ANALYSIS OF INTRAUTERINE CONTRACEPTION

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PREFACE

There has been a steady increase in the use of intrauterine contraceptive methods since some early models were available in 1960. At that time, no device was produced in large quantities and perhaps fewer than 100,000 women were using those devices available, such as the Grafenberg Ring, the Ota Ring, or handmade devices of surgical thread. By 1965, the method had been introduced into the national family planning programs of several countries and was used by several million women around the world. By 1974, estimates had increased to 15 million current users, with nearly 20 different devices being produced commercially. The most popular device was being distributed at the rate of half a million per month, and IUDs with pharmacologically active constituents had been developed. Countries known to have manufactured IUDs include Canada, Chile, Czechoslovakia, Denmark, Egypt, Finland, Hong Kong, India, Mexico, Pakistan, People's Republic of China, South Korea, Taiwan, United States, and U.S.S.R. In several Western countries, IUD use was spreading rapidly while use of other methods of contraception was either stabilized or declining.

Acceptance of intrauterine contraception reflected a remarkable change in attitudes of the medical profession over a relatively short period of time. To a large extent, their interest and acceptance of this method have been stimulated by comprehensive investigation on an international scale.

The exchange of scientific information has been facilitated by periodic international conferences sponsored by The Population Council. The First Conference, in 1962, brought together 48 physicians and scientists for a round-table discussion. In 1965, the Second Conference attracted 161 delegates for a plenary program of 28 invited papers.*

The present volume contains the proceedings of the Third Conference. A call for abstracts resulted in the submission of 87 papers from around the world. Only a portion of these papers could be accepted for presentation during the three days of meetings.

The Third Conference program was organized by an International Organizing Committee. Chaired by Carl Gemzell (Sweden), the Committee included: Lidija Andolsek (Yugoslavia), Carlos Gomez-Rogers (Chile), Fouad Hefnawi (Arab Republic of Egypt), Louis Hellman (United States), Charanpat Israngkun (Thailand), Tapani Luukkainen (Finland), and Leela Phatak (India). We are grateful to these colleagues for their work in reviewing abstracts and selecting papers for presentation.

We also wish to acknowledge with deep appreciation the Local Organizing Committee in Cairo: Fouad Hefnawi, Maher Mahran, Mahmoud Fathalla, Mahmoud Talaat,

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Mokhtar Toppozada, Gamal Serour, Zeinab El-Sobki, and Ahmed Safwat. The success of the meeting was due to a large extent to their tireless efforts. Similar attention to gracious hospitality was provided by the members of the Ladies Hospitality Committee.

We are indebted to the Secretary-General of the Arab League, Mr. Mahmoud Riad, for making available to the Conference the superb facilities of the Arab League Headquarters and the hard-working, efficient staff of that beautiful edifice.

A number of organizations provided important assistance in the award of travel grants to participants. These sponsoring organizations were: The Ford Foundation, International Development Research Centre, International Fertility Research Program, International Planned Parenthood Federation, The Pathfinder Fund, The Population Council, and the World Health Organization.

The Population Council organized and sponsored the Conference with a grant provided by a private foundation in the United States. Although this organization prefers to remain anonymous, its philanthropic interest in the well-being of people throughout the world deserves to be acknowledged publicly.

Finally, it is our pleasure to express our thanks to Madame Jihan El Sadat, First Lady of the Arab Republic of Egypt. When the Conference was in the early planning stages, we were inspired by her willingness to serve as honorary sponsor. Indeed, she has done more. Her opening remarks at the Conference, which are published in this volume, express the warmth, dignity, and wisdom which she added to the occasion.

Cairo and New York
March 1975

Fouad Hefnawi
Sheldon J. Segal

INTRODUCTORY ADDRESS

by

Jihan El-Sadat

First Lady, Arab Republic of Egypt

This international conference, now meeting in our country, is a notable event which deserves mention and analysis. It represents the phenomenon of international cooperation, whose participants seek the relief of human suffering everywhere.

Man has made extraordinary progress, and as a result, the world has become smaller. This small world has also become mired in problems created by such progress. The average life expectancy has increased, and the infant mortality rate has decreased due to God's will and the scientific advancement made for the protection, care, and health of mankind. But now the population is increasing in huge numbers, particularly in the developing countries where resources are a problem and the need for food is ever increasing. These are, in effect, problems which have been created by progress and at the same time, problems of socioeconomic injustice exist between the able world and the overpowered world, between the giant, economically developed nations and the developing countries who are struggling for life and for social and economic freedom.

