# A field study of Depo-Provera:

its use as a contraceptive method by women in a rural town in West Malaysia from February 1968 to December 1969

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## INTRODUCTION ON THE PROGRAMME

THE STUDY OF Depo-Provera, pharmacologically known as Medroxyprogesterone Acetate, a long-acting progestestional agent given as a single intramuscular injection, has been made since 1958 for the treatment of endometriosis and threatened or habitual abortion. Probably fifty or more field and/or clinical trials of Depo-Provera have already been made for the treatments mentioned above and also as a contraceptive method. However most of the past studies dealt more on the clinical aspects of the drug but this study is more concerned with the field aspects and its popularity as an additional contraceptive method to be offered by the National Family Planning Board (N.F.P.B.), Malaysia.

The national family planning programme in Malaysia was first started in June, 1966 with the inauguration of the N.F.P.B. Malaysia when the Family Planning Act No. 42 of 1966 was passed in Parliament. The operational service programme began in May, 1967 with the opening of seven family planning clinics at maternity hospitals under the first phase of its Operational Service Programme at the seven large municipalities, involving a total population of about 1.5 million. By the end of 1969, when Phase III of the service programme, planned to extend family planning services to all the remaining district hospital areas and some main and sub-health center areas, covering another 1.5 million persons, the N.F.P.B., Malaysia had 63

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main clinics and 310 satellite stations throughout the country. Since then, the oral pill has been the mainstay of the Malaysia programme with a consistent monthly average of about 92.0% of all its family planning acceptors registered as taking the pills, 2.0% on I.U.D.'s, 3.5% in favour of sterilisations (mostly tubal-ligations performed post-partum at hospitals), 1.0% using condoms and 1.5% trying on other methods which included the injection method (Depo-Provera) at a later period from February, 1968.

This study was started with the advice of Dr. Ralph Ten Have, who was then consultant to the Board and was sent by the Center for Population Planning, University of Michigan, under the Technical Assistance Scheme provided by the Ford Foundation. The authors also acknowledge the invaluable assistance given by both Dr. M. Subbiah and Dr. Nor Laily binti Dato' Abu Bakar of the N.F.P.B., Malaysia and Dr. Yuzuru Takeshita of the University of Michigan.

## Purpose of the study

The national programme relies heavily on only one method of contraception, the pills. Provera, which has been used since 1959, works in about the same way as oral contraceptives to prevent conception and like the pills, it has been round to be acceptable, safe and effective. Also due to some well-known though minor side-effects of the oral pill and often-times the adverse publicity of the pills in the press, the Board approved that a continuous field-study be carried out on women in a rural area in Malaysia to find out the acceptability, practicability and popularity of Depo-Provera as an additional injectable contraceptive method to be offered to the people. The study was designed to find out if side-effects, such as amenorrhea, spotting and other complaints, were experienced by women using this method of contraception. Many of these women tolerated the minor menstrual disturbances and still preferred the injection to any other method, but should they discontinue, a follow-up interview was made in this study to find out their reasons for discontinuation, what it was that bothered them most, and so on. This study covers all the patients (550) who have accepted the injection method from the start of the injection programme from 23rd February, 1968 till the cut-off date on 31st December, 1969.

# Study areas

The area selected for this study is a village called Sungai Besar, situated about 80 miles northwest of Kuala Lumpur, the capital of Malaysia. A mobile team, consisting of a medical doctor, assisted by two trained nursing staff from the Board in Kuala Lumpur, visited the clinic which is located at the subhealth centre, once in every two weeks at the beginning to provide family planning services. Now, the family planning clinic is being staffed by a trained nurse and an assistant nurse, both of whom have been trained and are employed by the Board on a regular fulltime basis.

