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DYNAMICS OF DEPOT MEDROXY PROGESTERONE ACETATE (DMPA) USE EFFECTIVENESS IN THE MATLAB FAMILY PLANNING HEALTH SERVICES PROJECT

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This report documents the levels of use effectiveness of DMPA over the 1977 to 1980 period of the Family Planning Health Services Project (FPHSP) that was initiated in October 1977. In this paper we present the continuation rates and net rates of termination according to first segment, first method and all methods criteria of DMPA. In all 4405 DMPA adopters at Matlab were given 3 month injection and subsequently 6 month injection. Life table methods show that continuation rates are higher by all criteria than corresponding rates among users of the Copper T IUD in Matlab.

The authors note that a regimen of switching women temporarily to pills for regularization of menses and back to DMPA again accounts for this high use effectiveness. The field procedures in Matlab are reviewed and methods for dealing with minor complaints are discussed. Net termination rates show that their system maintains low rates of drop-out for menstrual problems and thus high overall effectiveness of DMPA.

Implications for the national programme are discussed which include a recommendation to test field procedures for utilization of DMPA in the national programme.
I. INTRODUCTION

In the Bangladesh Second Five Year Plan injectable contraceptives were include among the contraceptive methods available in the National Family Planning Programme. As a consequence, the UNFPA was requested to make supplies of Depo Medroxy Progesterone Acetate (DMPA) available to the government. DMPA utilisation has nevertheless been largely confined to special projects of nongovernmental organizations. This paper reports on the performance of DMPA in a research study of the International Centre for Diarrhoeal Disease Research, Bangladesh (ICDDR, B).

The ICDDR, B first started clinic based DMPA injections at the John Hopkins Fertility Research Project Clinic in Matlab in 1974 (Khatoon, 1976), although systematic study of DMPA did not begin until August of 1976. Injectable contraceptives were offered in six villages served by the Contraceptive Distribution Project (CDP). Although this project focussed mainly on oral pills and condoms, DMPA was adopted by 103 women who were provided with 6 months injections (450 mg) of DMPA. In this study 70 women adopted 3 month injections (150 mg). The injections were given in the home by a male Health Assistant who was accompanied by a village dai. Norinyl 1/50 mg. tablets were supplied for use in case of menstrual irregularities. (Huber, et al., 1977). The results of this experience were sufficiently promising as to suggest that DMPA should be incorporated on the Family Planning Health Services Project (FPHSP) that was initiated in October 1977 (see Khan, et al., 1980). This report documents the levels of use effectiveness that were achieved over the 1977 to 1980 period of the FPHSP.

From the inception of the FPHSP DMPA has been a major service component. By January of 1978 63 percent of the 2242 total acceptors were using injectables. Gradually this percentage has decreased until by July 1980 47.3 percent of the total 4523 total acceptors were using DMPA. At present 40 percent of the 5063 total acceptors are using injectables. Although the proportion of DMPA use declined, this is due to the introduction of alternative methods which were also popular and effective in Matlab. Most important among these is the second most popular method, sterilization, which currently comprises 23 percent of all users and the Copper T, which currently comprises 20 percent of users. Oral contraceptives have gradually declined in popularity and currently account for only 10 percent of overall contraceptive prevalence.

1 The CDP is described in a report by Makhlishur Rahman et al., 1980.
2 Village dais were older women, often a widow, who were engaged to work in diarrhoea surveillance, and to inform Health Assistants of vital events.
3 A long term prospective study of the Christian Health Care Project corroborates well with the Matlab pilot study (see Malakar and Nokrek, 1979).
The FPHSP began in October of 1977 with the selection and training of a cadre of 80 literate married village women, most of whom were members of relatively high status families. These workers were recruited from households in the villages in which they were to work and are currently designated as Community Health Workers (CHW). Although literacy and social standing were important selection criteria, strong preference was given to candidates who were practising contraception. At the onset of the project 65 percent of the 80 CHWs were using injectables. Overtime the workers have switched to Copper T, orals and tubectomy, so that now only 8 percent are still using DMPA. Nevertheless, this personal experience with DMPA has undoubtedly augmented their understanding the management of menstrual irregularity and amenorrhoea and approaches to counselling DMPA clientele to anticipate such problems in the course of use. From this experience CHW have developed a modality of switching women to pills when concerns about amenorrhoea arise and then back to DMPA again when the menstrual pattern has been regularized.

