships must also certainly play their part. It is in my view not coincidental that when the price of essential foodstuffs went up sharply, so did the number of applications for vasectomies.

Another factor which advances the cause of sterilisation by vasectomy is the remarkable speed and ease of the Soonawalla technique. In August 1970, Dr. Soonawalla came to Ceylon at the invitation of the F.P.A. and did 11 cases demonstrating his new one-incision technique. I assisted Dr. Soonawalla in all 11 cases, and thereafter I adopted his technique for all my vasectomies. Now I am able, by means of this technique to perform vasectomies taking an average of 5 to 10 minutes on a case. This improved technique has undoubtedly given fresh impetus to our work.

For instance, in 1970, the figures for vasectomies performed by me in the F.P.A. Headquarters alone, are 35 in 1971, 115 in 1972, 142 in 1973 and in the first half of January this year 25 cases. Apart from these, I have carried out a number of vasectomies on various up-country and low-country estates. My impression is that the estate population have accepted vasectomy with enthusiasm.

I must also mention the part played by tradition in the question of the acceptability of vasectomy here. In 1968, Abayaratne and Jayawardene in their book "Family Planning in Ceylon" wrote as follows:- "Those people with a modern outlook, highly

achievement motivated are likely to take to family planning more readily than the traditional oriented people taking a fatalistic view of life." This sums up the situation admirably. I would go so far as to say that it should be our common aim to break down such traditional barriers while still preserving the essential values of our way of life. Not to do this would entail the risk, if I dare use the phrase in this context, of throwing the baby away with the bath water!

It must not be thought that all cases of vasectomies in Sri Lanka are drawn from the lower income groups. Professional men, executives, and a sprinkling of foreigners have all been my patients for vasectomy. Even in the private sector, considerable work is being done in this field. For instance, at the private hospital where I have been serving since 1951, a large number of sterilisations, both male and female, are carried out, and numbers are increasing.

Because of the intensive propaganda carried out by the F.P.A. in the plantation sector and incentives offered by the management, the response there to vasectomy has been very encouraging. The concern of our vasectomy patients is itself an important factor in the promotion of our cause; a satisfied customer is our best propaganda. I feel that if there was more co-ordination between the F.P.A. and government, the resources and machinery of government could be profitably utilised to achieve better results in our campaign. It is also true that hardly any propaganda is carried out in the villages by F.P.A. workers and government public health officers and this may explain the relative indifference of rural folk to our cause.

It is in this respect that we must enlist the help and co-operation of the local authorities and volunteers in the villages. If they are entrusted with the responsibility of disseminating the purpose and benefits of family planning by the simplest means – vasectomy – I feel that our battle will be largely won. Generous grants from foreign organisations have been made available to the Government of Sri Lanka. In our present crisis, the last thing we can afford in our campaign is apathy. We must harness all the means in our power to push it with vigour in all parts of the Island. The people of Sri Lanka are quick to learn from others. This is what is always said. We must put it to the test now. It is also true that family planning is a revolutionary concept with which we have quickly become familiar. It must not remain a concept. It must as speedily and safely as possible be translated into reality.

It is common place for me to say that acceptance involves a prior offer. It therefore depends to a great extent on what we – the F.P.A. – offer to the people and how we offer it. If we persuade people that they will have no need to stay even for a day in a hospital to have a vasectomy done, that it is painless and simple that the risk of complications is minimal that the operation need not be irreversible, then there is no reason why a large majority would find it unacceptable.

My own experience is that people are ready now to accept vasectomy. There is no stigma, social or otherwise, attached to it. We must, in other words, properly plan our Family Planning Campaign. It should be a powerful weapon in our economic battle against want and distress.

RECANALIZATION OF THE VAS DEFERENS

By

DR. F. P. SOONAWALLA

In the last few years, due to improvement in the techniques of vasectomy as well as its reversal, the success rate of recanalization has improved so much that vasectomy need not be an irreversible procedure.

The knowledge that an interrupted vas can be recanalized with 80% success helps in motivation for sterilization of the male, particularly of young couples with small families.

This paper is a review of our experiences of recanalization in 96 cases, the majority of which were done during advanced courses in family planning techniques organised by the Family Planning Association of India in collaboration with the Christian Medical Association of India in various centres throughout the country.

Indications

The indications for recanalization in this series have been:

Death of 1 or more children in 36;

Death of the only male child in 32;

Remarriage after death of the wife in 11;

Desire to have more children in 6;

Vasectomy done in unmarried young men in 4. (All four men in this group were of low mental calibre.)

In once case, recanalization had to be done to restore the man's alleged loss of sexual power wrongly attributed to vasectomy.

The first two groups comprise the largest number, since child mortality in the poorer class happens to be high. The last three groups evidently are instances of improper motivation. Vas to vas union was not possible in any of the patients explored for post-operative traumatic loss or congenital absence of vas.

Principles

For improving the results of recanalization it is necessary to appreciate the anatomy of the scrotal vas and the local changes that take place after vasectomy.

The vas lies posteriorly in the scrotum separated from the main mass of the cord. It is loosely encased in a well formed sheath, in which also lie the artery and fine nerves to the vas. The vas therefore cannot be mobilized easily unless this sheath is fully incised.

The artery running parallel to the vas gives out minute vessels every few millimeters, and stripping the vas for more than 6 to 8 mm. will tear these branches without causing evident haemorrhage but leading to avascular fibrosis of the segment. It is extremely important therefore to avoid excessive stripping of the vas both at vasectomy as well as during anastomosis.

Morphologically the vas in the scrotum is divided into two parts. The upper segment above the level of the upper pole of the testis has the appearance of a straight thick walled tube with a narrow lumen. As the vas descends behind the testis it tapers to form a narrow tube with a thin wall and a large lumen. This thin delicate tube is highly convoluted. Hence it is not possible to insert a nylon splint into the lumen beyond a few millimeters. The convolutions are held together by fine strands of areolar tissue containing minute blood vessels. An attempt to straighten out the loops by dissection will therefore either tear the vas or destroy its blood supply.

Considering these features one should realise the importance of not doing a vasectomy low down in the scrotum, or of not removing long segments of the vas, as success of recanalization of the thin convoluted segment is very low.

Changes after vasectomy

After ligation of the vas, the upper or abdominal segment remains patent and healthy. In none of our patients was it found to be blocked.

The testicular segment is subjected to continuous pressure and undergoes progressive dilatation for a period of 6 to 12 months. Although its outer size is only slightly enlarged, the lumen becomes 3 to 4 times its original diameter. This discrepancy in lumen and wall thickness of the two ends should be noted during anastomosis.

The changes of pressure are maximum in the thin epididymal tubules which dilate and may even rupture, leading to formation of sperm granuloma and obliteration of the epididymis. This form of blockage has been reported by Schmidt to occur in over 4% of cases and he emphasises the need to avoid massage or pressure on the epididymis.

Macrophages reported by Phadke and others appear in the dilated ducts and digest the stagnant sperm population. Absorption of the products of dead sperms seems to raise the sperm antibody titre in the serum. It is possible that the antibodies may create autoimmunity to one's own sperms resulting in production of sub-fertile spermatozoa after recanalization. This phenomenon is still to be proved.

The testis itself is subjected to minimal back pressure changes and shows histological evidence of decreased spermatogenesis with some peritubular fibrosis. These changes are reversible even after many years and up to old age. Restoration of adequate spermatogenic function takes from 3 weeks to 6 months and varies directly with the length of interval between vasectomy and recanalization. The longest successful recanalization with pregnancy in this series is 11 years.

The site of vas interruption shows varying changes. For the first few months after vasectomy either one or two nodules of fibrosis are seen around the ligated ends. These nodules tend to disappear after a year leaving only a palpable defect in the vas. If the blood supply to the vas has been affected by excessive mobilization or

by post vasectomy infection, the vas appears fibrotic and shrunken.

Rarely, if the testicular end has opened up, a sperm granuloma or a sperm cyst is found. If there has been infection around the ligated ends one may find a ligature granuloma or abscess.

Pre-operative assessment

A careful examination of the scrotum is mandatory before deciding on surgery. By gentle palpation one should note the condition of the vas, the ligated cut ends, level of vasectomy and detect any pathology in the cord, epididymis or scrotum. This information helps in selecting the more favourable side since as a routine the operation is done on the better side first. The other side is only done, if the first anastomosis has not been satisfactorily performed.

A testicular biopsy is advised only if the testis or epididymis feels abnormal. It has not been necessary in any of our cases.

General contraindications such as septic foci, urinary infection and diabetes should be ruled out.

Technique

The operation is simple, but needs meticulous technique with perfect haemostasis and asepsis. It should never be performed in haste by an impatient surgeon at the tiring end of a long operative session.

Although it can be done under local infiltration, general or spinal anaesthesia is preferred. The scrotal skin is incised for 1½" on its anterolateral aspect over the area of the excised vas, and the tissue layers are cut through till the nodules and vas are seen. These are caught in two vas forceps and delivered out of the wound. The sheath covering the upper segment is then incised till the pearly white healthy vas is seen. At this location the vas is fixed by holding the perivasal tissue with a mosquito forceps and sliced clean transversely with a knife.

A 23 gauge blunt tipped hypodermic needle is introduced in the lumen and 5 ml. of saline is gently injected into the abdominal vas. If the fluid flows freely, patency of the vas is established. This is a better method of confirming patency than by passing a 2-0 monofilament nylon or by vasography.

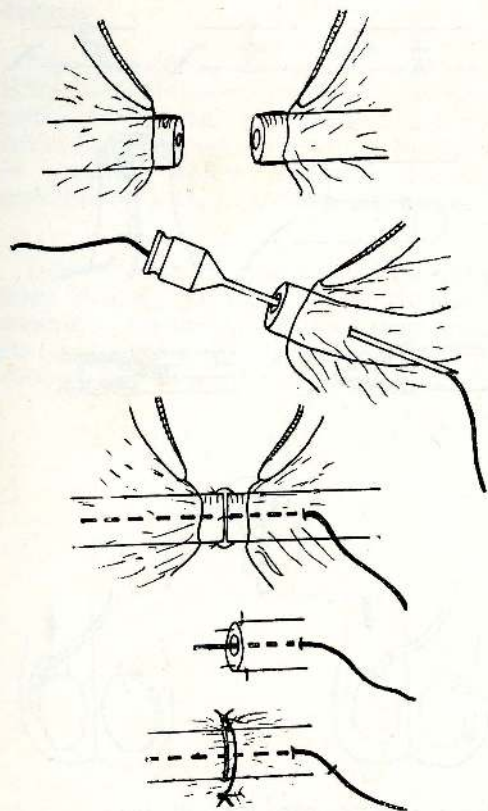


FIG. 1. Technique of end-to-end anastomosis:

Method of introducing the monofilament nylon splint and of suturing the vas are shown.

The testicular end is similarly dissected and when it is cut across, the milky fluid that exudes from it is examined for spermatozoa. When such fluid does not appear initially it may do so after gentle probing of the lumen with 2-0 nylon or irrigating with a few drops of saline. If the fluid does not appear at all the chances of successful recanalization are lower. This may be due to a block in the epididymis or non-function of the testis or merely due to a long interval after vasectomy. Testicular biopsy should be considered in such cases. The ligature nodule with the fibrotic vas segments is then excised and haemostasis achieved.

After both vas ends have been so prepared, a splint of 2-0 monofilament nylon is introduced into the testicular end to be brought out through the lateral wall of the vas, 1 cm. from the cut end. This can be achieved either by using an atraumatic needle

suture or by retrograde insertion through a 22 gauge hypodermic needle. The splint is inserted into the abdominal vas for 2 inches.

The cut ends are then approximated by 3 or 4 sutures of 6-0 or 7-0 polyester (Tevdek or Ethiflex) or nylon on an atraumatic non-cutting needle. The sutures should not enter the lumen of the vas and must create a water-tight apposition and good alignment. Magnifying devices such as operating binocular glasses are helpful for accurate suturing.

Sperm fluid spilled in the tissues should be washed away by spraying saline in the wound as otherwise it may produce a granulomatous reaction. The anastomosis is reinforced as well as sealed off by sutures taken through the perivascular tissues.

The splint emerging from the testicular segment is brought out through the scrotum, fixed with a suture and cut short. The operation is concluded by closing the cremaster and dartos with interrupted 3-0 plain catgut or Dexon and the skin with fine silk. A well fitting scrotal suspensory is applied.

Of the many methods of reunion that have been tried, end to end anastomosis with use of a splint has produced best results. Splinting seems necessary for better alignment and healing. Side to side techniques do not produce water-tight apposition and have shown poorer results. We have no experience with hollow endosplints.

Difficulties in anastomosis arise when vasectomy has been done low down or a long piece of the vas has been removed or destroyed by excessive stripping or post-vasectomy infection. In such cases the operation will have to be tailored to suit individual conditions.

When a thin, lower segment is to be joined to a thick upper segment, a proper end to end apposition is impossible. The best practical solution in such cases is to wedge the thin tube into a fishmouthed thicker tube over a nylon splint and hold them together with fine adventitial sutures. Failing this, implantation of the vas in the turgid head of the epididymis should be considered.

In cases where one end of the vas or the epididymis on that side is fully destroyed, bilateral exploration should be undertaken simultaneously with the hope of devising some form of cross-anastomosis or implantation.

Post-operative care

The most important aspect of post-operative management is avoidance of undue pressure on the scrotum or traction on the cord, which may lead to disruption of the delicate anastomosis.

A broad spectrum antibiotic and an anti-inflammatory agent such as indomethacin or oxyphenbutazone are given for ten days. The skin sutures are removed on the fifth day and the nylon splint gently pulled out on the seventh day.

Sex activity should be started after three weeks and then after a period of abstinence the first semen analysis is done. Subsequently examination is repeated at monthly intervals till an adequate count is attained or up to six months.

Results

Appearance of live sperms and attainment of a fertile semen sample depend on several factors including the age of the patient, the degree of testicular activity and the time lapse between vasectomy and recanalization. Though spermatogenic function of the testes is maintained up to old age, production and transport of sperms is delayed if recanalization is done many years after vasectomy.

In the majority, live sperms are obtained in the semen after one month and an adequate count is reached within three to six months. Successful impregnation will of course depend on other factors which contribute to the fertility index of the couple. This index, in many patients of recanalization age group, is low.

Follow-up in these patients is rather discouraging since a substantial number do not report for evaluation. Perhaps some of these are not interested in the result, having got operated to please their wives or are dissuaded by the thought of having to undergo repeated semen tests and a second operation in case of failure.

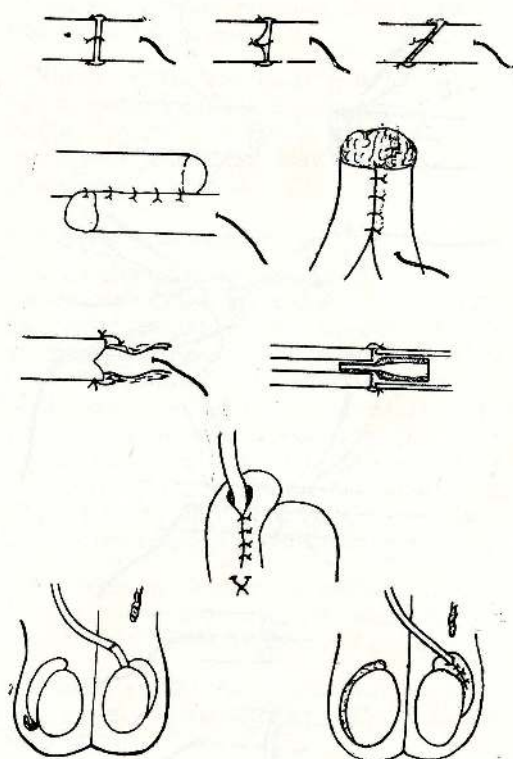


FIG. 2. Methods of Vas Recanalization:

From left to right and above down are shown, end-to-end, fish mouth end-to-end, oblique cut end to end, side to side, side to side in continuity, end to end implantation, endo-splint, vas epididymal implant, vas to contralateral vas, and vas to contralateral epididymis.

In this series, out of 96 cases, semen reports are unavailable in 78 and a positive count found in 62; a success rate of 82%. In 4 of these the count remained sub-fertile.

Obtaining reports on pregnancy has been even more difficult, for several reasons. 25 patients reported impregnation of their wives, and in 20, this occurred within a year of recanalization. The impregnation rate was therefore 42% in the 58 cases with adequate counts.

We have observed that if recanalization is done within two years of vasectomy, success in terms of early appearance of live sperms, rapidity of rise in number and of pregnancy rate are all on the high side.

Failures

The anastomosis is considered to have failed if a fertile semen sample is not obtained within six months. The sperm count may fail to rise if the stoma is not properly aligned or avascular fibrosis following excessive mobilization leads to stricture of the vas.

Total absence of sperms could be due to many reasons. Of these, we would like to emphasise disruption of the anastomosis due to suturing under tension, post-operative traction of the cord, obliteration of the

vas by granulamatus reaction around a sperm leak from the suture line and rupture obliteration of epididymal tubules.

Unfortunately, the peculiar anatomical features of the vas and the lack of opportunity of reoperation has prevented most workers from detecting the exact cause of failure in each case. However, of this we are certain, that the incidence of failure of recanalization of the vas can be greatly reduced by adopting the correct technique of vasectomy, and by meticulous technique in the management of recanalization.

EXPERIENCE IN VASECTOMY IN AN ESTATE PROGRAMME - MOBILE UNIT

By

DR. C. S. WICKRAMASURIYA

Never before in the history of Sri Lanka has there been a greater urgency for population control; for her economy today, especially with regard to her foreign exchange position has reached a critical point, due to an inadequate rate of economic growth, a decline in export prices and a tremendous rise in the price of imports. Unless the rate of population growth is brought well under control it is difficult to envisage any substantial benefits accruing from planning and development, however sincere the efforts are. In this context, the organisers of this International Scientific Congress on Family Planning have reason to be proud; for a Congress of this nature with such broad based participation could not have been better timed. I am confident that this would awaken in all of us an awareness and interest in family planning work such as there have never been before. I am happy at the opportunity I have today to make some contribution by relating my experience in vasectomy on the Estate Programme - which covers the plantation sector. It is about these people, whose untiring efforts have always helped to sustain Sri Lanka's economy, that I talk to you today.

The estate workers and their families constituting 9% of Ceylon's total population (12.7 million - 1971 census) are basically a mass of ill-educated people some of whom are just literate. It is unfortunate, that they continue to remain entrapped in the cruel web of circumstances, and suffer from the hazards of poor housing and sanitation, poor health of mothers and children and an inadequate education, thus giving them no opportunity to rise above this level.

According to figures provided by the Medical Director, Planters' Association there has been a reduction in the birth rate on estates from 43.2/1000 in 1950 to 25.4/1000 in 1972. The death rate for the

same period has ranged between 10 and 11 per 1000. In spite of a reduction in the natural increase, the total population on estates has continued to rise steadily. The economic pressures of day to day living and the non-availability of adequate work on estates to earn a reasonable wage, has made it almost impossible for them to continue to support many children and older people in proportion to the number of productive workers.

Family planning work had been introduced on estates from about 1955 and by 1966 there had been some demand for both male and female sterilisation. Here then was an indication, that the idea not only of spacing but also of limiting families had been conveyed to the plantation sector and family planning workers in this country must have been more than pleased that their efforts had not been in vain.

In view of this growing interest in vasectomy, the Family Planning Association and the Medical Director, Planters' Association decided to take a vasectomy programme to the estate community, and this idea led to the birth of the Estate Vasectomy Programme in "Mobile Units".

The Estate Vasectomy Programme which is arranged with the collaboration of the estate managements is geared to a team approach and consists of qualified and competent personnel - comprising of 1 surgeon, 1 nurse, 1 male attendant or nurse-aide and two health educators for motivation.

Health Education Publicity Programme

This starts about two weeks prior to commencing the vasectomy sessions, and one or two days are spent on each estate, having group discussion, talks and film shows.

Interest in family planning work among managers, estate medical assistants, midwives and trade union leaders on estates vary from active support to crass indifference, and a few are even antagonistic. A few of these trade union leaders, because of their ignorance, have dissuaded workers by even suggesting that vasectomy is an attempt at genocide of the Indian labour population. Perhaps greater active participation by medical officers in the area in educating them is the answer to overcome such misconceptions.

Interest in Vasectomy

Interest among members of the staff and workers vary. The more educated ones want answers to questions such as the nature of the operation, whether general anaesthesia is going to be used, whether ejaculation will occur after the operation and what happens to the sperms, and whether the operation can be reversed. Another question often asked is whether their ability to do heavy manual work would be affected after vasectomy.

When one works in this type of closed society where the people are also backward and impervious to new attitudes, one realises that motivation is no easy task. There have been quite a few instances where potential acceptors, having included their names in the lists for vasectomy, have literally changed their minds overnight. These are some of the experiences during motivation on the estates. Others being:

1. Opposition of wives to vasectomy, fearing that deleterious effects may follow, affecting either the husband's potency or health.
2. Fear of promiscuity by husbands, and this is particularly important on estates because of the environment in which they live and work.
3. Fear among potential acceptors that vasectomy amounts to castration.
4. Opposition on religious grounds was not significant, for the majority are Hindus among the Indians and Buddhists among the Sinhalese. However a few Catholics on estates have objected.

Incentive Bonus Scheme

As a motive for vasectomy each acceptor is given Rs. 30/- and three days' full pay

leave by the estate management. Estate medical assistants and midwives are also paid Rs. 5/- per acceptor, in order to solicit their support.

Reasons for Vasectomy

These have been more or less the same as in other societies and are:

Influence of motivation

Non-acceptability of other contraceptive methods

Unwillingness to subject wife to salpingectomy

For reasons of health of the wife

Because of the incentive bonus.

No study has been made of the actual numbers in each category. Perhaps it might be of cultural interest to note that a few acceptors among the Indian workers decided to have this operation done for the reason that after their daughters have attained puberty it is considered improper in their society for parents to have any more children.

The total number of vasectomies, their monthly distribution and the number of operating days per month from April - December '73 is shown in Fig. 1.

A total of 1106 vasectomies were done on 39 estates covering a total extent of 45,416 acres. 1056 were non workers and Field officers, field supervisors, clerks, estate medical assistants and drivers. The number of vasectomies per day has ranged from a minimum of 2 to a maximum of 39 with an average of 19.1.

Interest in vasectomy on estates is sustained. Because of the further demands from estates that we have already visited, I am confident that the vasectomy programme is fast catching on and with the increasing stresses and strains of day to day living, the demands for vasectomy are bound to increase and we hope to expand the services to meet this demand.

Age groups at marriage of the spouses of acceptors in the series is shown in Fig. 2.

A glance at this shows that the age groups 13-16 and 17-19 have the highest number of women. The youngest spouse was 11 and the oldest 34 years at marriage.

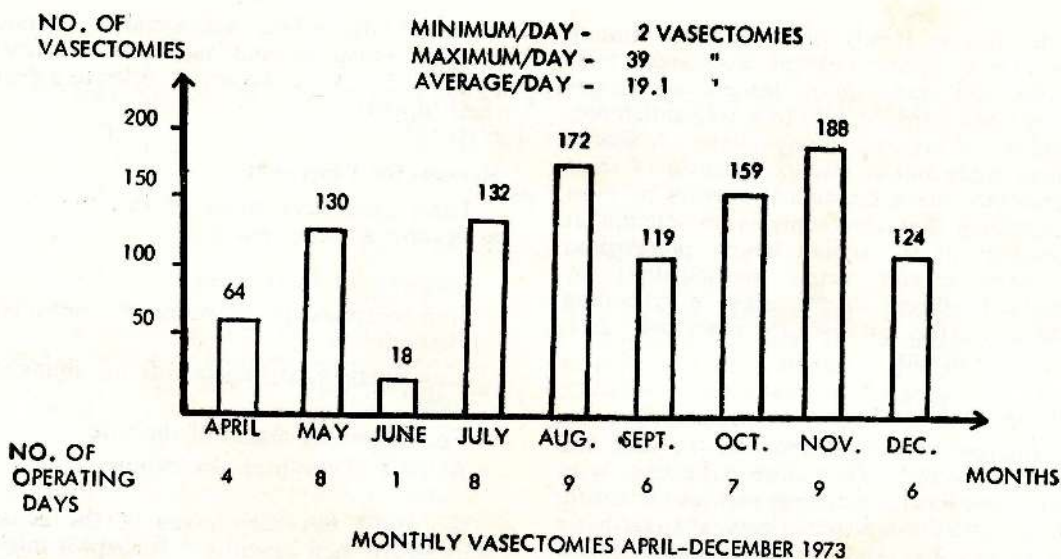


FIG. 1.

The reason for their being given away in marriage at such an early age, is probably because in the environment in which they live and work, it would be almost impossible for working mothers and fathers to have any surveillance on the moral conduct of their daughters. Perhaps another consideration is the fact that in this stratum of society early marriage has always been a dominant feature.

With these women getting married so early and being fertile for so long can we tackle this problem without recourse to permanent methods of sterilisation as an additional and an important line of attack in the war against population explosion? My answer would be "No". The distribution pattern of the children of acceptors is shown in Fig. 3.

- 492 acceptors forming 45% have 3 or 4 children
- 319 acceptors forming 29% have 5 or 6 children
- 158 acceptors forming 14% have 1 or 2 children
- 137 acceptors forming 12% have 7, 8, 9, 10 or more children.

There were 20 acceptors with one child and the wives of every one of them was pregnant. Now here was a situation we found difficult to get over, because despite all our attempts to dissuade these acceptors from having

their vasectomy done, we failed. In fact some of them kept chasing us from estate to estate and finally I gave in.

This is a startling revelation, that some fathers are now so deeply concerned about limiting their families - some in sheer desperation. This is not difficult to understand when you see their predicament, because in the majority of cases even one more addition to the family would mean the difference between existing and living.

So far the vasectomies have been done in the mobile operating theatre. On a few occasions estate hospitals have been made use of in which case they have been pre-selected and made ready according to instructions that have been sent. Sterilised linen/caps/masks/gowns/gloves are all taken from Colombo in autoclaved drums.

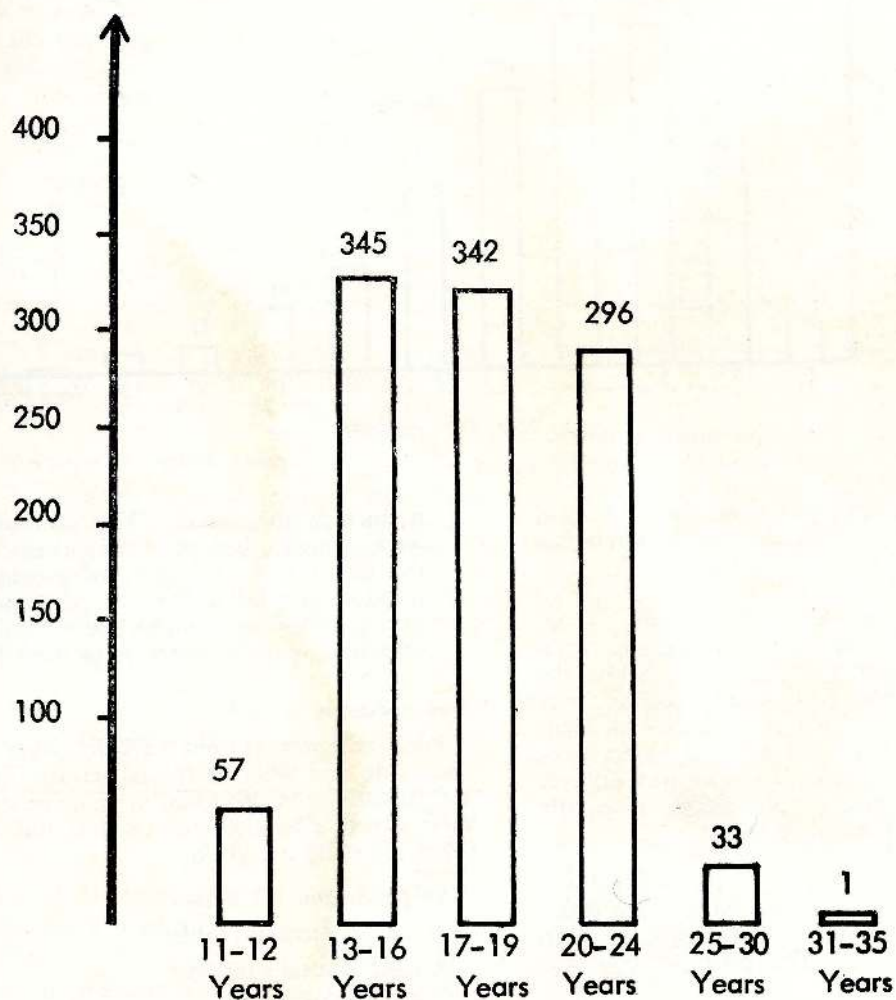
Pre-operative preparation

On the morning of an operating session consent forms signed by their spouses are collected and the acceptors are shaved and washed and are ready for operation. About 15 minutes before operation a 25 mg. tablet of chlorpromazine is given.

Features of operative technique

1. No gloves were used because of the greater ease with which the vas can be separated from the rest of the cord and held in position without gloves.

NO. OF
SPOUSES



AGE GROUPS OF SPOUSES AT MARRIAGE

FIG. 2.

TOTAL NUMBER OF ACCEPTORS - 1106
 " " " CHILDREN - 4857
 AVERAGE NO. OF CHILDREN/ACCEPTOR 4.4

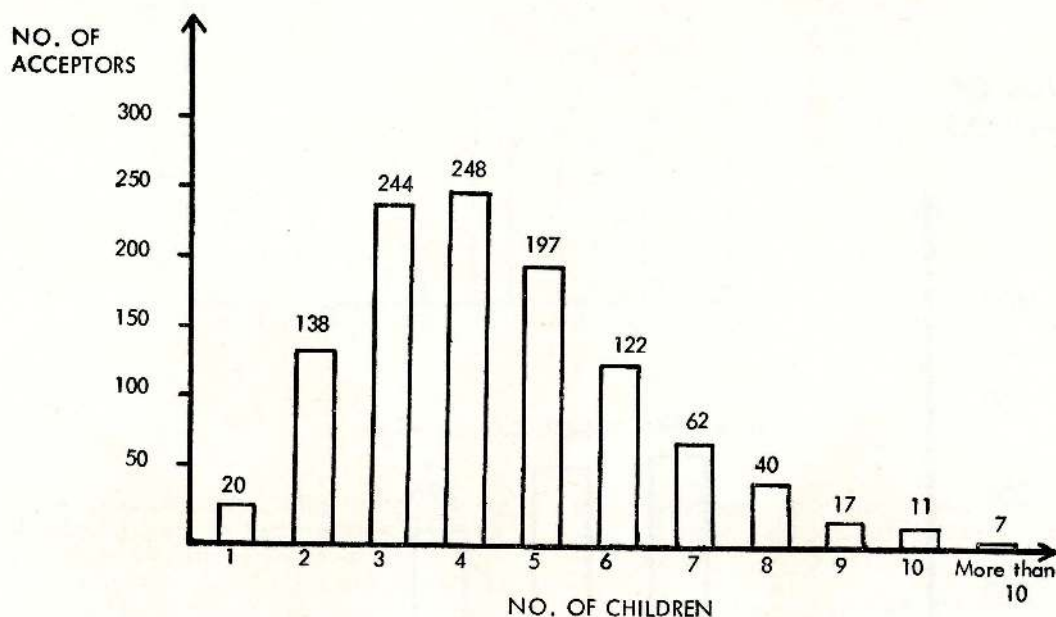


FIG. 3.

- 2% lignocaine has been used for local anaesthesia, sometimes with adrenaline 1:80,000.
- A single vertical incision about 3/4 cm. just to the right of the median scrotal raphe about 1/2 - 3/4 ins. below the root of the penis was used in over 95% cases. Two anterolateral incisions were used in the first 50 vasectomies and also in cases where it was difficult to manoeuvre the vas easily, especially in cases of retractile testes.
- About 1/2 - 1 cm. of the isolated vas on each side was excised and the distal end looped back and ligatured with No. 40 linen. The proximal end was also ligatured.
- Meticulous attention to haemostasis and gentle handling of the scrotum and testes, both factors which contribute to the successful result in the early post-operative period were strictly adhered to.
- Except very occasionally no skin sutures were used, and then too, vertical mattress sutures of catgut were applied

to include the dartos. The skin edges were caught between the blades of the distal end of a pair of mosquito forceps, just for a few seconds, and a dry dressing was applied after sealing off with compound tincture of benzoin.

Post-operative

Each acceptor is told verbally what he should do and what he should refrain from, and this advice is also listed in an instruction sheet which is handed over to him, and the following items are given:

Sulphadiazine for 3 days
 A few paracetamol tablets
 A cloth scrotal support
 and 20 condoms.

Additional pathology and abnormal scrotal findings

Inguinal hernia	2
Hydrocele	12
Cyst of the epididymis	2
Atrophic left testis	2
Absent left vas	2

Post-operative follow up

On the last day of each programme a post-operative follow up was done on each estate, and I was pleased to note that about 98% of the acceptors had turned up in response to our request made earlier.

The post-operative follow up is useful to:

- (i) Assess early post operative results, and note any complications or complaints.
- (ii) Reassure acceptors if they need it.
- (iii) Explain to them that for the first 3 months they will continue to be fertile and that they should resort to some other contraceptive method during sexual intercourse in order to prevent their spouses conceiving.

Though a few of their wives are on pills or IUDs, the majority (nearly 99%) take away the condoms we give them.

The estate medical assistants are provided with a list of the likely early post-operative complications and their management.

Post-operative complications

Post-operative complications have been few and Table 1 shows the list of complications, and their percentages are indicated against each.

The five acceptors who had scrotal haematomas were hospitalised.

TABLE 1

EARLY POST-OPERATIVE COMPLICATIONS OF VASECTOMY

Complication	No. of cases	Percentage
Oedema of scrotal skin	8	.72
Bruising of scrotal skin	2	.18
Bleeding from wound	1	.09
Scrotal haematoma	4	.36
Infection of wound	5	.45
Infection of scrotal haematoma	1	.09
Funiculitis	2	.18
Vasitis	8	.72
Epididymitis	6	.54
Vague lower abdominal pain	8	.72

Post-operative sperm count

Three months after a vasectomy programme a sperm count is done on the acceptors. In spite of their being informed early about the date on which collection is to be done, only about 50% presented their samples of seminal fluid for examination, and that too with a lot of persuasion. The results are shown in Table 2.

TABLE 2

SPERM COUNT FIGURES

Total no. of acceptors whose sperm counts were due at the end of December 1973	636
Total no. presenting for sperm counts	331
No. of positive counts	5
1st 4 positives were in the 1st 150 vasectomies	

Social consequences of a failed vasectomy giving rise to pregnancy

When working in closed communities such as this, one has to be aware of the fact that practically everyone on the estate knows who the acceptors have been, and it is most important to ensure that the spouses of these vasectomised acceptors do not conceive due to any shortcoming of our programme, for this can lead to all sorts of problems including disruption of family life. Infidelity is the indictment against the wife and it is difficult for her to defend herself. Shortly after I started working on the estate programme I actually witnessed such a case on the estate. Unfortunately in this particular case no post-operative sperm count had been done till after seven months, and by this time the wife was pregnant. A count done later on, was positive. The wife had been beaten and battered by the husband and both husband and wife had been subject to humiliation by others on the estate. I have digressed a little to stress the importance of a post-operative sperm count 3 months after the operation, as was offered to them during motivation. In actual fact the news of this isolated case had spread within the district and may to some extent go against future vasectomy programmes on neighbouring estates.

To the five acceptors who had a positive count in this series, re-vasectomy was offered with a further incentive of Rs. 50/-. One had the operation done, but the others have not shown any interest upto now, in spite of our explaining to them the consequences.

Evaluation of acceptance

I have so far been able to get the views from only 240 acceptors who underwent vasectomy between April and August 1973. I am glad to report that practically everyone of them had expressed satisfaction, and some of them who were trade union leaders and a few others, had even volunteered to participate in radio discussions, seminars or conferences connected with family planning work, in order to spread the message of vasectomy across to others.

Summary and conclusions

I have given my personal experiences of 1106 vasectomies done during a 9-month period from April to December 1973, on the plantations in Sri Lanka. The problems encountered and the social background of these closed communities have been touched upon, to emphasize the absolute need for a permanent method of sterilisation. Considering that this is a minor operation which can be done without hospitalisation, and with a minimum of pain and discomfort to the acceptors, with early return to work, I personally feel that this may be one of the most favourable methods for this stratum of society. It is perhaps important to comment that education and motivation in family planning should be directed more to the families with 2, 3 and 4 children so that they would limit their families before it is too late. Those who already have larger families, would because of the circumstances they are placed in today be more willing to accept sterilisation or some other method of contraception, including

abstinence, which I found was practised by quite a few males on estates.

I hope every effort would be made to increase the momentum of the vasectomy programme not only on the plantations but also in the rural areas where the population constitutes nearly 68.5% of the total population of Sri Lanka. They are much in need of it, and I hope that administrators and planners and also our medical colleagues, including those in the Ayurvedic System of Medicine, will give their unstinted support and co-operation to such a programme.

I must express my thanks to the staff of the Family Planning Association and the Medical Director, Planters Association, for having spared no efforts to make the necessary arrangements for the smooth functioning of these programmes. Finally I would like to express my appreciation of the very good work done by all members of the team who have had to work long hours on some estates. This programme could not have been so successfully carried out were it not for their team spirit and enthusiasm.

I can think of no better way to end than by quoting Robert S. MacNamara - President of the World Bank, who said - "Population explosion is an issue so hypersensitive, giving rise to diverse opinion - that there is an understandable tendency, simply to avoid argument and turn one's mind to less complicated matters and hope that the problem will somehow disappear. But it will not disappear, and what will disappear is the opportunity to find a solution that is rational and humane. If we wait too long that option will be overtaken by events. We cannot afford that, for if there is anything certain about the population explosion, it is, that if it is not dealt with reasonably it will in fact explode in suffering, explode in violence and explode in inhumanity."

**THEME: INTERRUPTION OF PREGNANCY
& ITS ROLE IN POPULATION
LIMITATION**

CHAIRMAN: Dr. A. J. Sobrero

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IMPACT OF INTRODUCTION OF LIBERALIZED ABORTION LAWS ON A CANADIAN COMMUNITY

By

DR. JOHN H. DICKINSON

In 1969 a very liberal abortion (and sterilization) law was introduced in Canada, where the previous law and custom had been previously relatively strict, austere, and primitive.

At Vancouver General Hospital, Vancouver, B. C., Canada, this resulted in:

- (a) 100 fold increase in abortion rate.
- (b) 50 fold increase in sterilization rate.
- (c) no significant drop in birth rate.
- (d) very likely an *increase* in pregnancy rate.
- (e) a clearly significant drop in maternal mortality.
- (f) a disappearance of criminal abortion and sequelae.
- (g) a gross overloading of hospital facilities.

- (h) a (temporary) very inadequate administration and performance of these procedures, with severe delay, and increased complications.

Also noted

- Complication rate 12 - 20 weeks was $2 \times$ that of 0 - 12 weeks.
- A great ethico-moral change in both profession and laity with respect to abortion and human life.
- A use of abortion as a method of B/C, as well as treatment of failed B/C.
- A disappearance of babies for adoption.
- A more permissive society.

Conclusions

Detailed planning essential.

THE IMPACT OF ABORTION

By

DR. PAMELA W. ALDIS

I FEEL

- (1) Abortion is **NOT** the answer to our permissive sexuality.
- (2) Abortion as a means of **FAILED B/C** is acceptable.

I believe that an Abortion Clinic or Facility separate from the Service Hospital should be set up **PRIOR** to a law change, and should service a geographical area -

This would

- (a) Relieve the work load on busy physicians.

- (b) Relieve the work load on the Anaesthetic Dept. in a Service Hospital.
- (c) Relieve nurses and other personnel who find the work distasteful.

This Facility would be staffed by full time personnel - Doctors, Anaesthetists, Nurses, etc. - set up on a day care or overnight basis. Often Volunteers are available who do feel a need to help these "pregnant unfortunates".

This Facility should or might enforce (by law if necessary) compulsory Birth Control for a period of one year following any abortion, staffed by adequate advisory personnel.

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I believe that there is a strong **LACK** of public education with regard to

- (a) Sexuality
- (b) Birth Control
- (c) V. D.

i.e. (1) Fathers and mothers often are shy and ignorant

(2) School programmes lacking or inadequate

(3) **Doctors** – who are – judgemental
– un-informed
– biased and rigid
– do not accept the need to refer where ethics or religion bar personal involvement.

Finally – I do believe that abortion has gone a long way towards solving the problem of some “High Risk Mothers”

i.e. the very young, the very old, the grand multiparous patient and the medically infirm, etc.

I, as a woman, will accept one mistake from anybody, but I do not accept abortion as a method of birth control for the general public.

A COMPARISON OF ABORTIONS PERFORMED ON AN INPATIENT OR OUTPATIENT BASIS AT S. S. G. HOSPITAL, BARODA, INDIA

By

PROF. ROHIT V. BHATT

Introduction

Following the passage of the new abortion law in April of 1972, it was expected that the number of abortions in India would show a dramatic increase. Although advance estimates indicated that as many as 2 million legal abortions would occur, the final results show that only 40 to 50 thousand legal abortions were performed.

The gap between the expectation and the final outcome, could have been due to a combination of (1) a failure of the government to give sufficient advance public endorsement to doctors and nursing homes, (2) ignorance of the people, and (3) a lack of advance publicity for the programme. The results for the second year should be much more encouraging, as steps are being taken to overcome such difficulties as the publicity problem.

If the second year does bring with it a dramatic increase in pregnancy termination, serious thought will have to be given to the impact of this increase on existing medical facilities. Indeed, if all patients who desire termination are admitted on an inpatient basis, the implications for those concerned, both other gynaecological patients and administrators, are staggering. Thus, it was of the utmost importance to determine whether outpatient abortion as reported in other countries by Beric (1971), Strauz (1971), Louis (1971), and Sood (1971) was acceptable in India. In particular, there was concern about the safety of the outpatient procedure as compared to the same inpatient procedure.

To examine this question, a study was carried out on 319 pregnancy termination patients at the S. S. G. Hospital in Baroda, India. All the procedures were performed after April 1972, and of the 319 patients,

162 were outpatients and 157 were inpatients. None of the patients had any significant pre-existing medical conditions, or had undergone any concurrent surgery except IUD insertion. The data were recorded on standard forms and were sent to the International Fertility Research Programme in Chapel Hill, North Carolina, U.S.A. for computer analysis.

Results

Since the results suggest rather insignificant differences between the inpatient and outpatient groups in terms of procedural outcomes and complications, they can be safely thought of as comprising a single patient group. Yet it is interesting to look at the "patient characteristics" separately, because of certain (important) differences. This is all the more significant because it suggests that the reported differences in patient characteristics do not interact with the outcome of the abortion procedure in any important way. Both groups show similar first procedure success rates.

Table 1 shows some interesting similarities and differences between outpatients and inpatients. While the mean age for both groups is about the same (25.9 for outpatients and 25.1 for inpatients), the outpatient group tends to be a little older (59.9 per cent above 24 years of age as compared to 50.3 per cent of the inpatients). In addition, employment rates are almost identical for both groups (10.8 per cent for inpatients and 9.9 per cent for outpatients).

Perhaps more striking are the differences between the two groups. For example, mean education for inpatients is 7.9 years as compared to 11.0 years for outpatients. The pattern for husbands is similar - 11.5 years for inpatient husbands and 13.7 for

TABLE I
COMPARISON OF SELECTED CHARACTERISTICS OF OUTPATIENT AND INPATIENT ABORTION CASES*

Characteristic	Outpatient		Inpatient		Characteristic	Outpatient		Inpatient		Characteristic	Outpatient		Inpatient	
	No.	%	No.	%		No.	%	No.	%		No.	%	No.	%
Age					Education (husband-currently married)					Contraceptive Practice Previous to Procedure				
20	6	3.7	33	21.0	None	1	0.7	5	4.3	None	84	51.9	100	63.7
20-24	59	36.4	46	29.3	1-3	0	0.0	2	1.7	Rhythm/withdrawal	7	4.3	0	0.0
25-29	60	37.0	38	24.2	4-6	2	1.3	6	5.1	Condom	59	36.4	44	28.0
30-34	29	17.9	22	14.0	7-9	9	6.0	10	8.5	Diaph/foam/jelly	1	0.6	2	1.3
35-39	7	4.3	12	7.6	10-12	37	24.8	44	37.6	IUD	1	0.6	2	1.3
40+	1	0.6	6	3.8	13+	100	67.1	47	40.2	Orals	8	4.9	4	2.5
Total	162	100.0	157	100.0	Unknown	0	0.0	3	2.6	Tubectomy	1	0.6	1	0.6
					Total	149	100.0	117	100.0	Vasectomy	1	0.6	4	2.5
										Total	162	100.0	157	100.0
Marital Status					Gainfully employed					Parity				
Never married	13	8.0	31	19.7	Yes	16	9.9	17	10.8	0	25	14.5	54	34.4
Married	149	92.0	117	74.5	No	146	90.1	140	89.2	1	41	25.3	23	14.6
Formerly married	0	0.0	9	5.7	Total	162	100.0	157	100.0	2	57	35.2	34	21.7
Total	162	100.0	157	100.0						3	28	17.3	29	18.5
Education (Patient)					Residence (outside usual catchment area)					4	7	4.3	11	7.0
None	7	4.3	22	14.0	Urban-local	137	84.6	111	70.7	5	3	1.9	4	2.5
1-3 years	1	0.6	5	3.2	Urban-outside	10	6.2	6	3.8	6	1	0.6	0	0.0
4-6	8	4.9	26	16.6	Rural-local	1	0.6	4	2.5	7	0	0.0	0	0.0
7-9	23	14.2	28	17.8	Rural-outside	14	8.6	36	22.9	8+	0	0.0	1	0.6
10-12	71	43.8	56	35.7	Total	162	100.0	157	100.0	Unknown	0	0.0	1	0.6
13+	52	32.1	20	12.7						Total	162	100.0	157	100.0
Total	162	100.0	157	100.0										

* Patients with no pre-existing medical condition. Concurrent surgery, if any, limited to IUD insertion.

outpatient husbands. There are also marked differences in residence and marital status for the two groups. 90.8 per cent of the outpatients are urban residents, whereas 74.5 per cent of the inpatients are urban residents. And, while 92.0 per cent of the outpatients are married, the rate for inpatients is 74.5 per cent.

Finally, in terms of reproductive history, the outpatient parity mean (1.8) is slightly higher than that for inpatients (1.6) reflecting the higher age of the former group. At the same time, the percentage of outpatients (48.1) using some form of contraception prior to this procedure was higher than that of inpatients (36.3).

Before moving to a discussion of the clinical findings, it should be noted that 33 patients (15 outpatients and 18 inpatients) were excluded from the comparison because their haemoglobin was below 10g/100 ml. There were no pre-existing medical conditions for any of the 147 outpatients and 139 inpatients. Seventy-two outpatients and 22 inpatients had an IUD inserted following the abortion, no other concurrent surgery was performed. Table 2 shows the allocation of *all* patients by patient status, gestation age and haemoglobin level.

In Table 3 the frequency of use of the procedure with associated success rates can be seen for all patients with haemoglobin 10 g/per 100 ml or above. It is clearly the case that the outpatient success rate is 100 per cent regardless of gestational age, and that inpatients with a gestational age of less than 9 weeks also show the same success rate for single procedures. However, for inpatients of 9 weeks and above gestational age, the picture is less positive. Of the 41 women who received intra-amniotic saline as a first procedure, 2 required a

second application of the same technique and 9 were given an oxytocin drip to complete the procedure. Of the 3 women receiving prostaglandin, 1 required intra-amniotic saline to terminate the pregnancy. Of methods which might require a second procedure, vacuum aspiration appears to have been most successful – only 1 of the 17 vacuum aspiration patients required a second technique (D & C) to complete the termination.

As a footnote to potential differences in inpatient/outpatient demands on medical facilities, it should be pointed out that significant differences in anaesthesia use are apparent regardless of gestational age. Looking only at vacuum aspiration patients, the following comparisons emerge: 5.2 per cent of outpatients with a gestational age below 9 weeks and none with gestational age of 9 weeks or more received a general or combined general and local anaesthetic. In contrast, 54.4 per cent of inpatients with a gestational age below 9 weeks and 55.6 per cent with a gestational age of 9 weeks or more received a general or combined general and local anaesthetic.

