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Operations Research

**Norplant[®] Implant
Use – Dynamics Diagnostic
Study: Indonesia 1991**

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NORPLANT[®] IMPLANT USE-DYNAMICS
DIAGNOSTIC STUDY: INDONESIA 1991

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ABSTRACT

Indonesia's national family planning program constitutes the largest introduction of the NORPLANT® implant* in the world. With the first five-year removals occurring in late 1991, the program was at a critical stage. The ANEORTA Project conducted a Use-Dynamics Study to look systematically at NORPLANT® implant use in the field. To prepare for that study, and to get early information on program functioning, BKKBN and the Population Council, in conjunction with Andalas University in West Sumatra and BKS-PENFIN in West Java, undertook a diagnostic study in the Fall of 1991.

Field teams investigated six clinics in each of the two provinces, interviewing service providers and examining records. Ten acceptors from each of the 12 clinics (a total of 120 acceptors) were visited in their homes to determine the feasibility of locating them and whether they were still using implants.

About 70% of the acceptors in each province had accepted from non-clinical sources, either "safaris" or mobile team visits. The four-year life-table continuation rate was 78%. No written information specifically devoted to the NORPLANT® implant was available either to providers or to clients. Available records generally matched official records, although significant gaps were found. All physicians and nurse-midwives, as well as many nurses, had some training, formal or informal in NORPLANT® implant insertion and removal. Contrary to expectation, clinical staff, records, and logistics all seemed generally adequate for five-year removal, although some problems can be expected.

The feasibility of the Use-Dynamics study was confirmed. The study allowed questionnaires and field procedures to be refined to enable the larger-scale Use Dynamics Study to begin in December 1991.

* NORPLANT® is a registered trademark of the Population Council, Inc., for subdermal contraceptive implants.



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EXECUTIVE SUMMARY

After five years of national programmatic use of NORPLANT® contraceptive implants, BKKBN implemented in 1992 a follow-up study of use-dynamics of implant users in West Java and West Sumatra Provinces, Indonesia, with technical support from the Population Council and implementation support from BKS-PENFIN, Bandung, West Java, and Andalas University, Padang, West Sumatra. A "Diagnostic Study" was implemented in October and November, 1991 in order to prepare for that study prior to final approval, and to get some early insights into implant program operations in advance of final results from the main study. This is a summary of findings from the Diagnostic Study.

The Diagnostic Study had two broad objectives: to obtain information to guide development of the larger Use-Dynamics Study, and to supplement existing information on implant service delivery with a field-based observation study to help BKKBN make necessary decisions for its implant program.

The study involved two main activities: field visits to 6 clinics in each of the two provinces, and follow-up interviews with samples of 10 acceptors from each of the 12 clinics. All field visits involved representatives from the Biomedical Research Center at BKKBN (Heru) and The Population Council (Miller), supplemented by representatives from the provincial BKKBN office and the cooperating research institute. The latter subsequently conducted the follow-up interviews.

Sampling of clinics was purposive, to represent the general experience of the two provinces within logistical constraints. The team interviewed service providers, examined records, and drew samples of acceptors from registration books in each clinic for later follow-up. There was little observation of service provision, and no visits to villages or clients.

The cooperating research institutes later hired and supervised short-term interviewers to locate the 120 sampled acceptors and fill out a 2-page questionnaire indicating success in locating acceptors and subsequent experience with the implants. Results were analyzed at BKKBN.

PROGRAMMATIC FINDINGS:

Clinic vs. non-clinic delivery. About 76% of acceptors in both provinces were from "nonclinical" sources, including both "safaris", involving several villages and organized transportation to a central point, and other non-clinical services, usually village-based.

Acceptability. West Sumatra has seen a high rate of early NORPLANT® implant acceptance, followed by a precipitous decline. In Lebak, acceptance began and remains high. Reasons for these patterns could not be fully clarified.

Availability of removal services. In the centers visited, capabilities were adequate to meet the expected demand for 5-year removals. In every visited center at least two providers were performing insertion and removal of implants, and the demand for removals at the busiest centers should not average much more than one per day during 1992 or for the foreseeable future.