In addition to training in family planning the CHWs received some training in MCH to include use of oral rehydration therapy (ORT) in the management of diarrhoea, tetanus toxoid for pregnant mothers to prevent tetanus neonatorum; iron supplementation to be given from the sixth month of pregnancy, and training in giving health education to mothers concerning the nutritional requirements of pregnancy, lactation and infancy. CHW have been instructed to advise mothers of the importance of the addition of solid supplementary foods for infants over six months of age.

In addition to the CHW activities of the FPHSP four subcentres were established, one for each of 20,000 population, which were staffed by female paramedics trained to offer simple curative services to children under five in addition to their usual family planning duties. Family planning included providing IUD insertions, menstrual regulation services for contraceptives failures and treatment of complications of contraceptive methods.

An important aspect of the FPHSP are fortnightly meetings of the CHWs and their supervisors with the physician in charge and the paramedic at each subcentre. On the meeting day the project physician gives consultation to

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The training consisted of two week theoretical and two week practical experience. Each regular fortnightly meeting at the subcentre is a training session in which refresher training and new topics are presented. All problems are discussed. (See Bhatia, et al., 1980).
the paramedic for any difficult cases. The physician provides referral services in the Matlab MCH-FP Clinic for cases requiring care on non-meeting days. Thus the Matlab system is a three-tiered service system which includes 80 female village workers serving 80,000 people with 4 female paramedics to provide back up in clusters of villages with approximately 20,000 population per block. These paramedics, in turn, have a female physician to provide technical supervision and back up for any health service or family planning problems. Actual administrative control is vested in a male paramedic administrator and male research officers who coordinate work of subcentres assistant supervisors, in turn, conduct subcentre meetings, solve logistic problems, assist with community liaison, and insure that workers are held accountable for performance and have the necessary resources to do their work.

In the paper that follows we first discuss field methods and procedures and the statistical methods and procedures for measuring use effectiveness. Next we report results beginning first with continuation rates according to three criteria: first segment rates, first method rates and all method rates. Then we examine net rates of termination according to reasons for stopping or switching at the time of DMPA termination. In this analysis our primary interest is DMPA use effectiveness. Therefore, we examine reasons for termination of DMPA with only cursory attention to the methods that may have been used subsequently. We conclude our discussion with a brief comparison of the use effectiveness of DMPA with the Copper T IUD in Matlab and draw upon this comparison for deriving recommendations and implications for the national family planning programme.

II. THE ADMINISTRATION OF DMPA IN THE FIELD

The FHSP has emphasized the cafeteria approach to family planning. In addition to injectables, oral pills, the Copper T IUD, tubectomy, condoms, foam tablets, rhythm, and traditional methods are offered to every eligible woman. All methods are discussed with a careful explanation of the advantages and disadvantages of each, including possible side effects. With the exception of tubectomy, all methods are offered to women in their homes. If DMPA is selected by the woman a signature/thumbprint is obtained on an informed consent form which has been read and explained to the client. Those women with postpartum lactation amenorrhea may start injections at six months postpartum. At first women were started as early as they wished postpartum since research has shown that there is no effect of DMPA on the quantity of breast milk. However, more recently concern has been expressed about evidence of secretion of DMPA in breast milk and hypothesized deleterious effects of the hormone in the infant (Koetsawong, 1982). Recent research fails to support this hypothesis, however, since Schwallie (1981) indicate that the amount of hormone absorbed through the gastrointestinal tract of the infant is insignificant.
For women who are menstruating, the injection is given within five days of the last menstrual period. No women were excluded from this analysis because they were pregnant at the time of the first injection although 4 were pregnant in the third month of use, and may have conceived prior to adoption. For our purposes, however, these four cases are treated as DMPA method failures.

Contraindications for DMPA use in Matlab are a history of jaundice, severe headache, breast tumour, varicose veins, polyuria and polydipsia (diabetes) and late menstruation (possible pregnancy).