If science is playing a role in this great theater, then politics also play a role. Conflicts are unavoidable and it is possible that such conflicts may lead to difficult decisions and hard results. But the hope remains that man will emerge victorious in the struggle for the betterment of mankind everywhere no matter how fierce the conflict between the powers that control the future.

Brothers and Sisters, we cannot escape these facts while we exchange ideas in the inauguration of this conference, which I hope will effectively contribute to the solution of the worldwide population problem.

Here, on our land, we are making a great effort to achieve the correct balance between our population growth and our resources. Our population has increased by over 5 million since 1967, and the average population density in inhabited areas has reached over 1,000/Km^2, not to mention the population density of Cairo, our capital, which has increased to over 26,000/Km^2. You can thus imagine what a great problem we are facing at a time when the world is threatened by decreases in food resources. Actually we have made a considerable effort in calling for family planning, and we have been able to overcome many of the obstacles that have been imposed by traditions, environmental conditions and educational background of our people to help us reach our goal. These are difficult obstacles to cross and many of the international agencies have helped us in our difficult struggle. While we have benefited from the experience of others, we still have a long way to go.

Thus, I warmly welcome this conference that includes a group of the world's best scientists in the field of family planning. I hope that we can participate through our limited experience, we look forward to its results which we will gratefully add to our newly born experience.

Egypt is happy to have you in this conference and truly welcomes your most valued mission. Egypt has faith in peace and believes that the new generations all over the world have the right to live a peaceful, hopeful, and cheerful life and to enjoy that life while giving generously what they can give unthreatened by the dangers and evils of war. They must have the right to build a happy family that is capable, by its own good resources, to enjoy a decent life.

This is today the struggle of Egypt: peace for building, peace for the happiness of mankind, and peace for a new world full of justice and prosperity.

CONTENTS

PART I

ASSESSING THE IUD EXPERIENCE

COMPARATIVE PERFORMANCE OF THREE TYPES OF IUDs IN THE UNITED STATES

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The objectives of this paper are to compare relative performance of three selected IUDs to assess the risks involved in their use relative to their potential benefits, and to compare the risks and benefits associated with IUD use with the corrresponding risks and benefits associated with other available contraceptive methods. The results discussed in this paper are mainly based on the data collected in two evaluation studies of IUDs, conducted under the auspices of The Population Council.

The first study represents the experience of about 31,000 women enrolled in the Cooperative Statistical Program (CSP) during 1963-1968. About 20 investigators participated in this study. The results included information on five major types of devices: Lippes Loops in four sizes, Margulies Spirals, Birnberg Bows, the steel ring, and the double coil.[1] The Loop D accounted for about 31 percent of all insertions, and some selected results for this device are included here for comparative purposes.

In the second ongoing study, the experience of about 36,000 women, amounting to an aggregate of about 28,000 woman-years of use of different devices, has been accumulated over a period of three years. About 80 investigators participated in this study. Four different models of the Copper T, the Copper 7, and a small number of Dalkon Shields are included in this study. The Loop D was also studied in a double-blind comparison with the TCu 200. In this paper selected results of the Copper T 200 and the Copper 7, based on the experience of these women up to March 31, 1974, are included.

In both of these studies extensive information was collected for each woman at the time of insertion as well as at each subsequent contact. Special attention was devoted to collecting information about accidental pregnancies as well as the outcome of these pregnancies. Women removing the device in order to become pregnant were followed up to obtain information about their subsequent fertility.

The life table technique of Tietze and Lewit is used to estimate different types of termination and continuation rates.[2] This procedure is slightly different from the one used by Potter, and it overestimates the continuation rates by about 6 percentage points at the end of two years. For simplicity, only the net rates that are additive are included in this paper. These rates are based on the first segment of IUD use and exclude the experience following their reinsertions.

Performance of Loop D

In the typical pattern of monthly termination rates of the Loop D, the incidence of expulsions and removals for bleeding or pain are highest immediately following the insertion, and both decrease sharply with the increase in the duration of IUD use. The incidence of removal, however, stabilizes at a higher level than the incidence of expulsion. The incidence of pregnancy is quite low and remains low. There is a slight tendency toward a lower pregnancy rate with the increase in the duration of use. (Pregnancies following unnoticed expulsions of the device are included in the pregnancy rate throughout this paper.) The total effect of this declining trend is that the continuation rate increases from seven out of ten women during the first year, to nine out of ten during the fifth year of use.