Continuation. Life-table continuation rates for the 102 acceptors interviewed were .94, .90, .82, and .78 for one to four years, respectively, with standard errors from 3% to 7%. Most women were using NORPLANT® implant for a substantial period, but removal prior to 5 years is realistically available. Menstrual problems constituted the most common reason for removal.

Training. In each center visited, between 2 and 6 providers had experience in implant insertion and removal; in many cases, training was local and informal, and emphasized clinical techniques more than counselling and education.

Information. There was no written information specifically about implants, either for providers or for clients, available in any center visited. In West Sumatra, this lack of information may have been a major contributor to decreasing implant acceptability. The need for better information was both observed by the teams and felt by providers.

Quality of services. Sufficient numbers of trained providers exist, and there were few supply problems. Providers reported problems with infection at the incision site and difficult removals. Client education and counselling appear to be quite limited. Mechanisms exist for client follow-up and support, but we could not judge their effectiveness. Providers report that insertion in non-clinical settings can adversely affect aseptic technique and time for counselling. Overall quality of care is probably comparable to that for other methods.

FINDINGS FOR PLANNING USE-DYNAMICS STUDY:

Record keeping. For all centers, official provincial totals were clearly based on real local data. However, in all centers there was less than a complete sequence of registration books dating back to 1986. K-IV (client card) records were found for 79% of sampled acceptor names. In Lebak, each clinic had a separate "helping" acceptor log, which was generally more complete than the register. For the Use-Dynamics Study, gaps in the registers will mean that sampling lists at the clinic level will be incomplete.

Ability to locate respondents. Eighty-six percent of sampled acceptors were successfully located. There appears to be a high rate of migration in West Sumatra, so extra funds may be needed to track down women outside the study kabupatens. Some of those lost to follow-up could probably have been found if more time had been available, and it appears that a follow-up rate of 90% - 95% should be achievable.

Fieldwork. In both areas, it was possible to locate more acceptors per interviewer per day than was anticipated in the original plan. Proper organization and the assistance of the family planning fieldworkers appear to be keys to success.

Questionnaire. The Diagnostic Study helped in sharpening the original questionnaire draft, which has been appropriately revised.

COMPARISONS WITH USE-DYNAMICS STUDY:

The Indonesia NORPLANT® Implant Use-Dynamics Study was implemented in 1992 (1). Most of the findings of the Diagnostic Study were confirmed; a few findings were proven incorrect, and some were not investigated in the same way in the main study.

Clinic vs. non-clinic delivery. In both studies, a considerable majority of insertions were reported as done in safari or group service. The proportion was higher in the main study -- 87% and 90% compared with 76% in both areas in the Diagnostic Study. The categories in the survey were defined differently, and presumably understood differently, than in the clinic records.

Acceptability. The acceptance patterns over time were from historical data, and not studied in the Use Dynamics study.

Availability of removals. Peak demand for removals had not been reached by the time of the Use-Dynamics Study, but it does not appear that this is likely to be a problem.

Continuation. Four-year continuation rates were 83% for West Sumatra and 81% for West Java, compared with 78% in the Diagnostic Study. Differences at other periods were similar. This confirmed the sense that early removal is realistically available, but that excessive levels of early removal is not a problem.

Training. Data were not comparable. The Use-Dynamics Study found about 60% of both doctors and bidans had formal training, but levels of informal training were not assessed.

Information. The Use-Dynamics Study discovered serious weaknesses in client knowledge, confirming the problem of lack of public information about NORPLANT® implants in the system.

Quality of services. The impressions of the Diagnostic Study were generally substantiated in the Use-Dynamics Study, in fuller and more quantitative terms. Client education and counselling appears to be the major weakness in quality of care. Reported infection rates after insertion were reported to be 2.5% in West Sumatra and 4.9% in West Java.

Record keeping. While gaps were found in the records of implant acceptors, these did not create a major sampling problem.