As a matter of policy, the first dose is a 150 mg. injection which prevents women from pregnancy for three months. If the first injection is tolerated and the woman so desires, she is switched to the six month regimen which requires a 450 mg. injection of DMPA. Because supply problems have arisen occasionally and the six monthly injection requires 450 mg. of DMPA, some switching from 6 month to 3 month injection has occurred. This practice is exceptional however and continuing users are typically maintained on the 450 mg. regimen. Intramuscular injections in the deltoid muscle are given by the CHWs in the home, using disposable needles and syringes. Only four injection abscesses have occurred in over 14,000 injections.

The role of the CHW in providing continuous follow up care cannot be overemphasized. The fortnightly visit of the CHW to every eligible couple in her area makes it possible to give close follow up and reassurance in case of side effects. This work routine requires between 100 and 200 household visits fortnightly. The regularity of the follow up has no relation to the interval of the injection. Therefore, from a programmatic viewpoint, women using six month injections are as carefully followed as those on three month injections.

Numerous studies of the problems that DMPA users encounter have revealed that irregular bleeding and amenorrhea are common side effects. CHW typically treat irregular bleeding by instructing women to take three oral contraceptive pills (Norinyl 1/50) immediately and one twice daily subsequently until the bleeding stops. Women are advised to continue taking one Norinyl tablet daily for an additional week following cessation of bleeding to prevent early breakthrough bleeding.

Amenorrhea has proved to be more troublesome to manage as it is often mistakenly associated with pregnancy. Amenorrheic women often express a desire to return to menstruation at which time they are switched to oral contraceptive pills for three or four months until periods are resumed. Women are then offered DMPA again. This policy has produced spuriously short use segments since brief terminations of DMPA use are suggested by field staff, but we have reason to believe that such
temporary switching has extended the overall use effectiveness of DMPA in Matlab. This issue will be formally investigated below.

Although both 3 and 6 month injections are used, it is not possible to compare the use effectiveness of the regimen because women routinely start on the three month regimen and switch to six months if there are no serious complaints. There is no area in Matlab where only 3 month injection are used, and thus no basis for comparison of regimen.

III. STATISTICAL METHODS AND PROCEDURES

The most salient feature of our data collection design is its prospective record system: the 4405 women who ever used DMPA were visited fortnightly and asked whether problems had arisen. Records were maintained to document each termination and the principal reason for termination. If some physical complaint was mentioned, the complaint was recorded along with the type of management, if any, and the person responsible for treatment. Since events were recorded prospectively, the data are free from memory bias. However, since data collectors were the CHW biases can arise if the respondent consigned spuriously high significance to problems that the CHW could deal with; namely, side effects and minor health problems. Thus procedures may bias results in the sense that the provision of services and the collection of research data are intermingled in the field. Although this may accentuate the role of "side effects" in our assessment of DMPA use dynamics, we have no formal test of this hypothesis.

The statistical methods employed in this analysis are life table methods developed by Potter (1969) for the study of IUD use effectiveness in Taiwan. In the plethora of work that has followed Potter's pioneering paper, use effectiveness has entailed research on the continuity of use, the conditional probability that a method will fail while in use, and the study of reasons for discontinuing. Conditional probabilities assess the net contribution of each reason for terminating to the overall rate of discontinuation.

Continuity of use is defined according to different criteria, each with a distinct conceptual contribution to understanding contraceptive use dynamics. The first segment continuation rate assesses the cumulative probability that a given contraceptive method will be used from the time of adoption without interruption as of a specified time. The interruptions to a segment can be switches to an alternative method followed by return to the first method. Thus use of DMPA followed by pill use and then by DMPA again terminates the first segment at the time that use was switched to pills. The first method rate assesses the extent
to which the segment rate is extended by intervening use and subsequent
DMPA use segments. Thus first method continuation rates are greater
than or equal to first segment rates. A measure of the overall continuity,
the all method continuation rate incorporates all contraceptive practice
between initial DMPA adoption and final contraceptive practice. Thus
all method rates are higher than first method rates.