Sungai Besar is located in the district of Kuala Selangor. The district population was estimated to be about 63,254 in 1965 and they were made up of about 90% Malays, 10% Chinese and the rest of the Indian and other ethnic group of population is assumed to be negligible. This population structure is, however, different from the overall racial composition of about 50% Malay, 37% Chinese and 13% Indian and other ethnic group of population in the whole country. In this study area, the Malays are mostly in agriculture while the Chinese are in business and fishing along the sea-coast.

## Fertility trend in the area

The number of births registered at police stations and health centers in the district of Kuala Selangor for 1966-1969 was obtained and the population of the area for that period based on the 1965 electoral-roll population, was calculated at an annual increase rate of 3%.

The estimated population and fertility trend of the area are shown in the following table.

Table 1
Estimated Population and Fertility
Trend of district of Kuala Selangor
(1965 Electoral-roll Population 63,254)

Year	Population Estimated	Number of Births Registered	Crude Birth Rate (Per 1,000 Pop.)
1966	65,150	3,172	48.7
1967	67,110	3,538	52.7
1968	69,120	2,847	41.2
1969	71,190	2,890	40.6

Table I shows an evidence of a high fertility pattern typical perhaps of the rural areas in Malaysia but the decline in birth rate between 1966-1969 does not necessarily indicate the effectiveness of the injection study project. It was noted that the first family planning session began on 23rd February, 1968 when the injectable steroid was offered as the main method of contraception. It would be interesting to observe the future trend of fertility in the area.

## Material and method

Depo-Provera is being supplied in the form of a sterile, aqueous suspension of 50 mg./ml. and previous studies show that various dosages, ranging from 50 mg. to 200 mg., had been injected at varying periods of time, ranging from every month to every six months into the deltoid muscle or the buttocks of the women taking the drug. The 150 mg. dosage has been found in past studies to be most acceptable as a contraceptive method.

We wish to place on record the kind assistance that was given by Dr. T. Vecchio, Director of Medical Research, the Upjohn International Company, Kalamazoo, Michigan. The Depo-Provera used by the Board in this study was supplied by the Upjohn Company in 3 cc, vials containing 50 mg./cc. of Medroxyprogesterone Acetate. An injection containing the above was used for intramuscular injection at 3-month intervals. The injection method was given free and without any age limitation to any married woman who wanted it as a contraceptive method. On the day of the initial injection, the woman was given a registration card and a return appointment was scheduled for three months from that date.

#### Tabulation of results

The individual questionnaires were edited, coded and then punched on cards. The three independent variables, Age at Acceptance, Ethnic Group and Number of Living Children, were examined and cross-tabulated against other selected variables but prior to this, the punched cards had been checked and verified for wild-codes by the use of the Center for Population Planning computer programme and the computer at the University of Michigan.

#### Results

This study is centered on interviews of women who have discontinued use of the injection method. Interviews were made at the patients' homes by two selected female field interviewers who knew their local rural area and the local spoken languages well. They were trained at the central office for a week. An interview took on an average of ten minutes to complete. None of the patients refused to be interviewed.

A total of 550 women accepted the injection as a method of contraception at the Sungai Besar Family Planning Clinic during the 23-month period under study, and at the cut-off date on December, 31st, 1969, 318 (58%) were still receiving regular injections at three-month intervals. The rest of the women (232) discontinued use of the injection; 176 of them (176/550 = 32%) were interviewed while the other 56 women (10%) were lost to follow-up, due mainly to migration (91%).

The 550 injection acceptors who have been registered since the start of the injection study programme in this area are compared with the overall family planning acceptors who have been reported for the cumulative period May 1967 -December 1969 throughout the country. It is observed that 52% of all the injection acceptors under study were below 30 years while the overall figure for the whole country was 56%. The injection acceptors under study and having three or less number of living children were found to be 34% compared to 43% for the whole country. The injection study area chosen is somewhat typical in ethnic composition of a rural town in the state of Selangor. In our injection study, 75% of the injection acceptors were Malays and 22% were Chinese, compared to 45% Malays, 43% Chinese and 12% for the rest of the overall family planning acceptors registered throughout the whole country during May 1967 to December 1969.