Ability to locate respondents. The response rate was 95% in West Sumatra, 88% in West Java. Contrary to the Diagnostic Study, migration from area was a greater problem in West Java than West Sumatra.

More generally, the Use-Dynamics Study confirmed the general perspective of the Diagnostic Study regarding the strengths and weaknesses of the implant service delivery system. At the time there were strong rumors, repeated in the international press, of vast numbers of implant acceptors without support or access to removal. The Diagnostic Study served to calm these fears, and at the same time raise other concerns, such as the lack of information, which are being followed up by BKKBN. The Use-Dynamics Study confirmed these in a broad perspective, with a larger and richer dataset.

DIAGNOSTIC STUDY REPORT

I. INTRODUCTION

NORPLANT® contraceptive implants are the first important, essentially new contraceptive method to be introduced in a generation, since the pill and the IUD first changed the technology of birth control in the 1960s (2). Since then, much has been learned about how specific contraceptives can best be introduced to a population, but with contraceptives which have long been part of programs elsewhere.

Indonesia's national family planning program constitutes the largest and most ambitious introduction of NORPLANT® implants in the world. Following clinical and field trials, NORPLANT® implants were formally introduced into the national program in 1986. Since then, the number of annual NORPLANT® implant insertions has increased rapidly: by December 1991 over one million insertions had been reported.

Although the Indonesian NORPLANT® implant program is unique in terms of its scale and its pace of expansion, it typifies many of the operational problems that other developing countries are likely to encounter as they expand their NORPLANT® implant programs. Debates have arisen on such issues as what type of personnel are appropriate for insertion and removal, what level of clinical facilities are needed, how to train providers, what information to provide clients, whether NORPLANT® implant is suitable for mass campaigns and other points.

Several steps have been taken to address these issues. The National Family Planning Coordinating Board (BKKBN) has addressed some issues on user's experience and service delivery (3) in several provinces. Yayasan Kusuma Buana (YKB) has addressed user experience (4,5) and continuation and removal (6) in selected hospitals among acceptors from the period prior to national programmatic usage, and conducted observations and interviews in a number of clinics involved in the national program (7). YKB and John Snow, Inc., are now contracted by BKKBN to implement a study in Sumatra to determine how best to keep records of adverse reactions and to ensure removal after the approved 5-year period (8). The BKKBN is participating in international epidemiologic surveillance of NORPLANT® implants (9), and has plans for other research. Nevertheless, by late 1991 there had been too little study of services or acceptors in the context of national programmatic usage, and much remained to be learned.

During 1991 BKKBN and the Population Council developed plans for "An Evaluation of NORPLANT® Implant Use Dynamics in the Indonesian Family Planning Program" to be implemented in West Sumatra and West Java Provinces in 1992, as part of the Council's Asia/Near East

Operations Research and Technical Assistance Project, with funding by USAID. The study, which began in December 1991, involved interviewing a sample of 3,107 NORPLANT® implant acceptors in West Sumatra and West Java to obtain life-table rates of continuation and removal by cause, as well as information on acceptor experience, knowledge and attitudes towards the NORPLANT® implant, and quality of care, including comparisons between those accepting in clinical vs. non-clinical settings. The study also included a survey of NORPLANT® implant service providers in the two provinces. The research was directed and coordinated by BKKBN; field work was implemented in West Java by BKS-PENFIN, a family health research institute in Bandung, and in West Sumatra by the Public Health Department of Andalas University in Padang.

During planning for the Use Dynamics Study, it became apparent that too little was known about record keeping on implant acceptors, whether from clinical or non-clinical sources, and about how to locate acceptors. At the same time, increasing concerns made it particularly important to obtain quick information about the nature of the implant program, especially as the first full year of scheduled 5-year removals approached. Accordingly, the Diagnostic Study to Evaluate the Prevalence of Clinical and Non-Clinical Delivery of NORPLANT® implants in the Indonesian Family Planning Program was developed, and approved by USAID in October, 1991. The study was implemented in October and November, 1991. This working paper is the report on that study.