Under all three criteria a pregnancy during the period of DMPA protec­
tion constitutes a termination due to method failure. Pregnancies
following termination are ignored. In the cases where a post adoption
pregnancy occurred and DMPA segments subsequent to pregnancy were noted,
we consider only the prepregnancy DMPA segments.

In keeping with the convention of assessing "net rates," we compute
conditional probabilities of each major type of termination. Net
rates measure the cumulative probability of terminating for some cause,
adjusting for the joint effect of other causes. Thus if six reasons
for terminating are recorded, six net conditional termination probab­
ilities will be computed which sum to the overall cumulative termination
rate, at a given point of time. One minus this rate is the continuation
rate, the cumulative probability of continuing use from adoption to
some point of time.

We compute net termination rate first for stopping and switching which,
in turn, is subdivided into pregnancy (method failure), convenience,
side effects, no need for contraception, desired pregnancy and other.
Owing to our special interest in side effects we subsequently merge
stoppers and switches and examine net conditional rates of stopping
DMPA by type of side effect.

IV. RESULTS

A. The Continuity of Use

Table 1 reports results for the three types of use effectiveness,
and figure 1 presents the Table I data in graphic form. Fully
58.3 percent use DMPA continuously for a year. The principal drop
is at month 3, presumably because women least tolerant of DMPA are
selected out at that initial period of trial. At the end of 24
months only 38 percent continue the first segment, by month 36 only
27.2 percent. Thus few women utilize DMPA as a permanent method
without interruption.

The substantial increase in continuity of use that distinguishes
first segment from all first method rates assesses the extent of
protection that accrues from switching clients off DMPA and then
back again: in the first year 66.3 percent continue DMPA versus
Table 1: First segment, first method and all method life table continuation rates for adopters of DMPA with sample cases and standard errors by ordinal month since adoption, Matlab 1977-1980.

<table>
<thead>
<tr>
<th>Ordinal Month (x)</th>
<th>First Segment(^a)</th>
<th>First Method</th>
<th>All Method</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(N_x)</td>
<td>(C_x)</td>
<td>SE(_{C_x})</td>
</tr>
<tr>
<td>1</td>
<td>4404</td>
<td>0.995</td>
<td>0.0010</td>
</tr>
<tr>
<td>2</td>
<td>4335</td>
<td>0.987</td>
<td>0.0017</td>
</tr>
<tr>
<td>3</td>
<td>4234</td>
<td>0.954</td>
<td>0.0031</td>
</tr>
<tr>
<td>6</td>
<td>3259</td>
<td>0.784</td>
<td>0.0057</td>
</tr>
<tr>
<td>12</td>
<td>2087</td>
<td>0.583</td>
<td>0.0072</td>
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<tr>
<td>18</td>
<td>1363</td>
<td>0.463</td>
<td>0.0076</td>
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<tr>
<td>42</td>
<td>22</td>
<td>0.213</td>
<td>0.0213</td>
</tr>
</tbody>
</table>

\(^a\) \(N_x\) is number of cases observed up to month \(x\), \(C_x\) is the cumulative probability of continuing through month \(x\), and SE\(_{C_x}\) is the corresponding standard error.
Figure 1: First segment, First method, and All method Life Table
Continuation Rates for Adopters of DMPA by Ordinal Month
Following Adoption, Matlab 1977-1980

Cumulative Percent Contin'g

Ordinal Month
58.3 percent continuing the first segment. This added protection of intervening use shows the substantial contribution of switching women back and forth between DMPA and alternative methods.

The upper most curve in Figure 1 shows the all method continuation rate: method switching nearly doubles continuation rates by month 36 and translates the first method use curve into a highly effective pattern of continuity of use. Over 80 percent use contraception over one year, and over half use a method over three years, a rate that is double the first method (DMPA) rate.

The findings reported in Table I and Figure 1 thus attest to the importance of follow up and method switching: women left on DMPA do not continue it long, but will practice DMPA at a high rate of continuity if alternative methods such as pills are available for interim use. Thus DMPA is intrinsically effective, because each injection provides 6 months of protection, but this intrinsic effectiveness can be greatly augmented if alternative methods are available. This observation becomes particularly striking when first and all method rates are compared. Clearly, the added protection of methods used subsequent to DMPA greatly extend overall use.