If it is assumed that one injection would protect a woman from getting pregnant for a three-month period, the retention rates at the end of 12 and 24 months were 63% and 41% as shown in Table 2. These continuation rates were fairly high and were as good as those for the oral pill which is the main contraceptive method provided since the beginning of the operational service programme of the Board in May, 1967.

In comparison with ethnic groups of the population in the district, the Chinese comprising about 10% of the district population, seemed to have a higher proportion using (21%) the injection method as a contraceptive. The proportion of the Chinese women lost to follow-up (34%) was also significantly higher, an indication of perhaps more mobility among the Chinese in this area. However, except for a small number of Indian women with a high rate of discontinuation, there was not much difference in continuing the method between the Malays (246/409 = 60%) and the Chinese (68/122 = 56%).

The younger age-group of women seemed to have a higher proportion of discontinuation. Over

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Table 2: Patient Retention by Number of Months since Entering Programme

Possible number of Injections	· 6	2	7	-4	<	6	7	8
of Injections		2	3	4	100		-	-
Possible number		- 1						75.
of Months Protected	3	6	9	12	15	18	21	24
No. who started in cohort	550	525	458	424	364	291	203	91
No. of Patients Protected	550	434	326	265	201	152	99	37
Prop. of Retention (%)	100	83	71	63	55	52	49	41

half (56%) of those women who were interviewed (176) came from women below 30 years. About 75% of these women were not using injection as a contraceptive method at the time of interview and about 22% who probably have restarted the injection method, answered that they were still using the injection method at the time of interview in June, 1970.

Proportion of discontinuation was found to be higher among the lower parity women with three or less number of living children for all injection acceptors. For each individual, reported complaints regarding side-effects since her last injection were recorded on her individual client record card at each injection. It was found from this source that the frequency of reported amenorrhea seemed to persist, regardless of the length of continuing with method. Complaints of spotting and bleeding decreased immensely when the women continued longer with this method.

The findings of this study show that amenorrhea (35%) seemed to have most bothered the women who discontinued the injection method.

Table 3

Percentage of Patients Still Using or Discontinuing Injection Method By Age.

	Total Injection Still Using Acceptors			Status in Programme  Drop-Outs					
Age Group			Still Using						
					'Total		Discontinued	Lost to Follow-up	
	%		%		%				
Under 20	100	(44)	43	(19)	57	(25)	(20)	(5)	
20 - 24	100	(138)	58	(80)	42	(58)	(43)	(15)	
25 - 29	100	(105)	56	(59)	44	(46)	(36)	(10)	
30 - 34	100	(132)	63	(83)	37	(49)	(34)	(15)	
35 - 39	100	(79)	62	(49)	38	(30)	(22)	(8)	
40 or more	100	(45)	49	(22)	51	(23)	(20)	(3)	
Not available	100	(7)	86	(6)	14	(r)	(1)	(0)	
TOTAL	100	(550)	58	(318)	42	(232)	(176)	(56)	

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Table 4

# Percentage of Patients continuing or discontinuing Injection Method by Ethnic Group

				Status in Programme  Drop - outs				
Ethnic Group District Population  Malay = 90 Chinese = 10 Indian & Other *	Total Injection	Still Using						
	Population	Acceptors		Total	Discontinued	Lost to follow-up		
	100 (409) 100 (122) 100 (19)	% 60 (246) 56 (68)	% 40 (163) 44 (54)	(137) (35)	(26) (19)			
Total	100 (63,250)	100 (550)	21 (4) 58 (318)	79 (15) 42 (232)	(4) (176)	(56)		

\*negligible percentage.

Irregular bleeding (20%) and other medical side-effects (11%) were the other main complaints that caused women in this area to discontinue using injection as a contraceptive method. None of the women in this rural area discontinued because of objection from the husband or other members of the family but 24% of the women did not say why they discontinued.