As would be expected, there is a difference in elapsed operation time for vacuum aspiration (single method used once) associated with gestational age (Table 4). With regard to other single methods used once only with inpatients, the average elapsed time for hysterectomies (4) was 65.0 minutes. D & C procedures (6) required 12.5 minutes, and the prostaglandin group (2) averaged 29.2 hours. Patients receiving intra-amniotic saline as a single method used once, without any complications (36) required an average of 27.8 hours, and those experiencing complications (5) required an average of 40.6 hours for expulsion of the placenta.

TABLE 2

ALLOCATION OF PATIENTS BY PATIENT STATUS, GESTATIONAL AGE AND HAEMOGLOBIN

Gestational Age	Number of patients			
	Outpatient		Inpatient	
	9 Weeks	9 Weeks	9 Weeks	9 Weeks
Haemoglobin 10g/100 ml and above	115	32	63	76
Haemoglobin below 10g/100 ml	11	4	8	10

TABLE 3
FIRST ABORTION PROCEDURE OUTCOME, BY PATIENT STATUS AND GESTATIONAL AGE

First Procedure	Outpatient						Inpatient					
	9 Weeks Gestational Age No.	%	Second Procedure Required No.	%	9 Weeks Gestational Age No.	%	9 Weeks Gestational Age No.	%	Second Procedure Required No.	%	9 Weeks Gestational Age No.	%
D & C	—	—	—	—	—	—	6	100.0	—	—	—	—
Vacuum	115	100.0	—	—	32	100.0	56	100.0	—	—	17	94.4
I-A Saline	—	—	—	—	—	—	—	—	—	—	41	78.8
Hysterectomy	—	—	—	—	—	—	1	100.0	—	—	3	100.0
Prostaglandin	—	—	—	—	—	—	—	—	—	—	2	66.7
Total	115	100.0	—	—	32	100.0	63	100.0	—	—	63	82.9
											13	17.1

TABLE 4

MEAN ELAPSED TIME FOR VACUUM ASPIRATION

<i>Outpatient</i>		<i>Inpatient</i>	
<i>Below 9 Weeks</i>	<i>9 Weeks and Above</i>	<i>Below 9 Weeks</i>	<i>9 Weeks and Above</i>
5.6 min.	8.2 min.	5.6 min.	6.8 min.

As Table 5 indicates, the complication rates for patients aborted by vacuum aspiration as the single method used once, tend to vary both with patient status and with gestational age (with the exception of IUD insertion for some patients, no concurrent surgery was performed on the groups). It would be expected that inpatients might exhibit a higher immediate complication rate than outpatients, and that this difference might well reverse for the follow-up complication rate. Although necessarily tenuous because of the small sample sizes, these data do display both relationships: ignoring gestational age differences, the immediate complication rate is higher for inpatients than for outpatients, and the follow-up complication rate is higher among the outpatients than the inpatients. Gestational age has an independent effect among the outpatients, with the 9+ weeks group having a higher total complication rate than the less than 9 weeks group.

As to the severity of the complications recorded, the one immediate complication for the outpatient low gestational age group was a cervical laceration not requiring suture. The two immediate complications among the comparable inpatient group, were a cervical laceration requiring no

suture and a case of pneumonitis. The four complications reported at the follow-up visit among the low gestational outpatient group included one case of bleeding requiring curettage, one case of infection requiring antibiotics, one case of irregular bleeding not requiring additional treatment and one patient complaining of low back pain. The inpatient low gestational age group reported two complications at follow-up; one case of bleeding requiring curettage and one case of bleeding due to an IUD inserted post-abortion requiring removal of the IUD.

The four complications reported at follow-up among the outpatient high gestational age group included one woman with bleeding requiring curettage, one suffering from both bleeding requiring curettage and infection requiring antibiotics and one patient with irregular bleeding for 10 days post-abortion, but of insufficient severity to require special treatment.

Finally, it is significant that of the 94 patients (22 inpatients and 72 outpatients) receiving IUD's concurrently with abortion, only one suffered any complication, and that was bleeding requiring the removal of the IUD at the follow-up visit.

TABLE 5

IMMEDIATE AND FOLLOW-UP COMPLICATION RATES AMONG INPATIENTS AND OUTPATIENTS BY GESTATIONAL AGE

<i>Complication</i>	<i>Outpatient</i>				<i>Inpatient</i>			
	<i>9 Weeks</i>		<i>9 Weeks</i>		<i>9 Weeks</i>		<i>9 Weeks</i>	
	<i>Gestational Age</i>		<i>Gestational Age</i>		<i>Gestational Age</i>		<i>Gestational Age</i>	
	<i>No.</i>	<i>Rate</i>	<i>No.</i>	<i>Rate</i>	<i>No.</i>	<i>Rate</i>	<i>No.</i>	<i>Rate</i>
Immediate	1	0.8	—	—	2	3.6	—	—
Follow-up	4	3.5	4	9.4	2	3.6	—	—
Total cases	115		32		56		17	

Discussion

A comparison between an inpatient and outpatient sub-sample of a group of 319 women receiving pregnancy termination at S. S. G. Hospital in Baroda, India, permits some important conclusions to be drawn.

First, with respect to patients of gestational age less than 9 weeks, it appears that the outpatients experience a slightly lower immediate complication rate with vacuum aspiration than did the inpatients. For patients of gestational age greater than 9 weeks aborted by vacuum aspiration, it seems that complication risk rises, although the small number of inpatients (17) of 9+ weeks gestational age, who experienced no immediate or follow-up complications, weakens this generalisation.

Significant differences in the type of anaesthesia required suggest that outpatient procedures make a markedly lower demand on available hospital personnel. In fact, it is apparent from this study that outpatient procedures, particularly for women below 9 weeks gestational age, are as safe and reliable as inpatient procedures. In the light of anticipated increasing numbers of pregnancy termination cases, it is important that this safety and reliability can be achieved at some economy for the hospital. It even appears to be the case that outpatient procedures do not differ in severity and number of complications from inpatient procedures, while at the same time enjoying a considerably higher success rate.

Thus, based on the existing data from Baroda, it seems that outpatient abortion is a safe and reliable alternative to inpatient abortion.

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ABORTION CASES TREATED AT THE DEPARTMENT OF OBSTETRICS AND GYNAECOLOGY — DR. TJIPTO MANGUNKUSUMO HOSPITAL, JAKARTA

By

DRS. HANIFA WIKNJOSASTRO, A. W. SUPARDI, ARIE DOODOH and ENDANG SUDARMAN

The Planned Parenthood drive was launched officially in Jakarta on Kartini Day (21st April, 1967) by Governor Ali Sadikin of the Special Capital Region.

It was within the framework of this Planned Parenthood Project that in 1972 a study was made on abortion cases treated at the Department of Obstetrics and Gynaecology of the Dr. Tjipto Mangunkusumo Hospital.

The Department of Obstetrics and Gynaecology forms part of the General Hospital where treatment is made available to quite serious abortion cases occurring particularly among the general population.

However, one must be mindful of the fact that the present survey does not give a complete picture of all abortion cases treated by the Department of Obstetrics and Gynaecology because the cases whereby patients did not return for a follow-up treatment or could not be traced to their home addresses had been dropped.

The present survey comprises 605 cases. This includes of the total number of abortion cases generally treated in the department as revealed by data collected covering some previous years.

TABLE 1
AGE GROUPS

Age	Number	Percentage
14 yrs	1	0.1%
15 - 19 yrs	33	5.9%
20 - 24 yrs	114	18.8%
25 - 29 yrs	192	31.7%
30 - 34 yrs	145	23.8%
35 - 38 yrs	93	15.3%
40 +	27	4.4%

Table 1 shows that most women undergoing abortions are of the age ranging from 25 to 29 years, the most favourable child bearing period.

TABLE 2
CASES IN CONNECTION WITH PARITY

Parity	Number	Percentage
0	77	12.8%
1	56	9.2%
2	86	14.2%
3	109	18.1%
4	105	17.3%
5	67	11.1%
6	54	8.9%
7	20	3.3%
8 or more	31	5.1%

Table 2 shows that many abortion cases are found in mothers with 3 paras.

TABLE 3
CASES IN CONNECTION WITH PARITY MARITAL STATUS OF CASES

Unmarried	2
Married	596
Previously married	7

Table 3 shows that abortions not only occur with those who are married but with those who are not married or have been previously married as well.

TABLE 4
DOMICILE OF PATIENTS

Urban region of Jakarta	486
Urban region outside Jakarta	29
Rural region of Jakarta	79
Rural region outside Jakarta	11

TABLE 5
EDUCATION OF PATIENTS

<i>Years of Education</i>		<i>Number</i>	<i>Percentage</i>
0	illiterate	40	6.7%
1 - 3) =	primary education	119	19.7%
4 - 6)		243	40.1%
7 - 9) =	secondary education	83	13.7%
10 - 12)		87	14.4%
13 +	high school education	33	5.5%

Table 4 shows that the greatest number of patients come from the city of Jakarta itself. It also shows that the Dr. Tjipto Mangunkusumo Hospital, as a top referral hospital also admits patients from outside Jakarta, for instance from Bandung or any other big city.

Table 5 shows that the majority consists of those who have had primary education and not far behind this group are those with secondary education.

TABLE 6
RELIGION OF PATIENTS

<i>Religion</i>	<i>Number</i>	<i>Percentage</i>
Islam	512	84.7%
Protestant	48	7.9%
Catholic	18	2.9%
Other religions	27	4.5%

Table 6 shows that the pattern of breakdown is more or less in conformity with the breakdown in religious groupings to be found in Jakarta and surrounding areas.

B. Results of previous pregnancies

TABLE 7
RESULTS OF PREVIOUS PREGNANCIES

<i>Pregnancy results</i>	<i>Number</i>	<i>Rate per 1000 pregnancies</i>
Born normally	1851	801.9
Abortion (pregnancy wastage)	448	194.1
Still-born	9	
Total of pregnancies	2308	

Table 7 shows that the abortion (pregnancy wastage) rate of 194.1% is quite high.

However, we are confident that this number can be reduced.

C. Children's death rate

Table 8 shows that women with more numerous previous pregnancies have a greater chance of having still-born babies. In cases with four or more previous pregnancies, the death rate is twice as high as in cases where women have only 1 to 3 previous pregnancies.

D. Tendency to have more children

The desire of having another child after an abortion does particularly exist among women of an age ranging from 20 to 29 years with previous pregnancies. Table 9 shows that those between 20 and 29 years of age (generally both those who have no previous children and those who have up to three children) still want to become pregnant again. This is in accordance with the factor that the most favourable child bearing period lies between the age of 20 and 29 years.

But Table 8 shows that those with 3 previous pregnancies should be advised to limit the number of their children, because the pregnancy wastage rate in cases with three previous children is high.

CLINICAL DETAILS OF PATIENTS

A. Gestation period

Table 10 shows that 67.4% of abortions occur in women with duration of pregnancies of 12 weeks or less.

TABLE 8
CHILDREN'S DEATH RATE OF ABORTION CASES

Parity	Number of women	Born children	Still-born children	Death rate
0*				
1 - 3	240	526	23	4.3
4+	288	1,325	137	10.3

*87 Women who have not had babies before, have not been entered in this table.

TABLE 9
DESIRE TO HAVE CHILDREN

Age	0	1-3	4+	Total
19 years	9.8	4.1	1.5	15.4
20 - 29 years	10.5	32.6	3.8	55.9
30 - 39 years	2.0	8.5	3	13.5
40+	1.5	0.5	0.5	2.5
Total	32.8	45.7	8.8	87.3

TABLE 10
BREAKDOWN OF CASES IN ACCORDANCE WITH
GESTATION PERIOD

Gestation Period	Number	Percentage
Less than 6 weeks	31	5.1%
7 - 12 weeks	377	62.3%
13 - 18 weeks	157	25.9%
more than 19 weeks	38	6.3%
Unknown	2	0.4%

25.9% of abortions occurred in women with duration of pregnancies of more than 12 weeks and less than 20 weeks.

Only 6.3% of abortions occurred in women with duration of pregnancies of 20 weeks or more.

B. Termination procedure

TABLE 11
PRIMARY TERMINATION PROCEDURE AMONG
ABORTION CASES

	Number	Percentage
Normal curettage (with or without dilation)	570	94.2%
Curettage with vacuum suction	17	2.9%
Digital, piton cure, prostaglandin, etc.	18	2.9%

94.1% were terminated with curettage and 9% with suction curettage (Table 11). This is going to change after our Department becomes equipped with a suction curettage instrument in 1972. However, although suction curettage is applied, generally the treatment is followed up with a normal curettage to ensure that the cavum uteri is completely cleaned.

C. Complications

TABLE 12
IMMEDIATE AND FOLLOW-UP COMPLICATIONS

Kind of complication	Number	Percentage
Bleeding and fever	84	13.8%
Fever	20	3.3%
Anaesthetic complication	7	1.1%
Pelvis infection	5	0.9%
Perforation	1	0.1%

There were 117 cases with complications that needed direct action before the patient could be released from the hospital. As a result of the follow-up treatment for two or more weeks, no significant complication is found later except for leucorrhoea. There were no cases at all that need a second curettage (Table 12).

D. Contraceptives before the last pregnancy

TABLE 13

CONTRACEPTIVES BEFORE THE LAST PREGNANCY

<i>Kind of Contraceptives</i>	<i>Number</i>	<i>Percentage</i>
Without contraceptives	549	89.0%
I.U.D.	17	11.0%
Oral	1	
Condom, coitus interruptus, rhythm	43	
Foam, jelly, other	5	

Table 13 shows that 11.0% of the patients had taken some contraceptive measures before becoming pregnant. Mostly these are the simple or traditional ones (73%) and are still found to fail.

E. Contraceptives

TABLE 14

KIND OF CONTRACEPTIVES SELECTED BY PATIENTS AFTER AN ABORTION

<i>Kind of Contraceptives</i>	<i>Number</i>	<i>Percentage</i>
I.U.D.	23	28%
Oral pill	42	51.2%
Condom	17	20.7%

Table 14 shows that if patients have the option of selecting between various kinds of contraceptives, the ones with the highest degree of success namely the oral pills are selected.

Summary

605 spontaneous abortion cases with a good follow-up at the Department of Obstetrics and Gynaecology of the Dr. Tjipto Mangunkusumo Hospital in Jakarta were studied in 1972 with the following findings:

- a. Most of the spontaneous abortions occurred between the ages of 25-29 years. This is in accordance with the most favourable child bearing period.

- b. 67.4% (more than 2/3) of the cases occurred with 12 weeks of pregnancy.
- c. Spontaneous abortions are mostly found in mothers with 3 previous pregnancies.
- d. The death rate of children of mothers with 4 previous pregnancies or more is at least twice as high as compared with mothers with 3 previous pregnancies.
- e. Most of the abortions were found with married women.
- f. After a period of five years of the family planning programme in Jakarta, which has been used as a pilot project only about 11% of the population is in favour of family planning.
- g. In general the method of using oral pills is more acceptable to those who have just had an abortion.

Suggestions

In view of the finding achieved with the survey, one should suggest to all those involved in the Family Planning Programme as well as to all health officials to intensify efforts to propagate the Family Planning Project and to get the public better acquainted with it.

Acknowledgements

In collecting these data, forms of the International Fertility Research Programme of the Carolina Population Center University of North Carolina were used for which we would like to express our gratitude.

Further we would like to thank Dr. Sunarya, the midwives Noor Zubayah, Tuty and Martinus and many others of the Department of Obstetrics and Gynaecology of the Dr. Tjipto Mangunkusumo Hospital to whom we are very much obliged for their valuable assistance.

TERMINATION OF PREGNANCY AS A METHOD OF LIMITATION OF POPULATION

By

PROFESSOR B. N. PURANDARE

Of all the methods that have been used from time to time, artificial termination of early pregnancy is the most powerful one to control the population explosion. Rapid and dramatic effects have been observed in some of the Western countries and in Japan; so much so, that in some of these countries the method is not encouraged now to the same extent as before. The method, though safe when occasionally carried out, is bound to affect the function of the genital organs when it is repeatedly undertaken in the same individual. One cannot avoid the development of cornual block or peritubal adhesion when sepsis occurs. If one were to depend solely on the termination of pregnancy as the method to control population growth, the demand for abortions would be so great that the existing medical services will not be in a position to function efficiently enough. As the availability of the method is known to the public, more and more will seek medical termination of a pregnancy and the best way to avoid the drawbacks mentioned is to encourage women to use an appropriate method of family planning after medical termination of pregnancy. In this way the incidence of repeated abortions can be reduced to a minimum. This is shown in Table 1.

TABLE 1

PREVIOUS INDUCED ABORTION IN 248 CASES

No. of abortions	No. of patients	Percentage
1	5	1.87%
2	1	0.38%
Total 3	6	2.25%

However in the countries where repeated medical termination of pregnancy is not discouraged or family planning measures are not insisted upon, it is nothing unusual to find women having had over a dozen

induced abortions and a world record of 36 abortions in the same women has been reported in Japan. This exposes the woman to the risk of development of the following complications:

1. Injury to the cervix and development of erosion, ectropion, unilateral or bilateral tear, chronic endo-cervicitis and an incompetent os if mid-trimester abortions are carried out.
2. Parametritis, pelvic venous thrombosis, pelvic peritonitis, fixed retroversion.
3. Block at the cornual end of the tubes.
4. Peritubal adhesions, and kinks and peripheral tubal block.
5. Broad ligament and pelvic abscesses, chronic intestinal obstruction and colic of the intestine.

All these complications can be reduced a good deal as the doctors get experience in the operative procedure. When the method is used as a nation-wide programme, one has to face the various complications. In the very early part of our study in 1972, many complications were encountered, when the medical men were receiving training in this procedure. They are presented in Table 2.

TABLE 2

COMPLICATIONS OF ABORTION IN 1ST 133 CASES

Nature	Early	Late	Total
1. Retained products of conception	0.8	—	0.8%
2. Uterine perforation	0.6	—	0.6%
3. Excessive bleeding	0.8	0.8	1.6%
4. Fever	6.0	1.5	7.5%
5. Anaesthetic complications	1.5	—	1.5%
6. Others	0.3	0.8	0.8%
Total	9.8	3.0	12.8%

All these complications decrease to an insignificant level as the surgeon acquires sufficient experience and the instruments used are sufficiently modified to favour reduction of these complications. Thus avoidance of general anaesthesia, simplification of the procedure so as to make it an outdoor procedure, and preparation of the

patient by proper counselling by the social workers, help to reduce the complications of medical termination of pregnancy.

Medical termination of pregnancy has come to be valuable in the family planning programme. This will be evident from Fig. 1 and Fig. 2.

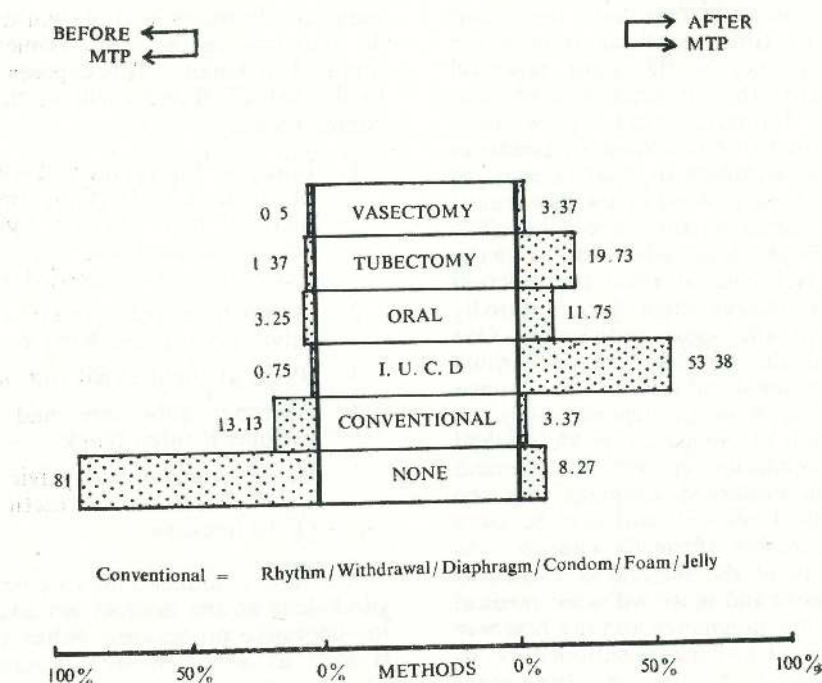


FIG. 1.

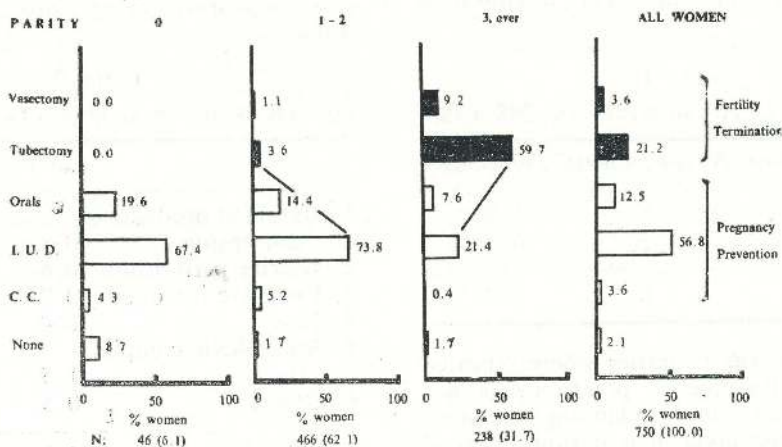


FIG. 2.

Before medical termination of the pregnancy this group of patients had a strong objection to the use of spacing methods and methods of termination of fertility, but after medical termination of pregnancy they accepted the various family planning methods without objection. In fact it may be said that medical termination of pregnancy proved to be a great motivator to the acceptance of family planning methods.

When termination of pregnancy is used for assisting the limitation of population, the procedure should be carried out during the 1st trimester of pregnancy. Late termination often creates more difficulties and complications. These could be very easily avoided by seeing that the early diagnosis is established by serological tests of pregnancy and suction curettage carried out within a fortnight as in the menstrual regulation

procedure. Serious complications can thus be minimised. The procedure can be used in a maximum number of women without waste of time and may help to curb the population explosion very rapidly. However it must be once again emphasised that no woman should have repeated abortions carried out in her life time. One abortion procedure may be allowed, after which one of the contraceptive measures should be insisted upon.

The advantage of the liberalised law of abortion is that abortions will be carried out as a surgically sound procedure and the criminal abortions which contributed to maternal mortality can be reduced at least to 1/5th its original figure. If facilities exist in any country for the termination of pregnancy then it is a safe method for limitation of the population of that country.

SOCIO-DEMOGRAPHIC ASPECTS AND MEDICAL IMPLICATIONS OF SPONTANEOUS AND ILLEGALLY INDUCED ABORTIONS AMONG PATIENTS TREATED AT SIRIRAJ HOSPITAL, BANGKOK, THAILAND

By

DRS. SUPORN KOETSAWANG, JANE GORDON *and* SAROJ PACHAURI

INTRODUCTION

A large number of different types of abortion patients are admitted to the Obstetrics Department of the Siriraj Hospital every year. These patients come at various clinical stages of threatened, incomplete, inevitable and septic abortion, and account for a heavy load of maternal morbidity and mortality¹. Abortion in these patients may occur either spontaneously or maybe illegally induced; this fact however, is usually concealed by the patient, due to the current illegality of abortion in Thailand. Thus it is often difficult to objectively evaluate the overall morbidity resulting from spontaneous and illegally induced abortions. The objective of this paper is to evaluate the medical implications of spontaneous and illegally induced abortions and to study the socio-demographic and reproductive profile and contraceptive behaviour of these patients.

MATERIALS AND METHODS

Data on 1,188 cases admitted to the Siriraj Hospital with septic, incomplete or

inevitable abortions were reported to the International Fertility Research Program (IFRP) at the University of North Carolina, Chapel Hill for compilation, processing and analysis (Table 1). The data were collected by the personnel at the Family Planning Unit of the Siriraj Hospital Bangkok, Thailand between January, 1973 and October, 1973 and were edited by both visual scanning and computer checking by the IFRP before analysis. Standardized forms were used for data collection to elicit information on socio-demographic characteristics, reproductive and medical histories, abortion classification and pertinent events related to the abortion procedures during hospitalization and at follow-up, the patients being followed up at two to four weeks after the abortion for 95% of the patients.

Subjects

The cases treated by D & C, as a single procedure, have been included in this analysis. None of these patients had any concurrent surgery. Five additional patients

TABLE 1

DISTRIBUTION OF PATIENTS BY ABORTION CLASSIFICATION AND FEVER ON ADMISSION TO THE HOSPITAL

Abortion Classification	Fever on Admission							
	No. Fever		With Fever		Unknown		Total	
	No.	%	No.	%	No.	%	No.	%
No pre-existing septic, incomplete/inevitable or threatened	3	100.0	0	0.0	0	0.0	3	100.0
Spontaneous	921	92.2	66	6.6	12	1.2	999	100.0
Therapeutic	5	100.0	0	0.0	0	0.0	5	100.0
Illegally induced	106	59.2	73	40.8	0	0.0	179	100.0
Other	2	100.0	0	0.0	0	0.0	2	100.0
Total	1037	87.3	139	11.7	12	1.0	1188	100.0

were treated by hysterectomy and one by hysterotomy with a concurrent tubectomy; these are reported separately. Marital status, presence or absence of fever at the time of admission to the hospital and the type of abortion were the controls used for data analysis on this group of women; patients for whom any of these variables were not available have been excluded from the analysis. Thus, 1,098 cases of which 932 were spontaneous abortions and 166 were illegally induced have been analysed in the present study. Patients were interviewed individually by specially trained public health nurses to elicit the circumstances of their abortion. With their kind and sympathetic approach, it is believed that accurate information was obtained from most of the patients. The method used to induce the illegal abortions was determined to be the intra-uterine instillation of fluid or paste.

Definitions

Several terms are used repeatedly in this paper, and in each case they are defined as follows:

Febrile – is the condition in which patients have an oral temperature of 38°C (100.4°F) or over at the time of admission to the hospital.

Currently married – this group included those women who were currently married (recognized as married by civil religious ceremony) and those who lived, by common consent, in a common-law marriage.

Not married – this group includes women who have never been married, as well as those who were formerly married (widowed, divorced, separated).

Gestational age – was calculated as the number of completed weeks from the first day of the woman's last normal menstrual period to the day the abortion was completed by D & C.

Excessive blood loss – was defined as blood loss estimated to be more than 100 ml.

RESULTS

Socio-Demographic Profile

The total population of women (1,098) in this analysis were sub-grouped into two main categories: (1) women admitted to the hospital with spontaneous abortions, and (2) those who were admitted after an illegally induced abortion. Within these sub-groups, marital status (currently married/not married) as previously defined, was thought to be of possible descriptive importance, especially among women seeking and illegal abortion (Table 2). There were

TABLE 2

DISTRIBUTION OF FEBRILE AND AFEBRILE PATIENTS WITH SPONTANEOUS AND ILLEGALLY INDUCED ABORTIONS BY MARITAL STATUS

	Abortion Status on Admission to Hospital											
	Spontaneous				Illegally Induced				Total			
	Afebrile No.	Febrile %	No.	Febrile %	Afebrile No.	Febrile %	No.	Febrile %	Afebrile No.	Febrile %	No.	Febrile %
Marital Status												
Currently married	864	92.7	56	6.0	48	28.9	30	18.1	912	83.1	86	7.8
Not currently married	8	0.9	4	0.4	51	30.7	37	22.3	59	5.4	41	3.7
Total ¹	872	93.6	60	6.4	99	59.6	67	40.4	971	88.4	127	11.6
Grand Total ²		932		8.4.9		166		15.1		1098		100.0

¹ Per cent of grant total within categories.

² Row per cent.

only twelve women who were not married who reported spontaneous abortions, thus they are not analysed separately. However, there is a distinction between the illegally induced women by marital status (Fig. 1).

Table 3 gives the demographic overview of the study population. The women were predominantly urban residents from the metropolitan capital of Thailand, Bangkok-Thonburi. The age distribution between the three major sub-groups (spontaneous, illegally induced - currently married, and illegally induced - not married) shows the youngest women were among the illegally induced - not married group (median age 21.2 years) and the oldest women (median age 28.3 years) among the spontaneous group.

Married women tended to have less formal education than the non-married. The husbands of the spontaneous group also appeared to have had less formal education than the illegal group.

Employment status varied only slightly between the groups. The youngest women (non-married) had the lowest per cent of employment. The currently married groups had only marginally higher employment.

The combined factors of age and parity did not distinguish the groups in an unexpected fashion. The majority of the births occurred to women within the ages of 20-30 in the married groups, with a median parity of 2.0 births. The median parity of the non-married women was 0.2 births, the majority of births were to the women under 24 years of age.

The study population was 99.8 per cent Buddhist. The distributions of the socio-demographic variables described here are known to be different for the Thai Muslim population.

The analysis of the number of additional children that the women stated they wanted, by the patient's age and number of currently

PER CENT DISTRIBUTION OF AFEBRILE AND FEBRILE PATIENTS WITH SPONTANEOUS AND ILLEGALLY INDUCED ABORTIONS BY MARITAL STATUS

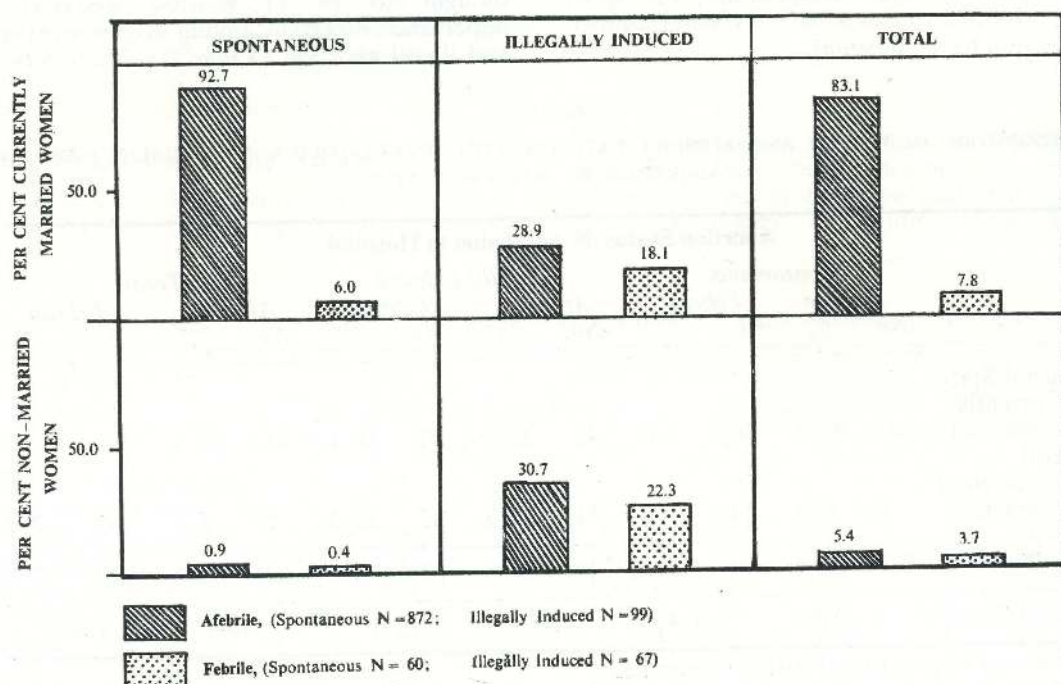


FIG. 1.

TABLE 3

DEMOGRAPHIC PROFILE OF PATIENTS WITH SPONTANEOUS AND ILLEGALLY INDUCED ABORTIONS

Characteristic	Spontaneous		Illegally Induced			
	Number N = 932	Per cent	Currently Married Number N = 78	Per cent	Not Married Number N = 88	Per cent
Age (years)						
20	86	9.2	7	8.9	30	34.1
20-24	215	23.1	29	37.2	38	43.2
25-29	223	23.9	18	23.1	13	14.8
30-34	171	18.3	11	14.1	6	6.8
35-39	135	14.5	10	12.8	1	1.1
40+	102	10.9	3	3.8	0	0.0
Median		28.3		25.0		21.2
Parity						
0	275	29.5	22	28.2	67	76.1
1	146	15.7	12	15.4	13	14.8
2	141	15.1	14	17.9	1	1.1
3	110	11.8	11	14.1	4	4.5
4	71	7.6	10	12.8	2	2.3
5	65	7.0	4	5.1	1	1.1
6	32	3.4	2	2.6	0	0.0
7	34	3.6	1	1.3	0	0.0
8+	58	6.2	2	2.6	0	0.0
Median		2.0		1.8		0.2
Previous Abortions						
0	707	75.9	60	76.9	82	93.2
1	155	16.6	12	15.4	6	6.8
2	48	5.2	3	3.8	0	0.0
3	9	1.0	2	2.6	0	0.0
4	6	0.6	0	0.0	0	0.0
5+	7	0.7	1	1.3	0	0.0
Median		0.2		0.2		0.03
Residence						
Urban	869	93.2	77	98.7	87	98.7
Rural	63	6.8	1	1.3	1	1.3
Gainful Employment						
Yes	598	63.2	50	64.1	55	62.5
No	343	36.8	28	35.9	33	37.5
Education (No. of years)						
Woman						
0	24	2.6	5	6.4	0	0.0
1-3	6	0.6	3	3.8	1	1.1
4-6	805	86.4	49	62.8	40	45.5
7-9	13	1.4	2	2.6	0	0.0
10+	84	0.0	19	24.4	47	53.4
Median		4.1		4.2		9.7
Husband*						
0	10	1.1	0	0.0		
1-3	4	0.4	0	0.0		
4-6	764	83.0	34	43.6		
7-9	11	1.2	1	1.3		
10+	131	14.2	43	55.1		
Median		4.2		9.7		

* In the group having spontaneous abortions, those women currently married = 920

living children, is represented in Table 4. All three sub-groups of women demonstrate the same pattern; the desire for one or more additional children decreases with age, as it does with the number of living children (Fig. 2).

The pattern of contraceptive acceptance before and after the abortion for the three groups of women is shown in Table 5 and Fig. 3. Although there are differences between the spontaneous and illegal groups, 56 per cent of the illegal group accepting some form of contraception after the abortion, the differences are remarkably slight. The method of post-abortion conception control most frequently selected within each group was the oral birth control pill. Of the total number of women accepting some method, 87 per cent accepted the pill. The highest acceptance was among the married women with illegally induced abortions (60.3%).

CLINICAL PROFILE

Abortion Status on Admission to Hospital

The abortion cases were classified into spontaneous and illegally induced in order to study their clinical characteristics. Since the presence or absence of fever at admission is an important determinant of the outcome of abortion, the febrile and afebrile patients were examined within each category.

The majority (84.9%) of the patients in the series had spontaneous abortions. Whereas, only 6.4 per cent of patients with spontaneous abortions had fever on admission, a larger proportion (49.4%) of the patients in whom the abortion was illegally induced were febrile on admission (Table 2).

Gestational Age

The majority (72.6%) of all the abortions occurred during the first trimester of pregnancy, although very few patients came to the hospital before the seventh week of gestation. While febrile, patients with spontaneous abortions showed an equal distribution in the first and second trimesters of pregnancy, one-fourth of the spontaneous and one-third of the illegally induced abortion patients were admitted during the second trimester of pregnancy (Table 6).

Anesthesia, Prophylactic Antibiotics and Prophylactic Oxytocin

All the D & C's, except one, were performed with analgesia only; in the one case, local anesthesia was used. General anesthesia was administered for all hysterectomy and hysterotomy patients.

The entire group of patients, except one, were given prophylactic antibiotics and all but three patients were given prophylactic oxytocin.

Complications

Immediate complications were recorded during the period after the abortion was completed by D & C to the time of the patient's discharge from the hospital. Follow-up information was obtained for 95 per cent of the patients. In the present series, none of the patients had any delayed complications when examined at the one month follow-up visit.

Spontaneous Abortions

Only 8.4 per cent of these patients had one or more complications; excessive blood loss and fever above 100.4°F were the complications reported for these cases. Five patients with spontaneous abortion required blood transfusions before treatment with D & C because of excessive blood loss before admission to the hospital and/or anaemia. Blood loss occurred more often and was more severe, thus requiring blood transfusion, in patients who were febrile on admission than in those who were not. Fever also occurred far more frequently after treatment with D & C in patients who had fever on admission, than in those who did not. Thus, the majority of patients (85.0%) who were admitted with fever had one or more complications. Of the patients with spontaneous abortion, 3.5 per cent had excessive blood loss and 5.6 per cent had fever (94.2% received additional antibiotics) (Table 7).

Illegally Induced Abortions

Of the patients with illegally induced abortions, 63.9 per cent had one or more complications. The complications reported were uterine perforation, excessive blood loss and fever requiring antibiotics (Table 8). Excessive blood loss was the most

TABLE 4

NUMBER OF PATIENTS WITH SPONTANEOUS AND ILLEGALLY INDUCED ABORTIONS WANTING ADDITIONAL CHILDREN IN RELATION TO THEIR AGE AND NUMBER OF LIVING CHILDREN

Additional Children Wanted		Age of Patients			Total		Number of Living Children					Total
		20	20-29	30-39	40+		0	1	2	3	4+	
S P O	No.	3	108	203	85	399	1	1	55	92	251	399
	%*	2.2	28.1	66.3	83.3	42.8	0.4	0.4	39.0	83.5	98.0	42.8
N T A N	No.	136	277	103	17	533	277	147	86	18	5	533
	%*	97.8	71.9	33.7	16.7	57.2	99.6	99.6	61.0	16.5	2.0	57.2
E O U S	No.	139	385	306	102	932	278	148	141	109	256	32
	%**	14.9	41.3	32.8	10.9	100.0	29.8	15.9	15.1	11.7	27.5	100.0
I L N	No.	0	8	15	3	26	0	0	5	6	15	26
	%*	0.0	17.4	71.4	100.0	33.3	0.0	0.0	35.7	46.2	88.2	33.3
	No.	8	38	6	0	52	22	12	9	7	2	52
E D G U	%*	100.0	82.6	28.6	0.0	66.7	100.0	100.0	64.3	53.8	11.8	66.7
	No.	8	46	21	3	78	22	12	14	13	17	78
	%**	10.3	58.9	26.9	3.9	100.0	28.2	15.4	17.9	16.7	21.8	100.0
(CM)												
I L N	No.	3	4	3	0	10	2	1	1	4	2	10
	%*	8.3	8.0	4.3	0.0	11.4	2.9	7.7	100.0	100.4	100.0	11.4
	No.	33	41	4	0	78	66	12	0	0	0	78
E D G U	%*	91.7	91.1	5.7	0.0	88.6	97.1	92.3	0.0	0.0	0.0	88.6
	No.	36	45	7	0	88	68	13	1	4	2	88
	%*	49.9	51.1	8.0	0.0	100.0	77.3	14.8	1.1	4.5	2.3	100.0
(NM)												

CM = Currently Married
* Column Per cent

NM = Not Married
** Row Per cent

One + = One or more

FIGURE SHOWING NUMBER OF WOMEN WITH SPONTANEOUS AND ILLEGALLY INDUCED ABORTIONS WANTING ONE OR MORE ADDITIONAL CHILDREN IN RELATION TO THE NUMBER OF LIVING CHILDREN

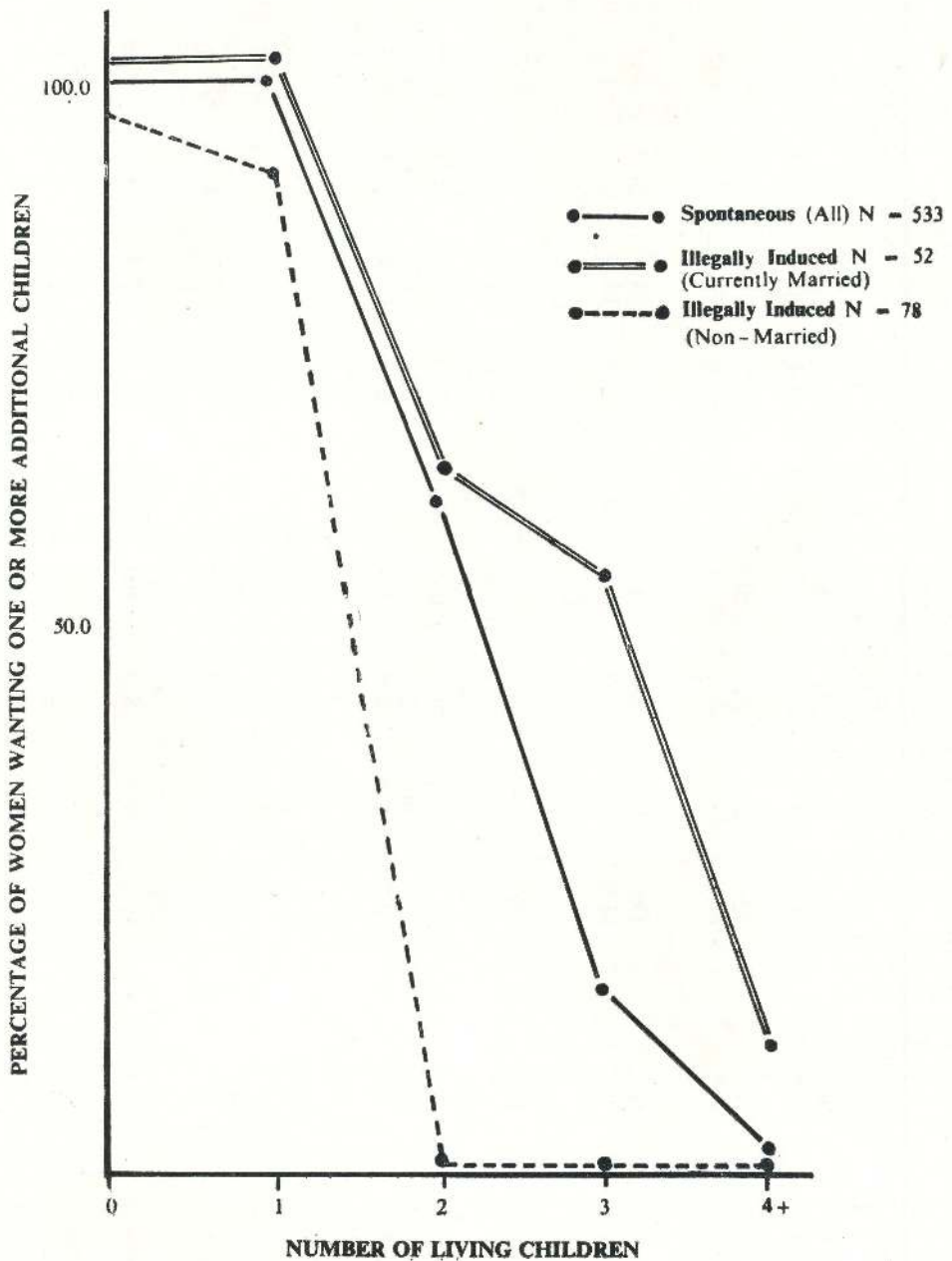


FIG. 2.

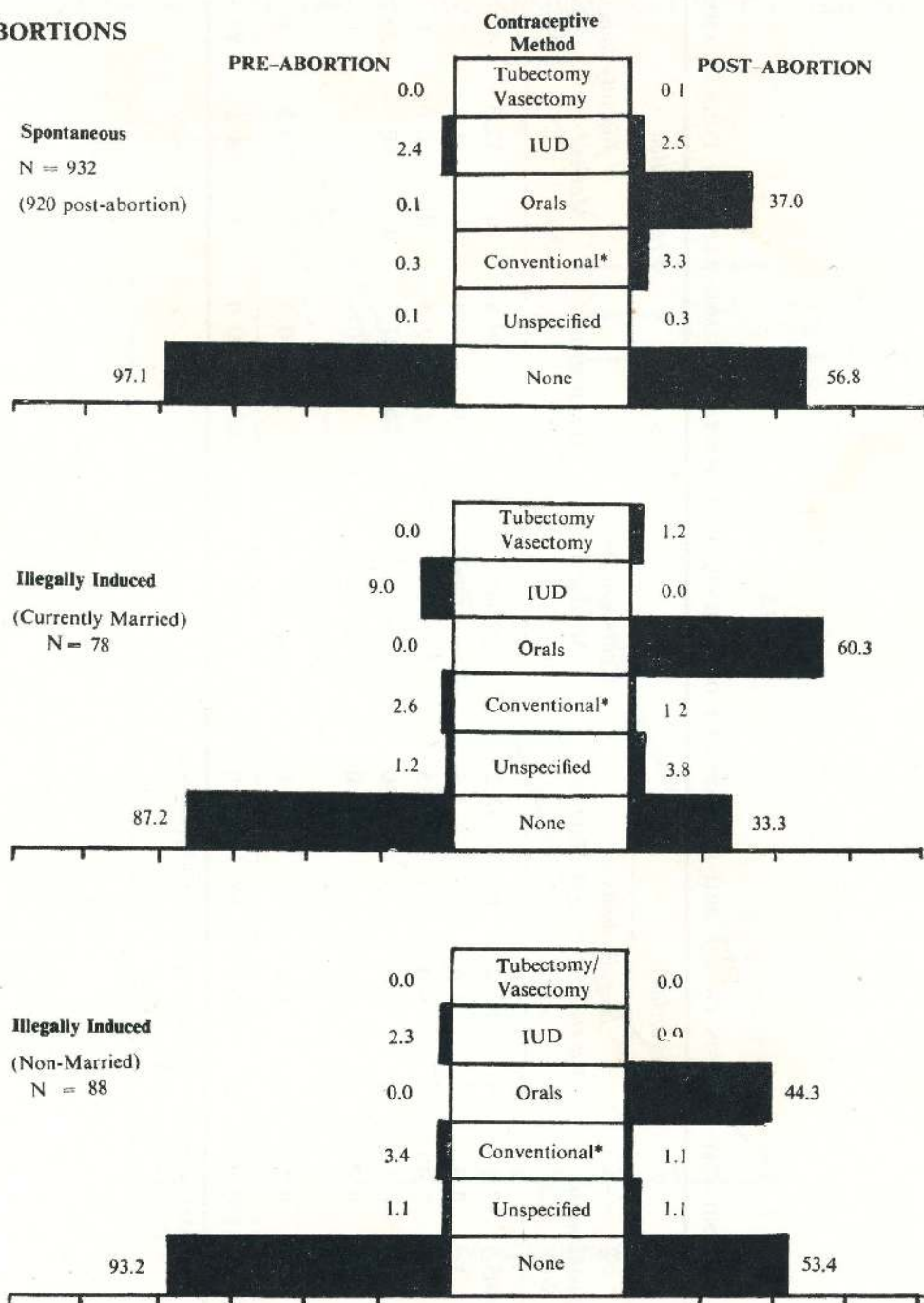
PRE AND POST-ABORTION CONTRACEPTIVE ACCEPTANCE OF PATIENTS WITH SPONTANEOUS AND ILLEGALLY INDUCED ABORTIONS

Pre-Abortion						Pre-Abortion						
Spontaneous			Illegally Induced			Contraceptive Method	Spontaneous		Illegally Induced			
No.	%		Married No.	%	Not Married No.		%	Married No.	%	Not Married No.	%	
905	97.1	68	87.2	82	93.2	None	523	56.8	26	33.3	47	53.4
3	0.3	2	2.6	3	3.4	Conventional ¹	30	3.3	1	1.2	1	1.1
22	2.4	7	9.0	2	2.3	IUD	23	2.5	0	0.0	0	0.0
1	0.1	0	0.0	0	0.0	Orals	340	37.0	47	60.3	39	44.3
0	0.0	0	0.0	0	0.0	Tubectomy	1	0.1	1	1.2	0	0.0
						Vasectomy						
1	0.1	1	1.2	1	1.1	Other	3	0.3	3	3.8	1	1.1
932	100.0	78	100.0	88	100.0	Total	920 ²	100.0	78	100.0	88	100.0

¹ Rhythm/Withdrawal/Diaphragm/Foam/Jelly/Condom

2 12 women lost to follow-up.

**PER CENT DISTRIBUTION OF PRE- AND POST- ABORTION CONTRACEPTIVE
ACCEPTANCE OF PATIENTS WITH SPONTANEOUS AND ILLEGALLY INDUCED
ABORTIONS**



*Rhythm/Withdrawal; Diaphragm/Jelly/Foam/Condom

FIG. 3.