A little over one-third of all women were using the original Loop D at the end of five years following insertion (see Table 1). The remaining 62 percent terminated use of the device during this period, many by removal (about 45 percent of the women); bleeding or pain accounted for half of the removals. About 12 percent of the women expelled the device, and 5 percent became pregnant.

Table 1

Net cumulative event rates per 100 users:* Loop D, first segment, five years[1]

Events and woman-months of use	1 year	2 years	3 years	4 years	5 years
Net					
Pregnancies	2.4	3.8	4.3	4.7	4.9
Expulsions	9.1	10.8	11.6	12.0	12.2
Removals					
Bleeding/pain	10.9	16.2	20.5	23.2	24.5
Other medical	3.1	4.9	4.9	6.7	7.9
Planning pregnancy	0.9	2.3	3.9	5.2	6.2
Other personal	2.1	3.8	5.0	6.0	6.4
Total events	28.5	41.8	51.2	57.8	62.1
No events	71.5	58.2	48.8	42.2	37.9
Woman-months of use	66,777	105,199	127,730	140,506	144,548

*Excludes insertions during first four weeks postpartum.

Performance of TCu 200

The patterns and levels of termination rates of the TCu 200 are different from those observed for the Loop D. The total probability of terminating the use of the TCu 200 during each of the six-month intervals is about the same except during the first six months and the second half of the third year (see Table 2). As expected, the removals for planning pregnancy and other personal reasons increases sharply with the duration of use. Excluding these removals, the percent of women terminating the use of the TCu 200 decreases with the increase in the duration of use from 13.4 percent during the first six months to 8.7 percent during the first half of the second year and stabilizes thereafter around 7 percent. The main

reason for this decline is the sharp decline in expulsion rates. Unlike the Loop D, the pregnancy rate with the TCu 200 does not show a declining trend; instead it shows a slight but insignificant upward trend during the third year of use.

Table 2

Net six-month termination rates per 100 users: TCu 200, first segment

Type of termination	Period since insertion (mos.)					
	0-6	7-12	13-18	19-24	25-30	31-36
Pregnancies	1.3	1.5	1.6	1.1	1.4	1.9
Expulsions	5.6	2.3	1.6	1.0	1.6	1.0
Removals						
Bleeding/pain	4.8	4.8	3.8	3.9	2.5	2.7
Other medical	1.7	1.2	1.7	0.8	1.1	1.5
Planning pregnancy	0.6	1.6	2.2	2.6	2.1	3.8
Other personal	1.0	1.4	1.7	1.9	3.4	5.3
Termination rates	15.0	12.9	12.6	11.3	12.1	16.2
Continuation rates	85.0	87.1	87.4	88.7	87.9	83.8
Woman-months of use	74,566	48,716	29,486	16,460	5,983	1,336
No. of women completing 6-month intervals	9,987	6,507	3.625	1,893	438	78
No. of 1st insertions	16,987					

About 58 percent of the women terminated the use of the TCu 200 at the end of three years (see Table 3). About 6 percent became pregnant, 11 percent expelled the device, and about 41 percent had the device removed. Unlike the Loop D, bleeding or pain accounted for less than half of the TCu 200 removals--about 17 percent--and another 18 percent had this device removed for personal reasons.

For various reasons the patterns and levels of the termination rates of the TCu 200 are not comparable to those observed for the Loop D. For example, the characteristics of women in both groups are quite different: The TCu 200 users were younger and of lower parity as compared to the Loop D users. (About 38 percent of the Loop D acceptors were women 15-24 years of age as compared to about 61 percent of the TCu 200 acceptors.) Only 2 percent of the Loop D was inserted in nulliparous women as compared to about 4 percent of the TCu 200. These differences in the composition of the two study populations are important mainly because of the differences in the termination rates among the subgroups of the study populations.