In studying the pregnancy history of the women after they received the first injection, it was found that the date of birth of the first or subsequent pregnancy after the injection was unavailable but but the status of the pregnancy in relation to initial acceptance of the injection method was obtained. It was found that 37 (21%) of the women interviewed (176) were pregnant at least once after they received the first injection. Of these cases, seven were pregnant within the injection protection period, nine women were pregnant after the protection period of the last injection and the condition of the rest (21) were indeterminable due to lack of information.

Among the 176 women who discontinued using the injection method, 23% of them said they were satisfied with the method. Only one woman answered in the negative but 76% made no comment when asked.

There was only one suspected method failure recorded among the 550 women who registered for injection as a contraceptive method at this clinic during the 23 months under study from February 1968 to December 1969.

## Conclusion

Depo-Provera (150 mg.) injected once every three months appears to be simple, acceptable, popular and effective as well, as a contraceptive method among women in a rural town in Malaysia. Acceptance of the method has been good and continuation of use has been very encouraging. The main cause of discontinuation seemed to have come from amenorrhea while irregular bleeding also bothered them very much. Acceptance among the younger age-group and the lower parity women was good though the proportion of discontinuation was found to be higher in both these types of women.

It is noted that similar findings and conclusions regarding the complaints, acceptability, popularity and effectiveness as well, have been arrived at in almost all past studies on the clinical and/or field aspects for women using the Depo-Provera as a contraceptive method.

The injection method continues to be provided to women in this rural area in Malaysia and the Board intends to carry on this continuous field study of the acceptability, popularity and the effects of the drug as a contraceptive method in this area. Meanwhile, more and more women are coming forward to accept this method of contraception and there is a growing demand for Depo-Provera in other parts of the country as well. Possibly, it may be added on to the list of contraceptive methods available at all the Board's clinics throughout the country in the near future.

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Table 5

Percentage Distribution of Patients by Number of Living Children by Current Status in the Injection Programme.

	2	Programme							
Total Drop-outs		-outs	Drop	All Injection Acceptors Still Using		Number of Living			
1441.00		Lost	ntinued	Discor					Children
0.4 (	(0)	o	(1)	0.6	(o)	0	(1)	0.2	0
7.8 (1	(6)	10.7	(12)	6.8	(11)	3.4	(29)	5.3	1
16.4 (3	(11)	19.7	(27)	15.3	(40)	12.6	(78)	14.2	2
13.4 (3	(8)	14.3	(23)	13.1	(46)	14.5	(77)	14.0	3
13.4 (3	(4)	7.1	(27)	15.3	(43)	13.5	(74)	13.4	4
11.6 (2	(5)	8.9	(22)	12.5	(36)	11.3	(63)	11.4	5
9.4 (2	(8)	14.3	(14)	8.0	(46)	14.3	(68)	12.4	6
27.6 (6	(14)	25.0	(50)	28.4	(96)	30.2	(160)	29.1	7+
100 (23	(56)	100	(176)	100	(318)	100	(550)	100	Total

Table 6

Percentage Distribution of Complaints
Reported by Patients who returned for
Injection by Number of Months since
First Injection

Spotting	
	Other
24.5	16.0
28.3	11.6
35.2	9.6
31.3	7-4
28.2	4.9
27.3	5.5
26,3	1.3
28.7	10.3
	26,3

Source: = clinic records

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Table 7
Reasons for Discontinuing Injection

Reasons	Discon	tinued				
Because of Preg	nancy				6.2	
Medical: (i)	Ameno	rchea			34-7	
(ii)	Irregul	ar bleedin	g		19.9	
(iii)	Other	side-effects	S		10.8	
Want more chil	dren				3.4	
Objection from	husban	nd			0	
Objection from	other	members	of	family	0	
Other reasons					0.6	
Not available					24.4	
Total	(3)	141		279	100	(176)

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