TABLE 6

DISTRIBUTION OF FEBRILE AND AFEBRILE PATIENTS WITH SPONTANEOUS AND ILLEGALLY INDUCED ABORTIONS BY GESTATIONAL AGE

Gestational Age (in weeks)	Spontaneous				Illegally Induced			
	Febrile No.	Febrile %	Afebrile No.	Afebrile %	Febrile No.	Febrile %	Afebrile No.	Afebrile %
7	2	3.3	57	6.6	2	3.0	5	5.0
7-12	28	46.6	598	68.5	41	61.2	64	64.6
13-14	9	15.0	120	13.8	18	26.9	20	20.2
19+	21	35.0	97	11.1	6	8.9	10	10.1
Total	60	100.0	872	100.0	67	100.0	99	100.0

TABLE 7

REPORTED COMPLICATIONS FOR SPONTANEOUS AFEBRILE AND FEBRILE ABORTION PATIENTS

Reported Complications	Status on Admission				Total	
	Afebrile No.	Afebrile %	Febrile No.	Febrile %	No.	%
Excessive blood loss						
No transfusion	13	1.5	4	6.7	17	1.8
Transfusion	7	0.8	9	15.0	16	1.7
Transfusion given (No excessive blood loss)	5	0.6	0	0.0	5	0.5
Fever (hospitalized one or more nights)						
Antibiotics given	3	0.3	46	76.7	49	5.3
No antibiotics	0	0.0	3	5.0	3	0.3
Women with one or more complications	27	3.1	51	85.0	78	8.4
Total Women	872	100.0	60	100.0	932	100.0

TABLE 8

REPORTED COMPLICATIONS FOR ILLEGALLY INDUCED AFEBRILE AND FEBRILE ABORTION PATIENTS

Reported Complications	Status on Admission				Total	
	Afebrile No.	Afebrile %	Febrile No.	Febrile %	No.	%
Uterine Perforation	0	0.0	2	2.9	2	1.2
Excessive blood loss						
No transfusion	35	35.3	14	20.9	49	29.5
Transfusion	3	3.0	4	5.9	7	4.2
Fever requiring antibiotics	2	2.0	66	98.5	68	40.9
Women with one or more complications	40	40.4	66	98.5	106	63.9
Total Women	99	100.0	67	100.0	166	100.0

common complication (38.4%) in non-febrile patients. Blood loss was severe enough to warrant a transfusion in 4.2 per cent of patients with illegally induced abortions; 29.5 per cent had blood loss estimated at more than 100 ml. but did not require a transfusion. Fever requiring additional antibiotics was seen to predominate in patients who were febrile on admission (98.5%).

Overall Complication Rates

All patients with illegally induced abortions had higher complication rates when compared to their counterparts among the spontaneous group. Complications occurred more frequently among patients aborting

during the second trimester (23.2%) than in the first trimester (14.3%). This trend was also observed in the afebrile and febrile sub-groups with the exception of afebrile patients with illegally induced abortions. As expected, febrile patients showed considerably higher complication rates than afebrile patients in both the first and second trimesters (Table 9 and Fig. 4). Furthermore, the complication rates for individual complications – infection, excessive blood loss and uterine perforation as well as the overall complication rates – were dramatically higher among the women with illegally, induced abortions (Fig. 5).

In addition to the illegally induced abortion cases analysed thusfar, there were five women

COMPLICATION RATES BY GESTATIONAL AGE FOR PATIENTS WITH SPONTANEOUS AND ILLEGALLY INDUCED ABORTIONS

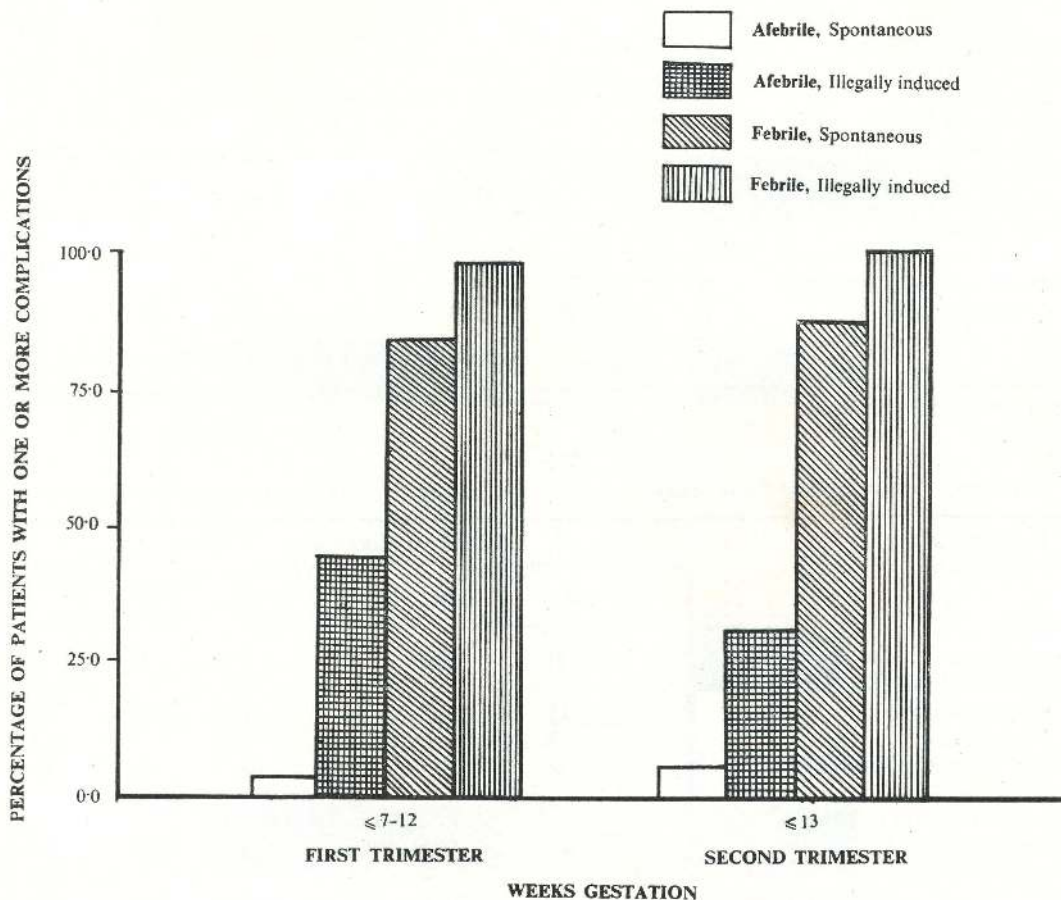


FIG. 4.

TABLE 9
COMPLICATIONS BY GESTATIONAL AGE AND ABORTION STATUS ON ADMISSION

Abortion Status on Admission	Patients-12 Weeks'			Patients-13 Weeks'			Total		
	No. of Patients	No. with Complications	Gestation Compli- cation Rate	No. of Patients	No. with Complication	Gestation Compli- cation Rate	No. of Patients	No. With Complications	Compli- cation Rate
Spontaneous									
Afebrile	655	16	2.4	217	11	5.1	872	27	3.1
Febrile	30	25	83.3	30	26	86.6	60	51	85.0
Illegally Induced									
Afebrile	69	31	44.9	30	9	30.0	90	40	44.4
Febrile	43	42	97.7	24	24	100.0	67	66	98.5
Total	797	114	14.3	301	70	23.2	1089	184	16.9

EXISTING COMPLICATIONS AMONG PATIENTS WITH SPONTANEOUS AND ILLEGALLY INDUCED ABORTIONS

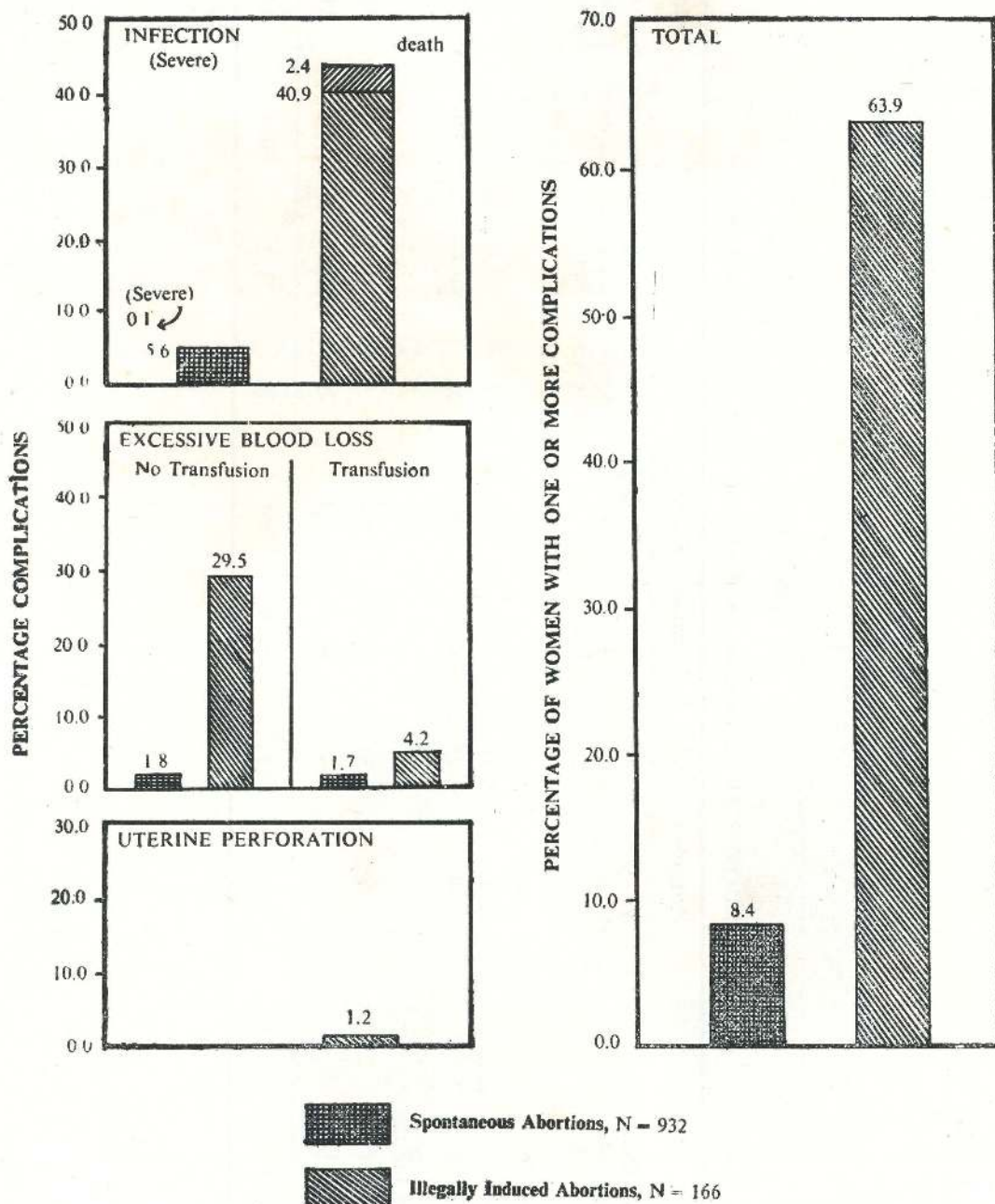


FIG. 5.

whose illegal abortions resulted in hysterectomy; peritonitis occurred in all of these cases except one. One of these patients also had renal failure and coagulation defects, another had developed gas gangrene of the uterus before admission to the hospital. An additional patient had her abortion completed by hysterectomy, with a concurrent tubectomy. Of the patients who had a hysterectomy, one was only 18 years old, unmarried and nulliparous; two were 24 years old, married and had no live births.

There was one death in this series. The patient, a 40-year-old multipara, was illegally aborted during the sixteenth week of gestation requiring a subsequent hysterectomy. She developed a pelvic abscess and peritonitis leading to generalized septicaemia which was reported as the cause of death after autopsy.

Procedure and Hospitalization Times

No significant difference was observed between the mean procedure time in patients with spontaneous and illegally induced abortions. Patients who were febrile on admission had somewhat longer mean

procedure times than those who were afebrile. For the afebrile patients, the mean procedure times were virtually identical whether or not complications were present. In the febrile group, however, the mean procedure times were lower in patients with complications than in those without (Table 10). This is almost certainly the result of the small number of febrile patients with no complications.

There was no substantial difference in the mean length of hospital stay among patients with spontaneous or illegally induced abortions. In both groups the patients who were febrile on admission had slightly extended periods of hospitalization regardless of the presence of complications (Table 10).

DISCUSSION

The population of women presented here represent a very select group in comparison to the current Thai population. This is better understood when the general demographic characteristics of Thailand are considered. The country is predominantly Buddhist with a total population of 38

TABLE 10

MEAN TIME TO COMPLETE SPONTANEOUS AND ILLEGALLY INDUCED ABORTIONS BY D & C AND SUBSEQUENT HOSPITALIZATION

<i>Status on Admission/ Complications</i>	<i>Procedure Time for D & C (minutes)</i>			<i>Time Hospitalized after D & C (nights)</i>		
	<i>No.</i>	<i>Mean</i>	<i>Range</i>	<i>No.</i>	<i>Mean</i>	<i>Range</i>
Spontaneous:						
Afebrile						
No complications	845	12.8	5-20	125	1.9	1-9
One or more complications	27	12.4	10-15	18	2.4	1-6
Febrile						
No complications	9	15.6	15-20	9	2.9	1-5
One or more complications	51	12.6	1-20	50	2.9	1-13
Illegally Induced:						
Afebrile						
No complications	59	12.9	10-20	53	2.0	1-5
One or more complications	40	12.8	10-20	39	2.1	1-6
Febrile						
No complications	1	15.0	15-15	1	4.0	4-4
One or more complications	66	13.5	10-20	65	3.0	1-33

million people as measured by the 1970 census. The population growing rapidly, is disproportionately young (the median age is only 16 years), and is predominantly rural and agricultural. Of the urban centres in Thailand, Bangkok-Thonburi is by far the largest and most concentrated. Half of the total population classified as urban and almost three-fourths of the population living in places of 20,000 persons and over are in this capital city³. These people represent only 14 per cent of the total country's population. This fact in itself restricts the profiles of the abortion patients in this study to urban-area residents. It can be safely assumed that the characteristics, resources and consequences for rural women would be very different in terms of abortion seeking behaviour. This refers not only to the women themselves, but to the illegality of abortion in Thailand. At present Thai law permits abortion by a medical practitioner on a woman whose health necessitates it or whose pregnancy resulted from rape or pandering. Buddhism enjoins its followers against the taking of life, thus many doctors are reluctant to perform abortions even under legal circumstances⁷.

It is interesting to note that the age distribution among the abortion patients in this analysis is quite different from the currently reported statistics from Bangkok-Thonburi. The women in our study are considerably younger; 37 per cent are between 15 and 24 years of age while the Thai statistics⁶ indicate that only 12 per cent of the women are in this age group. Within the group of women with illegally induced abortions, 63 per cent are under 24 years of age, the majority of them being unmarried. The overall proportion of married women in this study was 91 per cent, 86 per cent being the comparable figure for the metropolitan capital.

The level of education of the abortion patients shows that 85 per cent of the married women, regardless of abortion status, had completed a maximum of 4 years of school (the end of the 4 year primary school is one of the most natural stopping points in the Thai system since it is the level at which compulsory school attendance ends). The non-married women had achieved a higher median level of education, 9.7 years

(which would indicate completion of secondary school). The national figures for the level of education of women in Bangkok are approximately 40 per cent completing 1-4 years and an additional 12 per cent completing secondary school⁷.

The combined effects of age, education and marital status may be evidence of effects of selective migration of young, single workers and students from rural areas to the metropolitan area. This is a pattern which would tend to delay marriage and therefore wanted fertility. This could also explain why our group of non-married women with illegally induced abortions are so much younger, better educated and with lower fertility levels than the currently married group. Furthermore, the participation of women in the labour force in Bangkok-Thonburi is estimated at 37.5 per cent⁴ which is approximately half that of our study population.

Knowledge of and the attitude toward contraceptive use is beyond the scope of this study. However, there is a definite trend toward the use of oral contraceptives among the women after their abortions were completed (33%). The 1970 KAP study in Thailand indicated 36 per cent of the currently married metropolitan women, ages 15-44, who were interviewed were using a reliable method of contraception (IUD, pill, vasectomy, ligation, injection). Within that study, only 9.3 per cent of the women were using oral contraceptives.

If fever is considered as evidence of sepsis, 40.4 per cent of the illegally induced abortions in this series could be classified as septic abortions. Furthermore, it may be stated that 84.3 per cent of the patients with septic abortions had one or more complications after treatment with D & C. The morbidity rate was 27 times higher among the spontaneous septic abortions and twice as high among the illegally induced septic abortions than it was in the corresponding groups of non-septic cases. When these morbidity figures are compared with corresponding morbidity figures resulting from D & C used as a method for voluntary termination of pregnancies in Singapore⁵ where abortion is legal, the high cost of illegally induced abortions becomes apparent. The overall morbidity in this series was

10 times higher than it was for the Singapore series. The illegally induced abortions among the Thai women resulted in 39 times higher complication rates than in the women in Singapore. The mean hospital stay was also longer, 2-4 nights, as compared to that in the Singapore series where it was a maximum of 2 nights. This could be due to a difference in hospital policy regarding hospital stay. However, since patients in the Siriraj Hospital are admitted in an infected or potentially infected state, they are hospitalized long enough to complete necessary treatment and to ensure that infection is adequately combated and bleeding fully controlled; thus the cost of drugs, blood transfusions and hospital beds may be added to the cost of morbidity to measure the overall abortion costs. This high cost of abortion can be considerably minimized when unwanted pregnancies are legally terminated as outpatient by procedures such as vacuum aspiration.

The intrauterine instillation of paste or fluid was the method used for inducing illegal abortion in this series. Utus paste, a medicated, soft soap consisting of potassium iodide, thymol and astringents, has been widely used in several countries for induction of abortion. Datta and Thurston² compared Barnes' review of 71 cases, which attributed pyrexia and heavy blood loss to utus paste, to their own evaluation of this method in a series of 205 consecutive cases. Pyrexia occurred in 10 per cent of the patients; 2 patients (1.3%) suffered from urinary tract infection, 1.9 per cent required blood transfusion, and one patient developed pelvic peritonitis and died. In our series,

40.9 per cent had fever, 4.2 per cent required blood transfusion and 2 patients had uterine perforation. The higher infection rate in this series could be attributed to the fact that many of these patients had to seek illegal abortions which were often performed under uncontrollable conditions.

When estimating the morbidity due to abortion in this series, two facts must be recognized: (1) these are a self-selected group of patients from the city of Bangkok-Thonburi who have access to well organised hospital facilities, while the pre-dominantly rural population of Thailand does not have such facilities available; the morbidity and mortality estimated from this series is consequently an under-estimate of the total problem and (2) only some of the abortion patients from Bangkok-Thonburi are admitted to this hospital so a true measure of morbidity, even for this group, cannot be made from the data available to us.

SUMMARY AND CONCLUSIONS

This study demonstrates that patients with illegally induced abortions had higher morbidity than those with spontaneous abortions when comparing the reported complications by their gestation period and presence of fever on admission to the hospital. The interpretation of these findings, however, are subject to two constraints; (1) patients included in the study are a select urban group in comparison to the general Thai population, and (2) the cost of morbidity estimated in this group represents only a small fraction of a much larger problem.

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PROSTAGLANDINS AND THERAPEUTIC ABORTION

By

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Although prostaglandins are complicated molecules with the ability to affect every human organ, only one property has thus far proven to be of value to Obstetricians and Gynecologists – the property of PGE_2 and $\text{PGF}_{2\alpha}$ to effect delivery at any stage of gestation. PGE_2 and $\text{PGF}_{2\alpha}$ administered intravenously, intrauterine but extra-amniotically, intra-amniotically, and vaginally have been used to induce therapeutic abortion in the Clinical Research Unit of the North Carolina Memorial Hospital in Chapel Hill. Different protocols were used at different times to study the efficacy of the type of prostaglandin and the particular

protocol. The following is an overview of these experiences.

$\text{PGF}_{2\alpha}$ was administered intravenously to 15 patients between 8 and 22 weeks' gestation using three dosage schedules: Group I patients received 25 $\mu\text{g}/\text{min.}$ of $\text{PGF}_{2\alpha}$ for one half hour, progressively increased to 200 $\mu\text{g}/\text{min.}$ for 12 hours or until abortion occurred; Group II patients had the infusion rate increased at indicated times until they developed 350 Montevideo units of activity; Group III was infused with 25 $\mu\text{g}/\text{min.}$ for half an hour, increased to 50 $\mu\text{g}/\text{min.}$ for 18 hours or until abortion occurred. The number aborted in each group and the abortion times are shown in Figure 1.

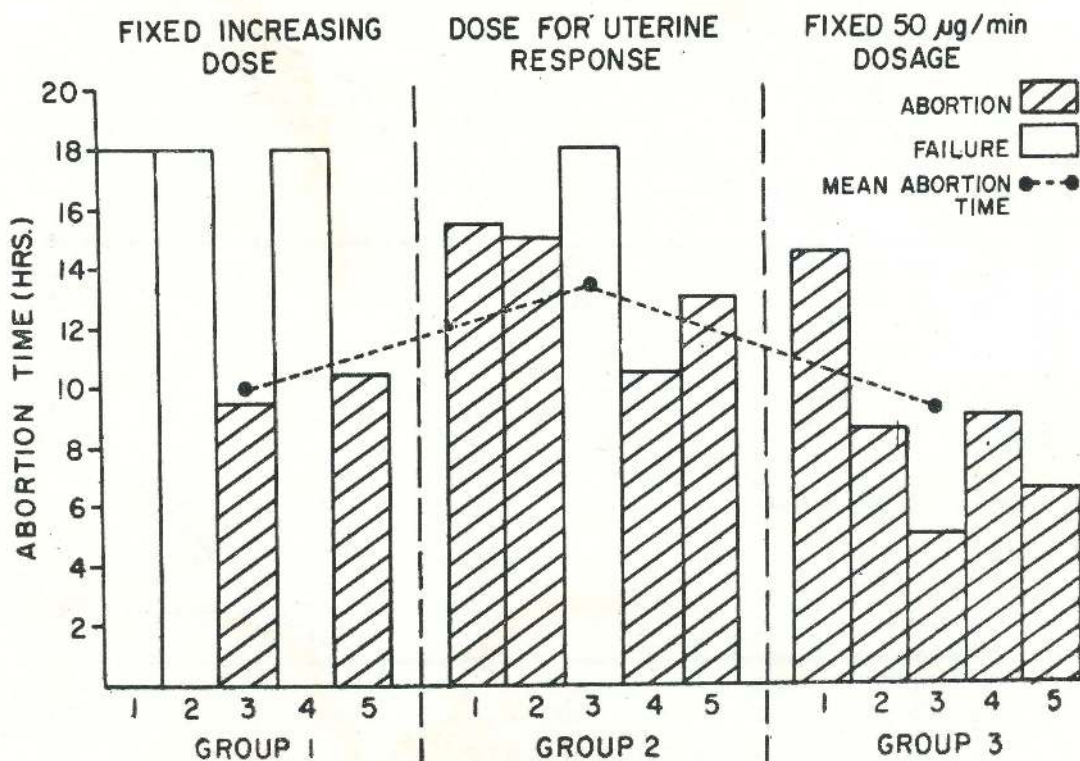


FIG. 1. Abortion Rates and Times for Patients Induced with Intravenous Prostaglandin $\text{F}_{2\alpha}$ by Three Dose Schedules. (Figure 1 of Reference 1)

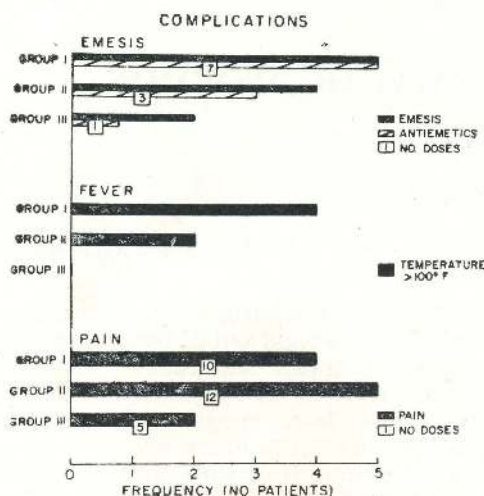


FIG. 2. Complications occurring with Intravenous Prostaglandin $F_{2\alpha}$ by Three Dose Schedules. (Figure 2 of Reference 1)

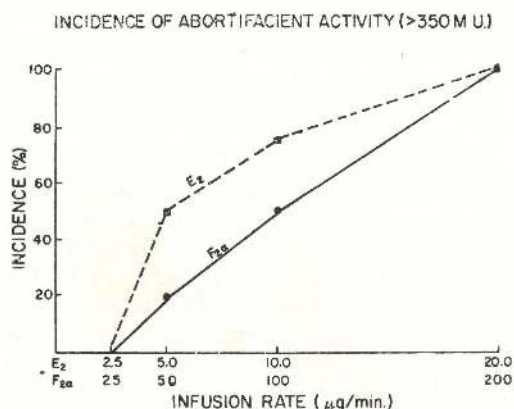


FIG. 3. Incidence of Abortifacient Activity for Induced Abortion with Prostaglandins E_2 and $F_{2\alpha}$. (Figure 2 of Reference 2)

COMPLICATIONS

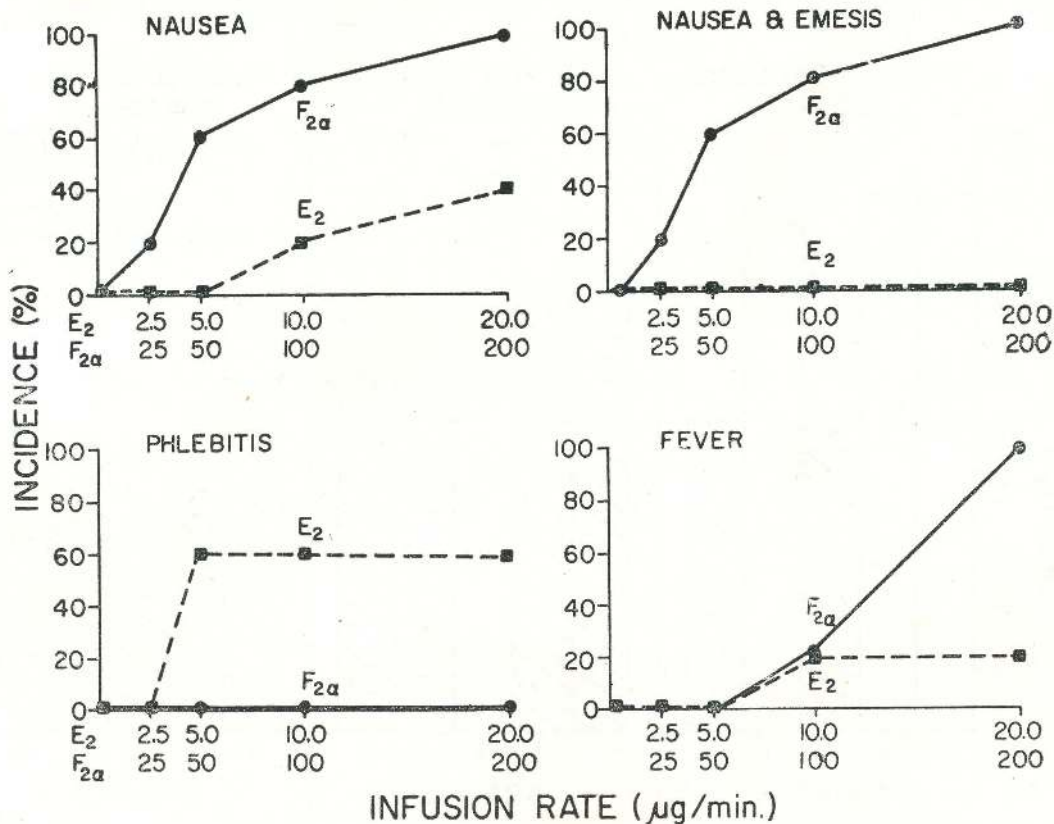


FIG. 4. Incidence of Complications for Induced Abortion with Prostaglandins E_2 and $F_{2\alpha}$. (Figure 3 of Reference 2)

Emesis, fever and pain were common complications. If vomiting was persistent an antiemetic was administered. The 50 ug./min. dose schedule was found to be superior to the other schedules (Figure 2). PGE_2 administered at one-tenth the dose of $\text{PGF}_{2\alpha}$ had a better abortifacient effect (Figure 3). Nausea and emesis were more frequent with $\text{PGF}_{2\alpha}$ and so was fever. Phlebitis occurred more frequently with PGE_2 (Figure 4).

Intrauterine but extra-amniotic administration of $\text{PGF}_{2\alpha}$ was studied in 48 subjects. This resulted in reasonably effective rates of abortion, but this method was not continued, as performing injections at two hour intervals is inconvenient and thought to be impractical for routine use.

A 50 mg. dosage of $\text{PGF}_{2\alpha}$ was administered vaginally in the form of vaginal tablets, vaginal suppositories or a 200 mg./ml. solution instilled into the posterior fornix. Fifty milligram tablets of $\text{PGF}_{2\alpha}$ were administered hourly; 50 mg. suppositories were administered every two hours and instillation of the 200 mg/ml solution was repeated hourly until abortion occurred or until the end of the trial period. About two thirds of the patients aborted in each group (Figure 5).

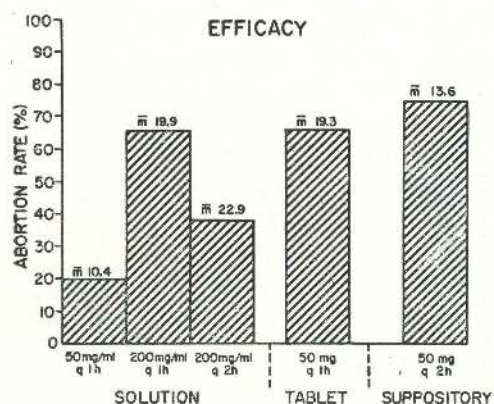


FIG. 5. Abortion Rates with Vaginal Administration of Prostaglandin $\text{F}_{2\alpha}$. (Figure 1 of Reference 3)

Though these were very effective dosage schedules, they were associated with incidences of complications, such as diarrhoea, vomiting, pelvic pain and vaginal irritation (Figure 6).

Results with intra-amniotic administration of $\text{PGF}_{2\alpha}$ have been most encouraging in mid-trimester abortions. Forty-one gravidae between 10 and 23 menstrual weeks' gestation were administered one of two dosage schedules. Fifteen milligrams were administered to 20 Group I patients; 25 mg. were administered to 21 Group II patients at the initiation of the study and repeated in 24 hours to those who had not aborted. The last 11 patients in Group II were premedicated 15 minutes prior to each injection with 10 mg. of prochlorperazine to attenuate vomiting. The results showed that the 25 mg. dose schedule was more effective than the 15 mg. dose schedule (Figure 7). The cumulative abortion rate for 200 patients injected with intra-amniotic hypertonic saline is also shown in the same figure.

Higher rates of abortion were accomplished when the $\text{PGF}_{2\alpha}$ dose was repeated within 24 hours, or increased to 50 mg. in a study comparing three dose schedules. Twenty-two Group I patients received 25 mg. of $\text{PGF}_{2\alpha}$ at the initiation of the study and an identical dose at 6, 24 and 30 hours if abortion had not yet occurred. Fifty mg. were administered to 24 Group II patients at the initiation of study and an identical dose 24 hours later if abortion had not yet occurred. The third group of 25 patients received 25 mg. at the initiation of the study and an identical dose at 6, 12, 24, 30 and 36 hours for those who had not yet aborted. All three dose schedules were more effective than those in previous studies; about 70% of the patients in Group I aborted within 24 hours and 95% within 36 hours (Figure 8).

In another study using a single 50 mg. injection of $\text{PGF}_{2\alpha}$, 77% of the subjects aborted within 24 hours and 95% aborted within 48 hours (Figure 9). There was no statistically significant difference in the cumulative abortion rates or mean abortion times between multiparas and nulliparas or subjects of different gestation ages (Figure 10). When prochlorperazine was administered prior to administration of $\text{PGF}_{2\alpha}$,

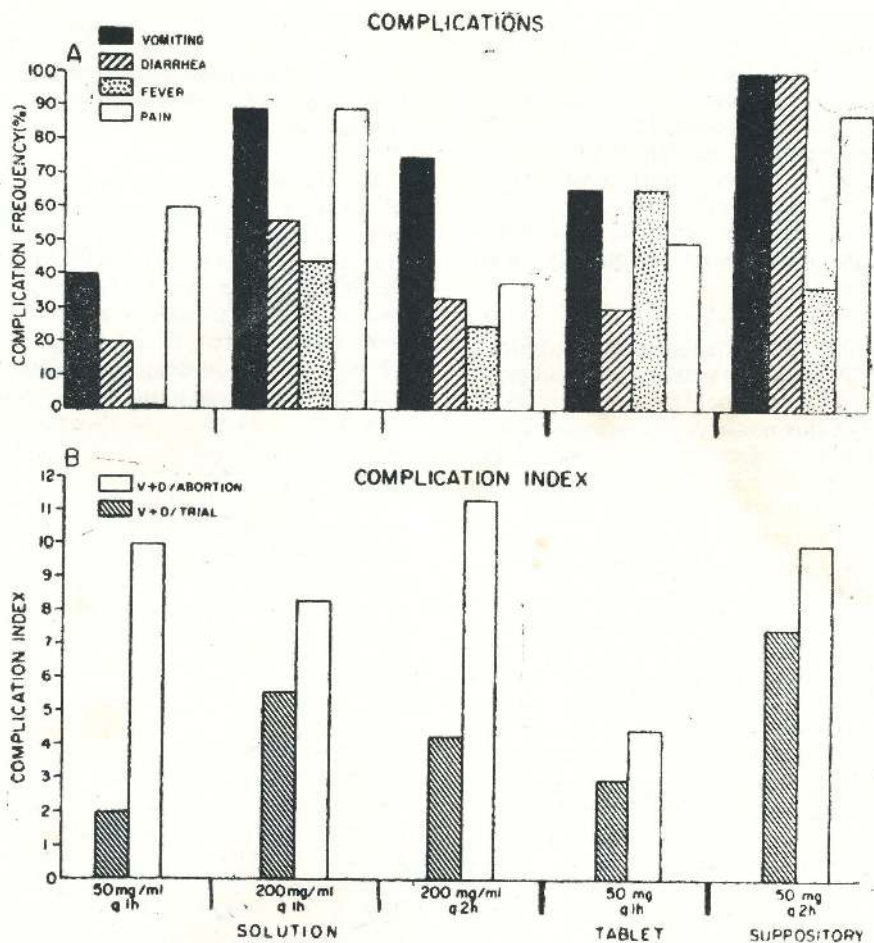


FIG. 6. Incidence of Complications for Abortion Induced with Vaginal Administration of Prostaglandin $F_{2\alpha}$. (Figure 3 of Reference 3)

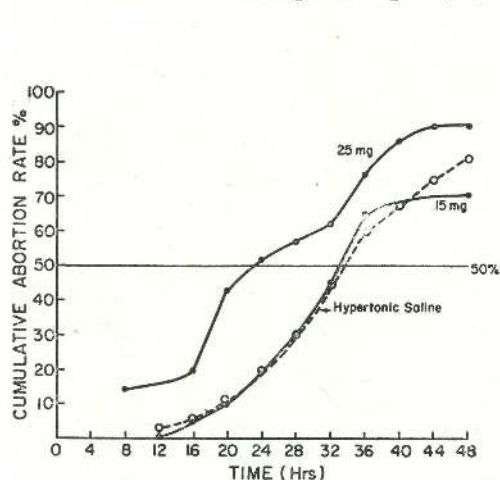


FIG. 7. Cumulative Abortion Rates for Patients Aborted with Two Dose Schedules of Prostaglandin $F_{2\alpha}$ and Hypertonic Saline. (Figure 1 of Reference 4)

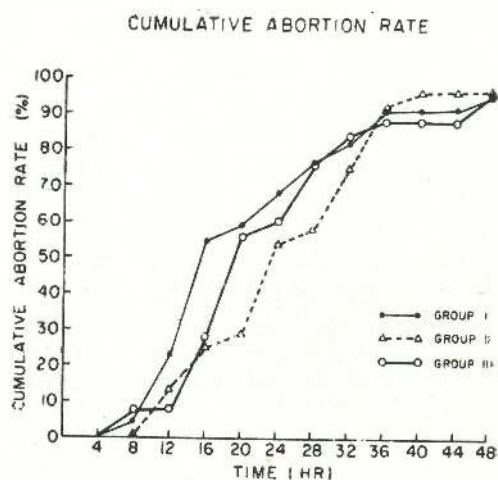


FIG. 8. Cumulative Abortion Rates for Patients Aborted with Three Dose Schedules of Intra-amniotically Administered Prostaglandin $F_{2\alpha}$. (Figure 1 of Reference 5)

the frequency of vomiting was significantly less (Figure 11).

The fifteen methyl analogue of PGE_2 was given intramuscularly to 15 patients between

7 and 20 weeks' gestation. All were given 5 micrograms intramuscularly every 4 hours until abortion occurred. The mean induction-to-abortion interval was 19.2 hours, with minimal complications (Table 1).

OVERALL CUMULATIVE ABORTION RATE

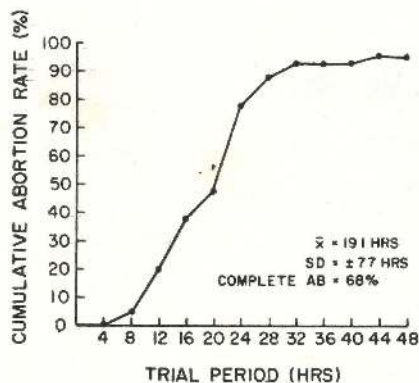


FIG. 9. Overall Cumulative Abortion Rate for Patients Induced with a Single Dose of Intra-amniotically Administered Prostaglandin $\text{F}_{2\alpha}$. (Figure 1 of Reference 6)

CUMULATIVE ABORTION RATE

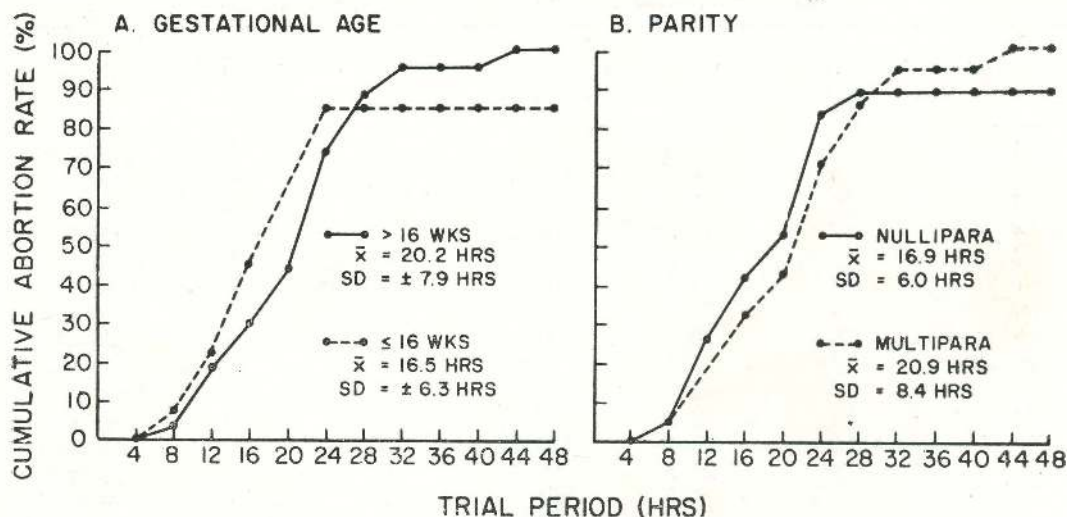


FIG. 10. Cumulative Abortion Rate by Gestational Age and Parity for Abortion Induced by Intra-amniotically Administered Prostaglandin $\text{F}_{2\alpha}$. (Figure 2 of Reference 6)

EMESIS

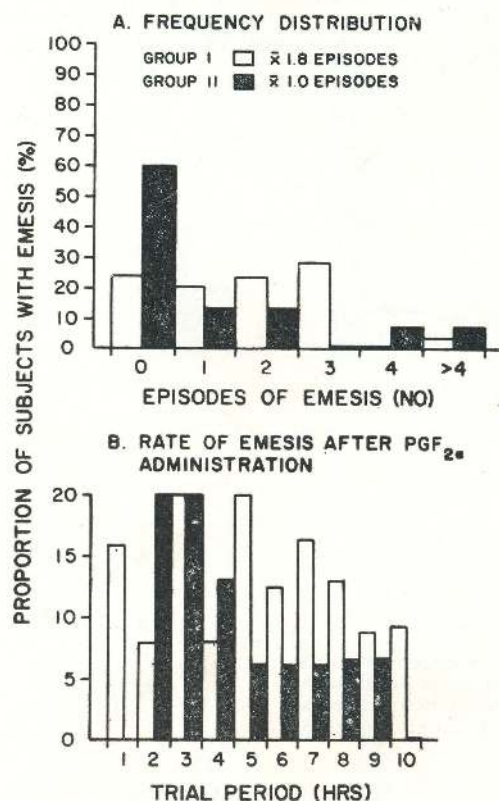


FIG. 11. Incidence of Emesis with Abortion Induced by a Single Dose of Prostaglandin F_{2α}. (Figure 3 of Reference 6)

TABLE 1
ABORTION COURSE AND OUTCOME FOR
15 PATIENTS TREATED WITH I.M. 15 METHYL E₂ ANALOGUE

Patient Number	Weeks of Gestation	Time Abortion (hr)	Maximum Temperature Elevation	Emesis	Diarrhoea	Result
1	7	31.5	102.4	0	0	incomplete
2	10	16.5	100.0	X 2	0	complete
3	10	2.0	99.4	0	0	complete
4	12	18.0	100.2	0	0	complete
5	13	27.3	98.0	0	0	complete
6	14	14.3	100.0	0	0	incomplete
7	14	25.0	98.8	0	0	incomplete
8	16	30.0	102.8	X 2	0	complete
9	17	13.5	99.6	0	X1	complete
10	17	48	100.0	X 3	0	failure
11	18	13.8	99.2	X 3	0	complete
12	18	16.0	100.8	0	0	incomplete
13	18	21.5	99.4	0	0	complete
14	20	7.3	101.2	X 3	X 1	complete
15	20	16.5	102.0	0	X 1	complete

Mean induction-to-abortion interval = 19.2 hours

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MENSTRUAL REGULATION — A NEW METHOD IN FAMILY SERVICE

By

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Introduction

Menstrual regulation (MR) is the term applied to any treatment which is administered within 14 days of a missed menstrual period to ensure that a woman is not pregnant or does not remain pregnant. Because pregnancy tests are not accurate at this stage of pregnancy, it cannot be reliably determined whether a woman is or is not pregnant prior to the procedure. The most common method of treatment is suction curettage using a small diameter, clear plastic, flexible cannula. Neither dilatation of the cervix or anaesthesia is usually required.

Other investigators^{1,2} have found MR to be a safe, simple and an effective procedure. In these studies, electric vacuum pumps were used as a source of negative pressure. In our study, MR was performed with a 4, 5 and 6 mm Karman cannula attached to a 50 ml Karman syringe.

Materials and Method

Between September 1972 and August 1973, 103 amenorrhoeic women underwent suction curettage at the Kandang Kerbau Hospital, Singapore. The data were reported on a standard form and were subsequently processed and analysed at the International Fertility Research Programme, Chapel Hill, North Carolina. Follow-up data were obtained for all subjects 2 – 7 weeks after MR. The subjects were generally healthy women requesting treatment of a missed menstrual period. The first 7 patients were admitted to the hospital and were given analgesia in the form of pethidine before the procedure. MR was carried out on the remaining subjects as an outpatient procedure and no anaesthesia or analgesia

were given. The objectives of this initial series of MR were to evaluate –

1. The effectiveness of MR.
2. The safety of the procedure.
3. The technical difficulties and time required to perform the procedure.
4. The accuracy of the Pregnosticon Dri-Dot pregnancy test, (Organon Inc., West Orange, New York 07052).
5. Post-MR acceptance of contraceptive methods.

(A) Data Collection

All data were recorded on a standard, one page form designed to obtain information on patient characteristics, past medical history and pertinent events related to the procedure. Follow-up data were recorded on the same form.

(B) Subjects

Most of the women were married (98.1%), Buddhist (66.0%), not employed (71.8%), under 30 years of age (52.4%) and of parity 3 or more (55.4%). The median age and parity for the group were 29.1 years and 2.8 live births respectively. About one-third of the subjects were less than 30 years of age and of parity 0–2, while 37% were over 29 and of parity 3 or more.

Prior to MR, 8.7% of the women had an induced abortion, and 13.6% had a spontaneous abortion. Two (1.9%) women each reported a child loss and 38.8% indicated they wanted additional children. (Tables 1 to 4.)

This work was supported in part by grants from Ministry of Health, Singapore (MH 95:01/1 Vol.6) and from the International Fertility Research Programme of the Carolina Population Center of the University of North Carolina at Chapel Hill.

TABLE 1

DISTRIBUTION ACCORDING TO AGE		
<i>Characteristic</i>	<i>Number</i>	<i>Per cent</i>
20	1	1.0
20 - 29	53	51.4
30 - 39	37	35.9
40+	12	11.7
Total	103	100.0

TABLE 2

DISTRIBUTION ACCORDING TO PARITY		
<i>Characteristic</i>	<i>Number</i>	<i>Per cent</i>
0	2	1.9
1 - 2	44	42.7
3 - 4	39	37.9
5+	18	17.5
Total	103	100.0

TABLE 3

DISTRIBUTION ACCORDING TO EDUCATION (YEARS) AND EMPLOYMENT

<i>Characteristic</i>	<i>Number</i>	<i>Per cent</i>
<i>Education</i>		
0	34	33.0
1 - 6	38	36.9
7 - 12	28	26.2
13+	3	2.9
Total	103	100.0
<i>Employment</i>		
No	74	71.8
Yes	29	28.2
Total	103	100.0

TABLE 4

DISTRIBUTION ACCORDING TO RELIGION		
<i>Religion</i>	<i>Number</i>	<i>Per cent</i>
None	10	9.7
Buddhist	68	66.0
Muslim	13	12.6
Catholic	4	3.9
Others	8	7.8
Total	103	100.0

Procedure

All procedures were conducted in a standard manner. After performing the Pregnosticon Dri-Dot pregnancy test, the patient was placed in the dorsal position. No preparation of the perineum and vagina were done. Sterile gloves and sterile instruments were used. After the cervix was visualized with a Sim's speculum the anterior lip of the cervix was grasped with a non-tooth Vulsellum forceps. Without cervical dilatation either a 4 mm, 5 mm or 6 mm plastic Karman's cannula was inserted into the uterus. This cannula was connected to a 50 ml Karman's syringe. After negative pressure is ensured with the Karman's syringe, the cannula is rotated 180° and at the same time, moved back and forth within the uterus until all the interior has been reached. Three signs of adequate evacuation were used:

1. gross examination of the evacuated products
2. the appearance of only air bubbles being suctioned
3. the gritty feeling of the cannula against the uterus wall.

No curette check is performed and the patients were asked to rest in an adjoining room for 10 - 20 minutes and then were asked to go home. The aspirated uterine contents were sent for microscopic examination. At about 4 weeks after the surgery the subjects were scheduled for a follow-up visit at which time a routine gynaecological examination and a repeat pregnancy test was performed.

In this series, 89 cases of MR were done by one author (D.V.) and all the 103 cases were seen and examined by the same author.

Definition and Criteria

Because of the variations in menstrual cycle length, the duration of amenorrhoea was calculated as the number of days from the first day of the last menstrual period to the day of surgery. The Pregnosticon Dri-Dot pregnancy test was interpreted as "positive" if definite flocculation did not occur; "negative" if flocculation did occur and "indefinite" if the surgeon was unsure if slight flocculation had occurred. Pregnancy tests were evaluated by gross inspection

without the aid of any magnifying device. The microscopic identification of any products of conception (villi, fetus or membranes) in the aspirated uterine contents, confirmed pregnancy.

Results

(A) Effectiveness

Menstrual regulation was effective. None of the 103 subjects showed a positive pregnancy test and/or signs or symptoms of pregnancy at the time of the follow-up examination. This gave a method failure rate of zero per cent.

(B) Safety

The incidence of complications was used to evaluate the safety of MR. Only two complications were reported. One subject had an episode of mild vomiting and this could be attributed to the effect of pethidine administered before the procedure. The other subject was admitted to the hospital for one night for lower abdominal pain following discharge from the hospital. On examination there was no evidence to suggest any signs or symptoms of pelvic inflammation.

(C) Technical Difficulties and Time required for the Procedure

No technical difficulties were encountered during the entire series and no additional operative procedure was performed on any subject.

Procedure time i.e. the time from the insertion of speculum to final removal of speculum, varied from 2-10 minutes with an average of 4.5 minutes.

(D) Accuracy of Pregnosticon Pregnancy Tests

The results of the pregnancy test were cross-tabulated with results of the microscopic examination (Table 5). There were two cases of false positives (4.4%) and one case of false negative (1.8%).