II. OBJECTIVES

The broad objective stated in the Diagnostic Study proposal was "to obtain more information about the delivery of NORPLANT® implants through mass campaigns."

The Scope of Work indicated that the following information was to be obtained:

1. The completeness and accuracy of the clinic records. This will be accomplished by comparing overall numbers of NORPLANT® implant acceptors through clinic records with service statistics on reported numbers of acceptors in each area. In addition, for each clinic, a random subsample of acceptors will be traced to their residence in order to establish the validity and usefulness of recorded address information.
2. The service delivery source of NORPLANT® implants -- from clinics versus mass programs. Of particular interest is the extent to which source of NORPLANT® implant service delivery varies between geographical areas.
3. The commonness of return to the clinic for complications following insertion, for all acceptors and by source of provision.

4. Levels of reported method removal among women returning to the clinic, for all acceptors and by source of provision.

In fact, the objectives of the study fell into two broad, overlapping types: first, to supplement existing information with field-based observations on the implant program, with particular reference to the issue of mass campaign service delivery; and second, to obtain information to guide development of the larger Use-Dynamics Study, particularly regarding the state of record keeping.

III. METHODOLOGY

A. Organization of Fieldwork

The diagnostic study had two main phases of field activity: visits to 6 clinics in each of the two provinces, and follow-up interviews with a sample of 120 acceptors, 10 from each clinic.

Dr. Heru, of the BKKBN Biomedical Research Center, and Mr. Miller, of the Population Council, conducted all 12 clinic visits together. They were accompanied in West Sumatra by representatives of the provincial BKKBN office and Andalas University, and in West Java by representatives of the provincial and regency (kabupaten) BKKBN offices and BKS-PENFIN. The teams met primarily with service providers in the health centers (puskesmas), typically involving interviews with the physician in charge (if available) and a senior bidan (midwife), and briefer dealings with other clinic personnel. The topics of the interview were in general consistent with the objectives of the study, but the specifics evolved over the course of the study and varied somewhat according to the clinic and the interests and knowledge of the clinic personnel. After the interview, the investigators reviewed clinic records in detail, including acceptor registration books, acceptor cards (K-IV records), and any other records which might be useful. Ten acceptors were sampled at each clinic, usually from the registration books. K-IV client record files were searched to determine how many of the cards could be found, and what follow-up information was available on each card. The same 10 acceptors were also the sample for the follow-up interviews. Typically a visit took 2 to 3 hours; allowing for travel time, it was generally possible to visit 2 clinics in a day, except for remote clinics.

The follow-up visits were conducted during the two weeks following the field visits under the direction of Dr. Faisal R. Djamal of Andalas University and Dr. Dinan Bratakoesoema of BKS-PENFIN, respectively. Local interviewers were selected, trained briefly, and given the lists of acceptors in each clinic to locate and interview at their homes, using a two-page set questionnaire. This questionnaire focused on two issues: location of the client (how many revisits, if not found why not, etc.), and whether the implant

was still in place (if not, when and why removed). The nature of the interviewers and the field procedures varied according to circumstances. In West Sumatra 6 recent graduates of a local health college were used as interviewers, and each was sent to a different health center, doing 10 interviews each. In West Java, where the study area was at considerable distance from Bandung but where distances were less, local high school graduates were recruited as interviewers and worked as a team, moving from area to area. The completed interview schedules were sent to BKKBN and analyzed centrally.

Fieldwork took place during October and November, 1992, and the analysis was completed by early December.

B. Sampling

West Sumatra and West Java were chosen for the Use-Dynamics study, and therefore for the Diagnostic Study also. West Sumatra has the highest rate of implant acceptance per capita of any province in Indonesia, but also, uniquely in the country, has a striking pattern of very high initial acceptance followed by a rapid decline in acceptance thereafter (see Table 1). Hence it would seem that West Sumatra might represent a particularly good example of problems in service delivery leading to declining acceptability. West Java has a middling acceptor-to-population ratio which, like Indonesia as a whole, has steadily increased since the inception of the national program. Lebak, the study regency, was chosen because it had by far the most early acceptors, from late 1986 and early 1987, so follow-up on 5-year users would be possible by early 1992. However, implant acceptance has remained high, so Lebak appears to provide an exceptionally positive example of implant acceptability. The two areas combined therefore contrast in instructive ways.