This is illustrated further by Figure 2 which subdivides termination rates of the first method into two subclasses: dropping, and switching. Figure 3 suggests that drop-out rates would be some fifty percent higher in the absence of alternatives of DMPA. Thus, while segment rates and first method rates are illustrative of a highly effective contraceptive method, the switching rate serves to emphasize the importance of delivering a package of contraceptive services: alternatives to DMPA which permit switching back and forth coupled with follow up and counselling produce a highly effective pattern of contraceptive use.

B. Reasons for Terminating

In Figure 3 we decompose the "net drop-out rate" from Figure 2 into subsidiary decremental factors. Clearly, the most important reason for terminating family planning after use of DMPA are complaints such as menstrual disorders, headaches, and the like. Since these problems can be treated or resolved by method switching, the Figure 3 rates are indicative of the extent to which the all method rate could be improved through better care of first method dropouts. By month 36, for example, as much as 15 percentage points could be added to the all method rate if side effect dropouts could be persuaded to accept alternatives to DMPA.

We shall return to an analysis of the components of "side effects" below.
Figure 2: First method net cumulative probabilities of termination by principal reasons for stopping DMPA, Matlab 1977-1980.
Figure 3: First method net cumulative probabilities of termination by principal reasons (drop) for stopping DMPA, Matlab 1977-1986.
A similar conclusion arises from the Figure 3 curve showing inconvenience as a reason for dropping contraception. Presumably such women desire to limit or space births but find injections or other features of DMPA to be grounds for stopping. These women and the women who finally drop contraception because of side effects are typically the source of additional use prevalence when new methods are added to the cafeteria. Thus Matlab use effectiveness data provide evidence that final terminators of contraception among first method drop-outs contain a large component of women who could be switched to some other method. Continuation rates, though high, can be further improved through provision of more methods made conveniently available combined with intensive follow up and care.

Aside from side effects and convenience no other reason for termination is important. The cumulative 36 month probability of terminating to plan pregnancies is only 6 percent, suggesting that spacing is not an important consideration among DMPA users. "No need" for contraception is also unimportant.

The low termination rate for pregnancy attests to the high efficacy of DMPA while it is in use. The first year failure rate is less than one percent and the three year net cumulative failure rate is only two percent. Clearly, DMPA is as effective as the Copper T and less subject to the compliance problems that lead to pill failures.

Figure 4 shows net cumulative rates among switches to other methods. Side effects and inconvenience clearly account for nearly all of the switching from DMPA to other methods.

In Figures 5 and 6 we ignore whether switching or stopping explains first method stopping and examine side effects as a cause of either dropping or switching. Figure 5 illustrates the difference between first and all method termination rates for all side effects combined and shows, not surprisingly, that side effects exert a more important role in the decision to terminate contraception altogether than it does in affecting first method DMPA discontinuation. In Figure 6 we decompose net cumulative side effect rates into subclasses. Since menstrual disorders are known to be clinically important, we distinguish menstrual complaints from headache, body pain, fever, and other types of problems that are less likely to be a consequence of DMPA use than a consequence of ill health that users mistakenly link with the method. As Figure 6 shows, pain and general health complaints are more important causes of DMPA termination than menstrual disorders. General health problems, much of which is likely to bear no clinical link with DMPA, account for cumulative net probability of 14 percent in three years, versus 10 percent
Figure 4: First method net cumulative probabilities of termination by principal reasons (switch) for stopping DMPA, Matlab 1977-1980.
Figure 5: First method and all method cumulative probabilities of termination by principal reason (side effects) for stopping DMPA, Matlab-1977-1980.
Figure 6: First method net cumulative probability of termination by principal reasons (side effects) for stopping DMPA, Matlab, 1977-1980.
for menstrual problems. Clearly, providers of contraception must be equipped to deal with such health problems, either through the provision common drugs such as aspirin or counselling to ensure that such problems are appropriately referred to trained paramedics or physicians for expert diagnosis and care.