The reliability of the pregnancy test in documented pregnancies varied with the length of amenorrhoea (Table 6). These data were analysed to determine the relationship between the probability of a negative pregnancy test in a gravida and length of amenorrhoea. Probability of obtaining a negative test in a pregnant woman decreases with the increasing length of amenorrhoea.

TABLE 5
RESULTS OF INITIAL PREGNANCY TEST AND MICROSCOPIC EXAMINATION

Results of Microscopic Examination			Initial Pregnancy Test				Total	
	No.	%	Positive		Negative		No.	%
Products of conception identified	56	54.9	55	98.2	1	1.8	56	100
No products of conception	46	45.1	2	4.4	44	95.6	46	100

TABLE 6
RESULTS OF INITIAL PREGNANCY TEST IN DOCUMENTED PREGNANCIES BY DAYS OF AMENORRHOEA

Days of Amenorrhoea	Results of Initial Pregnancy Test				Total	
	Negative		Positive		No.	%
	No.	%	No.	%		
32 - 33	2	100	0	0	2	100
34 - 35	20	57.14	15	42.86	35	100
36 - 37	12	35.29	22	64.71	34	100
38 - 39	10	38.46	16	61.54	26	100
40 - 42	1	20.0	4	80.0	5	100

(E) The Acceptance of Contraception

There was a significant change in contraceptive practice prior to MR (Table 7). Prior to MR, 27.2% of the subjects had not used any contraceptive methods compared to 4.9% at the time of the follow-up visit.

TABLE 7

PRE AND POST-MENSTRUAL REGULATION
CONTRACEPTIVE PRACTICE

Contraceptive Method	Pre-M.R.		Post-M.R.	
	No.	%	No.	%
None	28	27.2	5	4.9
Withdrawal/ Rhythm	6	5.8	2	1.9
Foam/Diaphragm/ Jelly	3	2.9	2	1.9
Condom	40	38.8	41	39.8
IUD	1	1.0	3	2.9
Orals/Injectables	25	24.3	45	43.8
Tubectomy	0	0.0	3	2.9
Vasectomy	0	0.0	2	1.9

Discussion

The results of this study agree with the results of other studies^{1,2} which have shown MR to be a safe, simple and an efficient procedure. This study indicates that MR is practicable as an outpatient procedure when a small diameter plastic cannula with a 50 ml syringe is used and without the necessity of an anaesthetic. The absence of major complications and failures of the procedure indicates that further study of the procedure in a larger series of patients is warranted. MR has potential as a effective method of fertility control alone or in combination with other methods. The use of two independent methods remarkably increases the efficacy as the failure rate of the combination is the product of that of the individual methods. The long term effects of single and repeated use of MR and any rare serious complications must be constantly evaluated. The need for more information about present and improved techniques of MR will require study of this emerging family planning method.

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MENSTRUAL REGULATION IN FERTILITY CONTROL

By

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I. Introduction

Menstrual regulation (MR) is the treatment of the delayed menstrual period—within 14 days of the expected onset of menses—to assure a non-pregnant state and re-establish regular menstrual periods in subsequent cycles.¹ Several methods of treatment are under study, including the use of natural prostaglandins² and their analogues.³ The most extensively studied method, now accepted in many parts of the world as good medical practice, is suction curettage.⁴ A 4, 5 or 6 mm. cannula is introduced transcervically into the uterus, usually without anesthesia, and vacuum is applied from any suitable source, such as an evacuated 50 ml. syringe. The superficial endometrium is removed with any products of conception that may be present.

II. Differences from abortion

Menstrual regulation differs from abortion in several respects. First, neither the patient nor the physician is sure that a pregnancy is being interrupted. The diagnosis of pregnancy cannot be accurately made by physical examination or with currently available pregnancy tests prior to 14 days delayed menstrual period. One can only estimate the proportion of menstrual regulation procedures that terminate pregnancies, based on the number of days the menses are delayed and whether a screening pregnancy test is positive or negative. Other maternal factors that may influence this proportion are age, lactation and recent use of steroidal contraceptives.¹ Pregnancy tests that are accurate within 14 days of an expected menstrual period, such as radioimmunoassay methods, are not likely to be readily available to most people of the world during this decade. Second, laws related to abortion are not applicable to menstrual regulation according to legal opinion.⁵ Finally, and most important, menstrual regulation is probably safer than abortion at 7–8 weeks' gestation by suction curettage, having only one-third the complication rate in one series.⁶

III. Similarities to abortion

Menstrual regulation is a post conceptive method of fertility control and may share with artificial abortion the credit for many of the social, economic and health benefits derived from improved control of fertility.⁷ No acceptable method of fertility control can match the demonstrated effectiveness of abortion in controlling rapid population growth—this planet's most pressing problem. The effect of abortion on birth rates in Japan⁸ and Eastern Europe⁹ and the subsequent rise in the standard of living in these countries support some economists' opinion that population growth must be slowed to achieve economic well-being.¹⁰ It is doubtful that any population has achieved the demographic transition from high to low fertility without significant use of induced abortion.^{11,12,13} Legalization of abortion reduces the need for abortion performed under less than ideal conditions and, therefore, the rate of septic abortion and maternal morbidity and mortality.^{14,15,16,17} Infant and child mortality rates¹⁸ and illegitimate births¹⁹ also fall where fertility control is suddenly improved by addition of post-conceptive means. Contraceptive methods, by contrast, are only slowly adopted and in very few countries can the introduction of contraception be definitely related to a decline in fertility.²⁰

Whether menstrual regulation will carry with it the delayed indirect complications of abortion, such as an increased rate of prematurity²¹ and stillbirth,²² remains to be demonstrated. If prematurity in subsequent births is related to cervical damage from mechanical dilation of the cervix and stillbirth is related to Rh sensitivity, menstrual regulation theoretically should not result in higher prematurity and stillbirth rates.

IV. Efficiency of the menstrual regulation (MR) procedure

The efficiency of menstrual regulation in fertility control can be measured in terms of

the number of births averted by the procedure. This, in turn, is dependent on: (1) its efficacy, (2) the proportion of patients who are pregnant, and (3) the use-effectiveness of the post-MR fertility control accepted.²³

MR is highly effective. A failure rate (continuation of pregnancy) of only 0.7 per cent was observed in studies involving 901 pregnant subjects.^{1,24,25} If the efficacy of MR is compared to contraception, the failure rate per MR procedure must be multiplied by the number of times the procedure is required per year when no other method of fertility is used—probably three times for women in their twenties and twice per year for women in their thirties.²³ The calculated failure rate of 1.4 to 2.1 per 100 women years of use is comparable to our best conventional contraceptives.²⁶

Assuming the MR procedure is effectively performed on a pregnant subject, there are several considerations that determine the births averted by the procedure. If not taken into account, the possibility that the pregnancy, without the intervention of MR, may have aborted spontaneously or ended in a stillbirth leads to an overestimate of births averted. In comparing a cohort of women using MR and one that does not, the length of pregnancy preceding spontaneous abortion, stillbirth, or live birth and length of anovulation following these outcomes must be considered.²³ Age of the women is positively associated with length of postpartum anovulation, number of fecundable months for conception to occur, risk of spontaneous abortion and stillbirth, secondary sterility, and therefore the expected birth interval when no fertility control is used.²³ These factors influence the number of births a cohort of women will experience with or without contraception. Births averted by MR administered to a pregnant woman may be measured by the ratio of births per woman in the cohort not using MR to backstop their contraception to MR procedures per woman in an otherwise identical cohort. While age and custom of breastfeeding will influence this ratio, the quality of post-MR contraception is its primary determinant. The more effective the contraception, the higher the number of births averted. With perfect post-MR contraception, 0.8 of a birth is averted

by MR on a pregnant woman, while only 1/3 of a birth is averted without contraception and only 1/4 of a birth if lengthy breastfeeding is customary in a comparable cohort of women not using MR.²³

To estimate the number of births averted by an MR service, it must first be determined what proportion of the MR procedures are performed on pregnant women. This proportion increases with the number of days missed menstrual period.⁴ In service programs which include any woman with a menstrual period delayed up to 14 days, approximately 50% are documented as pregnant by pathological examination of evacuated uterine contents.^{24,25} The estimate of births averted would, therefore, be only one-half the number estimated for a program including only pregnant women.

V. Efficiency of a menstrual regulation service

The effect of a menstrual regulation service in a family planning program goes beyond that of births averted by the MR procedure, per se. To the extent that contraceptive practice is improved by the clinic visit, additional births are averted. For example, when a non-contraceptor accepts sterilization after an MR procedure, two additional births may be averted.²⁷

Menstrual regulation, like abortion, is likely to be used by those who either use no contraception or use it poorly and who are obviously fertile and desire to control their fertility. MR can serve in this way as a "recruitment service" to family planning. The educational effort at the clinic will largely determine how this opportunity is used.

The ability of a contraceptive clinic to offer MR in cases of contraceptive failure during the first clinic visit for this complaint can assist in building an atmosphere of trust and concern around a family planning clinic to improve overall contraceptive acceptance. This service also permits the use of less effective but more widely accepted contraceptives for many clients using the family planning clinic or commercially available contraceptives.

VI. Estimating births averted

In an attempt to quantify the efficiency of a menstrual regulation service, the following definitions and relationships are defined:

BAS = Births Averted by Menstrual Regulation Service

BAP = Births Averted by Menstrual Regulation Procedure Performed on Pregnant Patients

BACB = Births Averted by Contraception Before Menstrual Regulation

BACA = Births Averted by Contraception After Menstrual Regulation

P = Proportion of Menstrual Regulation Cases Pregnant

N = Number of Menstrual Regulation Procedures Performed

$$BAS = N[(BAP \times P) + (BACA - BACB)]$$

Each of these factors may now be examined to determine their numerical range and what influences a particular level within this range.

Guidelines^{28,29} for estimates of births averted have been formulated according to the acceptance and use-effectiveness of particular contraceptives. The ranges for common contraceptives, including sterilization, are not precisely known but are now approximated as follows:

<i>Contraceptive</i>	<i>No. Births Averted</i>
Condoms	0.25-0.50
Diaphragm/jelly/tablets	0.25-0.50
Oral Contraceptives	0.50-0.75
IUD	0.75-1.00
Injectables	1.00-1.50
Sterilization	1.50-2.50

The value for a contraceptive method in a particular program will depend primarily on the age and parity of program participants and use-effectiveness of the methods. For the present estimate of BAS any difference in births averted by continued use of a method before MR and acceptance and use of the same method after MR is ignored.

The proportion of menstrual regulation cases that are pregnant at the time of the procedure will be influenced by regularity of the menstrual cycle (or error in calculating days menstrual period is delayed), maternal age, recent anovulatory state due to birth or steroid contraception, days delayed menstrual period and presence or absence of a positive pregnancy test.

Births averted by a menstrual regulation procedure on a pregnant woman have been described as ranging from 0.3 to 0.8 depending on the efficiency of post-MR fertility control accepted. The higher value (0.8) is achieved when perfect control, such as sterilization, is adopted and the lower (0.3) is obtained when the patient continues to use no fertility control.²³ The importance of post-MR contraception in estimating births averted is greater for younger than older age groups. A significant fraction of an averted birth accompanies the use of MR for older women regardless of post-MR fertility control used because the probability of a subsequent pregnancy declines as sterility rises with age. The estimate varies from 0.03 at 20 years to 0.31 at 40 years of age.³⁰ This effect, however, is not important until the woman reaches her later re-productive years and is, in part, vitiated by a corresponding increase in the risk of spontaneous fetal wastage from 0.10 at 22.5 years to 0.32 at 46.5 years of age.^{23,31} This factor increases the possible ineffectiveness of the MR procedure in terms of births averted. The effect of an increase in fecundable months for conception and mean postpartum anovulation with age appear also to be minor compared to efficiency of post-MR fertility control.^{23,31}

The acceptance of MR in a variety of clinic settings has shown a typical S-shaped curve - starting slow in the first months and building rapidly toward a plateau at the end of the year.²⁴ The absolute levels vary greatly from one community to another.

Two important factors determining whether MR will be readily accepted by a community are availability of the service and easy access to the service.³² The more readily, women can utilize the service on their own decision, the higher will be its use. In the most under-developed communities of the world this may mean taking the service to the

home by paramedical workers. Much can be done immediately by making MR available in existing family planning clinics. There will in any event be the expected urban-rural and ethnic group differences found for any new means of fertility control.²⁴

We can now illustrate the estimate of births averted by a particular menstrual regulation service using a few simplifying assumptions. These are that 100 procedures were done in a particular time – say one year, half of the cases were pregnant, half of the pregnant and non-pregnant cases used condoms as pre-MR fertility control and the other half used no contraception, and half of the pregnant and non-pregnant cases accepted sterilization and the other half an IUD insertion after MR. We will assume .375 births averted for condoms, .875 for IUDs and 2.0 for sterilization. Births averted by the procedure, per se, in pregnant women is assumed to be 0.8 for these effective means of post-MR fertility control. Our estimate of births averted for this service in one year is then:

$$\begin{aligned}\text{BAS} &= 100[(0.8 \times 0.5) + (1.437 - 0.187)] \\ &= 100[0.4 + 1.25] \\ &= 100 \times 1.65 \\ &= 165\end{aligned}$$

Thus, an estimated 165 births were averted by this service or 1.65 per MR procedure and clinic visit. The estimate will usually be uncertain because of lack of

accurate information on births averted by improved contraception associated with the clinic visit. It is a useful tool for the program administrator but not a substitute for scientific inquiry into births averted by fertility control programs.

VII. Optimal use of menstrual regulation

To maximize the efficiency of MR as a method of fertility control, the procedure should be performed on as few non-pregnant women as possible while at the same time treating a high percentage of pregnant women. Two variables to be considered in optimizing use of MR are days missed menstrual period and results of a pregnancy test.

Outcome of a screening pregnant test, the Pregnosticon Dri-Dot* test, by results of the pathologist's examination of evacuated uterine contents is shown in Table 1 for 1440 women undergoing menstrual regulation by vacuum aspiration within 14 days of a missed menstrual period. The data are taken from studies monitored by the International Fertility Research Program. The sensitivity of the test (per cent of positive results among confirmed pregnant cases) is only 53.5%. The specificity of the test (per cent of negative results among confirmed non-pregnant cases) is 91.4%. The test lacks the sensitivity that is desired when used within 14 days of a missed menstrual period.

TABLE 1

PREGNOSTICON DRI-DOT TEST OUTCOME BY RESULTS OF MICROSCOPIC EXAMINATION OF EVACUATED UTERINE CONTENTS AMONG 1440 WOMEN WITH 1-14 DAYS DELAYED MENSTRUAL PERIOD

Outcome of Pregnancy Test	Presence of Products of Conception						Total	
	Negative		Presumptive*		Positive*			
	No.	%	No.	%	No.	%	No.	%
Negative	604	59.9	111	11.0	294	29.1	1009	70.0
Indefinite	11	45.8	6	25.0	7	29.2	24	1.7
Positive	46	11.3	15	3.7	346	85.0	407	28.3
Total	661	45.9	132	9.2	647	44.9	1440	100.0

Sensitivity of test = 53.5% (346/647) Specificity of test = 91.4% (604/661)

* Arias Stella reaction or decidual change.

**Products of conception identified (villi, trophoblast, fetus, amnion or chorion).

Source: Pooled Data – International Fertility Research Program, 1974.

Figure 1 illustrates probability of pregnancy by days missed menstrual period when results of the Pregnosticon Dri-Dot test are positive (N=407), negative (N=1009) and for all cases regardless of test results (including 24 cases with an indefinite pregnancy test, N=1440). All curves start from the estimated pregnancy prevalence of 20% at time of expected menstrual period for women having regular unprotected intercourse. It is assumed that the pregnancy test does not differentiate pregnant and non-pregnant cases this early. Three observations can be made. First, a positive pregnancy test is quite helpful in diagnosing pregnancy, especially after the fourth day delayed menstrual period. However, due to the poor sensitivity of the test, a low percentage of pregnant cases will give a positive test result. Second, as would be expected, the prevalence of pregnancy increases by days missed menstrual period for all cases. Non-pregnant women at risk of coming to a clinic for menstrual regulation are more likely to have had a menstrual period the greater the days menses is delayed. The remaining women with delayed periods coming to the clinic are, therefore, more likely to be pregnant. Third, 25 to 30% of all women with a negative pregnancy test will be pregnant. Because of the low sensitivity of the test and the fact that approximately half of the women with periods delayed through 14 days are not pregnant, the great majority of women will

have a negative pregnancy test. Although false negative tests decline³³ with increasing days of amenorrhoea, this effect is balanced by an increasing prevalence of pregnancy, resulting in a flat pregnancy probability curve for negative test cases.

It must be concluded that present screening pregnancy tests make only a modest contribution to a menstrual regulation service. What is needed is a test with very high sensitivity (few false negative results) to exclude a larger percentage of non-pregnant women. An even lower specificity of the test could be tolerated, as currently all women with a missed menstrual period are receiving menstrual regulation in most programs in order to reduce the complications of later abortion for those who are pregnant.

With presently available pregnancy tests, a somewhat higher proportion of procedures will be done on pregnant women if all positive cases are done on the day the women come to the clinic and cases with negative pregnancy tests and less than 8 days delayed menstrual period are given an appointment near the 14th day when the procedure would be done on still amenorrhoeic women without an additional test. It is possible, however, that all benefits derived from this two-stage process would be lost by the gradual rise in complications of the procedure with increasing gestation.³⁴

It appears from what is known at this time that other considerations than results of a pregnancy test and days delayed menstrual period might be more important in the decision to schedule a second visit. These include anxiety of the patient and cost of a return visit. Some general guidelines can, however, be established.

Since the complication rate for MR procedures is one-third that for abortion at 7-8 weeks' gestation,⁶ at least one-third of the procedures should be on pregnant women. If only 20% of the women treated are pregnant, as would be the maximum expected in "menstrual extraction" at the time of the expected menstrual period, MR would not appear warranted as a fertility control method based on what is presently known about complications and pregnancy rates. The clinician seeing a

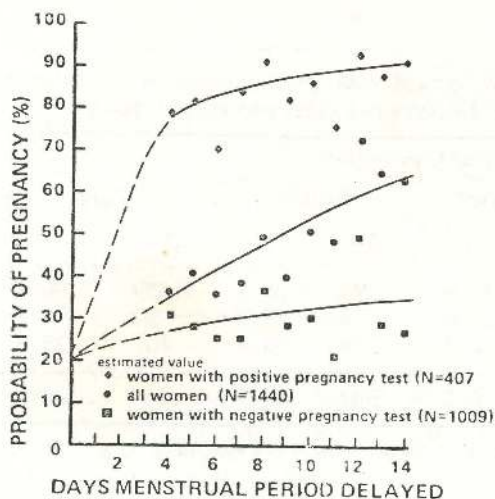


FIG. 1. Probability of Pregnancy by Days Menstrual Period is Delayed.

woman whose menses is only 5 days delayed and who has a negative pregnancy test may wish to ask her to return in a week. However, this decision should also be based on how anxious she appeared and whether it appeared very likely that she would keep her next appointment. This delay is indicated especially if the patient is a teenager, over forty years of age, lactating, or if she has recently been using steroid contraceptives. Clinics able to perform first trimester abortions might be more willing to ask the patient to return in an attempt to raise the proportion of MR procedures performed on pregnant women since they would be prepared to terminate unwanted pregnancies among women who failed to keep their appointment within 14 days of a delayed menstrual period. For communities where abortion is illegal, MR provides the only legal post-conceptive means of fertility control.⁵ In these communities it probably would be better to perform MR on the first visit rather than delay the procedure.

It does appear, however, that offering menstrual regulation to any woman concerned about an unwanted pregnancy up to 14 days missed menstrual period is good medical practice and will both improve fertility control and reduce the risk of complications associated with abortion after 14 days delayed menses. To routinely delay the decision to treat an unwanted pregnancy until the 7th or 8th week of gestation, when the diagnosis of pregnancy can accurately be made, is poor medical practice in light of what is now known about complication rates, that is, a tripling of the complication rate for abortions performed at or less than 6 weeks' gestation compared to abortion performed at 7 and 8 weeks' gestation.⁶ Improving the proportion of procedures done on pregnant women and thus avoiding unnecessary procedures must depend on characteristics of the woman, including her ability to keep a later appointment, the accuracy of pregnancy tests used and available resources for first trimester abortion.

This kind of clinical problem is not unfamiliar to the clinician. The surgeon faces a similar decision in the diagnosis and treatment of appendicitis. The patient's signs and symptoms become more typical of appendicitis over time, but so does the possibility of rupture of the appendix.

Complications of appendectomy before rupture of the appendix are so much lower than after rupture that the surgeon may perform appendectomy early – and include a percentage of cases with normal appendices – if the overall complications of all patients presenting signs and symptoms of appendicitis is thereby reduced.

To be precise in comparing risks of complications of a procedure on the same cohort at two time periods, an adjusted rate should be used for the first procedure that removes from the denominator women not at risk of undergoing the delayed procedure because of a definite diagnosis of not being pregnant. In the case of a menstrual regulation procedure, these are the women who would have a menstrual period or spontaneous abortion between the two time periods. This adjustment increases somewhat the comparable complication rate for the MR procedure.

VIII. Summary

Menstrual regulation is a useful addition to fertility control methods. Even with present technology using suction curettage, it is the safest, most effective post-conceptive means of fertility control. The demand for a post-conceptive method is so great, MR may make its most important contribution to fertility control as a "recruitment service" to other means of fertility control, and at the same time, make the MR procedure itself a more effective means of fertility control. If MR is substituting for legalized, induced abortion, there may be few or no net births averted and no net gain in recruitment of contraceptors; however, it would retain the advantage of having fewer complications. If MR is substituting for illegal abortion, it is quite likely there would be a net recruitment to contraception since the practitioner or illegal operations would not be a likely source of contraceptive advice and supplies.

The fact that with MR, the woman is not sure whether she is pregnant would also mean that she is not sure whether a contraceptive failure has occurred – which might favor more confidence in continuing the method.

An estimate of births averted by MR service is presented. The method is only an approximation useful for program

administrators. In particular, the range of estimates of births averted for different contraceptive methods will vary from place to place depending on the care and duration of their use.

The value of screening pregnancy tests is discussed and found to contribute little to MR services.

If menstrual regulation is to make its maximum contribution to fertility control, it must become more readily available and be combined with effective contraception or

convenient sterilization. More research is needed to make MR still safer and less dependent on medical facilities and professional skill.

Pharmacological methods of menstrual regulation holds great promise and might even lead to a self-administered method of menstrual regulation. It is likely that only a development such as this can assure a degree of population control equal to preventing the present prospect of a rise in mortality and deterioration of social and material well-being.

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MENSTRUAL REGULATION — RESULTS OF EARLY STUDIES

By

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I. Introduction

Early studies in menstrual regulation (MR) conducted by the International Fertility Research Program suggest that menstrual regulation by suction curettage is a safe, simple and efficient procedure. The procedure consists of the simple aspiration of the endometrium with a small size cannula and a vacuum source. It is associated with a rate of complications considerably lower than that associated with first trimester abortion and has, therefore, been suggested, even if the diagnosis of pregnancy cannot be definitely made.¹ The objective of this paper is to review the early findings of menstrual regulation studies conducted in New York, London, Bombay and Howrah, India, in order to evaluate the safety and effectiveness of MR in a spectrum of clinics in developed and developing countries and to study the socio-demographic characteristics, reproductive profile and contraceptive behaviour of women accepting MR.

II. Materials and Methods

Data Collection

All data were recorded on a standard, one-page form designed to obtain information on patient characteristics, medical data and pertinent events including follow-up data related to the procedure.

Definition and Criteria

All women requesting medical treatment for a delayed menstrual period of up to 2 weeks, except those with uterine enlargement disproportionate to that expected based on parity and amenorrhea, were included in the study.

The Pregnosticon Dri-Dot Pregnancy Test* was performed at admission and at 2-4 weeks follow-up. Subjects with both positive and negative initial pregnancy tests

were included in the study. The test was interpreted as "positive" when no agglutination was observed, "negative" if definite agglutination was observed, and "indefinite" if agglutination could not be detected with certainty. A pathological examination of the evacuated uterine contents was done to establish the diagnosis of pregnancy. The presence of any product(s) of conception (villi, trophoblast, fetus, amnion or chorion) was interpreted as histologic confirmation of a diagnosis of pregnancy. When no positive identification could be made by the pathologist or when Arias Stella reaction or decidual casts were observed, the classification was "presumptive evidence of pregnancy".

Pregnancy tests could not be done for the initial cases at the community clinics as facilities were not fully organized. Analysis of the clinical evaluation of the menstrual regulation procedure has been confined to subjects for whom complete data on pregnancy tests were available.

Subjects

Data from four studies conducted in London, New York, Bombay and Howrah, India are reported (Table 1). The subjects included in the studies were generally healthy women requesting treatment for a missed menstrual period. Studies in London and New York were done in collaboration with the International Fertility Research Program while the Indian studies were done with the cooperation of the India Fertility Research Programme.

The London study included 598 subjects who underwent MR with suction curettage at the IARTC.† Of the subjects in this series, 99.6 per cent received general anaesthesia and all remained in the hospital for one night. The cannula used was either the

* Organon Inc., West Orange, New Jersey 07052.

† IARTC is a London affiliate of Population Services International, Chapel Hill, North Carolina.

6 mm Karman Cannula* or a 4 mm Davis Cannula† and the source of suction was a Matburn Vacuum Pump.

TABLE 1

ACCEPTORS OF MENSTRUAL REGULATION IN THE LONDON, NEW YORK, BOMBAY AND HOWRAH DISTRICT CLINICS

Study	Number	Per cent
London	598	39.9
New York	442	29.5
Bombay		
Teaching Hospital	48	3.2
Community Health Clinic	97	6.5
Howrah		
Urban Clinic	209	14.0
Slum Clinic	82	5.5
Rural Clinic	69	4.6
Total	1497	100.0

The study at New York² was conducted on 442 subjects at the Eastern Women's Center to evaluate the concept of MR as an outpatient procedure. MR was done, in all cases (except one), on an outpatient basis using suction curettage with a 4, 5, or 6 mm. flexible, plastic Karman Cannula and a Sorensen suction pump as the vacuum source. No anaesthesia was used for 73.6 per cent of the subjects; 26.2 per cent of the patients required a paracervical block with 1% lignocaine.

Studies in India were done at Bombay³ and Howrah⁴. The Bombay service included two groups of women—one group of 48 subjects underwent MR at a public teaching hospital; and the second group of 49 subjects attended a community health clinic in a slum area⁵. The Howrah Studies were conducted by the Family Welfare Planning Project of the Humanity Association in urban (209 subjects), slum (82 subjects) and rural (69 subjects) communities through clinics equipped with minimal facilities, each serving a population of about 10,000⁵.

* Karman Cannula, Berkeley Bio-Engineering, Oakland, California.

† A 9-inch piece of 4 mm Portex, polythene, reference No. 800/100/660, Portex Limited, Hythe, England, tubing with a whistle tip cut 1/2 cm from its end.

‡ Lokmanya Tilak Municipal General Hospital, Bombay.

§ Streehitakarini Project, Bombay.

In the India studies, MR was performed for all subjects with a 4, 5, or 6 mm. Karman cannula and an evacuated 50 cc. plastic syringe. No anaesthesia was administered except in 2 cases.

D. Procedure

The procedure was performed in a standard manner in each study. The subject was placed in the dorsal lithotomy position and a bimanual pelvic examination was performed. The cervix was visualized and stabilized. The "no touch" technique was used to maintain sterility of the cannula. The cannula was inserted transcervically to the fundus and vacuum was produced by an electric pump or a hand syringe. A gentle in and out motion was made with the cannula being rotated several times to cover the entire endometrial surface. The procedure was continued until the uterus was completely evacuated, as judged by the following criteria:

- (1) gross examination of the evacuated products,
- (2) the appearance of air bubbles in the cannula, and
- (3) the gritty feeling of the cannula against the uterine wall.

III. Results

The results of the study are presented in two sections: 1) patient characteristics, fertility profile and contraceptive acceptance, and 2) evaluation of the menstrual regulation procedure.

A. Patient Characteristics, Fertility Profile and Contraceptive Acceptance

Patient Characteristics

The median age of women undergoing MR was higher in the London (28.5 years) and Howrah (28.2 years) series than in the Bombay (25.8 years) and New York (23.1 years) series. In the New York study, 61.1 per cent of the women were less than 24 years of age. Close to 50 per cent of the London women were 30 or more years old, and in Howrah, 41.2 per cent of the group was over 30 years of age. The women in

the Bombay study were a somewhat younger group - 77.3 per cent being under thirty years of age (Figure 1).

The median parity at all ages was highest in the Howrah series. The median parity figures were lower in London and New York

than in India. The median parity increased from 1.0 to 7.8 from the youngest to oldest women in Howrah, while it increased from 0.5 to 4.7 in Bombay. In London and New York, the median parity increased from 0.1 at 20-24 years to 2.8 and 2.7, respectively, at 40-44 years (Figure 2).

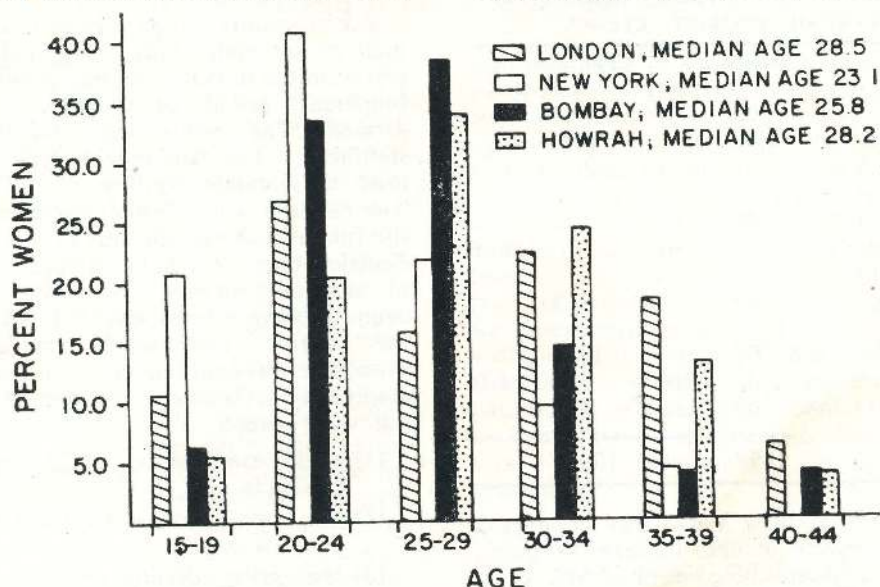


FIG. 1. Per cent Women by Age Accepting Menstrual Regulation in the London, New York, Bombay, and Howrah District Clinics.

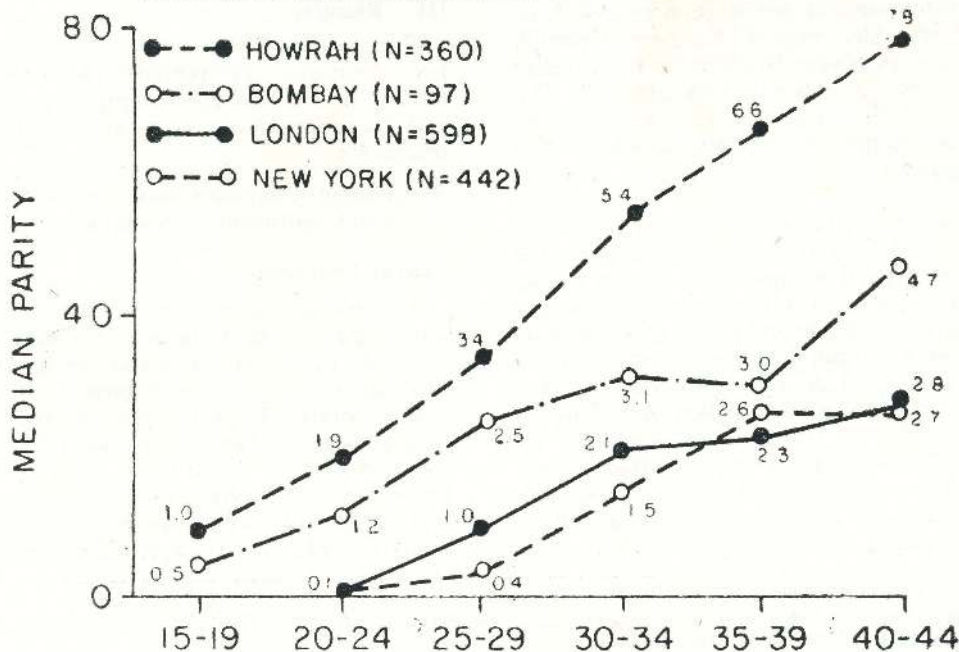


FIG. 2. Median Parity by Age of Women Accepting Menstrual Regulation in the London, New York, Bombay, and Howrah District Clinics.

In the London series, two-thirds of the women were from places outside London and 59.5 per cent were not employed. In New York, over 80 per cent were urban residents, 41.2 per cent were not employed and the great majority had more than seventh grade schooling. In Bombay, 99.0 per cent were urban residents, 69.1 per cent were not employed and 53.6 per cent had more than 7 years schooling. In Howrah, 81.4 per cent were urban residents, and only 18.1 per cent had 7 or more years of schooling (Tables 2-A and 2-B; Figures 3 and 4).

As was expected, the religions of the women in these groups varied. In the London study 58.4 per cent of the women were Catholic and 39.3 per cent were Protestant, while in the New York series 36.4 per cent were Catholic; 26.2 per cent, Protestant; and 13.1 per cent, Jewish.

In London 45.2 per cent of the subjects were not married while in New York 75.6 per cent were not married. The majority (more than 90%) of the subjects in the Indian series were married (Tables 2-A and 2-B; Figure 6).

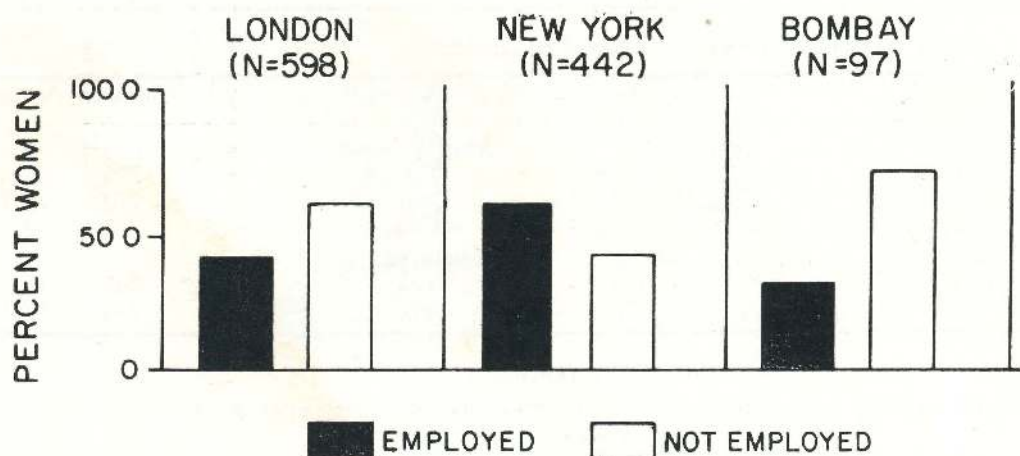


FIG. 3. Employment Status of Women Accepting Menstrual Regulation in the London, New York and Bombay Clinics.

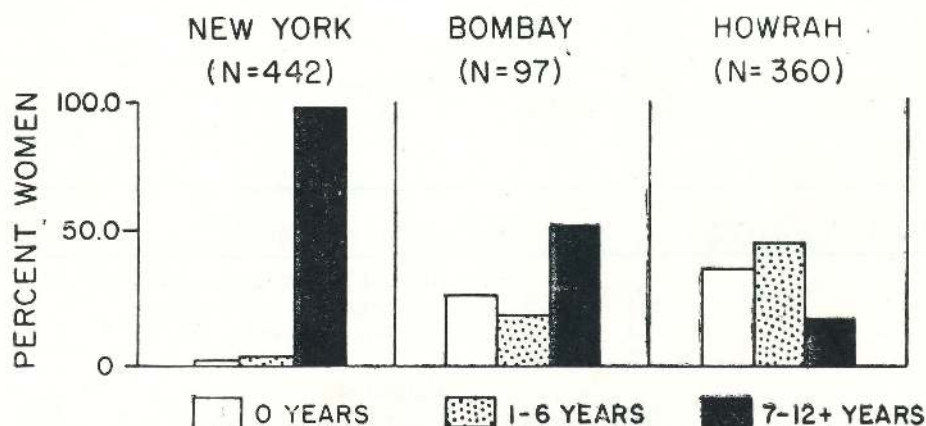


FIG. 4. Formal Education Received by Women Accepting Menstrual Regulation in the New York, Bombay and Howrah District Clinics.

TABLE 2-A

SELECTED PATIENT CHARACTERISTICS OF WOMEN ACCEPTING MENSTRUAL REGULATION IN LONDON AND NEW YORK CLINICS

LONDON - (N = 598) 31.6% urban residents.

Note: majority of the women were not local residents.

Religion			Marital Status		
Catholic	161	36.4	Married	108	24.4
Protestant	116	26.2	Non-married	334	75.6
Jewish	58	13.1			
Other	107	24.2			
Education			Employed		
0	3	0.7	Yes	258	58.4
1-6	7	1.6	No	182	41.2
7-12+	432	97.7	Unknown	2	0.4

NEW YORK - (N = 442) 80.1% urban residents.

Characteristic	Number	Per cent	Characteristic	Number	Per cent
Religion			Marital Status		
Catholic	349	58.4	Married	326	54.5
Protestant	235	39.3	Non-married	270	45.2
Other	14	2.3	Unknown	2	0.3
Education (Unknown)			Employed		
—	—	—	Yes	242	40.5
			No	356	59.5

TABLE 2-B

SELECTED PATIENT CHARACTERISTICS OF WOMEN ACCEPTING MENSTRUAL REGULATION IN BOMBAY AND HOWRAH DISTRICT CLINICS

BOMBAY - (N = 97) 99.0% urban residents.

Characteristic	Number	Per cent	Characteristic	Number	Per cent
Religion			Marital Status		
Hindu	70	72.2	Married	91	93.8
Buddhist	14	14.4	Non-married	6	6.2
Muslim	4	4.1			
Christian	9	9.3			
Education			Employed		
0	27	27.8	Yes	30	30.9
1-6	18	18.6	No	67	69.1
7-12+	52	53.6			

HOWRAH DISTRICT - (N = 360) 81.4% urban residents.

Religion			Marital Status		
Hindu	354	98.3	Married	359	99.7
Muslim	4	1.1	Non-married	1	0.3
Other	2	0.6			
Education			Employed		
0	130	36.1	Yes	0	0.0
1-6	165	45.8	No	360	100.0
7-12+	65	18.1			

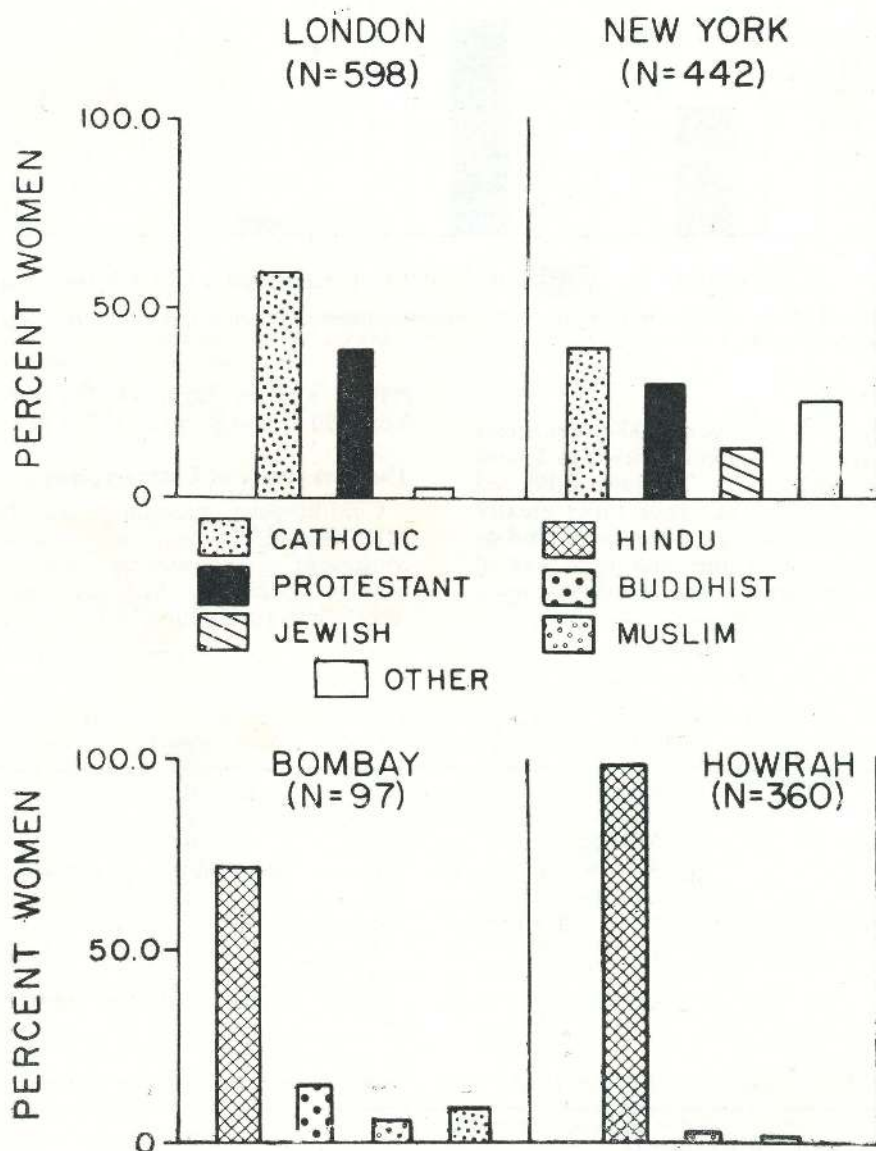


FIG. 5. Religion of Women Accepting Menstrual Regulation in London, New York, Bombay and Howrah District Clinics.

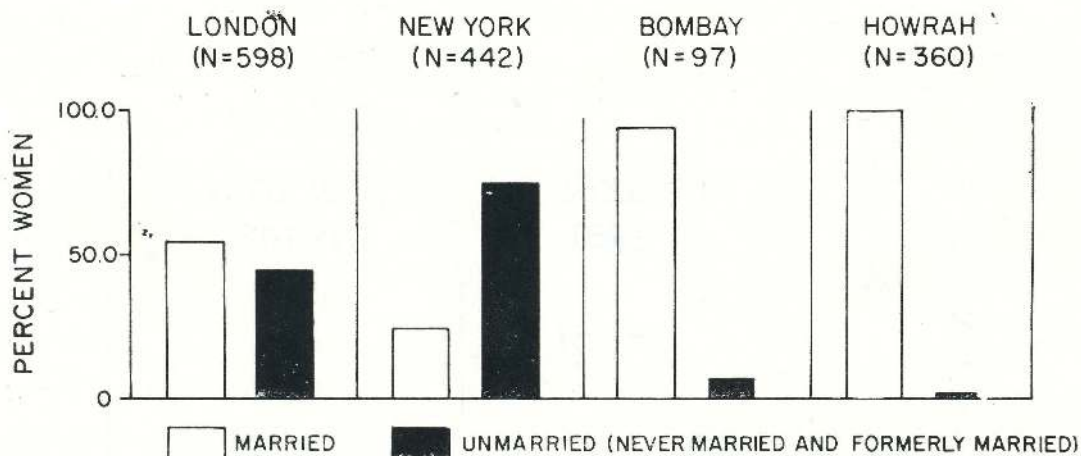


FIG. 6. Marital Status of Women Accepting Menstrual Regulation in London, New York, Bombay, and Howrah District Clinics.

Fertility Profile

The live birth rate per 1000 pregnancies was highest in the Indian series and lowest in the New York series. The rate of induced abortion was more than four times greater in the New York women when compared to that in the London women and more than 10 times that reported for the Bombay women (Table 3).

(111.2) and in favor of females in New York (90.3) and Bombay (77.2) (Table 4).

The Acceptance of Contraception

Contraceptive acceptance was high after MR among women who were offered contraceptive counseling indicating that women undergoing MR are likely to be receptive to such counseling. In the London

TABLE 3

PREGNANCY OUTCOME EVENTS PER 1000 KNOWN PREGNANCIES AMONG MENSTRUAL REGULATION ACCEPTORS IN LONDON, NEW YORK, BOMBAY, AND HOWRAH DISTRICT CLINICS

Event	London		New York		Bombay		Howrah District	
	N=591 ¹		N=440 ¹		N=97		N=360	
	Number	Rate ²	Number	Rate	Number	Rate	Number	Rate
Induced Abortion	83	85.4	185	366.3	9	35.0	8	5.3
Spontaneous Abortion	73	75.1	30	59.4	11	42.8	16	10.5
Still Birth	11	11.3	12	23.8	3	11.7	17	11.2
Live Birth	805	828.2	278	550.5	234	910.5	1477	973.0
Total Number of Known Pregnancies	972	1000.0	505	1000.0	257	1000.0	1518	1000.0

¹ Data, on all variables, available for only these women.

² Rate per 1000 (known) pregnancies.

The child loss rate per 1000 live births was highest in the Howrah series (133.4, about half of that in the Bombay series (68.4), and still lower in the London (26.1) and New York (14.4) series (Table 4 and Figure 7). The sex ratio was in favor of males in London (112.5) and Howrah

study, all women accepted contraception after MR and over 96 per cent of both Catholics and Protestants elected to use the more effective contraceptives (IUD's or orals); no significant differences were observed in the type of fertility control methods accepted by these two religious

TABLE 4

OUTCOME OF LIVE BIRTHS AMONG MENSTRUAL REGULATION ACCEPTORS IN LONDON, NEW YORK, BOMBAY, AND HOWRAH DISTRICT CLINICS

Outcome of Live Births	London		New York		Bombay		Howrah District	
	N=591		N=440 ¹		N=97		N=360	
	Number	Rate ²	Number	Rate	Number	Rate	Number	Rate
Living Children	784	973.9	274	985.6	218	931.6	1280	866.6
Male	415	515.5	130	467.6	95	406.0	674	456.3
Female	369	458.4	144	518.0	123	525.6	606	410.3
Sex Ratio ³	112.5		90.3		77.2		111.2	
Child Loss	21	26.1	4	14.4	16	68.4	197	133.4
Total Number of Live Births	805	1000.0	278	1000.0	234	1000.0	1477	1000.0

¹ Data on all variables, available for only these women.

² Rate per 1000 Live Births.

³ Living Offspring Sex Ratio (Number of males per 100 females).

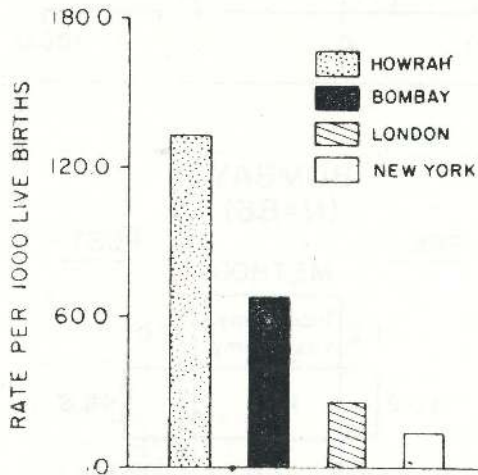


FIG. 7. Rate of Child Loss per 1000 Live Births Among Women Accepting Menstrual Regulation in London, New York, Bombay, and Howrah District Clinics.

groups. In the New York study, the contraceptive acceptance increased from 67.2 per cent before MR to 89.4 per cent after the procedure. Of the acceptors, 67.3 per cent accepted either IUD's or oral contraceptives. The Bombay study also showed an increase in contraceptive use as well as a shift towards more effective methods after MR. The Howrah study was unique in that MR was the only method of fertility control available in the community (Figure 8).