Three regencies in West Sumatra were chosen, both for the Diagnostic Study and for the Use-Dynamics Study: These were Padang Municipality (which, despite its name, is largely rural), Padang Periaman to the north, and Pesisir to the south. The choice of these regencies underrepresents areas to the interior, and far from Padang; but their experience with implants is fairly close to that of West Sumatra as a whole, both in terms of ratios of implant acceptors to population, and in terms of declining trends in acceptance over time. Judging from official published statistics, they also appear typical of the province in terms of levels of socio-economic development.

Sampling of clinics for the diagnostic study was purposive, using official acceptor data by year and the knowledge of our hosts. We sought a balance between "representativeness" and feasibility of visiting during a short stay. In West Sumatra, clinics were chosen with medium-to-high numbers of acceptors and either patterns of very high initial acceptance followed by rapid subsequent decline,

or continued moderate levels of acceptance (see Table 2). Clinics in Lebak were chosen for geographic spread around the regency capital, Rangkasbitung.

Within clinics, acceptors were sometimes sampled with systematic random sampling from registration books within selected years, sometimes at haphazard, depending on available time and circumstances. In any case, no conscious attempt was made to select acceptors according to any particular criteria, except for an attempt to get a broad representation by year of acceptance.

C. Study Limitations

A study involving 2 provinces, 4 regencies, 12 clinics, and 120 acceptors cannot, regardless of how choices are made, be considered representative of Indonesia or of the two chosen provinces. Two issues stand out here. First, standard errors of estimates involving clinics or acceptors must necessarily be unacceptably high. Second, the areas chosen have clearly exceptional experiences, positive and negative, for Indonesia, as indicated above. Hence any generalizations to Indonesia from this study are extremely hazardous.

Equally important, the perspective of the study is very limited. The viewpoint is entirely from the clinic: no attempt was made to determine client attitudes or concerns, or in other ways to elicit user perspectives on implants. No observations of clinical services were made, either in clinics or at mass campaign activities. Data were obtained only from provider interviews, clinic records, and very limited client interviews.

The study has other limitations as well. Information obtained was not fully consistent between clinics. (This was appropriate, given the exploratory nature of the study; but it limits the precision of the analysis.) Even given small sizes, samples were less than rigorously drawn at each level. The presence of a substantial team of outside investigators doubtless sometimes influenced responses (although the clinic personnel appeared to the interviewers to be generally candid, within sensible limitations).

Nevertheless, this effort represents one of the first systematic attempts to obtain information in the setting of the general national program, outside of the early trial centers. As such, until more comprehensive studies are done, it represents a significant increase in the existing body of knowledge.

IV. RESULTS

A. General Programmatic Findings

1. Clinic vs. non-clinic service delivery

In the registration books, acceptors (regardless of method) are routinely entered in columns labelled "within clinic" and "outside clinic". The meaning is generally clear, although there are some uncertain areas -- for example, when a safari is held in a regency hospital. In both provinces, about three-fourths of the acceptors were from non-clinical settings (579/748 in West Sumatra, 841/1108 in West Java; see Table 3). Proportions for individual clinics ranged from 0 (0/58) in Bungus, West Sumatra, to 98% (245/251) in Lubuk Alung, West Sumatra. The proportion from non-clinical sources appeared to decline over time in West Java and increase over time in West Sumatra, although given the sampling techniques and the considerable variability between clinics, the generalizability of this observation is uncertain.