The net cumulative rates of terminating from menstrual complaints are as low as 10 percent attests to the efficacy of the Matlab treatment and referral system. In a Thai study McCamlel and Pardthaisong (1974) found that fully 60 percent of a cohort of 682 women were observed to have had alterations in bleeding patterns over a two injection cycle of 6 month injections. Although such problems were common in the Thai study, they typically involved minor irregularities in bleeding pattern (4.3 percent) or amenorrhea (11.2 percent), and only rarely heavy bleeding (3.5 percent). Nevertheless, we expected this problem to account for a more substantial proportion of the terminations than were in fact observed. A clear lesson from the Matlab experience is that menstrual irregularities need not account for a substantial proportion of the drop-outs if follow-up is rigorous and workers are trained to treat problems as they arise. Most importantly, amenorrhea need not become an important reason for terminating DMPA if intermittent use of Norinyl is administered to restore menstruation between segments of DMPA use.

C. Comparison with the Copper T

The Matlab cumulative first method rates of continuing the Copper T and DMPA are presented in Table 2 along with net cumulative method failure rates and termination rates for complaints about side effects. As Table 2 shows DMPA has higher continuity of use and lower complaint rates than the Copper T as the methods are administered in Matlab. An implication of Table 2 is that DMPA has acquired an undeserved reputation of being "more risky" than the IUD and perhaps less effective. Both methods require careful administration, follow up, and referral services, but DMPA use effectiveness is superior to the Copper T when methods are provided with the same degree of care. Since our research shows that the dynamics of switching contributes to overall use effectiveness, the data attest to the efficacy of a multiple method programme with rigorous follow up and careful worker training to insure that women who encounter problems with a method have alternatives to stopping use altogether.

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1This assertion bears further investigation, since rates are unstandardized by age and parity.
Table 2: First Method Cumulative Continuation Rates for DMPA and the Copper T, Matlab.

<table>
<thead>
<tr>
<th>Ordinal Month</th>
<th>First Method Net Continuation Rates:</th>
<th>First Method Net Failure Rates:</th>
<th>First Method Net Rates of Termination for Side Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>DMPA</td>
<td>Copper T&lt;sup&gt;a&lt;/sup&gt;</td>
<td>DMPA</td>
</tr>
<tr>
<td>5</td>
<td>0.331</td>
<td>0.767</td>
<td>0.016</td>
</tr>
<tr>
<td>12</td>
<td>0.563</td>
<td>0.591</td>
<td>0.010</td>
</tr>
<tr>
<td>18</td>
<td>0.555</td>
<td>0.5029</td>
<td>0.012</td>
</tr>
</tbody>
</table>

<sup>a</sup> Based on 313 Copper T acceptors for May 1979 to May 30, 1980 period. These results are provisional and subject to revision.
V. IMPLICATIONS

Four principal implications emerge from our work with DMFA:

1) DMFA can be a highly effective contraceptive with use effectiveness that is at least equivalent to or perhaps superior to the Cooper T with lower rates of complaints from users.

2) Achieving high levels of DMFA use effectiveness, however, requires a comprehensive approach which offers alternatives to DMFA when problems arise. This, in turn, requires a trained cadre of workers who counsel women, care for their problems, and maximize their options in contraceptive care. We should not view the high level of DMFA use effectiveness in Matlab as evidence to support a DMFA campaign. Rather, it is indicative of the achievement that is possible in rural Bangladesh when multiple methods are delivered by a trained cadre of service workers with ancillary health care skills.

3) The promising result of DMFA in this special project represents a challenge to test approaches for using DMFA in the MOHPC system. Such an effective and popular method can be and should be used by the MOHPC, but the appropriate delivery system, training and supervisory scheme has yet to be devised.

4) Menstrual disorders are common among DMFA users. As the Matlab results show, however, such minor problems need not represent a serious problem for administering the method if women are fully informed of the potential for such problems and if field workers are trained and equipped to care for women when problems arise.

VI. CONCLUSION

DMFA is a contraceptive method which holds considerable promise for rural Bangladesh. Large scale field studies have demonstrated its safety1 and our current research attests to its efficacy when the method is administered by trained workers who are equipped to deal with minor problems if complaints arise.

1See the reviews by Nash, 1975, Rosenfield and Maine, 1980.
REFERENCES