B. Evaluation of the Menstrual Regulation Procedure.

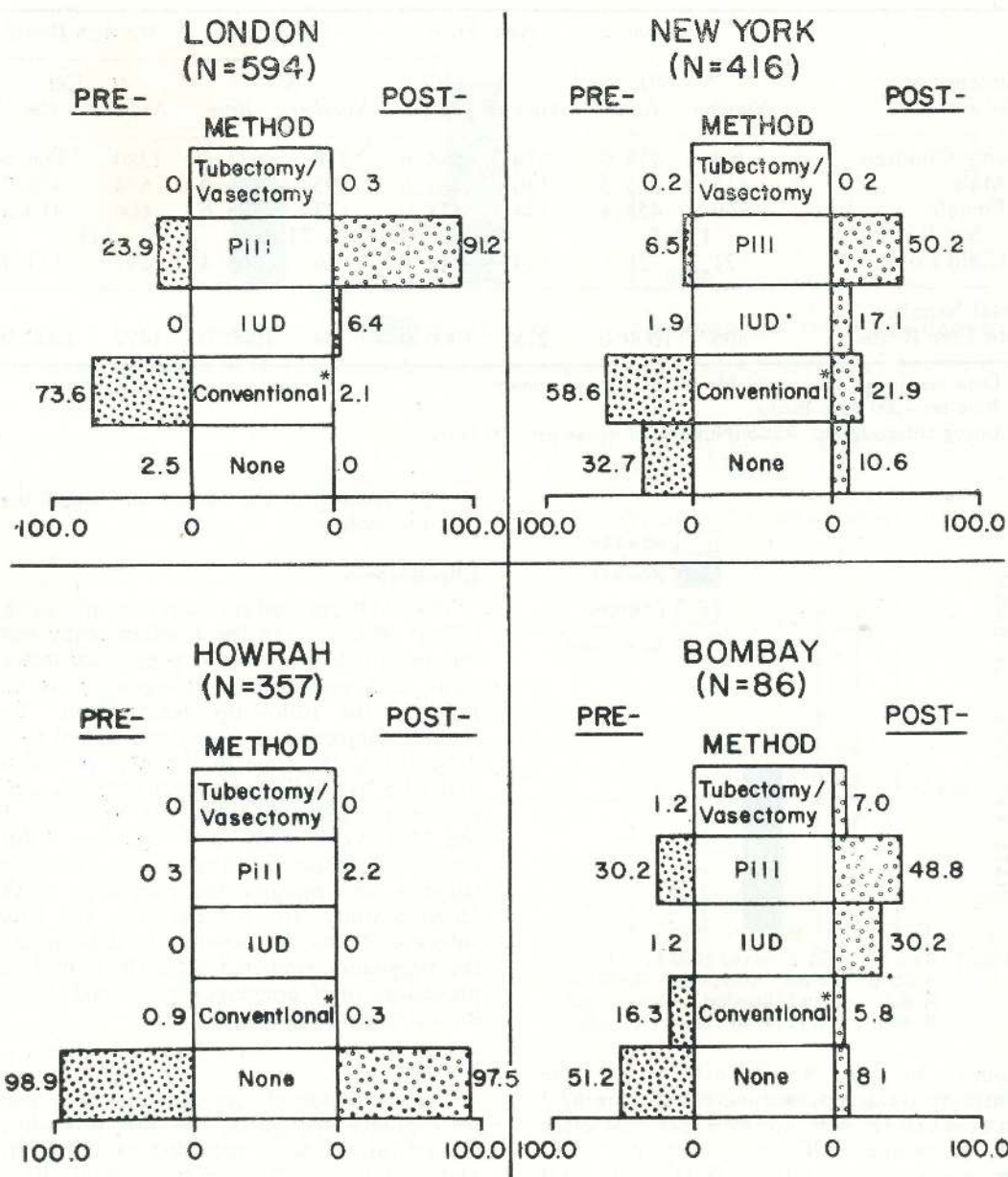
Effectiveness

The MR procedure was found to be highly effective. In the London study only one patient had a positive pregnancy test or signs and symptoms of pregnancy at the time of the follow-up examination. For the 401 subjects who were documented to be pregnant at the time of the MR procedure and who had follow-up pregnancy tests, the procedure failure rate was 0.25 per cent. In the New York study, a 2.9 per cent failure rate was reported. The failure rate for subjects with documented pregnancy in the Howrah study was 0.7 per cent; for three subjects, it was not possible to determine if the pregnancy occurred after the completed procedure or if pregnancy continued due to an incomplete procedure.*

Safety

The incidence of complications was used to evaluate the safety of the procedure. Complications were recorded as immediate and delayed. Immediate complications included those occurring from the time the procedure was initiated until the patient was discharged from the clinic; delayed complications included those occurring from the time the patient was discharged to the follow-up visit.

* If these cases were considered failures, the failure rate would be 2.9 per cent.



*Conventional = Rhythm/Withdrawal; Diaphragm/Foam/Jelly; Condom

FIG. 8. Percentage of Pre- and Post-Menstrual Regulation Contraceptive Methods Used in London, New York, Bombay, and Howrah District Clinics.

In the London study, 10 per cent of the subjects had immediate complications. Most complications (86%) resulted from the general anesthesia and the remaining were relatively minor complications that might be attributed to the procedure (Table 5). No additional hospitalization was required for any of the cases. No major complications such as uterine perforation, infection or blood loss greater than 100 ml occurred. No complications were reported in the New York study (Table 5).

In the Bombay teaching hospital, one patient had a cervical laceration (immediate complication), two had vomiting (immediate complication), three had spotting delayed complication) and one patient (developed salpingo-oophoritis. At the Bombay community clinic, one case of vomiting (immediate complication) and one of bleeding related to IUD insertion (delayed complication) were reported (Table 5).

In the Howrah series, one of the patients had a suspected uterine perforation (immediate complication) and two patients (0.6%) had prolonged bleeding requiring curettage (delayed complication). Thus, the complication rate was 0.9 per cent for the series. No surgical or technical difficulties were reported (Table 5).

The overall complication rate for 1455 subjects was 4.7 per cent with 4.3 per cent immediate and 0.5 per cent delayed complications (Table 5). In the London women, 79.0 per cent of the immediate complications were related to the use of general anesthesia. If these complications are excluded, the overall complication rate for the total group is 1.4 per cent.

Hospitalization and Procedure Time

In New York, Bombay and Howrah, MR was done as an outpatient procedure and

TABLE 5

REPORTED COMPLICATIONS AMONG WOMEN RECEIVING MENSTRUAL REGULATION IN NEW YORK¹
LONDON, BOMBAY, AND HOWRAH DISTRICT CLINICS

Reported Complications	London		Bombay		Howrah		Total	
	N=598 No. ³	%	N=97 No.	%	N=318 ² No.	%	N=1455 No.	%
Immediate								
Diarrhea	1	0.2	—	—	—	—	1	0.1
Nausea	3	0.5	—	—	—	—	3	0.2
Vomiting	4	0.7	3	3.1	—	—	7	0.5
Cervical Laceration	—	—	1	1.0	—	—	1	0.1
Suspected Uterine Perforation	—	—	—	—	1	0.3	1	0.1
Anesthesia Apnea	5 ⁴	0.8	—	—	—	—	5	0.3
Vomiting	44 ⁴	7.4	—	—	—	—	44	3.0
Total	57	9.5	4	4.1	1	0.3	62	4.3
Delayed								
Spotting/Bleeding	—	—	4	4.1	—	—	4	0.3
Bleeding (Requiring Curettage)	—	—	—	—	2	0.6	2	0.1
Pelvic Infection	—	—	1	1.0	—	—	1	0.1
Total	0	—	5	5.2	2	0.6	7	0.5
GRAND TOTAL	57	9.5	9	9.3	3	0.9	69	4.7

¹ No complications were reported among the women in the New York group (N=442).

² Complete data available only on these women.

³ Number of Women.

⁴ 99.6% of all women in the London group received general anesthetic.

hospitalization was not required for any of the women.

Procedure time was assessed from the insertion of the speculum to its removal. The mean time required for the procedure varied between 1.6 minutes and 13.2 minutes at the various clinics; the range was 1-20 minutes.

Prevalence of Pregnancy and Length of Amenorrhea in Subjects Undergoing Menstrual Regulation

The prevalence of pregnancy documented by microscopic identification of products of conception in the uterine tissue was 58.7 per cent in the total of 1257 subjects from London, New York, Bombay and Howrah. Among subjects with negative, indefinite and positive initial pregnancy tests, 47.3, 81.8 and 82.0 per cent, respectively, had definite products of conception identified (Table 6).

Table 7 and Figure 9 show the relationship between the length of amenorrhea and histologically confirmed pregnancies. It is noteworthy that 45.6 per cent of the women who were pregnant at the time of the procedure had been amenorrhoeic less than 35 days.

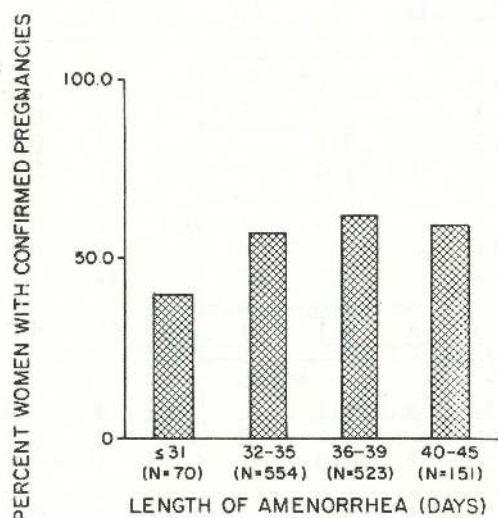


FIG. 9. Percent Confirmed Pregnancies by Length of Reported Amenorrhea Among Women Accepting Menstrual Regulation in London, New York, Bombay, and Howrah District Clinics.

More than half of the women underwent MR before 35 days amenorrhea in London and New York, while in the Bombay and Howrah series the majority of the women (over 80%) underwent MR after 35 days amenorrhea (Table 8 and Figure 10).

IV. Discussion

Menstrual regulation is the term applied to any treatment which is administered within 14 days of a missed menstrual period to ensure that a woman is not pregnant or does not remain pregnant.⁶ To evaluate this procedure, its efficacy, safety, efficiency and acceptability must be determined.

Analysis of the findings of early studies in England, U.S.A. and India show that MR is highly effective. The overall procedure failure rate from selected studies in these countries among 746 subjects with documented pregnancies was 1.5 per cent. In a study of 103 subjects in Singapore, no failures were reported.⁷ A study conducted at a free-standing, non-profit clinic at New York reported a 2.0 per cent failure rate.⁸

The safety of the procedure was evaluated by studying the complications attributed to MR. The complications reported in these studies varied considerably. The complication rate ranged from nil in the New York series to 9.6 per cent in the London series. The overall complication rate was 1.4 per cent* in 1449 subjects. In the London study, 86 per cent of the complications were anaesthesia related and the remaining 14 per cent minor (nausea, vomiting, and diarrhoea). The complications in Bombay were mostly minor (spotting and vomiting). The complication rate was 0.9 per cent in the Howrah study.⁴ In a similar study conducted in Singapore, the complication rate was 1.9 per cent.⁷

In another study in New York, an immediate complication rate of 6.4 per cent was reported; mild fainting reactions, bleeding and cramps were the only complications.⁹ A free-standing clinic in New York reported a 2.5 per cent incidence of endometritis, 20 per cent incidence of transient syncope and sweating requiring no treatment, and infrequently occurring severe abdominal cramps and bradycardia that subsided before the patients left the clinic.⁸

* Complications due to general anesthesia are not included in this rate.

TABLE 6

RESULTS OF INITIAL PREGNANCY TEST AND MICROSCOPIC EXAMINATION OF UTERINE TISSUE FOR ALL WOMEN* UNDERGOING MENSTRUAL REGULATION IN LONDON, NEW YORK, BOMBAY AND HOWRAH DISTRICT CLINICS

Initial Pregnancy Test	Histologic Evidence of Pregnancy						Total	
	No Evidence		Presumptive Evidence		Products Identified			
	No.	%	No.	%	No.	%	No.	%
Negative	294	34.9	150	17.8	398	47.3	842	100.0
Indefinite	6	2.9	32	15.3	171	81.8	209	100.0
Positive	29	14.1	8	3.9	169	82.0	206	100.0
Total	329	26.2	190	15.1	738	58.7	1257	100.0

* Women on whom complete data on relevant variables were available.

London	— N = 593	Sensitivity of test = 22.9% (169/738).
New York	— N = 353	
Bombay	— N = 40	Specificity of test = 89.4% (294/329).
Howrah	— N = 271	

TABLE 7

RESULTS OF MICROSCOPIC EXAMINATION OF UTERINE TISSUE BY LENGTH OF REPORTED AMENORRHEA AMONG WOMEN* ACCEPTING MENSTRUAL REGULATION IN LONDON, NEW YORK, BOMBAY AND HOWRAH DISTRICT CLINICS

Days of Amenorrhea	Histologic Evidence of Pregnancy							
	No Evidence		Presumptive		Products Indentified		Total	
	No.	%	No.	%	No.	%	No.	%
≤ 31	27	38.6	16	22.8	27	38.6	70	100.0
32-35	113	20.4	129	23.3	312	56.3	554	100.0
36-39	165	31.5	37	7.1	321	61.4	523	100.0
40-45	58	38.4	7	4.6	86	57.0	151	100.0
Total	363	28.0	189	14.6	746	57.4	1298	100.0

* Women on whom complete data on relevant variables were available.

TABLE 8

PERCENTAGE OF WOMEN ACCEPTING MENSTRUAL REGULATION BY REPORTED DAYS OF AMENORRHEA IN LONDON, NEW YORK, BOMBAY, AND HOWRAH DISTRICT CLINICS

Days of Amenorrhea	Per cent Women			
	London N=598	New York N=442	Bombay N=97	Howrah N=360
≤ 31	4.2	10.9	0.9	0.3
32-35	54.9	42.3	19.8	13.5
36-39	37.7	37.1	44.6	41.8
40-45	3.2	9.5	34.7	44.4
Total	100.0	99.8*	100.0	100.0

* For 0.2% of the women, days of amenorrhea was unknown.

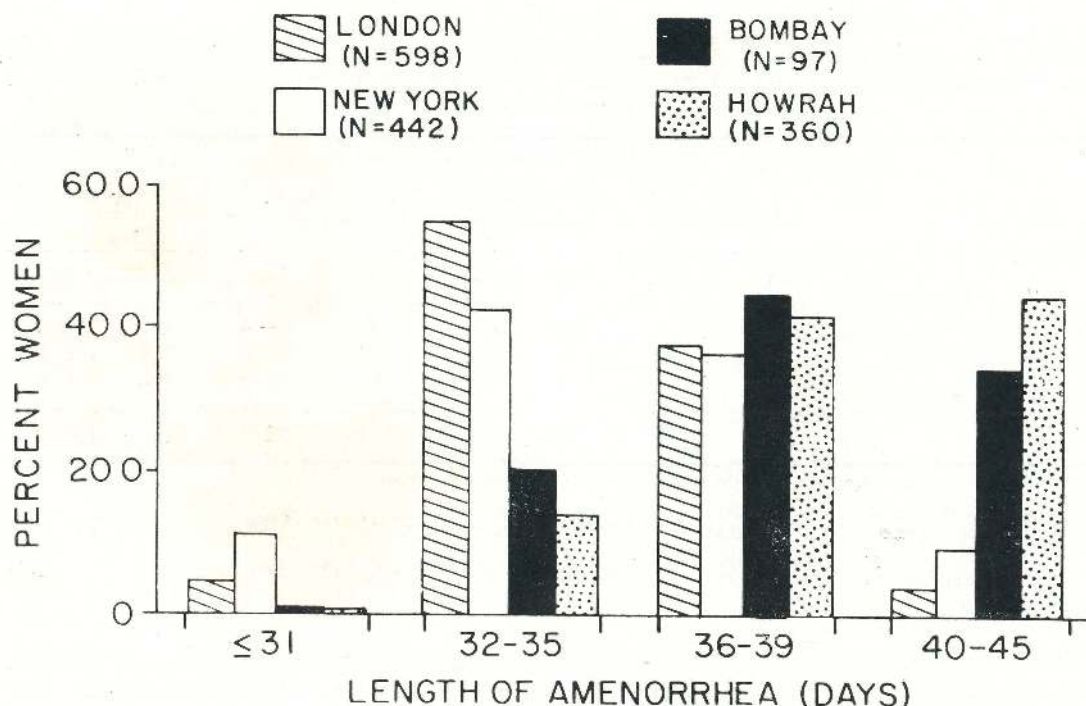


FIG. 10. Percentage of Women Accepting Menstrual Regulation by Reported Days of Amenorrhea in London, New York, Bombay, and Howrah District Clinics.

The International Fertility Research Program analyzed data on abortion from 20 hospitals in 9 countries on 4463 pregnant women and data on MR from 5 hospitals in 3 countries on 614 subjects. The efficacy and complications of MR in pregnancies less than seven weeks' gestation was compared to D & C and vacuum aspiration for pregnancies of seven weeks' gestation and over; the total complication rate for MR (1.3%) was lower than the complication rates for D & C and vacuum aspiration at any gestational age. The morbidity from abortion by suction curettage performed at 7-8 weeks' gestation was three times higher than the morbidity with MR.¹⁰

It has been suggested that MR be performed on women requesting treatment for amenorrhoea when this is the only sign of possible pregnancy. The pregnancy test is found to be unreliable until the women reach 42 days of amenorrhoea by which time the false negative rate decreases to less than 5 per cent.⁴ The incidence of pregnancy was 57.4 per cent when data from London, New York, Bombay, and Howrah were pooled. In another study where data were

pooled from five hospitals, it was estimated at 55.0 per cent.¹⁰ In a study done in Singapore, the percentage of pregnant women was 55.3.⁷

A review of the outcome of MR in several studies shows: (1) that the procedure can be performed on an outpatient basis,^{1,2,3,4,7} (2) that there is no need for hospitalization, (3) that anaesthesia is not required in a majority of the cases^{3,4,7} and (4) that MR is feasible not only in well-organized hospitals but also in community clinics with minimal facilities.^{3,4}

It is too early to accurately evaluate patient acceptance of MR since at present there are not enough facilities to provide the service to those presently requiring it. However, MR is being accepted by an increasing number of medical practitioners in the U.S.A. and other countries.⁶ In Bombay the community clinic showed greater utilization of MR services and at fewer days missed period than was shown at the teaching hospital facility.³ A four-fold increase in numbers of new MR acceptors was observed within eight months after the

Howrah Community Clinics were started; the rate of acceptance in the urban, slum, and rural clinics was similar, however, the proportion of urban acceptors was more than three times that of the slum and rural acceptors.⁴ To study acceptance, it is important to have community data. Such a study is planned in Howrah where denominator data will be available. An early finding of this study of MR acceptance shows that the service was not utilized by the eligible Muslim women from the slum and rural communities.⁴

The socio-demographic profiles of the women undergoing MR in London, New York, Bombay and Howrah showed some interesting features and differences across cultural lines. The New York women were, overall, the youngest to accept MR among the four groups; almost three-fourths of these women were nulliparous. While the median parity of women using the London clinic was nearly identical to the parity level of the women in the New York study, women in London had a significantly higher age. The women using the Howrah District clinics were at virtually the same median age level as the London group, but had markedly higher median parity (an average of 2.5 times higher), reported in each age category. The Indian women were predominantly married and Hindu, as expected, while the New York and London groups were Christian. The latter two groups had fewer married women – in London approximately one-half were married, in New York only one-fourth. The New York group had the highest levels of well educated and employed women. The women in Bombay had the least percentage of employed women, but their level of formal education was greater than that of the Howrah group.

The fertility patterns between the groups

follow along the lines expected of the more to the less developed countries. The four groups presented in this paper reflect the varying availability of family planning information and services, as well as cultural attitudes. The live birth rates were highest in the two Indian groups, lowest in New York, with London in the middle. The reverse was true for the rates of previous abortions (induced and spontaneous). This trend corresponds to the general profile of the New York women who were young, non-married, well educated and employed. However, when evaluating the outcomes of live births between the four groups, it becomes evident that the opportunity for survival of children is still better in developed countries and women in more developed countries are more willing to induce abortion. This fact continues to be considered a major contributing factor to the acceptance levels of fertility control measures. It may be suggested by the comparisons of contraceptive acceptance in London, New York, Bombay and Howrah, that post-menstrual regulation may be an effective period for recruitment of women to the use of the more reliable contraceptive measures when these are available.

V. Summary and conclusion

Results of early studies on menstrual regulation suggest that it is a simple, safe, effective, low-cost, acceptable procedure. Interesting cultural differences exist in the socio-demographic and fertility profiles of MR acceptors in London, New York, Bombay and Howrah. Post-MR contraceptive counseling appears to be an efficient means of recruitment for other fertility control measures. Large, long-term studies are needed to conclusively document the delayed effects, if any, that menstrual regulation has on menstrual patterns, infertility, prematurity and stillbirths.

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**THEME: EDUCATION OF NON MEDICAL
PERSONNEL IN A POPULATION
LIMITATION PROGRAMME**

CHAIRMAN: Dr. Helena Wright

**THEME: IMPLEMENTATION OF POPULATION
CONTROL PROGRAMME**

CHAIRMAN: Mr. M. Rajanayagam

THE HISTORY OF THE
CITY OF BOMBAY
FROM THE EARLIEST PERIODS
TO THE PRESENT

BY
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POPULATION AWARENESS IN EDUCATION

By

MRS. E. TYLER

The great need in today's world is for proper education for the use of birth control. Motivation is of prime importance. Through the excellent efforts of scientific and clinical researchers, today's physicians have a variety of good relatively safe methods to prevent conception. But the big universal problem is to spread the knowledge about these methods, as well as to awaken a sense of responsibility towards family planning that will help to ensure healthier and happier families. Whether the women are Egyptian, Indian, Mexican, European or American, when women anywhere in the world are aware that now in 1974, it is possible to intelligently control fertility, most of them are deeply interested, and eager to apply the information. There are still some whose deep religious convictions conflict with the use of certain new methods, or whose cultural morals deny them the opportunity, but more and more people today are grateful to make use of the information for family planning when they are educated properly.

To illustrate, the great variety of cultural attitudes that can exist in one big city we can take a look at Los Angeles, California. Attitudes toward illegitimacy for example can vary greatly within a relatively short geographical distance. For example, an unwanted pregnancy in Beverly Hills (where people are very affluent and mainly white Caucasians), is considered a disaster. There, illegitimacy still carries a stigma that creates deep feelings of shame. Both abortion or adoption if the baby is carried to full term, are the usual solutions. However, in East Los Angeles where the economic level is very low and the bulk of the population is black, there is no such thing as an "illegitimate child". A child is a welcome addition and no stigma is attached to its legal status. There are many areas of the city where a pregnant teenager has special esteem in the eyes of her peer group; so you can see how great a variety of attitudes still exists. Sexual experimentation for both sexes is an accepted practice in certain areas of the black and white community, while among other groups,

the Mexican-American community for example, a very marked double standard exists. A male youth is expected, in fact encouraged to develop sexual experiences whereas the "good" girls must remain virgins until marriage. As a matter of fact this philosophy is a basic concept of the puritan ethics that still permeates a great deal of the attitudes of the American people. Because of deep-rooted philosophic attitudes many young women, often college educated girls, reject the use of contraception unless they are married. They prefer to risk pregnancy rather than to admit to themselves the possibility in advance, that they might have a sexual encounter. They prefer to be "overcome by the passion of the moment" rather than be prepared. But when a pregnancy occurs, these same girls are the ones who often are the most emotionally scarred if they resort to having an abortion. However, the greatest immorality is to have an unwanted baby. The unloved or rejected children grow up to be the angry destructive people that are often dangerous members of their communities. Therefore adequate education in matters of love and sex must involve, and early in life, a deep sense of responsibility. Responsibility to one's own body, responsibility to the family, and responsibility to one's community which ultimately is responsibility to life on this earth. Just knowledge of physiology as well as education in the various methods and techniques of conception is not enough. From early childhood to maturity an on-going education for responsible living has to take place. No one is yet really taught how to become considerate lovers, and intelligent loving parents. It is a slow all providing process that must start in the home, be continued in the schools, and be included in education by the clergy and the medically trained. In fact, the responsibility for proper sex education permeates every level of our society.

The very early years, even before a child learns to understand speech they begin to learn attitudes. Mothers primarily, and

fathers, but also any handler of a young baby conveys to that child a great deal of feeling long before the child responds to words. How it is handled, the sound and tone of voice, and other subtle means of communication, tell a child about love and consideration, or anger, harshness or indifference. How the people in a family interrelate is very much a part of an infant's awareness. So whether we choose to be or not, we are all teachers of the very young, through every contact.

I have been privileged to witness different ways of teaching family planning in different countries. The family planning clinics in Hong Kong make use of an excellent film to show families in their dreadfully overcrowded communities. The story shows a contrast in life style between two young families. One a family has followed the traditional path of allowing family size to grow at will, in order to insure security for the parents when they reach old age. So we see a haggard father (about 30 years old) and a wan and sickly pregnant mother surrounded by a brood of 7 half-starved, poorly clothed children. The home is inadequate, food supply is scarce and there is no time for joy and fun in their daily struggle for bread. The other family have only two children about 2 years apart in age. They look happy. All the family is well dressed, well fed, and the home is cheerful and clean. The obvious well-being of the planned family contrasted with the sorry plight of the unplanned family is an attempt to overcome the ingrained belief that a family must have many children (especially because so many die in infancy and childhood), to be sure that a few, hopefully some sons, will grow to maturity and then be able to take care of the needs of the parents when they become old. To that end the young family suffers great hardships because of too many mouths to feed. These kinds of cultural philosophies are very difficult to combat. In large areas of the world these beliefs prevail. In India in the village where farming is the life, many hands to till the soil is the intent. So huge numbers of people sacrifice the comfort and happiness of the present, in the hope of security in the future.

But whenever I've had the opportunity to speak directly to the women—the mothers of a society, they have responded with anxiety to curtail their fecundity. I recall

an episode in a Bantu village in South Africa that was very revealing. We were being taken on a tour of the villages by the clinician who had treated these people for the past twenty years. I saw native women sitting in a group doing beautiful hand bead work. They were dressed in colourful skirts, with many necklaces and bracelets up to their elbows, as well as on their legs, but bare at the breasts. Most of them were surrounded by babies and small children of all ages. And quite a few were busy at work while infants suckled at their breasts. Occasionally an older child—some that looked 3 or 4 years old would go to an exposed breast and take a drink of milk. I asked up to what age children were permitted to nurse. The doctor informed me that the women were very permissive, and nursed the children up to age 4 or so; as long as the children didn't bite, they were allowed this activity. Then I asked him if the reason they nursed so long was because they perhaps thought that they were protected from becoming pregnant again while they were nursing mothers. He then asked them in their native language, and I was startled by the laughter it generated. I still remember their shining faces, looking at me, and all laughing very hard. They told him in effect, "Did I think they were stupid? Of course, they hoped it would prevent more babies but unfortunately, it didn't always work."

Until the time comes when a universally acceptable as well as very inexpensive and completely reliable method of contraception is developed, if ever, we will have to make use of the known methods now available. There is sufficient variety so that we can offer the so called "Cafeteria" approach in our Family Planning clinics; the women are informed as to the available methods, and can make a choice. If the doctor sees no reason to contraindicate that particular method for that individual, her choice is the method she is given. Otherwise with the doctor's guidance another method is prescribed. But the big problem is that great numbers of women in the child-bearing years do not come to seek contraceptive help. Sometimes it is total ignorance that fertility control is possible, but often it is cultural or religious inhibitions. Whatever the cause of their lack of use of contraception, proper education should motivate all women to want to have planned families so that children would always be born by choice, not chance.

THE ROLE OF PROVINCIAL AND DISTRICT ADMINISTRATORS IN POPULATION CONTROL PROGRAMMES

By

BRADMAN WEERAKOON

I propose to deal with the subject allotted to me in broadly three parts:

Firstly, I think a definition of terms is called for and I shall attempt to describe if not to define what Provincial or District Administrators, in fact, do and try to trace the relevance of their work to population control programmes.

Secondly, I shall attempt to outline the kind of role which the District Administrators could play or should play in population control programmes given the experience, skills and facilities that the Administrator possesses.

In the final part of my talk I shall describe in some detail the methods and procedures adopted in implementing a Population Control Project in an area of the Batticaloa district of which I am presently in charge as Government Agent.

2. Initially, I would like to dispose of the distinction implicit in the subject of 'Provincial' and 'District' Administrators. Although there were in the past officers who could have been described as Provincial Administrators, with the creation of 22 Districts into which Sri Lanka is now divided, most Administrators could be regarded as District Administrators. There are yet a few departments which find it convenient to group their officers in "Regions" not corresponding to the districts, but since these are mainly technical departments it would generally be true to say that one has today only District Administrators in this country. However, the main issue in a definition of terms would really not be that between the words Provincial, Regional or District but on the word *Administrators* and on what his functions are and what special role he can play in Population Control Programmes. Without spending too much time and without looking for a

text book definition, I think it is generally agreed that the distinction in functions between Administrators and Technical Personnel is quite clear. While Technical Personnel, say either a doctor or engineer would deal with a specialised area of activities and use his professional skills primarily in that area, the Administrators function is the more general one of management of men and materials and co-ordination. Administration in a very broad sense involves the techniques of mobilising people to achieve a given objective. It is now well recognised that it too has its own special skills which can be acquired but the only point which I wish to make now is that a District Administrator by virtue of his training and experience, gained while on the job, comes to possess a qualitatively different approach and skills from purely technical personnel.

3. Before I can get onto the role that a District Administrator *could* or *should* play in Population Control Programmes, the point needs to be made that in the past there has been very little that the Administrator did or has done in such Programmes. My views is that although the Administrators in developing countries could play a rather significant role in such projects they have not hitherto done so for a variety of reasons. Possibly the urgency of the problem might not have been sufficiently appreciated in some instances. Perhaps other items of national priority in some instances. Perhaps other items of national priority like self sufficiency in food, security and the maintenance of law and order might have been regarded as the primary functions of the administration. Certainly it would be true to say that until quite recently the interaction of the population problem on the other items of national priority was not seen so closely and clearly. Also quite obviously the question of the voluntary nature of family planning would have made

Government averse to throwing in the full force of the administrative apparatus of the State behind such a programme. So it was left entirely and solely to a technical department – the Department of Health to manage the programme assisted on the motivational side by voluntary organisations like the Family Planning Association.

In Sri Lanka, as has probably happened in the other developing nations too, in recent times the value of the comprehensive approach in dealing with developmental programmes has been appreciated. Along with this has come an acceptance of the idea of decentralization and the devolution of of greater responsibility and authority in dealing with local problems, to district level officials. Harmony among the decentralized parts is achieved by using the District as a base and regrouping the decentralised parts in an unity under unified control at the District level. To make the picture clearer and as an example of how it works we could take for a moment the agricultural sector in Sri Lanka.

For many years agricultural development in this country was seen as the function of the Agriculture Department assisted here and there by other technical departments, like the Irrigation and Agrarian Services Departments. But it soon became clear that the multifaceted nature of agricultural activity called for a co-ordination of the work of several departments each individually trying to reach the farmer. Moreover it was appreciated that each local area brought up its own peculiar problems. In one District it was the scarcity of land, in another shortage of water, in another lack of tillage power and so on. No blanket panacea imposed from the centre would answer adequately the special needs of the local area. And so a new organisational framework within which agricultural development was to take place was evolved, integrating the idea of decentralised decision-making and local co-ordination under the guidance of executive administrators and a political leadership.

I am not saying that this organisational framework can be borrowed lock, stock and barrel for the Family Planning Programme but I do wish to submit that certain relevant ideas can be drawn from this model in evolving a new approach to family planning

programmes in the developing world. I think at this stage it would be necessary to give somebody to the point I am making, and indicate especially for the convenience of those not familiar with the local scene, the system of decentralised administration which operates in this country. I believe a similar system of decentralised authority operates in most of the countries in Asia and Africa. In these countries which emerged into freedom after a period of colonial rule, we find usually a strong centrally controlled administration which extends to the periphery. At the peripheral points are District Secretaries manned by Government Agents in Sri Lanka, Collectors as in India and District Commissioners as in some African countries. They were the repositories of administrative power which flowed down from the centre. The Government Agent was, in fact, what the term implies, an Agent of the Government at District level, and the post came, therefore, over the years to be associated with a certain degree of influence, power and status particularly in the eyes of the local population. While it could be said that the growth of local Government institutions and elected members of Village Councils, Urban Councils and Municipal Councils did little to diminish the authority of the Government Agent as Head of the District Administration, the growing influence and power of the Members of Parliament in their electorates has certainly added another dimension to the power structure in the District. However, the main point I am trying to make here is that as a result of tradition which gives the post status, and the functions which have been devolved from time to time on the chief Administrator, a somewhat special position is held by the Government Agent of a District. The Government Agent as I said before is an agent for most of the central Government ministries, except the purely technical ones like Health, Irrigation & Power and Education. As a District Administrator the Government Agent and his staff handle such items as the custody of crown land and its development, the control, supply and distribution of food items, social service work, development of small industries, production of food, rural development, licensing and the collection of revenue. The work of the District Administrator therefore necessitate a thorough knowledge and understanding not

only of the physical background of the District but the attitudes, the hopes and fears and indeed the living culture of the various groups that inhabit it. In fact the first task of the new recruit to the District administration is to move round and get to know the people and areas and this is true of all levels of District officialdom.

4. I hope I have not strayed too much away from the main point I am trying to make which is that the powers and functions that the District Administration possesses might be employed purposefully and fruitfully in Family Planning Programmes. If we look for a moment at the facilities available to the District Administrator to achieve his objective of management and co-ordination we find that he has a whole range of officers reaching down to the village level. These officials exert a great influence on the lives of the people they meet by the various powers they possess, and functions they perform. The first level of officers directly under the Government Agent are the Divisional Revenue Officers who are in charge of smaller areas termed divisions within the same District and act as his assistants in pushing through a programme of work. Generally a District would have from eight to fifteen divisions each incharge of a Divisional Revenue Officer. Below the Divisional Revenue Officers and linked in similar manner to him are the village level officers termed the Grama Sevaks. Each D.R.O.'s division would have from twelve to twenty-five Grama Sevaks. Each Grama Sevaka's area would consist of one or more villages depending on their size and population. The Grama Sevaka deals with the 500 odd families in his area on a variety of subjects. The Grama Sevaka is often the law enforcement officer whom the local man first contacts. The ration book which is a very important document for every individual in Sri Lanka is issued, amended or surrendered through the Grama Sevaka. On a dispute regarding land the Grama Sevaka's report would be vital. An application for a gun, for relief of distress, or virtually for every request of the individual the Grama Sevaka's report would be important. Even a ceremony in the village becomes a matter in which the Grama Sevaka is involved and it would generally be true to say that any individual's first point of contact with the State is through this functionary. Even in his unofficial

capacity the Grama Sevaka has recognition and is usually on the committee of every village level organisation of which there are several in the typical Sri Lanka village. The Rural Development Society, the Young Farmers club, the Temple Committee, the Death Donation Society, Community Centre, library and even Cultivation Committee and the local co-operative branch would feel his weight. In colonial times, this functionary had the title of *Village Headman*. Now as befits the times he is the "Village Worker". It was said of the older Village Headman that he was the type of person who could collect 50 men in five minutes to get a job of work done. What emerges from this description of his role is that by virtue of his power and influence the Grama Sevaka can be a most potent motivator of any programme that the Government would wish to launch. In fact, it is by virtue of this influence that the Grama Sevaks, the D.R.O. and the Government Agent in differing degrees possess, that programmes like the voluntary repair of anicuts and irrigation channels which involve the mobilization of large number of rural people are chiefly done. My point is that such officers who are in constant touch with people could have a very useful role to play in moving the people to think in terms of family planning.

5. I now come to the final part of my paper which is a description of a recent exercise in mobilizing the resources of the District Administration and non-medical personnel in the community in a Family Planning Programme.

6. The basic objective of the project was to do an intensive motivational campaign in a selected area of the District using as agents volunteers chosen from the locality. For various reasons particularly that of the availability of specialised facilities like General Hospital and Family Planning Clinics the area chosen was that of the Municipality of Batticaloa and the Town Council area of Kattankudy, a town about four miles away from Batticaloa. While Batticaloa District itself has an area of almost 1000 sq. miles, it has a population of 260,000 (1971) with 52% being under 18 years of age. Kattankudy is almost totally Muslim in race and has the highest density of population per square mile in the country. The Municipality of Batticaloa which has a

Tamil majority is divided into seven Grama Sevaka's areas and the Kattankudy Town Council area into five areas. The total population of the Batticaloa Municipality area is 36,564 and the population within the Grama Sevakas areas varies from 8000 in the biggest to 3000 in the smallest. The Kattankudy Town Council area has a population of 18,839 persons. The Project Area therefore in total comprised of 55,503 persons. The objective of the project was to motivate all eligible married couples within the area to seek the services which are available in the area under the Department of Health. It also sought as general objectives -

- (a) the creation of positive public opinion about Family Planning;
- (b) the winning of leadership support for the Family Programme;
- and (c) reinforcing and sustaining the motivation of Family Planning Acceptors.

Eligible couples were defined as all married couples in which the female partner was less than 50 years of age. Even couples who were beginning to raise a family as indeed those who as yet had no children thus come within the target group. The procedures to be adopted in meeting the general objective were to be as follows:

Firstly, within each Grama Sevaka's Division the married couples considered eligible for the purpose of the Project would have to be selected. Secondly, these married couples would need to be contacted in their homes by suitably selected motivators who would provide the married couples with basic information as to the Services available in the project area. The final stage of the project would be assisting those who showed willingness to accept Family Planning to actually receive these Services. It became necessary to clearly define the area of action of the project, since there was no intention to take over or intrude upon the functional area of activity of the Department of Health. Initially in working out the objectives and the procedures, a strong District Committee was formed, which represented as far as possible all shades of official and unofficial opinion within the project area. The District Committee

contained in addition to the Government Agent as the Chairman, the Superintendent of Health Services, the Medical Officer of Health, the Obstetrician and the Gynaecologist of the Hospital, the Surgeon, the Divisional Revenue Officer, the Commissioner of the Batticaloa Municipality and the Director of Education of the District. On the non governmental side were representatives from the Young Men's Christian Association, the Young Men's Hindu Association, the Young Men's Muslim Association, the Young Men's Buddhist Association, the Rotary Club, the Ladies' Club and the local Girl Guide Association.

7. It was at the first stage of the project, namely, the selection of the eligible couples, that the utility of bringing in the District Administration into a programme of this kind was first seen. In normal circumstances getting this information would have needed a census type survey. Particularly in an unofficially handled project a great deal of time and money would have been spent on a house to house survey which may not, in fact, have yielded completely accurate information. However, by the involvement of the District Staff it was possible to cover this part of the project in a very short period of time with minimum expenditure of money. It was decided to obtain the basic information about each family through an existing Government form, called the householders list. This is a basic document which is available in every D.R.O.'s office which contains information on each individual living in the division broken up by Grama Sevaka's areas and streets. The information in the householders list consists of the full name of the persons who are usually resident in the house other than visitors, sex, age, race, citizenship, occupation and relationship to the chief occupant. Since the information has to be supplied in terms of the Food Control Act and the furnishing of false information is an offence punishable by law, this can be taken as a true and accurate record. However, there was a major problem to be solved before the information contained in the householders list could be so used. In terms of the regulations made by the Minister in charge of Food the information contained in the householders list could not be disclosed to any person other than the person to whom such information

related, or made use of for any other purpose except a food control purpose. However, there is a saving clause in the regulations which permits the Minister to allow such information being used for such other purposes as may be determined by the Minister. Permission was therefore, sought from the Minister in charge of the subject, and in view of the fact that population control was an accepted policy of Government, the required permission was granted. This immediately meant that a major part of the exercise of collecting the basic information through a census was rendered unnecessary. Since the householders lists themselves have to be retained at the D.R.O.'s Office, it was decided to transport such information as was necessary from the lists to a simple card which was devised for each family. This family card contained the names of family members, their age, occupation, ethnic group and religion and also a knowledge attitudes and practice questionnaire. The questions seek to find out from the couples their present attitudes to family planning, their state of knowledge about methods and techniques and specifically inquire whether they would like to have more information and advice.

8. Once the primary problem of obtaining data on the families had been settled, the major question was that of selecting the interviewers or motivators. The District Committee decided that this crucial business of information and education could not be handled by paid staff but should be made the responsibility of voluntary social workers of whom there appeared to be no dearth in the project area. The problem was how to get such persons to come forward to help in the project. Here we used the power and influence factors of District Administration officials referred to in the earlier part of my paper. Through the Divisional Revenue Officer and the Grama Sevaka, prominent citizens in the area who possessed the qualifications we had in mind were contacted and inquiries were made of them as to whether they would be willing to serve in the project. In the first Grama Sevaka's area which was taken up, our initial inquiries elicited 80 volunteers who indicated that they would be prepared to help. The general criteria for the volunteers was that they be married persons generally above the age of 45, and if possible, personnel

who are holding or have had at one time held responsible positions. The age, religion and occupation breakdown of the 40 volunteers finally selected in the first Grama Sevaka's area revealed the following:

1. Age-Average age	49.5
2. Religion - Hindus	37%
Catholics	33%
Christians	25%
Muslims	5%
3. Occupation -	
i. Presently working in Govt. or business	50%
ii. Retired personnel	36%
iii. Housewives	14%

They should have the leisure to engage themselves in a round of home visits. The 80 volunteers for the first Grama Sevaka's area were invited for a two-day seminar/training course to be briefed about the project and their role in it. The two day (weekend) seminar consisted of lectures by medical and lay officials, group discussions and 2 film shows. Since the volunteers lived closeby residential facilities were not necessary. However the faculty members mostly members of the District Committee joined the volunteers at meals. The lecturers dealt with the problem in the national perspective, its relation to the health of the family and individual, the role of the Government and the F.P.A., Family Planning methods and vasectomy, resistance to the family planning interviewing techniques and the processes of communication. Sixty persons attended the seminar and finally 40 volunteers were chosen for field work in the first Grama Sevaka's area. In general about three volunteers lived on each of the major streets in the area. This meant that the volunteers were likely to be well-known being persons of standing and long residence in the area. Since the total number of eligible couples in the Puliyantivu Grama Sevaka's division worked out to 418 each volunteer was responsible only for about 10 home visits. The volunteers were given one month's time in which to make their home visits. A further inservice training seminar of one day was held part of the

way through the month, so that difficulties encountered in the home visits could be ironed out.

The inservice seminar disclosed that the volunteers had in general had a favourable response from the homes that they had visited. The female volunteers had interviewed the female partners and the male volunteers the males. No instances were reported of refusal to accept the volunteers. Several volunteers stated that they had been asked whether pills could be supplied by them directly to the homes. The District committee had earlier decided that volunteers should not be used for this purpose, and it was therefore held that all such requests should be referred to the medical personnel in the field. Some couples had wanted to know whether medically trained personnel could talk to them at their homes particularly if they organised themselves into small groups. The following decisions were arrived at the inservice seminar:

- (a) The Family Health Centre recently established at the Batticaloa Hospital to be opened daily and the sale of pills and condoms to be made possible at the centre itself;
- (b) The volunteers to be given cyclostyled forms which would enable them to refer persons who wish to have pills or loops inserted to the Consultant Obstetrician and Gynaecologist at the Hospital. The Consultant Obstetrician and Gynaecologist is a member of the District Committee;
- (c) The volunteers to organise into small groups, couples or individuals who wish to have more detailed instructions, and arrangements to be made for medical and para-medical personnel to meet such groups in their homes.

Other than the meals supplied to the volunteers during the training seminar and stationery provided, no other expenditure was incurred on this part of the programme. The volunteers, in fact, rejected a proposal that they be paid an out of pocket allowance, and most of them accepted their work as being social service to the community. Since no travelling was involved and most of the homes were within easy reach by

foot, the volunteers did not have difficulty in fulfilling their targets. On a suggestion made by the volunteers themselves, the project was termed a Family Health Project rather than a Family Planning Project. The volunteers thought that this would provide them easier access into the home as they could then talk of health in general before coming to family planning in particular. The volunteers are also given a signed identity card by the Government Agent and the home visits are preceded by a general information letter to each family indicating that the house-hold has been especially selected for a project on family health. In addition, before the volunteers begin their home visits the Grama Sevaka's area in question is "prepared" by the screening of suitable films and spot announcements in different parts of the area. Publicity regarding the project and the important part being played by the volunteers was given in the national press, particularly in the Tamil medium newspapers. Groups of 50 to 75 people attended the film shows which were held at important junctions and in school premises within the Grama Sevaka's area. The films were supplied by the Family Planning Association of Sri Lanka.

The completed family cards are brought into the project office located at the Kachcheri by the volunteers or picked up by the Project Officer and the intensive follow-up with the responding couples is attended to by a small corps of paid workers who will supplement the work of the Health Department personnel. As soon as field work in one Grama Sevaka's division is over (i.e. in one month) the focus of activity shifts to the next area and so on until in a period of 12 months the entire project area is covered. This means in fact that while the volunteers of the first Grama Sevaka area are busy in the field, the selection of volunteers for the 2nd area and their training gets under way. It is important to note that the training is done in a selected location within that area and the volunteers work is limited to that area. By this the inconvenience to the volunteers is kept at a minimum. The Project Officer who is supplied with transport generally contacts the volunteers in his own home and keeps up a very close contact within him until the volunteers' duty is done. On the basis of approximately 40 volunteers per Grama Sevaka area, and 12

Grama Sevakas areas to be covered we estimate that almost 500 persons would have finally received fairly intensive knowledge about family planning in the whole project area during the 12 month period. These could be regarded as the "core" workers who would be helping in advising the contacts they have made down their streets, even after their particular interviewing role was over.

At the head of the project organisational set-up is the District Committee which has the overall responsibility for the execution of the programme. A retired Health Educator of the Department of Health who had worked in the area for several years was chosen as Project Officer. The Project Office itself is located in the Kachcheri which enables easy contact between the Government Agent and the Project Officer. It also gives a certain status to the Project itself. No finances are provided by the Government for the project and the funds for the Project have come out of an initial grant of Rs. 5,000/- from the Family Planning Association of Sri Lanka. These monies are held in deposit in the Kachcheri and are drawn as and when required. The expenditure of funds are for printing and stationery, the training of volunteers, operational expenses of film van and other incidentals like hire of halls for meetings and film shows. The salary of the Project Officer and driver cum-operator are met by the Family Planning Association.

9. This description of the role which the District Administration could play in Family Planning Programmes would be incomplete without a reference to the progress control function which is implicit, when the specialised activities of a Department become the subject of attention of a body of non-technical personnel. There is at least the taking of a new look at what is being done, if not an examination of the basic purposes of the whole exercise of Family Planning. Certainly in Batticaloa the examination of the work performed by the existing Health Services in the Family Planning area suggested new departures in strategy. The technical personnel, administrators and general public representatives on the District Committee area are in full agreement that the immediate problem as far as the Batticaloa District was concerned

was not so much the strengthening of service facilities but the linking up of people with the existing facilities. Strengthening of the facilities both equipment and personnel-wise was of course important, but these would remain unused until people were induced to move towards them.

The present statistics of levels of acceptance indicate the enormity of the task that lies ahead. In the 3 month period October, November, December (1973), when one takes the whole Project area of Batticaloa Municipality and Kattankudy, clinical and field services together achieved only the following monthly average figures as regards the use of facilities:

- (a) Condoms issued: 366 with 3 new acceptors per month.
- (b) Orals issued (pill packets): 108 with 10 new acceptors per month.
- (c) Loops inserted: 6 per month.
- (d) Sterilisation done – Tubectomies – 52 per month.

Vasectomies – Nil for the 3 month period.

It should be mentioned that the figures for tubectomies should be related not to the project area alone but to the two Districts of Batticaloa and the adjoining one of Amparai for which the General Hospital Batticaloa serves as a service centre. Condoms and orals are also available in the open market but since prices there are much higher the quantity sold through the market cannot be appreciably higher than the figure issued through the clinics and field staff. The figures above relate to services within the project area given in 3 clinics operating once a week, and the work of field staff like Public Health Inspectors and Midwives.

Measure these modest figures quoted above against our National Programme goals and are soon seen how necessary it is to mobilise total resources if the problem is to be tackled. To reduce the crude birth rate to 25 per thousand by 1975 it is said that 45% of the eligible couples (i.e. 2882 in the Batticaloa project alone) must practise

family planning; 2/3rd of this number (1921) should receive services at Health Department clinics; and the remaining third (961) should practice methods not requiring clinical services. The Batticaloa project aims at setting targets for new acceptors at the Government Clinics. It will estimate how many loops will be inserted, how many women will begin using the pill, how many couples will use other methods, and how many men and women will volunteer to be

sterilised. The task is of much a magnitude that the personnel of the Department of Health could not by themselves handle it. Drawing on the assistance of the District Administration and the skills and experience it possesses especially in mobilising local people would therefore appear to commend itself for general acceptance not only in Sri Lanka but elsewhere as well where the problem of population control has become one of the first national priorities.