Differentials in Performance of TCu 200

Age: The variations in the termination rates of the TCu 200 among different subgroups of the study population indicate that the age of the women, the parity, and the period since the termination of the preceding pregnancy have strong influence on the termination rates of the device. The chance of becoming pregnant decreases with the increase of age at insertion from 5.7 percent among women below

Table 3

Net cumulative termination rates per 100 users: TCu 200, first segment, three years of use

Type of termination	6 mos.	12 mos.	18 mos.	24 mos.	30 mos.	36 mos.
Pregnancies	1.3	2.5	3.7	4.4	5.2	6.2
Expulsions	5.6	7.6	8.9	9.4	10.3	10.8
Removals						
Bleeding/pain	4.8	8.9	11.6	14.2	15.6	17.0
Other medical	1.7	2.7	3.9	4.4	5.1	5.9
Planning pregnancy	0.6	2.0	3.6	5.3	6.5	8.4
Other personal	1.1	2.3	3.6	4.8	6.8	9.5
Termination rates	15.1	26.0	35.3	42.5	49.5	57.8
Continuation rates	84.9	74.0	64.7	57.6	50.5	42.2
Woman-months of use	74,566	123,282	152,768	169,229	175,212	176,548
No. of women completing 6-month intervals	9,987	6,507	3,625	1,893	438	78
No. of 1st insertions	16,987					
Percent lost to follow-up*	20.5	23.7	25.6	26.2	26.4	26.5

*This includes 12.1 percent lost to follow-up during the first month.

20 years of age to only 0.5 percent among women above 35 years of age (see Table 4). Similarly, both the expulsion and the removal rates for bleeding or pain decrease substantially with the increase in the age of the women. Consequently, the chance of terminating the device decreases with a higher age at insertion. For example, 52 percent of the women below 20 years of age terminated the device within two years as compared to 28 percent of those over 35 years. Excluding the removals for personal reasons, the termination rate is two times higher among women below 20 years of age than among those above 35 years of age (42 percent versus 20 percent).

Parity: The termination rate of the TCu 200 for the nulliparous women is about the same as that for the parous women (see Table 5). Both the pregnancy and the expulsion rates for these two groups of women are about the same. However, the removal rate for bleeding or pain for the nulliparous women is slightly higher than that for the parous women.

The termination rate of the TCu 200 decreases with the increase in parity at insertion from about 51 percent among women of parity 1 to about 32 percent among those with 5 or more live births prior to the insertion of the device. The maximum decrease is observed from para 1 to para 2, mainly caused by the differences in the removals due to personal reasons. After excluding removals for personal reasons, women terminating use of the device decrease from 36 percent among women with one live birth to 23 percent among those with five or more live births.

Table 4

Net cumulative termination rates per 100 users at 24 months of use by age of woman: TCu 200

Type of termination	Age of woman				
	15-19	20-24	25-29	30-34	35+
Pregnancies	5.7	5.4	3.7	2.5	0.5
Expulsions	14.9	9.3	8.2	6.4	3.0
Removals					
Bleeding/pain	16.1	14.9	13.5	9.8	13.2
Other medical	5.2	4.1	4.9	4.2	3.6
Planning pregnancy	4.3	6.7	5.7	4.2	0.5
Other personal	5.7	4.5	4.6	4.2	6.8
Termination rates	51.9	44.8	40.6	31.3	27.6
Continuation rates	48.1	55.2	59.4	68.7	72.4
Woman-months of use	30,514	67,478	41,142	17.860	11,997
No. of women completing 24 months	299	668	484	241	197
No. of insertions	3,278	7,053	4,057	1,606	969

Table 5

Net cumulative termination rates per 100 users at 24 months of use by parity of woman: TCu 200

Type of termination	Nulli-parous	Multi-parous	Parity			
			1	2	3 or 4	5 or more
Pregnancies	4.5	4.5	5.1	4.6	3.7	3.8
Expulsions	9.3	9.5	12.0	8.5	7.6	5.4
Removals						
Bleeding/pain	16.2	13.0	14.6	12.2	12.2	10.5
Other medical	4.2	4.6	4.7	4.4	5.3	3.0
Planning pregnancy	4.6	5.6	10.1	4.5	1.4	0.6
Other personal	4.6	5.0	4.6	4.8	5.2	8.3
Termination rates	43.4	42.2	51.1	39.0	35.4	31.6
Continuation rates	56.6	57.8	48.9	61.0	64.6	68.4
Woman-months of use	63,969	104.882	38,785	34,968	23,897	7,233
No. of women completing 24 months	469	1,415	433	467	384	131
No. of insertions	6,977	9,977	4,079	3,218	2,066	614

Interval since Last Pregnancy

Less than 3 percent of the TCu 200 insertions were made within ten days following the termination of a pregnancy, most of which were terminated by abortion. Only 23 percent of these women terminated use of the device at the end of the one year (see Table 6). The termination level in this group is equal to the level of those who had the device inserted at least three months following the termination of a pregnancy. The termination rate is highest if the insertion is done 11-31 days following a pregnancy, and it decreases thereafter.