CULTURAL FACTORS IN THE IMPLEMENTATION OF POPULATION CONTROL

By

RANJITH SENARATNE

By way of clearing the ground I must first make a few comments on the title of my talk. I take it that cultural factors are regarded as obstructive rather than otherwise. But I hope that this does not imply that the factors encountered by programmes of population control are in any vital sense different from those which are the experience of other schemes of initiated change. The title also seems to suggest that cultural factors are skittles to be knocked down. I hope that this is not what was intended and that this is merely my misreading of the title.

What I say is based on my experience in this country. I offer no regional perspective. Yet the central point which I shall endeavour to make is, I believe, equally true of other countries which share our general characteristics.

I do hope that the time allotted to this topic is no indication of the importance which this Conference attaches to it. Indeed I am tempted to ask which other factors are more important in the design of a programme of population control. It is clear from those studies which deal with culture and society that in every community, however rudimentary its technology may be, however simple its economic form, that there are elaborate procedures through which the connection between population and resources is controlled. Admittedly, such societies in attempting to ensure their stability and continuity place an emphasis on this connection which is somewhat different from our own—an emphasis on the expansion of population. This emphasis is often in conflict with the interests of the wider group, the nation, of which those small scale communities are a part. Yet if this emphasis is to be changed the obvious starting point is the examination of the complex from which it emerges.

For this reason I am unhappy with the term 'cultural factors'. If we are to confine ourselves to these, if we do not go beyond them, there is a danger that the real issues will escape us altogether. I could of course describe to you those aspects which are popularly described as cultural factors in this context. Children and fertility are extolled in folk mythology as well as in the classical literature. Among the Sinhala people children are referred to as 'Sampath'—fortune or wealth. The pumpkin vine, it is said can easily take the weight of all the fruit that it bears. The barren woman is an object of scorn, even derision, not merely in concept but also in institutional behaviour. The man without relatives is to be pitied.

A much longer catalogue could be given. There is a whole set of concepts which centre on kinship and which define the proper attitudes of particular roles. There is the value of people in relation to land and agriculture. There is the importance of caste supremacy. And arising out of these concepts there is a set of new ideas which attempt to counter the new influences of population control. As an example, artificial methods of control are regarded as injurious to health.

But will a full enumeration of these concepts and attitudes reveal to us the mechanics of the situation with which we have to deal? Can they be fairly regarded as the reasons for resistance? Will education and explanation be sufficient to demonstrate error and implication and so to transform behaviour? By and large the answer to all these questions is in the negative. This set of ideas, concepts and values are symptoms or manifestations of much deeper and more fundamental social arrangements. They are the form in which those deeper forces are dressed, the cultural expression

of structural features: or to change the metaphor, they are the tip of the iceberg.

From here on therefore I take the term 'cultural' not in its narrow but in its wider, inclusive, anthropological sense – almost as the equivalent of 'socio-cultural'. But even if I enlarge my subject in this fashion I have to restrict it in another sense for lack of time. I cannot even mention many of the more important constituents of the problem and I shall confine myself to what appears to me to be the central issue.

In the opening paragraph of one of Jane Austen's novels a family of ten healthy children is referred to as a fine family, echoing no doubt the sentiments prevalent at that time. A century later a family of this number of children in England would probably not have been regarded as such but yet Dr. Stopes encountered much opposition in her endeavours. Today, to those living in that country the ideas of Jane Austen's time concerning family size, must appear strange and even Dr. Stopes battle must seem remote and unreal.

I would like to use this as the background against which to identify three elements which are important for our present discussion. If we consider any particular area of activity there is a prescribed behaviour, there is an attitude which is the background or the logic of that behaviour and there is a wider system of values from which this attitude derives. Therefore, if we attempt to promote a certain term of behaviour and if we experience opposition in doing so, we have to go two steps back and look at the relevant attitude as well as at the conflicts with the general system of values which the proposed behaviour will involve. Now it is these values, attitudes, behaviours elaborated further as concepts and norms which we recognize as culture. We can take the value system as fundamental because it is to this that we are ultimately referring prescribed behaviour. There is a point about the value system which we have to note. In reasonably integrated, homogeneous, small scale societies, its value system is also an integrated harmonious whole. It does not, generally speaking, hold sharp contradictions in delicate balance. In such situations it is likely that norms of family unity will receive continuous and

consistent stress. It is unlikely that along with this there will be a highly individualistic economic ethic. This is not to say that individual behaviour will always conform, but that the broad range of behaviour is in accordance with these norms. At this stage then we might note two points of importance.

1. To what extent are family planning programmes in conflict with the systems of values of the different sectors of this country – the different ethnic groups, rural sector, urban sector and so on.
2. The second point is that any scheme of family planning affects that area with which much of the system of values of a small scale community is concerned – the area of kinship. In such communities kinship is not merely a bio-social fact, but also the framework within which much economic and political activity takes place.

It is to be clearly appreciated then that a family planning scheme posits its new norms for this vital area of social life.

Let me now get back to the system of values and to a simple construct of which it is one element. If I have so far regarded the system of values as being fundamental in relation to behaviour I would now like to suggest that it is one of three elements which are fundamental to the understanding of the dynamics of any community. The other two are the complex of resources and the system of relationships. To my mind these are the three essential elements in terms of which we have to understand change and developmental activity. It is particularly important to look at all these elements when we consider a subject like population because increases are large or small depending on the corresponding increase in resources. So what is the relationship between these elements that I am suggesting?

Every community has available to it a certain set of resources. In some cases these are limited entirely to its geographical boundary, i.e. it is a self-sufficient community. It neither buys nor sells outside. In most instances however, this is not so. It has trading and employment opportunities outside its own boundaries to exploit

which it must produce services and goods within. The pattern of this varies from place to place, from area to area, with the result that each complex of resources produces a characteristic system of relationship. In certain parts of this country the relationship between landlord and agricultural worker or tenant is the significant one in the system of formalised relationships. In other parts this is a non-existent relationship. In these latter cases relationships between neighbours on the basis of equality of income, of educational level, of social status – this may be the dominant type. Now broadly speaking, a system of values is a reflection of the complex of resources and the system of relationships which it generates. And since we have already linked up this system of values with attitudes and behaviours we are now in a position to see that there are five important elements in the framework which we are now attempting to establish. To recapitulate there is a complex of resources which generates a system of relationships, which give rise to a system of values out of which issues an attitude which governs behaviour.

The question before us is why certain areas are receptive to family planning programmes while the trend in others is one of rejection. And if we go further, we can also ask the question why there are differences between sectors within the same area. There is much to say in answer to this question beginning with the five elements which I have mentioned and bringing in other related variables, the problems of regional specificity and so forth. I would have liked to do this particularly as I have had the opportunity recently of directing a study in 10 different areas of this country. I have however, to content myself with a few brief comments.

The fundamental consideration here is the nature of the complex of resources. When a high percentage of the income of a particular area is external in its origin

when it is urban-based, when the influx of cash is the result of services sold to urban and provincial centres the acceptance of the idea of family planning is usually greater. The prescribed behaviour is different and the attitudes are different because the value systems have altered. This reflects a new system of relationships which is a result of access to new resources. People who enjoy external incomes, which are generally higher than village incomes, do not need kinsmen and neighbours in the way that others do. They can afford to pay for the services that they require. In such situations, activists and field officers do not have to fight cultural factors in quite the way that they might otherwise have to. People no longer look askance at barren women, and children have ceased to be 'Sampath'.

In the other type of situation, exchange of services, links of reciprocity have to take the place of the purchase of services. Kinsmen are important, i.e. people are important. It is not surprising therefore, that the value system reflects this pattern of relationships and determines the attitude of rejection.

I need hardly point out that research which explores this line of thinking is still in its nascent stage – and not merely in this country – despite the vast amounts of money which have poured into the study of population. Much more empirical research sensibly analytical rather than merely quantitative has to be done as the basis both for the evaluation of present programmes as well as for evolving sound and defensible policies. After such a statement it would seem premature to suggest any line of action. But it seems fairly clear that there are many parts of this country in which family planning programmes have little chance of success given, on one hand the present complex of resources and on the other, the weapons at the disposal of the initiating agencies.

PARAMEDICAL TRAINING OF NURSE-MIDWIVES FOR FAMILY PLANNING IN NEW YORK CITY

By

W. B. ROGER BEASLEY

I take this opportunity to express my sincere thanks to the Family Planning Association of Sri Lanka for the honor of being invited to attend this distinguished Scientific Congress, and to the Pathfinder Fund which made it possible for me to have the privilege of participating in these discussions. I am grateful to each member of the Family Planning Association, its staff and its committees, for the gracious attention they have given to my physical comforts during these sessions, as well as to the intellectual stimulation which has been provided.

The plenary sessions of this Congress have been addressed to the technical problems of contraception and have focused on intrauterine devices, abortions, sterilizations, and hormonal contraceptives. The medical aspects of family planning are receiving meticulous attention and it is very important to have good tools.

But it is also important that the good tools be made available. The delivery of these contraceptive services to the people who need them is an aspect of family planning deserving equally great attention. How do we provide each woman with an IUD or with pills, or injections, or whatever she is willing to use? What source of manpower provides these services? And where are they to be provided?

The first response is almost automatic: the doctors will provide the contraceptive clinical services and they will be available in the outdoor clinics and hospitals.

Our experience in the City of New York is that we do not have enough doctors to meet the demand. The State University of New York at its Downstate Medical Centre is able to provide contraceptive services to 8,000 new patients annually only because it has a staff of nurse-midwives trained to

do so. It is able to provide follow-up contraceptive care to over 11,000 patients annually because nurse-midwives are trained to do so. The Department of Obstetrics and Gynaecology of this Medical Faculty cannot provide enough physicians to attend these 500 patient visits each week. In order to meet the demand, this department has provided special training in contraceptive services to its nurse-midwifery staff, and has turned the responsibility for these services over to the midwives, while the obstetricians continue to provide direction and consultation for problem cases. This use of nurse-midwives in this large metropolitan medical centre has freed the doctors for more difficult work and seems to assure good family planning care to the women of the area.

In his address, on Monday, Sir John Peel pointed out that, "family planning programs require more than doctor-based services in developing countries with large rural populations". Those areas must utilize a different approach, a different, health manpower.

World-wide experience indicates that physicians trained in modern scientific medicine are reluctant to work in rural areas. Doctors are trained to utilize sophisticated diagnostic equipment, to work with an extensive hospital staff, and they expect to be able to have frequent consultations with other doctors. None of these expectations can be met in rural areas. Rural health services, rural health centres, are notorious for not having a physician available and therefore rural health services depend on nurses, on professional midwives, and other paramedical personnel.

Nurses will accept these difficult rural problems and the courage and skill with which nurses manage in rural areas deserves increasing medical support as well as respect.

Rural health services are so planned that nurse-midwives alone are responsible for normal prenatal, delivery and post partal care, and they are expected to refer the abnormal cases to the physician. Our experience in New York indicated that normal contraceptive services can be provided by nurse-midwives with special training, and again, that abnormalities or problems can be appropriately managed either by the use of standing orders or by referral to the physician.

This presentation is an attempt to describe the Downstate New York training programme for nurse-midwives and an invitation to my fellow physicians and professors to consider its potential and possible application in their own Department of Obstetrics and Gynaecology.

The Downstate Medical Centre is responsible for over 6,000 deliveries a year as well as approximately 7,000 induced abortions a year. The abortions obviously must be cared for by the medical staff. However, the nurse-midwives provide 66% of the prenatal care and 40% of the deliveries of those 6,000 women who constitute the normal obstetrical case load. And the nurse-midwives provide post-abortion and post-partum care, including family planning, to more than 90% of those women who return to clinic.

These clinical services are utilized for the training of approximately 40 American nurse-midwives a year in addition to the medical students and residents. This Department of Obstetrics and Gynaecology has long been aware of medical manpower problems in other areas and for the past 6 years has accepted a total of 170 midwives from other countries for training in family planning; these have included 68 from Asia, 43 from Africa, 18 from South America, 7 from Europe (who were actually W.H.O. staff trainees) and 34 from North American countries.

The aims of the Downstate Training Program have been clearly identified. The primary goal is to train nurse-midwives and physician-midwife teams to manage family planning clinics. To accomplish this the trainees must learn a variety of skills including:

1. The motivation of patients.
2. The provision of all types of non-surgical contraceptive services; this includes oral contraceptives; the fitting of vaginal diaphragms, the insertion and removal of IUD's, and the traditional methods.
3. The diagnosis and management of minor gynaecological problems associated with contraception.
4. The appropriate referral of persons who desire sterilization as well as those who have problems of infertility.
5. Counselling and dealing with minor psychological problems associated with contraception.

The second goal of this program is to provide training and to be a reference source for nurse-midwives and physician-midwife teams wishing to plan and establish either service projects or clinical training programs in family planning.

Student selection

There are three requirements for admission to this training program.

1. The applicant must be a midwife; that is, she must be certified as a midwife in her own country. This requirement is open to interpretation; many countries do not have midwifery training programmes as such, but provide some kind of obstetrical training during nursing education. Various combinations of training experience can be acceptable. Some candidates are university graduates with ill-defined midwifery training; others are well-trained professional midwives with no nursing education, and many have a combination of nursing education plus midwifery education. Trainees progress in training at different rates, but by the end of the program, all achieve a similar level of competence. The motivation of the individual trainee rather than previous education seems to have the greater effect on the level of competence which is attained.

2. A trainee must be fluent in English, French, or Spanish. Since there are large numbers of patients at Downstate from each of these language groups, French and Spanish speaking trainees have the

opportunity to deal with patients using their own language, an essential in clinical training.

3. The applicant must be affiliated with a health service which will allow her to utilize the new skill and knowledge which she will acquire at this program. A follow-up survey on the graduates of this program indicated that no more than 50% of the trainees have ultimately become involved in family planning in a manner similar to the nurse-midwives on the staff at Downstate. This is not the result of an inadequate commitment on the part of the trainees, but a hesitance on the part of physicians and health services to use fully the skills of nurse-midwives. Ideally, both the applicant and the health service in which she will work, should be interviewed before the trainee is accepted; obviously this is not practical when applications are received from all over the world. However, teams of physicians and midwives are encouraged to apply for concomitant training. This enables the physician to see the kind of work the midwife can do, and allows the physician and midwife to work together, modifying their traditional relationship into that of colleagues.

Every effort is made to accept applicants in groups on an institutional or organizational basis which may lead to the establishment of a local training program. For example we have at present 7 trainees from the Ministry of Health of the Philippine Government. In the last class there were 3 staff members from the Fabella Hospital in Manila.

This training program has been organized into courses which are three months long; courses are offered three times a year and begin in June, September, and March. No more than sixteen trainees are accepted in any one class, so that the ratio of students to faculty does not exceed 2 to 1. When a 1 to 1 ratio has been maintained, trainees have made rapid progress and reached a high level of competence because of the opportunity to work with a greater number of patients and to have a closer working relationship with the instructor.

Faculty

The Administrative and Faculty responsibilities are carried out by the eight staff

nurse-midwives who have special training in family planning. The nurse-midwife who directs the educational aspects of the program selects trainees, schedules classes, seminars, and field trips, and arranges the final evaluation of each trainee. Clinical services are coordinated by a second nurse-midwife who regulates patient flow in the clinical teaching areas as well as the staffing for clinical tutoring. A third nurse-midwife assumes the responsibility for daily visits to the abortion wards. She helps to motivate women to use contraception, provides contraceptive supplies and instructions, and encourages women who have just undergone abortion to have their follow-up examinations. Two midwives who are particularly fluent in French and Spanish assume chief responsibility for patients from Haiti and Latin America and work with French and Spanish speaking trainees. The time-consuming work of reviewing charts and laboratory reports preparatory to large clinic sessions is shared by all.

Each of the nurse-midwives acts as a clinical instructor and teaches the techniques for patient interviewing, breast and pelvic examination, basic laboratory diagnostic procedures, and IUD insertions. The diagnosis and treatment of specific vaginal and pelvic infections is taught by the nurse-midwifery staff with medical consultation available when needed. The personal concern and dedication of each of these nurse-midwives is thought to be the most significant factor in the success of this program.

Medical staff is provided by members of the Department of Obstetrics and Gynecology at Downstate. Two full-time physicians, (one obstetrician and one public-health) are available to provide clinical consultation to the midwives as additional lecturers for classroom teaching. Other faculty members who have specific interests in demography, sexuality, infertility, or genetics are regularly called upon for special seminars. Selected areas of Paediatrics are presented by the faculty of that department.

Content of curriculum. Table 1

As previously stated, the primary goal of this program is to teach the management of family planning clinics, including the motivation of patients, the provision of all types

of contraceptive services, the diagnosis and management of associated minor gynaecological and psychological problems, and the appropriate referral of persons desiring sterilization and persons with problems of infertility. In order to fulfil these objectives, the midwife must acquire a diversity of clinical skills. For this reason, a minimum of 50% of the training time is spent in clinical activities.

TABLE 1
FAMILY PLANNING FOR NURSE-MIDWIVES
OUTLINE OF TRAINING

	Hours	%
Classroom Lecture—		
Discussions	67	16.8
Weekly Obstetrics Seminar	11	2.7
Tutorials & Assigned Study	65	16.3
Clinical Work	197	49.4
Visits to Family Planning		
Resources	17	4.3
Special Group Activities	42	10.5
Total	399	100.0

In order that this clinical experience be as meaningful as possible, clinical training is supplemented with classroom instruction. These didactics actually begin before the trainee starts to work in the clinic. Table 2 outlines the subjects dealt with in the classroom. Lecture discussions with slides and films are provided to review the anatomy and physiology of reproduction and other subjects which have been taught in basic midwifery. This instruction also emphasizes the non-pregnant state and provides the factual information which is essential if the midwife is to become expert in dealing with the normal non-pregnant pelvis and knowledgeable about its common pathology. The anatomy lectures progress into a detailed discussion of the procedure for breast and pelvic examination. In addition, there is an overview of the various methods of contraception which focuses on indications and contraindications of each method.

When the trainee has acquired sufficient background information, she is introduced into the clinical setting.

TABLE 2
I. SUBJECTS FOR CLASSROOM LECTURES—DISCUSSIONS

1.	Anatomy and physiology of the breast, technique of breast examination	..	2
2.	Anatomy and physiology of the female reproductive organs, technique of pelvic examination, special aspects of post-partum and post-abortion examinations	..	4
3.	Vaginal discharges, laboratory methods, diagnosis and management of vaginitis and cervicitis	3
4.	Overview of all methods of contraception	3
5.	Endocrinology of female reproduction, hypothalamus-pituitary-ovarian axis	..	3
6.	Oral contraception	2
7.	Mechanism of action of intrauterine devices and insertion techniques	..	3
8.	Indications for the diaphragm, instruction for fitting and patient training	..	3
9.	*Diagnosis and management of pelvic infection	3
10.	*Menstrual disorders	2
11.	*Demography	3
12.	*Sexuality and contraception	6
13.	Motivational techniques	2
14.	*Infertility	3
15.	*Sterilization—vasectomy and tubal ligation	3
16.	*Sickle cell disease as an example of genetic problems	3
17.	*Pediatrics and family planning including keeping the baby alive, growth and development of infant, nutrition, immunization, gastroenteritis, respiratory infections	10
18.	Nurse-midwifery in the United States	3
19.	Organization and management of a family planning clinic, record keeping	..	4
20.	*International Planned Parenthood Federation	2
	Total		67

Clinical instruction is usually provided on a one to one basis. The trainee is led by the instructor through the history taking process and the information-motivation phase, then she is taught the technique for physical examination and under supervision, the trainee is allowed to carry out the examination. When the trainee becomes proficient in this procedure, she is allowed to do the examination by herself. Each trainee is assured of the opportunity to perform a minimum of 150 pelvic examinations and 100 breast examinations; she will insert a minimum of 20 IUDs and fit at least 5 vaginal diaphragms. This clinic experience should enable the trainees to develop expertise and confidence in the provision of these services.

The trainee spends half of each day working in the clinic and the other half of the day attending intensive classroom instruction. This instruction centres around an in-depth presentation of each contraceptive method. It includes a study of endocrinology and oral contraceptives and a detailed explanation of the IUD. The various types of IUDs are described and demonstrated with emphasis placed on the Lippes loop, as this device is easy to insert and to remove, and is the most widely used device around the world to-day. A discussion of the characteristics, the advantages and the disadvantages, of each device is followed by a study of the mechanism of action of the IUD. Finally, such traditional methods of contraception as the vaginal diaphragm, foam and condom are discussed. As the trainee becomes more proficient in the clinical management of these methods, round-table discussions held at the end of morning clinics will provide the necessary review of theory.

Following the study of contraceptive methods, the problem of infection is introduced; vaginitis, cervicitis, endometritis, and pelvic inflammatory disease are considered. Systematic methods of diagnosis and treatment of these complaints are outlined. The treatment of menstrual disorders is also discussed. Lectures are given on male and female methods of sterilization so that nurse-midwives can become sufficiently knowledgeable to counsel patients about this subject. Finally, the problems of infertility are presented.

As patients who attend the clinics come from different referral sources, (Table 3), and have a wide range of medical backgrounds, trainees must develop the capacity to meet the particular clinical needs of a variety of patients. This degree of flexibility is vital since the trainee will be confronted with a significant number of pathological conditions which she must learn to recognize, some of which she will learn to treat, while others will have to be referred to a physician.

As a thread tying together clinical and didactic instruction, and as the standard for medical management, an illustrated Procedure Manual in Family Planning for Nurse-Midwives has been developed and printed in English, Spanish and French. This manual incorporates guidelines for patient interviewing, step by step instructions for pelvic examinations and for the insertion and removal of three different types of IUDs, guidelines for the selection and use of oral contraceptives, procedures for fitting diaphragms, as well as detailed steps for diagnosis and management of pelvic infections.

What are the results of these services provided by nurse-midwives? First, let me

TABLE 3
PERCENTAGE OF WOMEN ATTENDING CLINICS FROM DIFFERENT REFERRAL SOURCES

	<i>Post Abortion</i> <i>N-3799</i>	<i>Post Partum</i> <i>N-3317</i>	<i>Walk in</i> <i>N- 785</i>	<i>Total</i> <i>N-7901</i>
Oral	56.3	48.0	43.2	51.1
IUD	29.8	19.0	29.6	25.2
Diaphragm	1.5	1.9	12.2	2.7
Other	1.6	6.0	3.6	3.7
Nothing	9.3	15.1	10.5	11.9
Unknown	1.5	10.0	0.8	5.0
TOTAL	100.0%	100.0%	100.0%	100.0%

say that in the more than 6,000 IUDs inserted by the nurse-midwives, there has been only 1 known perforation.

I am sorry not to present accurate life-table continuation rates for this service; such rates are being developed. However Table 4 gives some idea of what happens to some 14,000 patients.

In Table 5 we can see some changes that have occurred in the choice of contraceptives during the past several years.

A very interesting bit of data from a rural mid-wifery service where in a remote mountainous area a population of some 12,000 people receive contraceptive care by nurse-midwives only is shown in Table 6. This is a population that might be the equivalent of a Primary Health Centre. Note that the absolute numbers of births has decreased and the birth rate fell from 40 in 1950 to 23 in 1970, and subsequently to 16 in 1973.

TABLE 4

METHOD OF CONTRACEPTION AT TIME OF REGISTRATION AND AT TIME OF LAST VISIT 1967 - 1973

		At Registration		At Last Visit	
		N	%	%	N
Pills	..	7027	48.1	44.6	6519
Injectables	..	82	0.6	0.3	48
IUDs	..	5739	39.3	30.1	4395
Diaphragms	..	699	4.8	7.8	1147
Traditional	..	661	4.5	6.5	944
Sterilization	..	42	0.3	4.3	623
None	..	302	2.1	6.1	887
Unknown	..	60	0.3	0.3	47
Total	..	14612	100.0	100.0	14610

TABLE 5

CONTRACEPTIVE METHOD ACCEPTED AT TIME OF REGISTRATION

		Pre 1970	1970	1971	1972	1973
		%	%	%	%	%
Pills	..	52.2	34.0	47.7	46.2	50.9
Injectable	..	0.8	1.1	0.1	0	0.1
IUDs	..	40.7	49.7	37.7	34.3	26.8
Diaphragm	..	2.4	7.2	7.8	7.0	6.6
Traditional	..	1.9	5.5	4.3	8.6	10.0
Sterilization	..	0.1	0	0	0.5	1.8
None	..	1.7	2.4	1.8	2.4	2.9
Unknown	..	0.2	0.1	0.6	1.0	0.9
Total	..	100.0	100.0	100.0	100.0	100.0
		N = 7269	N = 2075	N = 1565	N = 2174	N = 1529

TABLE 6

FRONTIER NURSING SERVICE FAMILY PLANNING 1960 - 1970

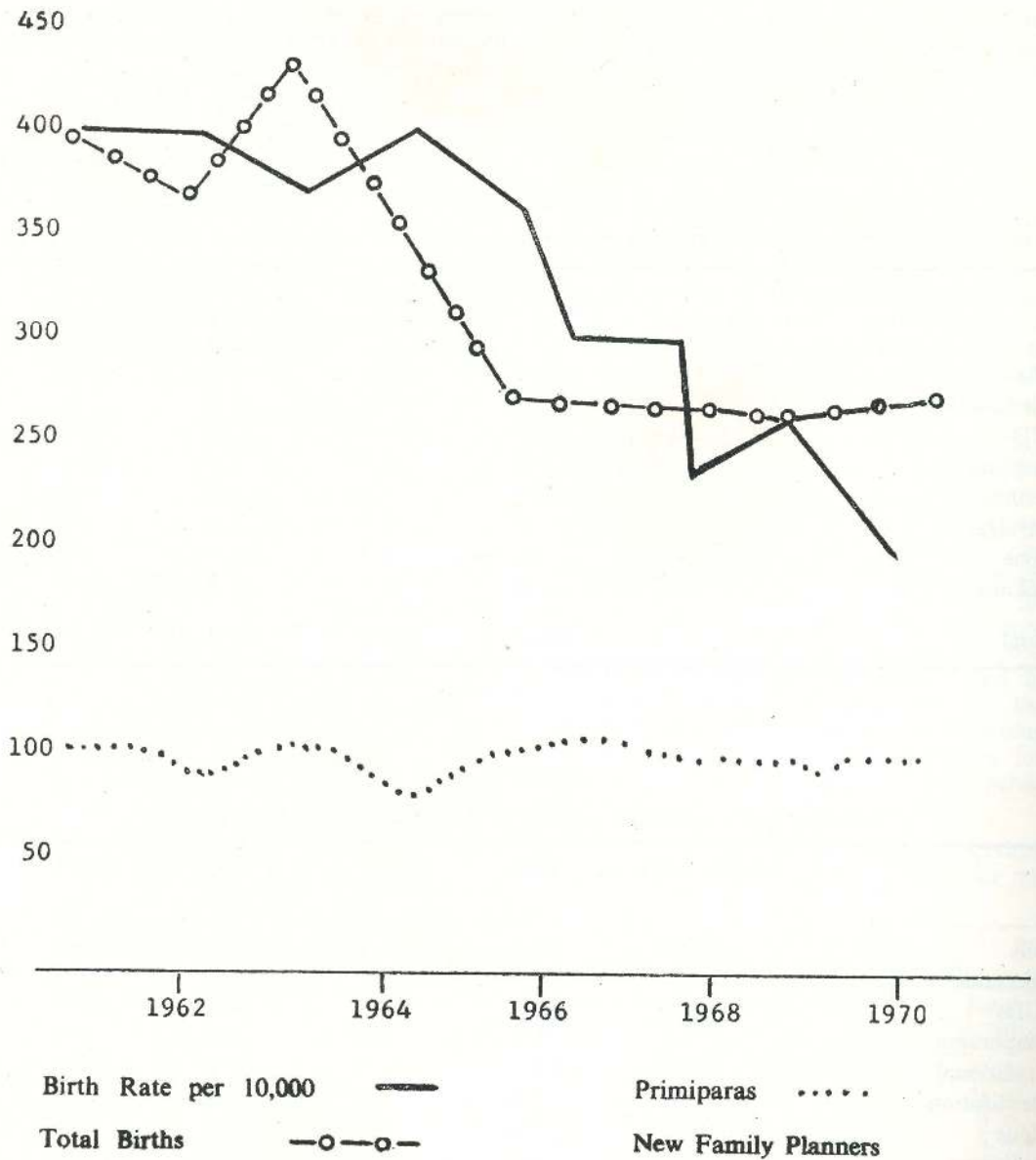


TABLE 7
PROGRAMS TRAINING NON-PHYSICIANS AS FAMILY PLANNING SPECIALISTS

			<i>Admission Qualifications</i>	<i>Weeks of Training</i>	<i>Numbers Trained</i>
Harbor General Hospital	R.N.	21	26
			NONE	24	28
Downstate Medical Centre	R.N.	6-8	40
			M.W.	12	185
Einstein Medical College	H.S.	60	12
Hartford Hospital	R.N.	16	3
University of Florida, College of Medicine	R.N.	24	27
Nebraska, College of Medicine	H.S.	12	5
Planned Parenthood of Wisconsin	R.N.	12	10
Frontier Nursing Service	N.M.W.	12	120
University of California, at San Francisco	R.N.	6	80
Planned Parenthood, New Jersey College of Medicine	R.N.	12	30
				12/208	566
				17	

Table 7 lists 10 educational institutions in the United States which offer training in clinical contraception to non-physicians. Although most are open to registered nurses, at least one, the Harbor General Hospital in Los Angeles, has no education

requirements for admission.

Mr. Chairman, thank you for the opportunity to present this experience with nurse-midwifery training in family planning.

TRADE UNIONS AND THE IMPLEMENTATION OF FAMILY PLANNING PROGRAMMES

By

LAKSHMAN DE MEL

Sri Lanka has a virile and well-organised trade union movement with a history going back to the early part of the century. The number of trade unions today is 1620.

The majority of workers are members of trade unions which are equally well organised both among the plantation workers in the rural areas, and among the industrial workers in the urban areas. Among the larger groups of workers, it is perhaps only agricultural workers doing seasonal work in the paddy fields that have no trade union organisation of their own.

Among the various groups in the community to which the message of family planning could be successfully carried, organised workers, without doubt, constitute a special target. Why is worker participation in this sphere considered important and what is the role the trade unions could play? Limitation of population has now come to be recognised as a basic factor in economic development. As such, the Government has to play the main role in population policy programmes. However, such policies will not be completely successful unless they receive broad-based support through popular participation. It is in this context that the participation of the working class through the trade unions becomes significant.

The majority of working class parents have big families. It is they who suffer most as a result of the economic ills to which unchecked population growth has contributed in no small way. Excessive increases in population nullify the efforts of the workers towards greater productivity and better living standards. Big families with an increasing number of dependants become a burden on a proportionately smaller working population. Whatever they earn, the adults will have to spend on food, clothing, medical care, schooling and other facilities for their children. As a result, a working class

family will have hardly any savings. These dependants will eventually become young men and women joining the labour force and they will join the ever increasing mass of unemployed or under-employed youth. This will become a threat to the security of employment of workers and reduce the bargaining power of trade unions.

An important aspect where industrial productivity is concerned is that a worker with family worries resulting from big families, will not be able to give of his best at the work place. It has been observed that the rate of industrial accidents is high among fathers of big families. These are some of the considerations that should make the working class specially interested in family planning and population policies.

How best could the working class be drawn in to participate actively in family planning programmes? In most fields, there has always been a gap between the awareness of the problem and the adoption of solutions. This is so in the sphere of family planning too. In a generally conservative social set up like ours, with traditional ways of thought to be broken through, it is important that if the message of family planning is to be taken to the homes of individual workers, it should be done through leaders in whom workers have confidence. It is they who could function as opinion builders and form the connecting link.

Since family planning is largely a matter for personal decisions, correct education for purposes of motivation is essential. This education is possible at several levels through the trade union movement. Trade union involvement depends on motivation and the involvement of trade union leaders themselves. Leaders at the top level alone will not be adequate for this purpose. Leadership has to be found at different levels in the

working class movement and in the working life of the people. The workers in Sri Lanka, being intelligent and well organised, it is possible to mobilise them through well planned programmes.

The first National Trade Union Seminar on Population and Family Planning was held in Colombo in July, 1972. The participants "enthusiastically endorsed the willingness of the trade unions to fully support and actively participate in family planning activities in Sri Lanka in co-operation with the government, employers and the Family Planning Association". Among the recommendations adopted were:

- (a) National Committees should be set up for two sectors of the labour force, one for workers in urban areas and one for the estate sector. Attention is, however, drawn to the need also for activities in the rural sector.
- (b) The two proposed committees should consist of representatives from Government, employers, trade unions and the Family Planning Association.
- (c) The Department of Labour should, through its Workers' Education Branch organise training, education and motivational work.
- (d) Tutors in Workers' Population Education should be trained to organise classes and other educational activities.
- (e) At work place level in factories and estates should be formed work place committees (labour management committees) including paramedical personnel, worker motivators and family planning personnel.
- (f) District level committees should form a link between the national committees and the work place committees.
- (g) In the estates and factories workers should be selected for training as worker motivators.

Accordingly, when the Department of Labour formulated its two National Projects for Workers' Education in Population and Family Planning Activities, an attempt was

made to incorporate as much as possible of what was recommended at this seminar. Of these two projects, one is for plantation workers and the other for urban workers. A National Advisory Committee, on a tripartite basis consisting of representatives of employers, workers and the Government departments involved in the programme, comes at the apex of the organisation.

This committee divides itself into two sub-committees, one for the plantation sector and the other for the urban sector, again on a tripartite basis. District committees, also on a tripartite basis, are being set up to help in the functioning of the projects in the districts. In the plantations, estate committees consisting of workers, supervisors and management representatives will be established at estate level. In the factories, factory committees will be set up on a similar basis. The plantation sector project envisages training of 2000 worker motivators during a period of 3½ years. In the urban sector, a nucleus of 30 worker motivators or educators will be trained and entrusted with the responsibility of conducting a series of meetings at work places during working hours. Thus, trade unions will form the most important channel of communication among the plantation workers and the urban workers.

The Department of Labour has so far conducted seven workshops for workers in these two sectors at a regional level in important centres in the Island. The number of participants at each such workshop was in the region of 35 to 40. They have been from the shop steward level and are key men and women to whom the average worker looks up for guidance and assistance in their day to day problems.

By selecting worker motivators, we have attempted to establish face to face communications in family planning. Face to face communication is one of the most popular methods suitable for the dissemination of family planning information. This is possible in different ways such as visiting of homes, conducting group meetings. There are, however, many problems associated with face to face communication. If, for instance, home visiting is to be adopted, a large number of visitors is required. The personnel required, will therefore, be an important constraint to the success of the

method. If a category of visitors like public health midwives is to be relied upon, it will not be possible for adequate staff to be made available for extensive home visiting. Besides, the number of persons to be handled by each visitor will also be quite small. Supervision of visitors may also not be quite easy. A very serious drawback will be the absence of efficient transport. This is specially so in areas like the plantations where transport to and from and within the plantation is a problem. There is a further drawback in that at the time the visits are made the workers, be they on plantations or in an urban area, may be away at work. The age differential between the visitor and the worker is also an important matter that deserves consideration. If the age gap is excessive, then the visits may not serve much purpose.

The selection of workers as motivators and getting them to organise meetings have the following distinct advantages:

- (a) The selected worker will be a known person who is expected to motivate. The group he is expected to motivate will be, by and large of the same age, and share the same community of interests. No better unit for the successful communication of family planning information perhaps could be found.
- (b) Organising these groups at plantation or factory level at a time convenient to the group when participants would be most receptive will be an advantage. These will be informal discussion groups. The experience we have had in the seminars and workshops conducted so far show that there is an initial shyness or reluctance on the part of participants, particularly women to discuss the subject without inhibitions. This may be due to -
 - (i) the formal atmosphere of the seminar or workshop;
 - (ii) the fact that the participants are strangers when they first meet, being not from the same place of work;
 - (iii) the presence of those of a different or higher level of education and different strata of society such as the lecturers, organisers and the staff.

However, where groups of workers of the same line rooms or of colleagues of the same shop who share the same canteen and welfare facilities, are concerned, this feeling of being amidst strangers should not arise. Group discussions of this nature could also foster husband and wife communications. At present, in a largely traditional and conservative society like ours, husband and wife communications on family planning is poor. Group communication will also help participants to get over the initial embarrassment or shyness to discuss the subject. Among the other problems that impede the success of human communications are various attitudes of mind towards the whole concept of family planning and contraception.

It is still not uncommon for a large number of people to consider contraceptive practice as being not respectable and to talk about it as being embarrassing or unmentionable. To change such attitudes and to make contraception practice acceptable as being commonplace is a difficult task. Group communications where the village itself, or the majority of villagers participate should help correct this attitude. The very fact of large scale participation should be adequate to give the subject status and respectability in the eyes of the community.

The body of rumours, myths and prejudices that has grown around the subject of family planning is another serious obstacle. These prejudices and myths spread fast and wide specially in rural areas among the less educated groups. They also tend to strengthen the pockets of conservative opposition and help to make communication difficult. These rumours reflect a wide variety of aspects of community life such as ethnic, religious and political.

Learned religious dignitaries who are powerful opinion builders within their group have been known to be openly opposed to family planning activities and to express their opinion both in writing through the Press and in speeches. They feel that natural causes such as famines, plagues, earthquakes etc., should take care of the excess population. Correcting the prejudice created by such propaganda is not an easy task. There is the belief that family planning activities will lead to the majority community

being reduced to a minority, while minority communities fear that they will be completely wiped out in due course. Where one's health or physical well-being is concerned, many a false belief has got accepted. For example, the belief that vasectomy is the same as castration, or that it causes loss of virility in the male.

Fears have also been expressed that easy availability of contraceptives through non-clinical sources leads to their abuse, thereby contributing to a fall in moral standards.

Irresponsible reporting in the newspapers of cases, either true or imagined, of instances where tubectomy or vasectomy have failed, as may happen in rare cases, have also caused serious problems in the success of group communications.

Participation of workers as motivators with the blessings and the active co-operation of the trade unions should go a long way in countering these myths and prejudices and in making a worthwhile contribution towards spreading the message of family planning.

PROBLEMS OF FAMILY PLANNING PROGRAMMES ON PLANTATIONS

By

DR. L. V. R. FERNANDO

Plantations form a major part of the agricultural sectors of many countries of Asia, Africa and South America, and in most of them the proportion of plantation land to cultivated land is quite high. In addition, in the smaller countries like Sri Lanka, Malaysia and Mauritius, the cultivated area itself represents a very high proportion of the whole territory. The plantations therefore play a vital role in the economies of many of the developing countries, some of which are almost wholly dependent on the export of their plantation products. As a large proportion of the active population in the developing countries is engaged in agricultural pursuits and in turn a large proportion of these agricultural workers are engaged in working on the plantations, the health, safety and welfare of the plantation workers has an important bearing not only on the productivity and economy of the plantations but on the financial stability and growth of the countries themselves.

The opening up and working of the plantations has always been dependent on the availability of a plentiful supply of labour. By their very nature, plantations are situated in comparatively isolated locations, away from large urban centres, and consequently plantation managements are called on to undertake the total care of their labour forces including their families – the services they are required to provide ranging from the basic ones of housing, water supply and sanitation to medical, education and social welfare.

The high birth rates that prevail in most of the underdeveloped countries are paralleled on the plantations and result in a steady increase in the plantation populations. In view of the commitment to the care of entire families, the problems of large families are more acutely felt by the plantation industry than by most others. Apart

from the comparatively small number of adults, who are past their working years, the bulk of the dependants comprise the very large numbers of infants, pre-school children and children under 14 years. These are all groups which are totally unproductive and are at the same time a severe strain on estate resources. It is in the direct interests of the plantation sector to encourage the small family, and to provide education, motivation and services for family planning.

Fortunately, the plantations provide the ideal conditions for the introduction of such services. As the labour force and their dependants live in virtually self-contained colonies, they are comparatively easy to reach, relatively well disciplined and can be conveniently organised into groups for educational and motivational purposes. Furthermore, by long standing tradition most of the larger plantations are provided with their own medical institutions – dispensaries, maternity homes and even hospitals and employ their own medical and paramedical staff. Consequently, plantation labour are accustomed to being provided with on-the-spot medical services. The conditions already exist on to which family planning services could be grafted without too much effort or expense. However, the introduction of such services has not always proved to be easy and a host of problems have been encountered in doing so. It is these problems which I shall concentrate on in this paper.

In the early days the basic problem was the virtually total lack of appreciation and knowledge, on the part of all concerned, of the need for, and the value of family planning. This included the labourers as family units, organised labour in the form of the plantation unions, the on-the-spot management like the estate superintendents and assistant superintendents, estate medical personnel like estate medical assistants and estate

midwives and lastly the managing agents and principals, who control expenditure and formulate management policies. The prime need, at that stage, was education and motivation at all these levels.

There was not much difficulty in convincing plantation managements. The fact that considerable savings could be effected by reducing the number of births on the estates became obvious, once it was pointed out that, apart from a reduction in the direct cash outflow for the payments of maternity benefits and the cost of free milk to infants, each extra child meant a greater outlay of estate resources. It was evident also that limitation and spacing of children would have a direct bearing on the state of health of estate mothers and their children, resulting in a healthier work force with its potential for increased productivity.

The need for extra expenditure on family planning work, in times bedevilled by high taxation, high costs of production, static prices of the produce and reduced profits was one that might normally have produced some resistance on the part of the employers, but the costs were greatly reduced by the fact that voluntary agencies, like the Family Planning Association, the International Planned Parenthood Federation and the different United Nations Agencies were only too willing to provide help in the form of personnel, equipment and material.

Convincing the managements was only a beginning. The interest taken in the programme by the men in direct charge of the estates, i.e. the estate superintendents and their assistants was even more important and this aspect had to be tackled, both at personal level and at planters' meetings. Next came the estate medical assistants and estate midwives. It was found that many of these paramedical personnel did not always take too kindly to the extra work involved. There was at first a feeling amongst many of the estate medical assistants and midwives that family planning was not a part of their normal duties and that it was something extra which they had been called on to do. It became necessary at this stage to point out that family planning was merely another extension of preventive medicine, aimed at improving the health and living conditions of the workers.

Training courses for estate medical assistants and midwives, and regular visits to estates by a propaganda officer of the Family Planning Association, specially detailed for work on the estates, helped to gradually change this attitude, though there are still some pockets of indifference.

But ultimately the success of family planning programmes on the plantations depends on its acceptance by labour, and this can only be achieved by convincing them that it is they who stand to benefit. The plantation unions are the key to bring about this understanding. Without union backing, all too often, the workers tend to look on the employer's efforts as being something which is being advocated for the employer's benefit. This attitude was quite common at the beginning and there were even instances of active opposition by the Unions.

Happily, in the last few years, much progress has been made by establishing communication with and obtaining the understanding and support of the major plantation unions. The establishment of a working relationship with the unions, in the field of family planning, has been greatly helped by the work of the I.L.O. in sponsoring a series of Family Planning Seminars for labour and management in the last couple of years. With the development of the current Worker Education Programme being conducted by the I.L.O. and the Labour Department under the aegis of the U.N.F.P.A. Programme, it is expected that the active participation of the unions will be available in helping with the education and motivation of labour.

In most of the developing countries, the Government medical services are stretched to their limits, particularly in the rural areas, in which the plantations are found. Due to shortages of personnel and equipment, the provision of family planning services in Government Institutions in the plantation areas has been inadequate, with the result that acceptors referred to these Institutions from the plantations are often turned away due to clinics being cancelled without warning or pressure of other work. This may lead to frustration and resistance on the part of these acceptors, as well as potential acceptors, as no one fancies the idea of wasting time in hospitals, or being turned away after a

long and tedious journey. Consequently, the only effective method is to provide the services on the plantations themselves, and this pattern has been followed with marked success in the last few years. Conventional contraceptives like condoms and oral contraceptives were made available through the estate medical institutions, at subsidised prices. While condoms cause few problems, the distribution and usage of oral contraceptives is a different matter. The selection of acceptors, proper record-keeping of sales and usage, checking of regularity of use and advice in case of complications, could only be entrusted to persons with sufficient training, illustrating the importance of having a sufficiency of well trained and experienced paramedical staff for employment on the plantations.

When it comes to insertion of IUDs or sterilisations, there is little that can be done by the paramedical staff on estates. Specially trained personnel and equipment are required and this can only be made available either at the nearest Government Family Planning Clinic or by the use of mobile teams, which visit the estates and provide these services on the estates themselves, using the estate medical facilities in which to carry out the operations or by using fitted "operating theatre" type mobile clinic vans.

After many years' experience with family planning programmes on the plantations, the Family Planning Association of Sri Lanka and the Planters' Association Estates' Health Scheme, working in conjunction, have developed what is perhaps the most effective and efficient unit to fill this need. Each complete mobile unit consists of two sections - An Education/Motivation section and a Service section. The Education/Motivation section first spends 2 or 3 days on the plantation, depending on the size of its population, giving group talks and film shows, interviewing families and generally setting up acceptors. The Service section then follows and provides on-the-spot IUD or sterilisation services.

An indication of the effect of making the services available on the estates is provided in the figures of vasectomy acceptors on estates in the last few years. In 1969, 1970 and 1971, there had been 19, 47 and 85 acceptors respectively in over 500 estates

of the Planters' Association Estates' Health Scheme. Since the single mobile unit commenced operations in February 1972, it has done 436 cases on 36 estates in that year, and 1447 cases on 56 estates in 1973. These figures speak for themselves and bear out the contention that the only effective means of promoting the acceptance of family planning in the estates is by taking the services to the estates.

Planning and operating a successful mobile unit programme involves the exercise of considerable logistical skill. A whole host of factors has to be taken into consideration - selection of groups of estates in fairly close proximity to each other, liaison with them about suitability of dates, the availability of accommodation and meals for the differing grades of members of the team, follow-up of operated cases, intervals between programmes for reporting, evaluation and rest, and maintenance and repair of vehicles.

Once a programme is under way, a certain amount of flexibility of approach is essential in order to deal effectively with the unexpected situations that can and do crop up from time to time. The recruiting of trained and experienced, surgical, nursing and motivational staff to undertake a job which involves so much travelling and long, irregular hours of work, presents a major difficulty. Dedication to the job and an ability to work together with others as a member of a team is essential. The motivational work, has to be geared to the varying working hours on the plantations. It is the propaganda officers who make the initial 'break-through' and it is actually on their assurance that the acceptor takes the plunge. In approaching the subject therefore, the presentation has to be sound and geared to the type of audience being addressed. The use of audio-visual equipment plays an important part in the work of the education-motivation section and there is a constant need to keep the material fresh and topical. Turning out posters, with punch and appeal to special groups, and getting films in Sinhala and Tamil, depicting local situations, is difficult, apart from being expensive.

The need for follow-up services has to be kept in mind. It will not do at all for a unit to turn up on an estate, insert IUDs

or perform vasectomies and then not be seen again for months afterwards. Complications, even relatively minor ones, can arise and unless attended to promptly and relief and reassurance provided, the next programme is bound to suffer. In the case of vasectomies, not only is it necessary to ensure follow-up visits a few days after the operation to attend to minor complications but it is also necessary to check the results of the operation approximately 3 months later by examination of the seminal fluid. Obtaining these test samples has been one of the greatest difficulties encountered in the vasectomy programme.

Incentives in the form of cash payments to both acceptors and promoters, leave with pay during convalescence, transportation expenses where necessary, and free subsidised contraceptive materials, have been found to play a very big part in the furtherance of plantation family planning programmes. The incentive payments to estate medical assistants and midwives have gone a long way towards overcoming the objections that some of them raised at one time about family planning being outside the scope of their normal duties. Small though the payment is, it has worked wonders in producing a change of attitude on their part. The incentive payments to acceptors of sterilisation were certainly responsible for attracting the initial groups of acceptors but increasingly, the financial aspect is gradually becoming a secondary consideration.

The concept of maternity benefits has come under fire from many family planners

in recent years. Maternity benefits they say are an invitation to produce more children and as such their payment cannot be reconciled with current Government expenditure on family limitation programmes. Others advocate restricting the payment of maternity benefits up to a maximum of three children. I am inclined to go along with this view, with the proviso that the quantum of benefits be doubled in respect of the first three children. Unless there is some counteroffer such as this, the Unions will find it hard to agree a reduction in what is considered to be a hard won privilege. The greatest drawback with the present method of payment of maternity benefits is that it does not ensure that it is the mother herself who gets the benefit of this allowance, in the form of improved diet and intake of supplements, both during and immediately after her pregnancy.

As a result of our experience on the plantations in this country, I am convinced that this particular system of mobile units, operating at individual enterprise level, is the most effective means of ensuring quick and significant results from an organised sterilisation programme, aimed at the agricultural sector or organised industries, like the mining and petroleum industries, which are sited outside the urban areas and are by their nature called on to provide a full range of services for their workers and their families. In fact I would go further and advocate the use of similar mobile units as the answer to carrying family planning services to the rural populations not only of Sri Lanka but of most of the other developing countries as well.

THE ROLE OF COMMUNICATION WITHIN A FAMILY PLANNING PROGRAMME

By

ANTON GUNASEKERA

The importance, of establishing certain levels of social and material well being before family size could be voluntarily reduced, cannot be over emphasised.

All of us who are involved with the subject of population and family planning have had varying experiences in regard to the social, cultural and other obstacles that lie in our path. These obstacles are encountered in varying degrees in all countries and in all cultures. If you tell a couple with too many children that "family planning can help preserve the health and well being of the mother and the children", you have diffused only a small part of the total message. A little bit of information might set a person thinking, but it cannot bring about a sudden change of attitude. People, in whichever part of the world they inhabit are by nature prone to react rationally to a change of circumstances. When it makes sense to have fewer children they will have fewer children. To determine what makes sense to the people is the task and responsibility of the family planning communicator.

Within the brief period at my disposal, I cannot dwell in detail on the complicated subject of media selection and frequency of media usage. But it is relevant to state here that we in Asia and Africa have been over-dependent on the conventional media – Press, Radio, Cinema, TV, the colour brochure and poster – while paying lesser attention to the cultural or folk media, through which we can reach more people, equally effectively. But that is a different topic.

Given certain selected media, how do we use them effectively to communicate to motivate to adopt a social innovation such as family planning? The communication model I now present to you is based on the attitudes, behaviour, susceptibilities and

beliefs, of people, irrespective of their nationality, ethnicity, cultural or religious background.

The model presupposes the existence of certain psychological pre-requisites that have to be satisfied in people, before they could be motivated to adopt an innovation.

The pre-requisites are:

- (a) Provision of adequate information.
- (b) Legitimation.
- (c) Use of high credibility sources.
- (d) Proof of social acceptance.
- (e) Positivising of attitudes.
- (f) Self referral.
- (g) Competence.

In a phased family planning communication campaign, the content of information that could be diffused in the form of educational and motivational material is perhaps limitless.

This is particularly so when we have to deal with two different aspects of the same issue; firstly, the promotion of the concept and secondly, the promotion of the product, namely the means by which the idea could be effectively implemented.

This behavioural model answers both aspects of the promotional effort. Let us suppose that we are about to launch a communication program among a sample of the population which has been least exposed to family planning messages. I will now outline the basic format through which the model can be operated in such a community. The messages you will hear are merely samples to illustrate the use of each pre-requisite.

Information

"Family planning is a social service, not just a means to space or limit births." Under this category of descriptive information,

you can have a whole array of messages that would help drive home the concept.

Legitimation

"The family welfare clinic in Pahathkande, Ratnapura, will be declared open by the Minister of Social Services. It will be in charge of the District Medical Officer of Ratnapura."

Two prominent and respected figures have been introduced to legitimise the service programme. The residents of the area look up to them as opinion leaders. Added to it is the confidence that the people have in a Minister of the Government and the area medical authority both of whom have given their blessings to the service.

High-Credibility Source

The internationally reputed Australian surgeon, Dr. Walter Griffith, states thus in regard to fears expressed about vasectomy. "Within the last eight years, I have performed nearly 500 vasectomies on males in the age group 30 - 50 years. Honestly, I have not had a single complaint from any one of these cases that virility had been affected as a result. On the contrary, some have turned up months later to say how thankful they are because the vasectomy has given them an extra dose of virility."

There is a wealth of communication research on individual and group responses to statements attributed to high credibility and low credibility sources. Apollo 11 and Neil Armstrong's stepping on the surface of the moon is a case in point. You will recall the banner headlines in the press and the running commentaries over the radio in connection with this event. But millions of semiliterates in Asia, Africa and Latin America refused to believe the moon-landing. Long after the event, rural dwellers in the developing world called it a simulation somewhere in the rugged mountains of the North American continent. Research has subsequently shown that a great deal of authenticity built up, only after the Soviet Press and Radio carried messages of congratulations from the Soviet leadership to the US President and the three astronauts. The high-credibility source in this instance was the Soviet mass media, the basis being that the Russians would not have publicly acknowledged American super-

iority in the race to the moon, were it not a real moon-landing.

Likewise, in order to clear doubts and misgiving about religious opposition to family planning, the high-credibility source that can be used to the fullest advantage is a statement from a high dignitary of that religion. This kind of information that is put out, or the material that you use to neutralise an antagonistic point of view should always be attributed to a high-credibility source whose views and opinions are authoritative.

Social Acceptance

"Planning families is a way of life among all nations. Today 100 million couples all over the world are spacing or limiting child births through contraception. In 1973, 60,000 couples in Sri Lanka practiced family planning. Ask your area public health nurse or midwife for confidential advice on how to plan your family."

In a message of this kind, you have produced good evidence of social acceptance. The man or woman who receives this message is convinced at some stage that he or she is not an isolated family planner. Society has accepted family planning. And, probably, his or her neighbour could be practising family planning. Messages which reinforce social acceptance should strive to convey the idea that modern society respects couples who carefully plan for fewer children among whom more benefits could be shared.

Positivising Attitudes

In the field of attitudinal change, social psychologists often refer to what is called the "balance" theory. Let us assume that there are three persons A, B and C who form the corners of a triangle. A is in agreement with B on a given issue. C, however, does not see eye to eye with either A or B on this same issue. The "balance" theory suggests that in a bid to change the attitude of C, both A and B will exert their influence on C at different times and by different methods until such time as C yields. Having yielded, C will continue to look around for others in his reference group who are also in agreement with A and B. The triangle attains equilateral balance only when C positivises his attitude in line with A and B.

Perhaps, the most difficult pre-requisite to satisfy is this stage of permanent attitude change. The considerably high rate of contraceptive discontinuation which has been evident in the annual acceptor returns of most Asian and African countries is attributed to the failure of family planning workers to clarify and dispel subsequent doubts and suspicions which have arisen in the minds of certain practising couples.

Self-referral

Even after being subjected to high pressure motivation, most prospective acceptors are known to refer back to themselves whether the total acceptance of the new idea would subsequently leave behind adverse effects. This is the stage of self-communication. "I do agree that my three children could be given a better deal in life if I limit my family at this point. But should I practice the rhythm method or should I use some contraceptives?" "Having heard that man's talk today, I think I must limit my family. But do I get a vasectomy done, or should I ask my wife to agree for a tubectomy?" Questions such as these often create a degree of dissonance in the minds of prospective clients. The vasectomy advertisement which is currently appearing in the local newspapers has a clear message. "I am a father of four" has certainly helped many fathers

to get out of this dissonance and finally decide on vasectomy.

Competence

Communication research has proved conclusively that women rather than men rate high among discontinuers. A feeling of incompetence to continue to practice family planning was expressed by 36 out of 45 practising mothers in a sample survey conducted by the Thai Government Family Planning Communication Division. The reasons attributed include absent-mindedness, husband's drinking habits, the need to nurse toddlers, general debility, appearance of adverse effects, etc. A total communication campaign that fails to accommodate and provide for messages that could build a feeling of competence among men and women who are newly practising family planning, is bound to encounter considerable numbers of early discontinuers. Viewed as a whole, a communicator must strive to satisfy all these psychological pre-requisites if he is to ensure the achievement of family planning targets. Whether the communicator is adopting the face to face, group or mass media communication approach, it is the kind and content of factual information that finally draws in a convinced clientele to our clinics.

**THEME: ROLE OF NURSING & AUXILIARY PERSONNEL
IN POPULATION LIMITATION**

CHAIRMAN: Prof. Malcolm Fernando

EDUCATION OF NURSES AND MIDWIVES IN FAMILY HEALTH

By

MRS. P. L. N. DE SILVA

1. Introduction

The Family Health Programme in Sri Lanka has, as one of its objectives, the reduction of the birth rate from 3.2% to 2.5% by 1975. The importance of the roles of the nurse and the midwife in realising this objective has now gained recognition. This is self-evident when we examine the health personnel available for effecting any health programme in Sri Lanka. Out of a total strength of about 40,000 persons of all categories of health workers, nearly 10,000 are nurses and midwives. Therefore, on numerical strength alone the impact of the nurses and midwives on this programme can easily be visualised. Due to the peculiar socio-cultural situation in which we find ourselves in regard to family planning, it is considered likely that a female health worker would be able to reach and win the confidence of the mothers, would-be-mothers and even others, with a view to spreading the message of family health with emphasis on family planning. These two reasons, place on nurses and midwives of this country, a serious responsibility.

There is no doubt that family health and family planning are specialised subjects considering the importance that is now being attached to them by all people who are sincerely interested in the future of our country. These considerations bring into focus the need to have adequately trained nurses and midwives, as they are now called upon to shoulder a considerable part of the responsibility of achieving the objectives of our Family Health Programme - i.e. the improvement of the Health of the Nation by reduction of births.

2. In-service Family Health Education for Nurses

There are about 6,000 nursing personnel, functioning both in the institutions and in the field throughout the Island. A small proportion of them have been trained in the current concepts of family health programmes.

The nurses, both in the institutions and in the field who handle the family health

programmes also receive an "on-the-job" training adequate to carry out their day to day functions.

It is now considered necessary that every nurse in the country should have the benefit of a specialised training in family health and therefore, an in-service education programme on family health has been developed by the Family Health Bureau of the Ministry of Health with aid from the UNFPA and other Agencies.

This programme has as its overall objectives -

- (1) the gaining of additional knowledge in Family Health and the Family Health Services in Sri Lanka.
- (2) the development of new skills and attitudes, in order to function more effectively within the Maternal and Child Health Services, with emphasis on family planning.

The duration of the programme is 5½ days. It includes a pre-test and a course ending test and is conducted by a specially trained team consisting of:

- (a) A nursing tutor
- (b) A supervising public health nurse or public health nursing tutor
- (c) A health educator
- (d) A medical officer maternal and child health
- (e) An obstetrician and
- (f) A paediatrician

This team will handle about 30 nurses at a time. This in-service programme will be primarily conducted in a School of Nursing. There are nine Schools of Nursing in seven major districts. Therefore, nine programmes will be running concurrently in the Schools of Nursing. It is also proposed to establish these courses in six other districts, where the facilities for health training are available.

The course has been designed to expose the trainees to an awareness of the scope of

the national family health programme, and its need for our country. It also enlightens the trainees, on the latest knowledge regarding the various techniques available for family planning. The responsibilities of the various members of the health team, in respect of the Family Health Programme are discussed, and the nurses' role of co-ordination, as a member of that health team is emphasised.

The skills required to carry out health education are developed, and a knowledge of family health extension is imparted.

As the health education component plays a key role in the success of a programme of this nature, the trainees are encouraged to utilise the points at which the lives of the public, interest their official duties - i.e. O.P.D. clinics, hospital visiting times, home visits and school lectures and while caring for patients.

3. Family Health Education for Student Nurses

In the seven basic Schools of Nursing, there are at present 800 student nurses. About 400 pass out annually as qualified nurses from these schools. To equip this pre-service sector in family health and family planning the 3 year curriculum has been appropriately extended and amended to incorporate these concepts into the existing courses for students. This integration manifests mainly in the maternal and child health component of the curriculum. Theoretical knowledge is correlated with practical work in the institutions and in field situations, with a view to developing their skills.

4. Post-Basic Education of Nurses in Family Health

There is a Post-Basic School of Nursing in Colombo where all categories of trained nursing personnel are encouraged to assume higher levels of responsibility. Family health and family planning have been integrated in greater depth in courses conducted at this Post-Basic School for such nurses, so that when they go in charge of institutions and teaching programmes, they will be responsive to the needs of the family health programmes of our country.

5. Family Health Education for Public Health Nurses

Public health nurses are trained at the Institute of Hygiene, Kalutara. Their curriculum has already been raised to strengthen the family health component of the programme.

6. Psychiatric Nursing Education

There is a Psychiatric Nursing School at Mulleriyawa which provides all trainee nurses, concepts and experience, conducive to understanding human behaviour in all its aspects. This psychiatric nursing experience equips the nurses to function as family health extension workers at a more sophisticated level. The practising midwives too are given a short introductory course in mental health concepts, which helps them to interact more effectively with men, women and children they meet.

7. In-service Family Health Education for Midwives

There are nearly 4,000 midwives serving in the field and in institutions of our country. In the field, they are the grass-root workers. They are the health workers who come into contact with the mothers and their families in the first instance. Therefore, they play a vital role in the dissemination of family health knowledge to the community.

To enable them to fulfil this responsibility, most of the practising midwives have been given short term courses in family planning at Bandaragama and Ulapane, where such courses were conducted with aid from S.I.D.A.

These midwives also receive an "on-the-job" training in family health in their places of work.

With a view to standardising and upgrading this service, a special institutionalised in-service educational programme has been developed, as in the case of the nurses, by the Family Health Bureau of the Ministry of Health. This programme too will be primarily based on the School of Nursing and six other centres, and will be conducted by a team of trainers especially trained for the purpose. It is also a 5½ day programme and the course content is designed to equip the midwives to function more effectively.

8. Pre-service Education of Midwives

Upto now, the midwives were trained 'on-the-job' in certain approved hospitals. The midwifery curriculum provides the training of midwives for a period of 12 months in the institution and 6 months in six field training centres. A decision has now been made to provide the midwifery training for the future recruits in the Schools of Nursing. The curriculum is now being reorganised with a view to integrating family health knowledge in greater depth.

9. Assistance for strengthening of Nursing & Midwifery Education

For motivating nurses and midwives towards family health work, and for their preparation at higher levels, scholarships and fellowships of short and long term duration, have been made available by organisations that assist the health services of our country, such as the WHO, UNFPA and C-Plan.

Assistance by way of teaching material, equipment and consultancy services has also been provided by organisations such as the WHO/UNICEF/SIDA.

In fact, a comprehensively planned project for strengthening nursing and midwifery education has been financed by the UNFPA for a period of 4 years, commencing from 1973, costing nearly $\frac{1}{2}$ million dollars.

10. Suggestions

In Sri Lanka about 80% of the births occur in institutions. All normal deliveries are attended on by nurses and midwives. Immediate post-partum insertion of the IUD's can be undertaken by qualified

nurses trained to do this. The advantage is that a doctor need not be called for each delivery where a mother has agreed to receive an IUD. The technique of the insertion of an IUD is well within the competence of a qualified nurse if the little additional training is given to her.

11. Conclusions

The F.A.O. bewails the fact that millions of people go hungry and many more suffer from "hidden" hunger. At the same time, the WHO may triumphantly announce that life expectancy has extended by another 10 years. We, health workers, will certainly have to resolve this population problem, created mainly by medical science. Family Health programmes are the only available answer to ensure that only the people for whom society can provide security, food and living space, are born into this world. We will have to work towards the reduction of births so that our population will be consonant with the facilities that we could possibly provide. In this tremendous task, the responsibility cast on nursing and midwifery education is to supply nurses and midwives adequately trained in family health, to the community. It will be clear from the "in-service" and "pre-service" courses that have been discussed, and the operational plans that have been designed to obtain full coverage of all nurses and midwives, that our responsibility will be fulfilled as quickly as possible.

On behalf of the nursing and midwifery education authorities in Sri Lanka, I give the Family Planning Association that assurance.

UTILISATION OF NURSES AND MIDWIVES IN FAMILY HEALTH FOR POPULATION LIMITATION

By

MISS HILDA DE SILVA

Introduction

I thank the Chairman of the Organising Committee for inviting me to talk on 'Utilisation of Nurses and Midwives in Family Health for Population limitation'.

Before I discuss the main subject, I wish to pay a tribute to the pioneer of the 'Birth Control Movement', Mrs. Margaret Sanger to whom the world owes a great debt of gratitude. I am proud to mention this, as Margaret Sanger was a nurse who courageously began her work half a century ago and the fitting memorial to Margaret Sanger is that more and more Governments are now working for the goals which they once forbade or ignored, when single-handedly she began her humanitarian crusade half a century ago.

Concept of Family Health

The concept of family health covers all aspects of Medicine in a very wide sense. Every member of the Health Team, both medical and paramedical, contributes to the promotion of family health in relation to population limitation. The most important aspect of a family health programme would be centred on planned parenthood; the efficiency of a family planning programme for the community depends on team effort as much as any other health programme.

However, there are a few key members of the team, namely the doctor, nurse, midwife, the public health nurse, health educator and inspector and the medical social worker.

My topic is limited to the utilisation of the nurses and midwives in such a programme.

The role of Nurses and Midwives in a Family Health Programme at present

In Sri Lanka today, the nurses and midwives form the largest group of qualified workers who are employed by the Health Department to deliver direct family health

services to the community both in the institutions and in the community.

The total strength of nursing personnel of different categories in Sri Lanka is 6024 and that of midwives is 3231. These two categories form over 25% of the total health manpower of the Island. They are directly involved with the family planning programme both in the health institutions and in the community.

The supervisory categories such as matrons, assistant matrons and ward sisters have been trained in family planning aspects as trainers. Hence most of them are competent to guide their own staff. All nurses who are qualified in midwifery as well as the midwives, have had family planning aspects in their revised curriculum. Nurses qualified in midwifery have had $4\frac{1}{2}$ years of training and the midwife has had $1\frac{1}{2}$ years of training. Some midwives are attached to institutions and some in the field - $\frac{1}{3}$ in institutions $\frac{2}{3}$ in the field. My comments on midwives are in respect of those attached to the larger medical institutions.

In relation to family health, these personnel have instruction on family planning, population trends, their impact on the national economy and health of the nation, the need for an effective Family Planning Programme in Sri Lanka and the Government policy in relation to such a programme.

How Nurses and Midwives contribute to the Family Planning programme

- (a) Opportunities for teaching the patients and the public
 1. In the clinics
 2. In the out patients departments
 3. In the ward situation
 4. In the community, (field visits, her own neighbourhood)
- (b) Opportunities for motivation.

Mainly antenatal, post-natal and paediatric clinics, maternity wards, paediatric wards, other clinics, O.P.D. and general wards, in the community, field visits, neighbourhood.

Nurses and Midwives as effective members of a Family Planning programme

They function in close relationship with patients and the community. In their daily work they come in contact with people, often in distress or in anxiety and the patients as well as their relatives look up to the nurse as an intimate friend as well as an advisor and place immense trust and confidence in her. In relation to our culture, the female members of the family feel more free to discuss their problems with a nurse or midwife, who therefore has a unique opportunity for providing family health care.

Nurses and midwives come in contact with patients and relatives directly at the outpatient departments, or while giving personalised care – e.g. giving a bed bath making the bed or carrying out any treatment, and they get a suitable opportunity to collect information relevant to family health matters and to provide family health care and health education.

During visiting hours the nurses utilise the opportunity to discuss matters with husband or wife of the patient to dispel fears and misunderstanding or to explain family planning methods – e.g. sterilisation procedures and to obtain first hand information about the health of other members of the family, especially children.

In the specialist clinics the nurses identify and utilise opportunities and discuss methods which could be adopted under clinic conditions.

Due to the very close association, it is the nurses and midwives who get first hand information with regard to resistant individuals and they deal with them by referring them to the medical staff for care or guidance.

Nurses motivate people, screen them – i.e. those who need family planning and persons with sub-fertility problems and refer them to the correct source for guidance.

The services of nurses and midwives are utilised for the preparation of patients for surgery, preparation of instruments and the distribution of contraceptives. The nurse plays an important role in assisting the surgeon in surgical techniques observes them after surgery, gives necessary post operative care and follows up these patients.

The nurses and midwives advise mothers on nutritional requirements in pregnancy and lactation, teach and assist in selecting food according to the economic abilities of the families. They are also responsible for teaching proper environmental sanitation, about immunisation and its importance, and about types of services and benefits available and directing patients to the correct agency.

They assist the medical staff in preparing the clinic with equipment and supplies for Family Health Services, advise patients on facilities available at the clinics, the different contraceptive methods available, advantages and drawbacks of the different methods, and what the patients should do in case of adverse effects. They also give personal care to dispel fears and misconceptions about family planning.

How Nurses strengthen the Family Health Programme

In order to strengthen the Family Health Programme the nurses assist the medical officer to organise conferences for staff in the institution and conduct inservice education programme, refresher courses in order to keep the staff up to date with knowledge and make them familiar with current problems and new policies.

In order to carry out the National Family Planning programme effectively, nurses learn to understand their role, and the roles of the medical staff as well as other health workers and how they complement each other. Nurses guide and assist other staff – e.g. midwives, by formulating programmes of the work for the nursing staff and midwives, while supervising and co-ordinating work of the different officers.

When a patient is discharged, the nurses make the patient aware of the options open to him or her as regards family planning practice.

Family Health Centres are being set up in every hospital, similar to the system that exists in the Colombo Group of Hospitals where every eligible patient is directed to the Family Health Unit before he or she leaves hospital for necessary guidance. There should be a recording system on the case notes to ensure that family health advice has been given to every eligible patient who seeks treatment in all our medical institutions both in Government and private sector.

Importance of Periodical Evaluation of the programme

The main objective of this Family Planning Programme, which is a component of the total Family Health Programme, is to reduce the crude birth rate to 25 per 1000 by 1975. In order to achieve this objective,

it is of vital importance to evaluate the programme. Nurses and midwives are responsible for maintaining records (e.g. birth rates, clinic attendance) assisting the medical staff to check records and returns pertaining to statistics of Family Health programme, and interpreting and reporting on data periodically. Further, they are in a unique position to observe the progress of the programme, how well it meets the needs of the people, and what problems the people have in utilising the service.

I earnestly hope that the efforts of the Family Health Bureau of the Ministry of Health, and the Family Planning Association, will succeed in reducing the birth rate of Sri Lanka, in order to build a healthier and a happier nation.

THE ROLE OF PUBLIC HEALTH NURSES AND MIDWIVES IN THE FIELD OF FAMILY HEALTH

By

MRS. C. M. NANAYAKKARA

The origin of the present pattern of field health services in Sri Lanka dates back to 1926 when the Health Unit system was first introduced. Since then, certain changes have been made from time to time to meet the demands of a rapidly expanding service.

The Frame-work of the Field Health Services

For effective distribution of Health Services, the country is divided into 15 Health Services divisions which are in charge of a Superintendent of Health Services. Within the divisions, there are 100 areas in charge of a Medical Officer of Health. Six of these areas are utilised for training of health personnel as well. In the training centres there is a full complement of Public Health Nurses. Each nurse is assigned to an area of 10 – 12,000 population, where there are two to three Public Health Midwives. The remaining M.O.H. areas have one to two Public Health Nurses who are attached to the main office and they function more in supervisory capacity. At divisional level there is a Supervising Public Health Nurse who is responsible to the Superintendent of Health Services for the work of all the Public Health Nurses and Midwives of the area. The organisation and execution of the training programmes for nurses and midwives are carried out by Tutors (Public Health) who are Public Health Nurses with specialised nursing education qualifications.

The Public Health Nurse and Her Functions

The Public Health Nurse is a qualified nurse midwife who has had a further 9 months' training in Public Health Nursing. Having had a minimum of 3 years' experience in bed-side nursing in hospitals and a total number of 4½ years training, this nurse is in a privileged position to perform all aspects of health care in the family health programme.

The Public Health Nurse plays a supervisory and advisory role in respect of

maternal health care. But she is mainly responsible for the health of infants, pre-school children and school children in her area. She also has the overall responsibility towards the welfare of handicapped children. In the field of family planning she plays the dual role of supervisor and worker as well.

Responsibility towards Ante-natal Care

The Public Health Nurse has to ensure that all expectant mothers have been registered by the field midwife early in pregnancy and that the mothers receive medical care as needed, that regular home visits are paid, and whether the midwife recognises and utilises the suitable entry points to introduce family planning.

Natal Care

The Public Health Nurse is expected to supervise home deliveries conducted by the field midwife and assist and guide where necessary regarding health education in family planning as indicated.

Post-natal Care

During this period the care of the newborn and motivation for family planning is emphasised.

Infant and Child Care

The Public Health Nurse's main responsibility being the care of the child, she devotes much attention regarding the nutrition, medical care and immunisations at clinics, in the home and the school. With regard to the welfare of handicapped children the nurse has to visit periodically the orphanages, creches and children's homes in her area and carry out immunisations and assist in the medical examinations.

The health of the school child is also her concern. The arrangement for medical examinations, correction of defects, health

education and immunisations are her main responsibility in the school.

In the field of family planning, apart from her general role as a motivator, she has to undertake specific duties as a distributor of contraceptives including the pill, assist at Family Planning Clinics and follow up work.

The Public Health Nurse has an important part to play in maintaining correct records relating to the above activities.

The field midwife who is designated as the Public Health Midwife has had her training in midwifery at an institution for one year at the Health Unit for 6 months.

After her 1½ years' training, she is either employed in the hospital or field. In the field she is assigned an area of 4 to 5,000 population.

The Supervising Public Health Midwife

In areas where there are one or two Public Health Nurses or none at all, the Supervising Public Health midwife assists in the supervision of the field midwives. They also assist in the training programmes of pupil midwives.

Functions of the Field Midwife

The field midwife is responsible for the care of mothers during antenatal, natal and post-natal periods including the care of the newborn. Where there is no full complement of Public Health Nurses, she has to play an extended role in the elementary care of the infant and preschool child and assist in school health work. She is the front line technical health worker in the implementation of the Family Health programme. She also has been given an extended role with the regard to immunisations.

Her general duties consist of the following:

The field midwife acquaints herself with all the pregnant mothers in her area, registers them early in pregnancy and ensures that periodic medical examinations are carried out. During her home visits she imparts advice on nutrition, hygiene of pregnancy and makes suitable arrangements for the confinement. She also motivates mothers for family planning as indicated.

The field midwife is expected to conduct normal deliveries in the home in keeping with standards laid down by the Health Department. During the post-natal period she has to pay at least five visits within the first 10 days after delivery. In her routine care of the mother after delivery, she pays special attention to any abnormalities occurring during this period and seeks medical advice. She has to see that proper lactation is established and maintained and correct feeding techniques are followed.

In the sphere of family planning she reinforces advice given with regard to family planning and makes suitable arrangements in the case of acceptors.

The midwife is responsible for the preparation and other connected activities with regard to antenatal, child welfare and family planning clinics. Her part in family planning activities include the motivation of mothers, distribution of contraceptives, arrangement for clinic visits, assisting the Medical Officer at clinics, follow-up visits and maintaining records.

In conclusion I wish to state that there is much scope for improvement in the quality and quantity of the Public Health Nursing and midwifery services regarding family planning work in the field. In this connection a highly organised "in-service" education programme is being carried out by the Family Health Bureau of the Department of Health Services of Sri Lanka.

PARTICIPATION OF HEALTH EDUCATORS IN FIELD PROGRAMMES

By

MR. B. A. COORAY

Having given deep thought to the subject at hand, I am prompted to place before you for discussion the main theme for today which enquires as to the role of nursing and auxiliary personnel in population limitation. The obvious answer to this, springs from the statement that health education is an integral part of all health programmes and requires the active participation of all categories of workers. It is in a background such as this, that the Health Educator must address himself to his own role and responsibility. It is now well over a quarter of a century since health education began to take the form we recognise today. Although this is only a very short time to examine the role of the Health Educator in the field of population limitations, it provides sufficient time for us to view this role in its limited perspective.

I would therefore base my paper first to get a glimpse into the need for health education in a population limitation programme and then proceed to analyse briefly the problems and challenges to health education. Next in a logical sequence would be the mechanics of the teaching-learning process and finally the role of the Health Educator.

Need for Education in Family Limitation

People are likely to take constructive health action when they fully understand the implications of unrestrained population growth and when it does not conflict with other goals they have, that are important to them. Most of the educational plans have been very superficial and mechanistic. They are developed on the assumption that people can be pushed or coerced into participation through massive information campaigns or through financial or similar incentives. Family planning efforts seem to overlook the fact that the programme deals with human beings and human beings do not like to be treated as objects or as a means of achieving a target of I.U.D.

insertion. Therefore, the population problem has its own supporting education component which in turn should support the programme. Any attempt to do away with either the service component or the education component of this programme would give rise to disastrous results. It is important that the educational, including the informational efforts of all agencies be carried out together in a co-ordinated manner. Little is derived from a programme limited to information conducted by one agency, when the timing of the information has not been geared to the scheduling of services.

We must accept the concept that we do not change or educate people but that people educate and change themselves. We now have substantial evidence to show that when people are personally involved in determining their own activities, interests and morale are heightened and goals are more likely to be reached. There is today sufficient research evidence to show that mass media are effective in giving individuals information and changing specific attitudes, but are not very effective in actually changing well-established patterns of behaviour. If as Dr. William P. Shepard has stated, education will in the future become an increasingly important approach to public health, then all workers should become as familiar as possible to new advances in the field of learning. He emphatically states that there are no short cuts, bag of tricks or manipulative devices for effective educational work.

Problems and Challenges to Health Education

Health education is not without problems, especially as it involves a process of change in an individual, his way of thinking, his attitudes and feelings and above all his behaviour. When a Health Educator attempts to bring about a change in fertility trends which is directly connected to sex

behaviour it is not devoid of its emotional tensions and suspicion.

One other drawback is the inadequacy of avenues for professional growth, especially in the developing countries; the absence of teaching faculties with provision for advanced studies in health education.

To many the specialised role of the Health Educator is not known. Failure to realise this specific role tends to make unnecessary demands on him. This at times could end with severe handicaps to the programme, apart from striking the very basic professional qualities the Health Educator is required to nurture, i.e. emotional stability and creative ability.

To some, education is a convenient and recognizable label whose vague meanings are sufficient to cover whatever situation it may be called upon to describe. The professional Health Educator often is willing and eager to provide such coverage under his broad umbrella.

Social and cultural barriers with die-hard religious biases contribute much to the ineffectiveness of a population programme. But they are to be expected and should not be considered as insurmountable. Transformation into a better social order, and acceptance and prestige are a few of the basic human urges common to any individual or community.

The lack of education and behaviour research on family planning is severely felt. The limitation in research findings is all the more lamentable since the success of family planning services depends upon the voluntary participation of the people.

Of the studies that have been made, the largest group deal with knowledge, attitude and practice, which are usually referred to as K.A.P. Studies. They indicate a fairly high level of knowledge, favourable attitudes, but much lower reported practice. There has also been research in the field of communication. Most of these are concerned with the mechanics of the communication process, the message, and the media, but do not throw light on the interaction of the receiver to the sender or the perception of the message by the receiver.

How much information and understanding of the reproductive process, contraception, and male and female physiology, is essential to the consistent practice of family planning? A dearth of these studies is a great impedance to education and should stimulate those concerned in this field.

Listing these difficulties and limitations is not intended to detract from the desirability; instead they are mentioned, because most of the difficulties can be obviated or at least reduced, if they are recognised. Plans can then be made to solve such difficulties before they grow into serious personnel problems. Joint staff planning and decisions will do much to reduce such problems.

Role of the Health Educator

To many the role of the Health Educator is one of teaching, training or educating and is identified directly with the community and with its multiplicity of problems. Therefore they expect the Health Educator to give doses of information through all available media. But let me reiterate that every one who has a stake in a programme is an educator. Doctors, nurses, administrators, labourers or social or religious leaders – all of them have a responsibility for education. These categories of workers need to equip themselves with adequate and appropriate skills to suit them to the task of teaching. The major portion of the professional Health Educator's role is to provide such skills, guidance and counselling to these workers and prepare them for such tasks. It may sound paradoxical, but is nevertheless true to say that the professional Health Educator may not do direct teaching at community level but plays the role of an "enabler". This may tend to place the Health Educator in the position of a "super administrator", and may at times tend to disassociate him from the community at large. Let me therefore briefly highlight some of his more legitimate functions which identify him closely with the "field" in community working situations. His major function is to identify the education component of any programme. In the context of population limitation, he would identify the education component and then assess the resources etc. in order to draw up a suitable plan for implementation. I would summarise the major functions of the Health Educator as follows:

I. Educational diagnosis of a problem in the community

This he does by analysing the available community data related to the problem:

- a. Morbidity, mortality etc.
- b. Population size, sex, age distribution, race, cultural factors, education and other data upon educational problems.
- c. Customs, traditions and attitudes.
- d. Climatic conditions, seasonal variations etc.
- e. Knowledge, attitudes and practices of people.
- f. Channels of information and communication.
- g. Other existing programmes of social change.
- h. National, regional and local organisations.

II. Planning the educational aspects of programmes

- a. Define the educational component of programmes.
- b. Determine objectives of the educational programmes.
- c. Identify resources for educational programmes.
- d. Involve others who will be responsible for the implementation of programmes.
- e. Plan for timing of programmes to be in tune with other programmes in the community.
- f. Select and test possible methods, media and material.
- g. Calculate the cost of the educational activities in terms of personnel, time, material etc.

III. Operation and conduct of programmes

- a. Identification of groups or individuals involved in the educational programme and stimulation of their support and participation.
- b. Establishment and maintenance of effective working relationships with all agencies.

- c. Co-ordination of the planning and their activities with the Department and outside agencies.
- d. Reporting on the progress, obstacles and results.
- e. Role of guidance and supervision to staff.

IV. Preparation of other personnel for Health Education

- a. The preparation of other health personnel in health education and assisting in the general educational programmes are principal functions of the health educator. This he attempts by direct teaching assignments.
- b. Demonstrates the proper use of various methods and material and sound education principles during staff education programmes.
- c. Orientation programmes for new workers.
- d. Makes helpful contributions by way of an educational consultant to staffs and administrators.

V. Evaluation

A realistic approach is adopted in evaluation in terms of personnel, time, money and efforts.

- a. Determines the efforts necessary for the attainment of programme objectives.
- b. Carries out qualitative and quantitative analysis of inputs vs. results.
- c. Defines criteria of measuring.
- d. Evaluation of the reliability of the instruments and the validity of measurements.

VI. Research

The conduct of studies and simple research may be an additional function which the Health Educator may undertake, especially in the absence of other competent personnel.

Conclusion

As a growing profession we have faced many dilemmas. At each step on our

path to professional growth, we have found it possible to make at least a start in resolving them attempting to meet each new problem with the broader perspective which has grown out of our previous experiences. In this process of professional maturity, we have reason to be proud of our progress. The community we serve and the "field" programmes we conduct, the numerous

friends who value the services of the Health Educator and, above all, the numerous requests from the community for the solution of their multiplicity of problems all bear testimony to our professional contribution. Today the Health Educator finds himself working with others to find solutions to the most crucial of all global issues, namely the unplanned procreation of man.

**THEME: DISTRIBUTION OF CONTRACEPTIVES
BY NON-DOCTOR PERSONNEL**

CHAIRMAN: Prof. Malcolm Fernando

THE COMMERCIAL DISTRIBUTION OF CONTRACEPTIVES

By

DR. T. R. L. BLACK

Historically, the principal sources of contraceptives have been shops of one kind or other. Even today more people obtain their contraceptives from shops, than from organised Family Planning Services. In view of the rapid rate of population increase and slow expansion of medical facilities it is safe to predict that commercial channels and do-it-yourself methods will continue to be the principal source of family planning for a very long time to come. For this reason, we have to begin to understand the mechanics of commercial contraceptive distribution and learn from past successes and mistakes. Moreover, given the magnitude of the problem and the evident inability of public and private agencies to marshal adequate human, technical and material resources, we must begin mobilising all sectors of society, of which the commercial marketing institutions are particularly relevant.

The family planning movement has been and still is highly suspicious of contraceptive retailers and marketing in general. The feeling seems to be that it is wrong to capitalise on this particular human right.

As a consequence of this attitude, few family planning organisations have any knowledge of the extent of their local contraceptive markets or what relevant resources exist in the business sector. Until the last three or four years, few attempts were made to quantify commercial sales of contraceptives. And in spite of all the evidence such as Coca Cola in Timbuctoo, sardines in Nepal, sanitary napkins in the African village shop and so on – the techniques and machinery of marketing have been largely ignored. Yet the indications are that marketeers are highly successful at the business of innovation, motivation and supply – the very functions which are basic to family planning and at which we have not been overly proficient. The purpose of this paper, therefore, is to explain what is meant by commercial distribution of

contraceptives and to give some insight into why we should begin to harness marketing resources for birth control activities.

Strictly speaking when we talk about the commercial distribution of contraceptives we mean the sale of contraceptives for profit, but in family planning circles we mean the promotion and distribution, or marketing of contraceptives through commercially motivated channels whether for profitable or social reasons. We are interested not only in local contraceptive markets but also in what has been dubbed 'social marketing' – the use of commercial marketing techniques, resources and skills to attain social objectives. From a family planning point of view, the question is "What are the contraceptive manufacturers doing in the market place and how can the resources of the business community be utilised?"

The existing contraceptive market situation is significant. Sollins and Belsky have estimated that if we exclude China and the Eastern bloc countries, some 80 per cent of the world's contraceptives are still supplied through commercial channels. Recent studies have tended to confirm their estimate. The IPPF survey suggests that of the 500 million women at risk, at least 31 per cent are regularly practising some form of family planning but that only one third are doing so under the guidance of organised programmes. Market surveys of thirteen developing countries have demonstrated the key contribution of the commercially available contraceptives even where substantial public sector programs exist. For example, the Estinghouse Population Centre Survey found that in Venezuela, a country without a significant family planning programme, 84 per cent of acceptors obtain their requirements commercially. In Thailand, on the other hand where there is a strong voluntary association, 64 per cent do so. In South Korea, a country with a major

government effort, some 20 per cent still buy their contraceptives commercially.

Such surveys have also revealed a number of serious barriers to the expansion of commercial contraceptive markets. The principal obstacle to market expansion is the high retail prices, or the cost to the customer, of contraceptives. Contrary to popular belief, this is not necessarily due to the cost of manufacturing or even excessive profiteering by the trade. It is often a function of the legal restrictions as well as import and other duties imposed by local governments. The two principal legal barriers are the "pill-only-on-prescription" requirement and the "no contraceptive advertising" laws. Such measures raise prices by limiting promotion of activities and the depth of distribution thereby increasing the costs of market development. Duties and other taxes increase costs directly at the point of importation and in the shops.

If such legal restrictions and duties were removed, it is possible that contraceptive retail prices could be reduced in many countries by as much as 60-70 per cent. For this reason family planners should work to identify the local barriers to commercial contraceptive market growth and work for their removal. The legal and tax concessions required would cost governments very little in lost revenues, and would almost certainly result in doubling of many contraceptive markets. The economic benefits alone, from the decrease in births, would more than compensate for the lost tax revenues. Indeed, in view of the social desirability of contraceptive sales it would pay many countries to give the manufacturers tax incentives and even grants for developing their markets.

However, the implications of commercial distribution go beyond the development of the profit motivated market. In family planning we are in the 'innovation-business'. We are involved in the difficult task of changing attitudes and practices of consumers, solely by means of persuasion. This is very different from the treatment of clinic patients. We are engaged in an active process of creating customers for contraceptives and birth control services. By definition this is marketing.

Therefore, since a marketing industry already exists, we should use it. It is a system which quite clearly has an efficient management capability. It possesses a body of 'know-how' about demand creation which is demonstrably effective. It also embraces a major grass roots distributive network which can be used to supplement the rather limited clinical facilities at our disposal. After all there is nothing unique or mysterious about contraceptives, and marketeers are responsible for most of the major changes in consumer patterns of consumption. With the possible exception of the IUD, contraceptives are non-durable consumer goods and therefore amenable to mass marketing techniques.

There are three aspects of family planning on which, in my view, the mobilisation of the marketing industry could have a profound impact, namely: distribution, promotion and programming philosophy.

The use of commercial channels of distribution opens up the prospect of overcoming the weakest aspect of family planning delivery—the limited number of service outlets. Now that the availability of the pill without a prescription is gaining acceptance, the commercial distribution channel offers the possibility of placing both male and female contraceptives in almost every store in a country. In most countries there is one shop or retail outlet of one kind or another for every 500-800 people. It also opens up the prospects of developing alternative modes of distribution. The postal services in many countries are reliable, cheap and capable of reaching the majority of the population. This raises the prospects of contraceptive mail-order, a method of distribution which is widely used in the United States and Europe. Another possibility is the contraceptive vending machine, as used extensively in Sweden, while the Japanese have demonstrated the success of door to door contraceptive sales teams. In other words, commercial channels can be used to make contraceptives as readily available as a packet of cigarettes.

The involvement of the advertising profession in family planning promotion offers exciting prospects. Because of social and political pressures birth control promotion has been unduly reliant on information and education through face-to-face or

personal selling. Unfortunately, although direct selling is relatively effective it is expensive and severely limited by the sheer numbers involved. The use of advertising offers the prospects of a major shift in strategy towards a broader spectrum of promotion with greater emphasis on subtle motivation and mass media. It would also result in more specific product or service related campaigns, thus shifting the focus away from the current emphasis on demographic horrors and genital anatomy to the more personalised and sex-related themes which so successfully sell almost everything these days. Involvement of the advertising agencies would almost certainly provide a badly needed injection of creativity into the whole family planning promotion business, which in turn would probably enhance the effectiveness of our customer recruitment.

Equally important, involvement of marketing professionals in family planning would introduce a new facet to our programming philosophy – the customer orientated marketing concept. The exigencies of medical practice, especially in rural areas, is such that the major preoccupation of the medical worker is with the existing case load. Under such circumstances it would be surprising if the collective consciousness of the medical profession had not become unduly focused on the clinical and administrative problems of health care delivery. The marketing profession, on the other hand, is preoccupied with the characteristics, wants and preferences of actual and potential customers. The customers are considered to be the ultimate experts and therefore the pivot around which decisions and strategies are evolved – an orientation which is noticeably lacking in most family planning programs.

That the commercial marketing industry is of potential value to family planning is no longer a question of speculation. Last year the Indian Nirodh Social Marketing Programme sold some 80 million condoms at subsidized prices through shops on a nationwide scale. The Swedish RSFU Family Planning Organisation has been marketing contraceptives through shops, vending machines and mail-order for over twenty years. Six years ago they began using the services of a very creative advertising agency with the result that their

share of the Swedish condom market rose from 10 to 35 per cent, while sales trebled to over 20 million a year. In Kenya, a controlled pilot project has clearly demonstrated the value of the marketing process. The Kinga condom advertising campaign created, in just one year, a rural condom market from nil to 0.24 pieces per capita: about one tenth of British consumption. It also markedly increased family planning awareness especially amongst the 18 – 30 year old group. There have, of course, also been failures. A two million dollar family planning advertising experiment in the U.S. was a spectacular flop, principally because, I believe they used an advertising agency to mount a rather traditional albeit highly creative I & E promotion as distinct from consumer product type advertising campaign.

This is not to say there are no problems in harnessing the private sector marketing industry. First there is the very real barrier of mutual suspicion – the family planner tends to regard the marketing man as some kind of money grabbing showman, while marketers are cynical about the time wasting committee and 'expert' worship of the family planner. There is also the very real problem of language and concepts. The commercial and family planning vernaculars are mutually incomprehensible. Family planners talk about patients, the commercial man about customers. Conceptually the marketing man is strongly customer and profit orientated, while the family planner is biased towards the medical profession and fund raising. The marketer is also used to living directly with his results, in a tightly evaluated environment of costs, sales, profits etc. This is in direct contrast to the rather relaxed state of affairs in family planning.

But despite such difficulties, real or imagined, collaboration between the family planning movement and the marketing industry is essential if we are to overcome the two major draw-backs inherent in the current approaches to birth control, which are:

- (1) the restricted nature of the technologically and capitally intensive clinical delivery system, and
- (2) the lack of extensive grass roots community involvement.

Unless we simplify and broaden our channels of distribution and directly implicate larger sectors of the community in the family planning effort, we are unlikely to achieve effective voluntary birth control. The use of the various components of the marketing industry, such as the advertising agencies, the distributors, the wholesalers as well as village shop keepers and hawkers,

for family planning presents the opportunity of dramatically improving distribution while at the same building a truly community based programme. Such a move would also create an extensive and influential body of vested interest in the family planning process. In which case, I believe, we might just avert the impending demographic disaster.

DISTRIBUTION AND SUPERVISION OF ORAL CONTRACEPTIVES

By

DR. MALCOLM POTTS

1. Confidence in a Method

When Dr. Gregory Pincus came to Sri Lanka in 1960 the number of oral contraceptive users in the world could be counted in tens, or hundreds, or thousands. Experience was limited to a few years. In those days it was reasonable to conclude that this novel method of contraception should be dispensed by doctors. Today, there are perhaps 45 million users, of whom an estimated 15 million are in the Peoples Republic of China. Experience of use is well over a decade and a half. Today we have a knowledge and assurance about the pill which allows us to adopt new methods of distribution and supervision.

It is appropriate for this first International Scientific Conference to take the leadership in devising new distributor systems. The scientists among us know the rate at which new biological discoveries are being made. We can appreciate the need for prolonged animal testing and very careful clinical trials before a drug is registered for widespread use. It can cost a pharmaceutical manufacturer millions of dollars and take well over ten years to get a new drug to pass all the requirements of the U.S. Food and Drug Administration.

We would all like better methods of fertility regulation, but even when they have been invented of necessity, it will be a long slow process introducing them. By the end of the decade, the major methods such as pills, condoms, IUD, vacuum aspiration and sterilisation are likely to remain.

Even when a new method has been through a massive and detailed programme of animal tests and closely supervised clinical trials it is still impossible to exclude rare but perhaps very important adverse effects. Sir Alan Parks said some years ago, that the problem with the Pill was that it was impossible to prove it was safe for everyone to use until everybody had used it for a generation. We

cannot short circuit the confidence which prolonged large scale use alone provides.

There are still unknowns about the Pill but our confidence in its safety is vastly greater than when Gregory Pincus first spoke about the Pill in this city. For example, Sir Richard Doll and Professor Martin Vessey, who did the first important studies on thromboembolic disease in Britain have now shown an apparently *protective* effect of oral contraceptive, as in the case of breast disease. We now know that amongst Western women the Pill makes a very rare disease to thrombosis, somewhat less rare but still very uncommon. Such an adverse effect has not been demonstrated for Asian women and it is uncertain if it exists.

Amongst Western women the Pill makes a very common condition namely, benign and malignant breast disease, significantly less common. On biological grounds we may expect this finding to apply to Asian women as well as to Western women.

Paradoxically, while epidemiologists have discovered more and more about the Pill the individual doctor in his clinic has had the humbling experience of realising that his ability to help users was low. We have no predictive tests for those women who may be at risk with the use of the Pill. It was shown in England recently that among several hundred women who have refused the Pill, it was always the history and never the pelvic examination that lead to the refusal. It was also discovered that most of the women refused by one doctor were in fact given the Pill by another; interpretations of the woman's history were arbitrary.

The Pill is safer than most drugs available without prescription.

The user makes her own diagnosis – she does not want to get pregnant. The dose is constant. Overdose is not lethal.

The I.P.P.F. Central Medical Committee reviewed the whole problem of oral contraceptive supervision and distribution in April, 1973. (The full text has been circulated).

2. The Physicians' Perspective

In all countries doctors have a solemn and binding duty to use their skills as effectively as possible. In developed countries every aspect of medical care is becoming increasingly expensive: it costs as much to keep an average patient one day in an American hospital (now over \$500/-) as the annual per capita income of many Asian countries. In the rural areas of most developing countries the ratio of doctors to people is 1 : 100,000 or less, in towns many doctors are in private practice or administration. Everywhere doctors are busy. Nowhere do doctors want to do work which they can reasonably and responsibly share with others. In fact, the expense of our training, the fees we command and above all our own self respect, oblige us to share as many tasks as possible with our colleagues in the health team.

3. Programme Needs

Many family planning programmes are now at a watershed. Given that new technology will only change slowly, and recognising that in many programmes our present recruitment of acceptors has levelled off far below that necessary for a demographic impact, we have to ask, "where do we go next?"

Three answers are possible and I think this conference is showing very plainly that the community needs and deserves all three:

1. Elective male and female sterilisation
2. Early abortion on request
3. Innovations in contraceptive distribution and promotion.

4. Community Needs

In relation to the distribution and promotion of contraceptives we are at an exciting and crucially important time of opportunity. Family planning programmes can undergo a revolution in scale and effectiveness in the next few years.

The Prime Minister of this country knows by her intuition what we as "experts"

have all too often overlooked. In her inaugural address, Mrs. Bandaranaike called upon us to look at the socio-economic background of the people we serve, and reminded us that no amount of scientific research by itself would solve the population problem.

The users' perception of the distribution system and the users' perception of the available methods is as important as the physiological and pharmacological attributes of the method.

The key to successful family planning is to make the distribution system fit the users' needs, not the user fit the system.

We have not been all that successful. In the past, we have tried to "motivate" the user to come to "our" clinics; to attend a service designed to meet the doctors' perceptions of how family planning should be dispensed.

The confidence we now have about the Pill allows us to take it out of the clinics and put it in the community. The ethical obligations to use our precious and expensive skills wisely compels us to make this change. Fortunately, all the available evidence suggests it is a move that will immeasurably benefit every aspect of family planning.

Now we have a technology that allows us to begin to meet the user's needs. The marketing of condoms foreshadows what will be achieved with Pills. In the course of the last few months 3300 new family planning clinics have been opened in Sri Lanka - for this is what shops undertaking the subsidized marketing of *Preethi* condoms are - and the number of contraceptive outlets has been multiplied by five at a stroke.

Marketing is the art and science of pleasing the user. Marketing skills are welcome in family planning. Sometimes marketing is misused. For example, in the Philippines, as in many developing countries, the aggressive marketing of tinned and powdered milk for babies is substituting an unnecessary, costly, potentially harmful, second-rate product for a more convenient, natural product - namely breast milk. So one poor country spends \$30,000,000 on baby feeds each year, equivalent to the IPPF global

budget for all aspects of family planning. If I was Minister of Health, I would put baby milk on prescription and take the Pill off.

It is hardly surprising that the aggressive marketing of a good, necessary and wanted product – namely contraceptives – can be uniquely successful.

Unsupervised, over-the-counter sales of the Pill already meet the needs of the middle classes in most countries. Social justice demands the subsidised marketing of the same product to the poor and the IPPF is supporting such approaches.

However, one of the major problems facing us all in the closing decades of the twentieth century is to keep pace with changing opportunities. Human beings find 'unlearning' even more difficult than learning, and doctors are no exception. Doctors find it difficult to adjust to the fact that an auxiliary midwife in Thailand, can distribute the Pill as well or better, than they were taught to do it only a few years ago. In many places even the user has come to expect a doctor to distribute oral contraceptives and we must help show that new ways are possible and better. The fact that the IPPF has trained 8000 school teachers in Brazil to give out the Pill is perhaps a surprise, but it is true. Where we had 13 clinics for 1.5 million people, hopefully reaching 4% of eligible couples we can now reach a target of 25%. Previously we spent 8% of our budget on contraceptives and over half on personnel costs, now we spend more than half on contraceptives and less than one third on personnel.

In Columbia, housewives and selected store-keepers dispense the Pill through a programme partly devised by the IPPF President Mr. Tamayo. Over the past 30 months 6,700 women have joined the scheme, the pregnancy rate among the Pill users is 1.62 per 100, and the concentration rate (50 – 86% at 12 months, 49.6 – 78.4 at 18 months) one of the highest in the world. Only 2% of women have had real problems.

In many countries – The Peoples Republic of China, Laos, Columbia, Brazil, Antigua, even parts of the U.S.A. part or all of the Pill distribution is being carried out by specially selected and appropriately trained

lay people – at a subsidised price (some at no cost as in Brazil).

We don't have a perfect word for these new systems, but I call them *community based* distribution of contraceptives, as opposed to clinic based. The essential features are –

Local distributors are selected and trained (usually for one day). They usually serve 20 to 200 users. Therefore their work is only part time and any remuneration is based on items of service or profits from sales. A system is created whereby women with problems can be referred to clinics. Easy transfer is planned for the Pill and condom users to other methods, such as IUDs and vasectomy.

Therefore these community-based distribution systems supplement and extend clinic and health centre work. Doctors and midwives now deal with problems, not routine cases, and can concentrate on IUDs or the surgical methods of fertility regulation.

The IPPF can obtain free of charge and *outside* regular budgets, as many oral contraceptives and condoms as an Association can distribute. The Governing Body has unanimously set aside \$800,000 to further distribution systems. Associations may sell or distribute contraceptives free. Our only obligation is to use any money generated to further some aspect of family planning.

Ayurvedic Practitioners

I am a western trained doctor, with degrees in medicine and pure science. I can describe the morphological changes in the endometrial mitochondria in response to exogenous hormones at different stages of the menstrual cycle, or I can tell you about the statistical significance of case control retrospective epidemiological studies. I can tell you very little about the feelings, the fears, the lives, the hopes of a villager in Sri Lanka.

Many of the western trained doctors at this scientific conference have done much to develop the technology of contraceptives, but we have a poor record of applying our inventions.

In Sri Lanka you are fortunate in having a substantial body of ayurvedic practitioners. You have a skill with people that the Western doctor often lacks. The Prime Minister, the IPPF Secretary General, and many of us have welcomed the participation of ayurvedic doctors. We at this conference say "Please help us." "Please take the Pill we have invented and tell us how to distribute them." In other words we have done the easy part, now please help us with the difficult bit. Perhaps we should say that we are sorry we have been so taken up with our microscopes and statistics that we failed to consult you earlier.

Summary

We have better oral contraceptives than previously, less oestrogen, less risk. We know a lot more about them. We are increasingly confident of their safety. The

need for routine medical supervision of every user is past.

Contraceptives must be accessible in economic, geographic and social terms.

Oral contraceptives are entering a new era, and the role of family planning clinics is changing. The Pill can and should be distributed from *within* the community; every village, every district must have a well-advertised distributor.

In Sri Lanka we have the opportunity of seeking the assistance, skill and long traditions of ayurvedic medicine to help in distribution, supervision and problem-solving. In this aspect of family planning. Sri Lanka, will I am sure set an example to the world. Those of us who are guests in this country will watch your experience with anticipation, fascination and excitement.

THE USE OF MASS MEDIA IN NON CLINICAL DISTRIBUTION OF CONTRACEPTIVES

By

MR. ANANDATISSA DE ALWIS

Non-clinical distribution of contraceptives aims at making selected contraceptives available to people at points of distribution close to their homes and work-places. The moment a decision is made to make a contraceptive available outside of clinics, hospitals or pharmacies we enter the territory of marketing. Marketing is divisible into two areas. One is the marketing of goods for profit and the other is non-profit marketing which is social marketing. The concept of social marketing is that a product or service is marketed to achieve optimum acceptance without regard to a profit motive. It is easy at this point to conclude erroneously that the absence of a profit motive in the mind of the social marketer must be followed by a disregard for the rules of marketing.

Marketing (social or otherwise) has one basic law by which it is governed. This is the law that the consumer for whom the product is intended is the most important element in the entire process. All of the numerous things necessary to be done in marketing have to be looked at from the point of view of the consumer. This attitude of mind is described as consumer orientation. When therefore, we enter the field of marketing we have to follow the rules of that science or we risk failure.

There is an accepted discipline called the marketing mix. The marketing mix is a combination of a number of ingredients:

- The right product,
- The right price,
- The right package,
- The right distribution,
- The right research,
- The right advertising.

It is an error to suppose that one or other of these ingredients is less important or that one

or two of these may be entirely ignored. Marketing experts have learned at tremendous cost all over the world that when any one of these factors is not right, the project fails. However right the product might be, if it is not delivered at the right time or in the right place or in the right package or at the right price, the exercise must fail. To take an example, the right price is not necessarily the highest or lowest price, and when we return to the first principle of consumer orientation we will find in it the guide to decision making on what the right price must be. It is not what the marketing man thinks it should be, or the advertising expert thinks it should be. All of these experts may be very eminent but if they are really marketing oriented they will realize that only the consumer can decide what the right price should be. There are numerous studies of marketing success and failure which bear testimony to the truth of this statement. If a price is too high in relation to products that are considered safe, sure, reliable and so on, there would be consumer resistance. Conversely, if the price is too low from the consumer's point of view or it ignores the costs of placing the product in the right packages at the right time in the right place with the right advertising then also there will be consumer resistance. How does one arrive at the correct decisions?

The techniques of marketing research are employed in the marketing of these decisions. The function of marketing research is to deliver the necessary information to the decision-maker.

I will not go into a detail about all of these elements in the marketing mix because we must go on to the subject of the use of mass media in the non-clinical distribution of contraceptives.

These preliminary remarks were necessary to place the exercise against the proper

background, because it is all too easy to come to the conclusion that a method of contraception considered safe, sure and reliable has only to be distributed to as many points as possible and the availability announced to the people and they will queue up and buy it. Such simplicity belongs to the grave-yard of marketing failures.

Social marketing of contraceptives, links fertility control to specific products. Having selected the right product it takes cognizance of all other ingredients of the marketing mix. It thus becomes a function different from the traditional and very important function of family planners all over the world, that of education and information. The educational and information inputs through mass media seek to create awareness of the size of the problem, the urgent need for fertility control, the universality of family planning information on methods sanctioned by medical opinion, the offer of pamphlets, booklets and advice at clinics and motivation of the people towards the use of these facilities. Non-clinical marketing, however, is directly linked to specific products, and motivates the people to the purchase and continuing use of such products.

To my mind the best way to illustrate the use of mass media for such a project is to present the case study of a project launched in this country. The product used was the "condom" and the marketing objective was to secure the maximum use of this contraceptive for males and to motivate such users to continue using the product in family planning.

The condom available was "Durex" and from there on many weeks of study and discussion were necessary in order to ensure that all the ingredients of the marketing mix were right.

Firstly, the product. The condom as a contraceptive device has the sanction of safety and reliability provided a fresh condom is used on every occasion. A study of the market, however, led us to the conclusion that "Durex" was associated in the past with promiscuity and extra-marital love. It also had the disadvantage that the name, by and large, meant little or nothing in the consumer market. Motivational studies related to marketing have shown

that if a product name offers a promise acceptable to the market and has no objectionable meaning to the consumer, it has a greater chance of success in the market place. Various names were considered, tested by marketing research, and the name "Preethi" was adopted.

In this country there are two major language groups – the Sinhala and the Tamil, and the name had to be meaningful to both races. Preethi means happiness in Sinhala and Tamil. We considered other aspects of condom usage such as the interruption of sexual fore-play. The ideal name should compensate for this irritating necessity and offer a positive instead of a negative appeal. "Preethi" was such a name. We then developed a symbol that would be associated with the name, once again guided by consumer orientation in the judgement of its effectiveness.

The marketing organisation then had the right product, the right price and the right package. It was ready to take it to the right places.

A study of the reach of mass media such as the Press, Radio and Cinema led us to the conclusion that sections of the market would not be reached by them and in order to reach such people we prepared a folder which was available at all retail points and was prominently displayed in a container. This folder was written as a direct message to the prospective customer giving him information, assurance and motivation on family planning.

Mass media such as the Press, Radio and Cinema provide the cheapest method of reaching millions of people quickly. In contrast it would require the continued efforts of hundreds of people visiting homes or addressing group meetings to reach a large population with any particular message and the cost of doing so on a national scale would be enormous.

In preparing an advertising campaign to promote "Preethi", we used the standard techniques of market research in order to find out the degree of awareness of family planning in the country. This information was analysed by market researchers and was the basis of a motivational advertising campaign.

A successful campaign in one country cannot be copied in another territory without expert consideration. Great care has to be taken to assess the social, moral and cultural climate in each country. We were aware that the cultural, social and religious susceptibilities of the people would be offended if the advertising approach was strident or tried to shock people into the use of contraceptives. We had to consider that young children would be exposed to the advertising and care was taken to get the message through to adults without revealing such detail as would embarrass the parents. We were mindful of the respect due to sexual love in the home.

When, for instance, we began advertising in newspapers all we printed was the symbol. This was intensively repeated and achieved the object we had in mind, that of arousing universal curiosity and interest.

This was followed by an advertisement associating the symbol with the brand name "Preethi" in three languages. Once again for several weeks that was all the advertising in the newspapers and in the cinema. The object of making the name "Preethi" memorable was successfully achieved. The third stage was to announce what "Preethi" was, and in doing this we deliberately broke a rule in advertising namely, that in announcing a new product there should be a clear statement of what it is and how it should be used. For the reasons stated earlier all we said was that "Preethi" was a simple, safe, sure and trusted way to plan families. The advertisements showed the symbol, the package in which it would be available in shops, the package in which it would be available to the customers and the price at which it would be sold.

While these advertisements were attracting attention and providing information the marketing organisation responsible for distributing the product put up signs and displays of the product in 2,000 outlets throughout the country. The total possible retail outlets for mass distribution in the country have been calculated as between forty and fifty thousand. The marketing organisation, however, were very selective in the approach and restricted the initial effort to 2,000 shops. There were excellent reasons for this restraint. In the philosophy of marketing there is a tried and tested

principle called the positioning of a product in a market. For instance, if a product is sold on a kerb (or a "pavement" as we call it in this country) it loses social acceptability. When we ask people to accept a product as a simple, safe, trusted way to plan their families it would be damaging this concept to be non-selective in its distribution.

Furthermore, we were not merely distributing, but marketing, and these are quite different things. Mechanical distribution is often easy to achieve but proper marketing turns the retailer into doing more than selling a product. We were engaged in social marketing of a family planning device, and by using the restraint I have described and by spending time on each retailer we were converting them into family planners as well.

In a country where retailers had shown reluctance and had been socially embarrassed even to stock a condom, within a few months, we were able to convert 2,000 of them into sharing the total effort, as informed, educated, and serious family planners helping in their own way to solve a great national problem.

The number of retail shops now displaying and selling "Preethi" has increased to over 3,000 and this achievement, in a period of only 4 months, is a success story of great significance to family planners.

We then proceeded to motivate the people to go to the retail shops. In presenting this advertisement, great thought was given to the restraints we had imposed on ourselves. We went on the basis that children are precious and must always be welcome, but that until a parent decided that he wanted another child he could rely on "Preethi" as a simple, safe, sure, way to plan his family. In order to remove what we knew to be general embarrassment in discussing this problem, we began by saying that millions of people all over the world already planned families and that the subject was no longer a matter for whispers. This approach, to our mind, was an extremely important reason for the success of the motivational campaign. We did not tell the customer as much as we would have done in the case of another product, about its use and we deliberately maintained a low profile in the input of

information. We expected that such an approach would make it easier for parents to read and discuss the advertisement without embarrassment in the home. Subsequent events have shown that these objectives have also been reached and that this restraint has helped to make this campaign acceptable throughout the country.

In visually presenting the idea in the advertisements, great care was taken in selecting a father and son who could be photographed for advertising purposes.

"Preethi" has now become a welcome and acceptable method of family planning by a considerable section of people in this country. Sales of the product have reached an average of 300,000 condoms a month, and in family planning terms this represents a degree of fertility control.

Of course it is too early to evaluate the results. Further motivational and marketing inputs are needed and are likely to increase the number of acceptors. The project offers many lessons to be learned as it grows. It is also the testing ground of the claim that the skills of marketing and advertising have a great contribution to make to the global problem of population control. All the great minds engaged on this problem in the hospitals and medical laboratories in the world share one common purpose, that of making the result of their work available to millions of people. Family planning has to be marketed and a part of the marketing process is mass communication and motivation, and in that process, the specialized skills in advertising necessary for mass media communication are an indivisible part of the success that all of us together strive to achieve.

SRI LANKA: THE IMPACT ON A FIELD PROGRAMME OF ALLOWING PARAMEDICAL PRESCRIPTION AND RESUPPLY OF ORAL CONTRACEPTIVES

By

DR. NICHOLAS H. WRIGHT

Introduction

In 1966 family planning was officially declared an integral part of the Maternal and Child Health Programme of the Ministry of Health, in Sri Lanka. Oral contraceptives were made available at selected clinics after physical examination by a medical officer, but more emphasis was placed on the IUD and sterilization. In April 1968, however, the Ministry reduced the cost of oral contraceptives by half to 75 cents (then about U.S.\$0.13) and authorized prescription and resupply of pills by trained field midwives* outside the clinic, but under medical supervision. Using available data, this paper will describe and analyze the immediate effects of this policy decision.

Results

The decision to allow paramedical distribution of the pill at a reduced price, greatly expanded availability. In effect, over 2,000 new, mobile, distribution points were authorized - at the midwife's house, the client's house, and in-between. The results were soon apparent in the program's service

statistics as shown in Table 1. The increase in the acceptors of oral contraceptives in the second half of 1968 is clear. Overall, new oral contraceptive acceptors represent 62 per cent of the gain in total new acceptors between 1967 and 1968. By 1969, oral contraceptive acceptors were 45 per cent of all acceptors in that year. The gain in pill acceptors in 1969 accounts for almost all of the gain in total acceptors, 1969 over 1968. Acceptors of the IUD remained constant over the three year period while the estimated number of female sterilizations increased.

It was hoped that paramedical distribution and a lower price would also promote higher continuation, perhaps approaching the known high level of IUD continuation. For example, follow-up studies of IUD acceptors in 3 health areas in 1968 and early 1969 had shown 24 months continuation rates of 80, 79 and 70 per hundred first acceptors respectively.¹ On the other hand, preliminary impressions and a small follow up study using clinic records alone indicated in early 1969 that oral contraceptive continuation rates were much lower.

TABLE 1

SRI LANKA: NUMBER AND PER CENT OF NEW ACCEPTORS OF FAMILY PLANNING BY METHOD, 1967, 1968 AND 1969**

1968 AND 1969						
Period		Oral Contraceptives	IUD	Sterilization	Other	Total
1967		8,892(24)	18,506(50)	3,616(10)	5,681(15)	36,695
1968	Jan. - June	5,617	10,110	—	—	—
	July - Dec.	10,397	10,505	—	—	—
	Total	16,014(33)	20,615(43)	5,210(11)	6,325(13)	48,164
1969		25,284(45)	19,537(34)	5,200(9)	6,766(12)	56,787

**Acceptor totals for 1968 and 1969 are higher than official figures because of adjustment for unreported female sterilizations.

Source: Report on New Acceptors of Family Planning, Office of the Medical Statistician, 1968 and 1969, Ministry of Health, Colombo, Sri Lanka.

* Field midwives in Sri Lanka have 8-10 years of basic schooling, one year of professional training with 6 months field practice under supervision and a one week family planning course.

It was clear that the policy changes of 1968 had helped to increase the number of new pill acceptors, but it was not clear that these trends represented an equally substantial gain for the programme in terms of continuing effective use of contraception. A follow-up study in mid-1969 documented the problem in two of the Island's provinces, Galle and Kalutara.² Table 2 summarizes the 1969 findings on continuation in a sample of 1966-1967 acceptors, i.e. women accepting before the oral contraceptive policy change. The technical aspects of the survey are described elsewhere².

TABLE 2

SRI LANKA: NET CUMULATIVE CONTINUATION RATES PER 100 ACCEPTORS BY FIRST METHOD AND ALL METHODS BY FIRST METHOD TO 24 MONTHS

	<i>First Method</i>			
	6	12	18	24
Orals	49	40	35	30
IUD	86	80	75	68
	<i>All Methods by First Method</i>			
	6	12	18	24
Orals	65	58	52	47
IUD	91	84	80	75

Continuation rates for IUD wearers in Table 2 are consistently higher than pill acceptors. The mean age of IUD and pill acceptors in the sample was 30.0 and 29.6, years respectively. Neither age nor parity can account for differences of this magnitude. When only the first method is considered, the difference is more than twofold at 24 months. When all methods are considered, allowing for other method continuation after discontinuing the pill or the IUD, the differences between pill and IUD acceptors are reduced, but still marked. Post-acceptance pregnancy rates in Table 3 suggest that (1) pill users and IUD wearers had comparable rates but that (2) when unplanned pregnancies during use of a second method or after discontinuation of all methods are included, pill acceptors have two to three-fold higher pregnancy rates. Table 3 summarizes the relative demographic effectiveness of the two

methods and, in the methods column, reflects the sharp differences in continuation shown in Table 2.

TABLE 3

SRI LANKA: POST-ACCEPTANCE PREGNANCY RATES PER 100 ACCEPTORS DURING USE OF FIRST METHOD AND UNPLANNED PREGNANCIES DURING USE OF A SECOND METHOD AND AFTER TERMINATION OF ALL CONTRACEPTION AT 24 MONTHS

<i>Method</i>	<i>First Method</i>	<i>All Methods</i>
Orals	4	44
IUD	3	17

A supplementary questionnaire in the Galle-Kalutara follow-up survey obtained additional information on patterns of pill use.² Seven per cent of the interviewed pill acceptors never actually used the pills after undergoing examination at the clinic and purchasing the pills. Early discontinuation, before the second cycle, characterized 20 per cent of the study sample. Given the high early discontinuation rates of the sampled 1966-1967 pill acceptors, only some of them could have benefited from the 1968 policy decision. Table 4 reviews the source of pill resupply among interviewed continuing users compared to discontinuing users who took more than one cycle of pills.

Not surprisingly, discontinuing users were much more likely to name the clinic as the usual source of supply in Table 4. Almost half the continuing users did so too, however, suggesting that paramedical distribution was not effectively implemented in all areas in 1968. It also should be said that some acceptors may have preferred to return to the clinic and that some field midwife posts were vacant during 1968. Continuing users were more likely to name a usual source of supply that involved the midwife outside the clinic. Very few pill acceptors switched to the private sector, presumably because of the three to fivefold price differential per cycle.

Basic continuation rates by usual source of supply are seen in Table 5. Save for the clinic as a usual source of supply, the rates for other sources are based on small numbers. A combination of clinic and midwife appears to favour significantly higher continuation,

TABLE 4

SRI LANKA: USUAL SOURCE OF ORAL CONTRACEPTIVE RE-SUPPLY FOR CONTINUING USERS AND DISCONTINUING USERS TAKING MORE THAN ONE CYCLE

Usual Source of Supply	Per cent*	
	Continuing Users (N = 74)	Discontinuing Users taking more than One Cycle (N = 129)
Clinic	46	73
Midwife, at client's home	16	10
Midwife, at midwife's home	4	6
Midwife, at client's and midwife's home	7	1
Clinic and midwife at client's home	18	8
Clinic and midwife at midwife's home	8	2
Private drug store	1	1

* Because of rounding, cumulative per cent may not equal 100.

TABLE 5

SRI LANKA: NET CUMULATIVE CONTINUATION RATES PER 100 ORAL CONTRACEPTIVE ACCEPTORS AT 6 AND 12 MONTHS BY FIRST METHOD AND BY USUAL SOURCE OF SUPPLY*

Usual Mode of Delivery of Source of Pill Supplies	Months	
	6	12
1. Clinic and/or private pharmacy	56***	41***
2. Midwife at client's or midwife's home or both**	69	60
3. Combination of 1 and 2 (excludes private pharmacy)**	87***	74***

* This table omits women who never took pills or took only one cycle from the clinic. Thus, first method continuation rates are higher than would be expected from table 2.

** Rates based on less than 50 women.

*** Rates significantly different ($P < .50$).

but this is not true for the midwife alone as usual source of pill supplies, although the figure are suggestive. It should be re-emphasized that all pill acceptors represented in Table 5 received their first supply at the clinic. Following that first visit, different patterns of resupply emerged.

Discussion

It has been suggested from a demonstration project in Thailand that a policy allowing paramedical prescription and distribution of oral contraceptives will both increase acceptance and improve continuation.³ Clearly, the 1966-1967 pill acceptors in Sri Lanka sampled in the Galle-Kalutara follow-up survey did not benefit greatly from the 1968 policy decision to allow midwife prescription and distribution. It could be argued from Table 4 that continuing pill users naming a usual source of supply involving the midwife (53 per cent) would have discontinued without the policy change. Against this reasoning is the fact that 27 per cent of discontinuers in Table 4 had the benefit of the policy change and still discontinued. Further, by 1968, the remaining continuing users were a highly selected group and might have continued using pills without the help of paramedical distribution. Both Tables 4 and 5, then, suggest that midwife distribution of pills may have helped some 1966-7 acceptors, but only those who continued on into 1968.

Other data from Sri Lanka supports the impression that paramedical distribution did not lead to higher oral contraceptive continuation in acceptor cohorts after the policy change. A study of 242, 1968-1969 oral contraceptive acceptors in Kurunegala Province - an area culturally similar to Kalutara and Galle - yielded a 12 month first method continuation rate of 41,¹ almost identical to the 12 month first method rate in Table 2. In Batticaloa Province, a culturally dissimilar area, the 6 month continuation rate among 1969 oral contraceptive acceptors was 30.¹ In both of these areas, paramedical distribution had not changed the pattern of early discontinuation observed in the 1966-7 acceptor cohort. There was evidence suggesting that not all field midwives were actively implementing the new policy, however, and, in Batticaloa, many positions were vacant at the time of survey. Despite the reduction in price, it

was found that many women could not afford to buy the pills from month to month and the supply line was vulnerable to breakdown because of the vagaries of international shipping and difficult-to-control local factors.

Additional post-1968 data on pill continuation in Sri Lanka is not available. The total number of new acceptors in 1970 levelled off and actually declined 10 per cent in 1971,⁴ largely due to political factors. The number of pill acceptors remained constant in the 1969-1971 period, but increased to 32,300 in 1972, 45 per cent of all acceptors in that year.⁴

The available data from Sri Lanka suggests that while a policy of paramedical prescription and distribution of oral contraceptives is likely to increase acceptance, it may not improve continuation rates outside a carefully pilot area. Such a policy is amply justified, but is not likely to completely fulfil the promise suggested in Tables 4 and 5 in the absence of other critical programme inputs.

A study of field midwives' working behaviour undertaken in 1970-1971 suggests the nature of some of the problems and needed programme inputs.⁵ The problem of pill supply stock-outs, unfilled midwife positions, and inability of some clients to pay for the pill were all confirmed. In addition it was found that a significant number of field midwives (1) were favourable to family planning but were not sure what was expected of them and did not always consider family planning as important as their other duties, (2) felt a lack of support from the Medical Officer of Health, (3) gave very incomplete motivational talks and dealt with side effects with considerable uncertainty, (4) did not screen potential pill acceptors for side effects, instruct them properly on how to take the pills or mention likely side effects, (5) did not usually mention alternative methods to discontinuers, and (6) did not often carry pill supplies with them on their home visits. The need is clear for more retraining, supervision and a simple, but high priority expectation of what should be accomplished. In all fairness, it would be possible, in some degree, to make similar observations about the performance and needs of peripheral personnel in most national family planning efforts.

This is not an argument that oral contraceptives should be restricted or made unavailable. There is suggestive evidence from the International Postpartum Programme that their availability attracts women who would not otherwise be attracted to family planning programmes.⁶ Oral contraceptives in a mass programme are difficult to handle from the point of view of programme administration, not to mention the problems acceptors have, in sustaining motivation daily.

If continuation rates for a method are low, the number of women who must be processed to maintain a desired current contraceptive practice level in a given population rises rapidly. For example, if the mean using time is 5 years (consistent with 80 per cent continuation at one year), only 6 per cent of eligible women must enter the programme each year to maintain an oral contraceptive practice level of 30 per cent. With a mean using time of two years, however, about 15 per cent of eligible women must enter the programme each year to maintain the 30 per cent level.⁷ Further, with low continuation rates, the most fertile women become pregnant and are lost to the program. It has also been pointed out that, with low continuation, the experience of most pill acceptors is with the complications of the early months. Thus, the experience is biased toward the more troublesome months of pill taking and, as it spreads through the eligible population, probably dampens new recruitment.⁸

These considerations impose a very considerable burden in programme management, centrally and peripherally. Moving to a policy of non-clinical and/or paramedical prescription and distribution of pills is a necessary step to take services to more women, especially in countries with limited medical resources. It does not solve the basic problems of supply line, acceptor counselling, and, most important, peripheral follow-up of pill acceptors. As seen in Sri Lanka, such considerations appeared to limit the potential scope of the policy.

On a personal basis, an IUD acceptor is better off in continuation and pregnancy protection. Both kinds of acceptors benefit the programme and the boost of distributing pills through paramedical channels is worth

the administrative load. Nevertheless, clinic and field staff who appreciate the problems associated with oral contraceptives and are aware that initial method selection is a powerful determinant of effectiveness in preventing unwanted pregnancy in Sri Lanka and in other countries⁹ will be better able to give realistic counselling at the time of method choice.

Summary

After a 1968 policy decision by the Ministry of Health to cut the price of oral contraceptives by half and to allow non-clinical prescription and distribution of the pills by trained field midwives under medical supervision, pill acceptance increased steadily. Whereas in 1967, of 36,695 new acceptors, only 24 per cent took orals from the clinic, by 1969, 45 per cent of 56,787 new acceptors took pills from the clinic or in the field.

It was expected that continuation of pill use under the new policy might approach the known high level of IUD continuation. The available data, admittedly limited, suggests that this did not happen. Other factors appeared to limit the potential scope of this sound policy decision.

The IUD continued to prove much more effective than oral contraceptives in preventing unplanned pregnancies, largely due to the higher continuation rates of IUD acceptors. Pill users and IUD wearers,

however, had similar post-acceptance pregnancy rates.

It is clear that the greater availability of pills increased the number of acceptors, and that there was a gain, although not a concomitant one in overall programme effectiveness. The administrative requirements of managing a large programme where a repetitive method like the pill is popular, but not long-continued, are considerable. Initial method selection – as between oral contraceptives and the IUD – appears to be the strongest factor in predicting personal effectiveness. Better counseling by programme clinic and field staff toward a more realistic choice of method at first contact, and supporting that choice in the following months, is indicated.

Acknowledgements

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SUMMARY OF THE CONGRESS PROCEEDINGS

By

DR. A. HERXHEIMER

To summarize the proceedings of this Congress which has occupied us all for a whole week is a very challenging and probably impossible task, and all that I can hope to do is to pick out some general themes and highlights from the many contributions. I should like to emphasise that in doing so I have had a lot of help from the Chairmen and Moderators of the sessions – but of course, what I shall say represents only my own, and not necessarily their opinions.

I want to begin by saying that this Congress has been an excellent and forward-looking way of celebrating the 21st birthday of the Family Planning Association of Sri Lanka. For many of us a great bonus of this Congress was the opportunity of meeting so many distinguished people from other countries, some of whom we had until now only been able to admire from a distance. Their enormous experience and diverse enthusiasms greatly enriched the proceedings.

The inauguration of the Congress by the Prime Minister and the Health Minister was a most welcome and encouraging demonstration that the Government of Sri Lanka is taking the population problem seriously, and realises that effective family planning can make a major contribution to the health and prosperity of the community.

The proceedings fell naturally and logically into three parts – first, discussion of the population problems in the world, and in this island in particular; second, discussion of the medical and scientific aspects of the methods used in family planning and third, discussion of the practicalities of applying these methods in a population, so as to provide an effective and comprehensive service for all who need family planning.

Sir John Peel made some very important points about the factors other than birth control that influence birth rates and family

size. One factor is the perinatal and infant mortality in a community where this is high, the birth rate also tends to be high, and mothers have little incentive to limit births. A second major factor is the number of women who marry and the age at which they do so. The smaller the proportion who marry, and the later they do so, the lower the birth rate will be. Social measures to encourage postponement of marriage are therefore worth serious consideration as a part of any population policy. A third factor is fashion in family size. We did not hear much about the importance of these factors in Sri Lanka. But apart from birth rates, family size is obviously affected by the acceptance and effective use of the whole range of family planning facilities, from the condom to abortion and sterilisation, and much of the later part of the Congress was devoted to this.

Dr. Linton Snaith made a more detailed examination of present world trends in fertility. It was particularly interesting to compare the trends in Sri Lanka with those in Korea and Taiwan, where quite different methods have been in use in the last 10 years. The greatest fall in birth rate occurred in Korea, as a result of a liberal abortion policy.

Among the sessions dealing with the specific methods used in family planning, hormonal contraceptives were discussed under the experienced and entertaining chairmanship of Dr. E. Tyler. Their high effectiveness is not in doubt, and the discussion centred mainly on the relative merits of different ways of administering them – their acceptability and practicalities. But the highlight of the session was a brilliant discourse by Dr. J. Goldzieher provocatively entitled “Alleged thromboembolic and carcinogenic hazards of contraceptive steroids.” He persuasively argued that the mere association of small numbers of cases of thromboembolism with the use of the pill was very far from even suggesting a

casual relationship, but I suspect many of us felt that such a view was perhaps too dogmatic. Nevertheless, I think we can all accept that any risk of thromboembolism is very small – and so far it seems that the risk is virtually non-existent in countries such as Sri Lanka where thromboembolism is very rare. My own contribution to the discussion concerned the problems of making valid comparisons between different preparations, different methods of using them and also between different populations of acceptors. Such comparisons have until now been very uncommon but the information they could provide is badly needed both by individual clinicians and by those responsible for large scale family planning programmes.

Dr. (Mrs.) H. Wijemanne gave a summary of the experience with oral contraceptives in Sri Lanka, which remain remarkably acceptable here and constitute a major part of the family planning programme. Because of their importance, later sessions devoted much time to ways of improving their distribution and supervision of their use.

The remainder of the session was mainly concerned with reports of the large scale use of medroxyprogesterone acetate (Depo-Provera) the long acting progestogen injection. This has had a remarkable success in Thailand as we were told by Dr. Mc Daniel and Dr. Suporn Koetsawang. The popularity of this method of contraception in South East Asia was also evident in Sri Lanka, as we learnt from Dr. (Miss) Siva Chinnatamby.

A rather different use of hormones, for post-coital contraception, was described by Dr. H. Lehfeldt from New York. He has given ethinyl oestradiol 5 mg. daily for 5 days to his often neurotic patients as soon as possible after unprotected intercourse. The method is especially valuable in cases of rape. He made the point that this is only an emergency measure and subsequent discussion brought out that it can be further backed by menstrual regulation if subsequent menstruation does not occur.

In the session on intrauterine devices it was a particular privilege and pleasure to hear the inventors of the loop, Dr. J. Lippes

and of the Copper IUD, Dr. Zipper. It was clear from the very large experience reported in this session that no device is perfect, but that there are some consistent differences in pregnancy rates, expulsion rates and bleeding. However, at least equally important is the training and experience of the inserters, because different devices require rather different techniques for safe and satisfactory insertion.

Both the Lippes loop and the Copper device will continue to have an important role in family planning programmes in future. Whether other devices have important advantages will only be settled by further careful comparative studies. Dr. R. Bernard suggested that some of the characteristics of the M device and the Copper device might valuably be combined in a new design, but this will of course take many years to be developed.

The subject of abortion was fascinatingly introduced by Dr. J. Dickinson and his wife Dr. Pamela Aldis from Vancouver. They described what happened in Canada following the introduction of liberal abortion laws in 1969. This had resulted in a 100-fold increase in abortion rate, a significant drop in maternal mortality and disappearance of criminal abortion and sequelae. Another significant feature was a change in the attitudes to the conceptus as a viable human being.

Dr. Aldis stressed that while abortion had gone a long way towards solving the problem of some high-risk mothers, she does not condone repeated abortion.

Drs. R. V. Bhatt, S. Koetsawang and A. Doodoh reported their experiences with abortion. Their main points were that outpatient abortion is a safe alternative to inpatient abortion. Motivation of family planning is not always powerful and there is a sudden enthusiasm when a pregnancy is ended, so that abortion provides an ideal opportunity to start family planning. This was also strongly emphasised by Professor B. N. Purandare from India.

Drs. E. Kessel, D. Vengadasalam and R. Bernard discussed their experiences of menstrual regulation by the method of suction curettage, a new concept of family

planning. It was effective and there were less complications than with abortion and could be performed in places where abortion was still illegal.

It was generally accepted that a policy of encouraging abortion of unwanted pregnancies is at present the only method of quickly reducing the birth rate.

The use of prostaglandins was discussed rather more briefly than planned and we all regretted the absence of Professor Karim, but it seems that though these drugs have given us many scientifically fascinating insights, their practical use is so far disappointing and unlikely to be very important at least until new and better, analogues are discovered.

In the session dealing with female sterilisation, Professor Purandare estimated that 30 per cent of puerperal patients needed sterilisation in the immediate post-partum period.

The procedure of choice was tubectomy via the abdominal route. All speakers agreed that, as a younger group of patients now seek sterilisation, a reversible procedure was needed to instil confidence. Professor R. Palmer gave an impressive survey of the choice of techniques, paying particular attention to the effort needed to train surgeons in the use of the different methods and the instruments needed. Of course like any surgical procedure, abdominal sterilisation carries a definite morbidity.

Vaginal sterilisation by colpotomy was advocated by Professor Purandare as possibly the ideal procedure for interval sterilisation for a mass programme. He reviewed a series of 15,000 cases, including cases done in sterilisation camps, under conditions that were far from ideal. The morbidity was very low.

The technique he described requires no expensive instruments and can be performed under a low spinal anaesthetic which is particularly suitable for use in sterilisation camps.

The advantages of the vaginal procedure were:

1. The short stay in hospital – about 36 hours.

2. Less post-operative pain.
3. No abdominal scars.
4. Use of simple instruments.

Dr. T. Kumarasamy presented recent results with laparoscopic application of clips by the Hulka technique, but its relation to the others have still to be evaluated.

Dr. J. Zipper described the use of quinacrine (mepacrine) as a method of endo-uterine chemical sterilisation. He stated that when a combination of mepacrine, lignocaine and adrenaline ("Dr. Zipper's intrauterine cocktail") was used, a rate of tubal occlusion of 94% was achieved. It was a simple procedure and may well prove to be a true breakthrough in sterilisation procedures. Dr. Zipper claimed it carried a pregnancy rate of 2.9% which was no higher than with the other surgical procedures done in Chile.

Vasectomy was discussed with unanimous missionary fervour by speakers from Canada, India, Malaysia as well as Sri Lanka. All stressed how simple, quick and safe the procedure is, provided that the operator has been properly trained. Outstanding advantages are its low cost, and the fact that it can be performed satisfactorily almost anywhere, even at railway stations.

In looking back on all the sessions dealing with the different procedures and techniques, what strikes me is that the different professional groups involved tend to focus somewhat narrowly on the method they practise, so that only a minority of individuals can see the methods in relation to one another. The clearest example is the apparent isolation of female sterilisers (gynaecologists/obstetricians) from vasectomists (surgeons). The full-time family planning doctors focus on pills, injections and IUDs and often pay rather little attention to sterilisation, vasectomy and abortion. Relating all these activities to one another to provide a balanced menu is something that the doctors and family planning programme co-ordinators will have to tackle.

The last third of the Congress was concerned with all aspects of training of personnel, the organisation and implementation of family planning programmes, involvement of the whole community in them and

perhaps most important for the immediate future, effective methods of distributing contraceptive supplies and services.

Many different aspects of the training of personnel were considered. Mr. Weerakoon described the use of local Government personnel in implementing a family planning programme. In a recent project, Government officers including "Village Headmen", combined with ad hoc volunteers for the purpose of motivating local fertile couples to use existing family planning services.

It was interesting to note that the problem was tackled locally using local personnel. Each village headman is responsible for a tiny handful of participants each of whom he knows well. They were indentified from Government ration-book lists. Each participant was sent a letter of introduction before being visited by a volunteer. The volunteers were chosen from local opinion leaders, and they and the officials were given a two-day seminar before hand.

Such a project was workable in other areas of Sri Lanka, since the Government Administration and infrastructure was universal. Mr. Weerakoon felt that the principle of using a variety of officers from a variety of interested Ministries was necessary in the light of the high family planning targets in Sri Lanka.

Four short papers outlined education of nurses and midwives in family health, including family planning; use of nurses and midwives in Institutions, public health nurses in propagating family planning as well as the role of health educators.

Family planning training has been integrated at all levels of nurses and midwives training and special 5½ day in-service programmes have been devised for qualified nurses and midwives.

In Institutions, nurses and midwives have been trained to advise, motivate and encourage family planning work on all suitable occasions in their work. Most hospitals now have family health centres to which eligible patients can be referred for family planning advice before discharge. Health educators are being taught to bring family planning education into their work.

Dr. N. Wright reported a survey on the effectiveness of established midwives in distributing oral contraceptives. They were not as effective as might have been hoped, and probably would need more thorough training than it had so far been possible to give them.

Dr. R. Beasley described the logistics of family planning delivery systems in New York as being very difficult – even at a level approaching that of developing countries. He then referred to an institution which trains nurse-midwives to be combined educators and suppliers of contraceptives. 90% of the contraceptives supplied by the institution are supplied by the nurse midwives. Only abnormal cases are referred to doctors.

Another Institution cited by Dr. Beasley will train not only nurses and midwives but *anyone who can pass the rigorous training*. A typical course takes 3 months and includes intensive courses in anatomy, endocrinology, infection and family planning methods. Each trained worker thus understands the clinical aspects of family planning and can supply the various contraceptives of the clinic visitor.

Dr. R. Senaratne stressed the necessity of understanding the different cultural patterns within any given country. For example, rural self-employed adults regard children as wealth, but as urbanisation increases and villagers search for jobs in the city their attitude toward children changes, in regard to economic value at least.

Mrs. E. Tyler described her experiences in educating potential contraceptors in the United States. She felt that very poor families with many children do *not* think of their children as wealth; in fact the children are thought of as a liability.

A healthy attitude toward sex, including physiological and contraceptive aspects, depends on proper indoctrination of the child during the first six years of life. When "family life" education is an unobtrusive part of all education older children usually devote only a small part of their energies to further sex education, while those children who are denied a spontaneous sex

education at an early age often have an abnormal interest in the subject, and tend to experiment more, some times with disastrous results.

A survey in the U.S. reported that 98% of responding parents wanted sex education in the schools. The reason for this was thought to be that many parents are unequipped psychologically for the role of sex educator. The majority of practising physicians were also thought to be less than perfect as instructors to their patients, and that is not surprising since little is taught about it in medical schools.

Mr. M. Rajanayagam chaired a session on implementation of family planning programmes in which many different aspects were discussed. The implementation of a programme in the tea estates was described by Dr. L. V. R. Fernando, and its importance there and elsewhere was underlined because of the large numbers of non-working dependants. The managements need to become much more aware of the benefits that can be obtained at low cost by such programmes.

Opening the session dealing with the distribution of contraceptives, Dr. T. R. L. Black from Kenya emphasised that not enough urgency was apparent at this Congress concerning the overwhelming problem of over-population faced by the world. He suggested that a complete reorientation in thinking was needed in the distribution of contraceptives. This must call on many different sections of the community, and not rely only on the medical and paramedical section. He outlined the way in which shopkeepers and other marketing resources could play a major part.

Mr. Anandatissa de Alwis from a leading advertising agency in Sri Lanka illustrated this in detail by describing the campaign mounted in Sri Lanka to sell "Preethi" condoms, and the careful market research and marketing methods used. The campaign has very successful. The sale of condoms has already reached 300,000 a month.

In a rousing and enthusiastic contribution Dr. M. Potts described how very high continuation rates with oral contraceptives

could be obtained by distribution at village levels through shopkeepers, post offices and others in close touch with the women needing the supplies. He felt strongly that instructions should be simple and that medical and paramedical staff should be reserved for dealing with problems and not bothered with straightforward distribution. He quoted from the International Planned Parenthood Federation's statement on distribution of oral contraceptives that "the limitation of oral contraceptive distribution to doctors' prescription makes the method geographically, economically and sometimes culturally inaccessible to many women. As a consequence, deaths and sickness to women and children, which might otherwise be avoided by the voluntary limitation of fertility, continue".

He also emphasised that the IPPF can obtain free of charge and *outside* regular budgets, as many pills and condoms as an Association can distribute. The governing body has unanimously set aside \$800,000 to further distribution systems. Associations may sell or distribute contraceptives free. Their only obligation is use any money generated to further some aspect of family planning.

He ended with a plea for the use of ayurvedic practitioners and midwives in Sri Lanka to undertake some of this work.

Finally, I think, we were all impressed with the remarks made by Dr. F. Sai, assistant Secretary General of the IPPF at the official dinner. We can all share his earnest hope that involvement of the ayurvedic doctors and traditional midwives would become a reality in Sri Lanka, and that less emphasis would be given to the scientific and more to the practical aspects of availability and distribution of contraceptives.

I think this Congress has been very successful, and having delivered myself of this rather subjective attempt at a summary, I would end by thanking our hosts most warmly for all that they have done for us. The Congress itself has been quite hard work for us participants, but the work done in organising and running it was of course vastly greater, and we very much appreciate that.

CLOSING ADDRESS

By

PROFESSOR D. A. RANASINGHE

Ladies and Gentlemen:

We have been deliberating for five long days. Participation has been scientific, intelligent and devoted. We, as Family Planners, have known for a long time that, to make maximum impact, our schemes must involve not only medical personnel but also others, who are in constant contact with people who are of child-bearing age. I would like to go further and say that we hope that those of you, who earlier may not have been quite convinced of the need and urgency of limiting population, will go away from here with new ideas; and that you will not only implement the various policies of Family Planning as advocated by both Government and the Family Planning Association, but also discuss the things you have heard and learnt with colleagues who were not so fortunate as to attend our Congress. Although our efforts have to some extent been successful – we have managed to bring our birth rate down over a period of 21 years by approximately 9 per thousand (from 38.3 to 29.4) this, in the present context, is totally inadequate. Our target is to reduce births to 25 per thousand by 1975. It is an ambitious figure, and I do not think we can attain it, unless everybody works with real enthusiasm and conviction. With all our new problems: the unexpected oil crisis, the food crisis and the electricity crisis – the question of family planning has assumed a new dimension of dire urgency. I appeal to you not to dismiss this as an academic proposition. It might very soon become a matter of life and death to all of us.

We have been fortunate that in spite of a very real travel problem so many delegates thought it worth their while to undertake the journey, and attend our Congress, thereby giving it a lift to heights we could not possibly have achieved without them. The standard of discussion was consistently mature, because our distinguished foreign guests brought their vast experience and

knowledge from many parts of the world to the discussions. We are deeply grateful to them. We wish them all a safe and happy journey home; and may be some day, in the not too distant future, a return to our Island home.

Now I want to thank our medical personnel, among whom I include the ayurvedic physicians, the nurses and midwives, for their interest and enthusiasm; for the large numbers in which they attended, and for contributing greatly to the proceedings of the Congress by the liveliness of their participation on all discussion I once again stress the need to carry the message of Family Health to the remotest corners of the Island. I am glad that we also had a number of non-medical personnel who participated; who took an active part and enlightened us in some useful and related subjects, which are essential for a full implementation of the programme.

I would also like to thank the Ministry of Health, the Department of Health Services and the Department of Ayurveda. We are especially glad that so many ayurvedic physicians attended, because they are the people who can help us to achieve our objectives quickly. There are many more people whom I have to thank – it has taken an army of volunteers to organise the Congress, then to implement it and keep it going, smoothly and efficiently, from day to day – and night to night. We have only to glance at the Congress programme to realise the large number who have worked so hard, and sacrificed so much of their time. I think we all agree that the Congress has succeeded far beyond our expectations. I must also mention our Office Staff, the personnel of the Transport division, and other officers of the Association. They have been working very long hours and with a great sense of devotion to duty. In my capacity as President of the Association I thank them, and would like to tell them

how much we appreciate their unstinting service.

A special word for our translators. This is the first time that the simultaneous translation system has been used in this Hall. Without translation from the English to the Swabasha we might as well not have bothered to have a conference at all. The whole concept of the Congress rested on the premise that we must cater for everybody, irrespective of their language, and this would not have been possible had we not been able to translate. Simultaneous translation is a new and most exacting art, and there has been great satisfaction and pleasure at the very high standard achieved. The Electronic Section of the Congress Hall Staff was most efficient and courteous throughout, and we appreciate this very much.

To the authorities of the Bandaranaike Memorial International Conference Hall and all the workers, I extend my thanks, for their help and forbearance.

The Conference would not have been possible without our financial benefactors. Our thanks are due especially to the Canadian

International Development Agency and the Canadian Family Planning Association, for providing a very generous grant to meet our expenses.

Finally we come to Dr. (Miss) Siva Chinnatamby. She is the Honorary Medical Director of the Family Planning Association of Sri Lanka as well as the Chairman of the Organising Committee of the First International Scientific Congress. She is the one who conceived the idea of a Congress and who spent months working out each detail, and implementing these ideas through the various committees she set up. She was the hub around which the wheel turned; and as we all know, without a hub - there is no wheel. We cannot express our gratitude and appreciation enough for the way in which she has given of herself to this Family Planning project, with no thought of time and effort. We hope she will reap the fruits of her labour by seeing a vastly improved Family Planning Service in the Island, leading to a dramatic fall in our birth rate and better a standard of living for our people.

And now I call upon you to close the First International Scientific Congress.

The following papers were also read at the first International Scientific Congress in Family Planning:

NEW INTRA-UTERINE DEVICES

by Dr. J. Lippes

EARLY EXPERIENCES OF MENSTRUAL REGULATION SERVICES AT A TEACHING HOSPITAL & A COMMUNITY HEALTH CLINIC IN BOMBAY

by Drs. S. D. Kannikkar & I. Parikh (read *by* Dr. R. Bernard)

A COMPARISON OF FOUR METHODS FOR DETERMINING THE PREVALENCE OF INDUCED ABORTION IN TAIWAN 1970-71

by Drs. Paul Harper & Rowland Rider (paper read on their behalf *by* Dr. Emmavar)

INDUSTRIAL EMPLOYERS' ROLE IN POPULATION LIMITATION

by Mr. Mallory E. Wijesinghe

ROLE OF INTERNATIONAL AGENCIES IN POPULATION PROGRAMMES

by Dr. Majeed Khan (Co-ordinating Officer, UNFPA in Sri Lanka)

The scripts were not available for publication.

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