"Non-clinical services" fell into two distinct categories. The term "safari" was used to mean a large gathering, generally involving several *puskesmas*, at a central point, with transportation provided from clients' villages, and a variety of activities, not limited to family planning. The other type of non-clinical service involved health providers going to villages to provide family planning services. Re-supply of injectables, for example, was often handled in this way, and implants also were sometimes inserted in such settings. The clinic records did not distinguish between these two types, so it is not possible to get quantitative estimates of proportions. Both types were frequently mentioned; some centers seemed to rely more on safaris, others on village services. Some centers have discontinued non-clinical services in response to a recent Ministry of Health directive, but not all.

Providers differed in their assessment of the affect of safaris on quality of care. Some expressed concern about the lack of proper aseptic conditions, while others felt that conditions in the clinics themselves, were not better. Similarly, while providers generally felt that there was no time for proper counselling in the safari setting, some noted that there also was little time in the clinics.

It has been suggested elsewhere that safaris and other group services can be used to facilitate a coercive tendency. Our interviews did not seem to be useful for obtaining reliable information on this issue. We obtained no indication that there had been specific pressure on women to adopt implants, as opposed to other methods. However, many providers stressed the positive effects of group service on acceptor morale. Not only is it useful to women to have services brought to them, or to be provided with

transportation to the services, but women are far more comfortable dealing with family planning in the company of friends and neighbors. Going alone to a clinic provokes anxiety, far more than going in a group to a safari or to a village center. Group service also helps to reduce the social gap between providers and clients.

2. Acceptability

For Indonesia as a whole, implant acceptance rose quickly in the years after introduction in 1986, and has continued to rise, although more slowly, in recent years (Table 1). Both West Sumatra and Lebak Regency represent areas with comparatively high ratios of total acceptors to population, but achieved by different paths.

In Lebak, the number of implant users since introduction in 1986 has risen steadily in official estimates to 14,505, or 16% of all current contraceptive users, in 1990-91, third in prevalence behind injectables and pills (Table 4). It accounts for more than half of all acceptors of "most effective methods" (sterilizations, implants, and IUDs). New acceptor statistics have remained fairly constant since 1986-87 in the 6 centers investigated. The reason generally given for the high acceptance rates is that Lebak is a culturally conservative area where sterilization is difficult for religious reasons and the IUD is unacceptable because of the necessity of touching the genitals; hence NORPLANT® implants, which fill the need for long-term contraception, is popular. It also appeared that, at least in comparison with West Sumatra, the clinical system was better prepared to support the introduction of a new method, with more clinics and personnel to cover a given area.

In West Sumatra, acceptance was the highest in Indonesia in 1986-88, but has declined markedly since then (Table 1). The data for the province as a whole conceals even more striking declines in many individual clinics, where after an initial burst, acceptance has dropped quickly to very low levels (e.g., several clinics in table 2). It is important to understand why, so the experience is not repeated elsewhere.

Unfortunately, since the study was conducted after the decline had occurred, we cannot give clear answers to this. One hypothesis, consistent with the recall of some local observers, is as follows: a local revival of the safari system in the mid-1980s coincided with the introduction of NORPLANT® implants. As a new method with several attractive features, the implant was vigorously promoted in the safaris and enthusiastically adopted by users. However, with little written information available to either providers or clients (see below), side effects, difficulties in removal, and other drawbacks were exaggerated by both providers and clients, and the method got a poor reputation. In clinics where the method was more calmly introduced, this has not happened.

Whether this hypothesis is true, or the reason lies elsewhere, cannot be easily answered at several years remove from the fact.

3. Availability of Removals

There has been considerable concern expressed about the availability of implant removals, both before and after the recommended 5-year period. This concern has several aspects. For example, sufficient trained staff may not be available; providers may resist doing removals prior to five years; or clients may not be aware of the need for removal and not be contacted to come in.

In the centers visited, the existence of sufficient personnel is not a problem. In each center, there were at least two providers with removal experience. Given the numbers of acceptors per center, the burden of removals will not become excessive. For example, the largest number of insertions in a center in any one year was 364 (Cipanas, Lebak, 1989-90). This suggests fewer than 1.5 removals per working day needed in 1994-95, or less than one hour of trained staff time, with a doctor and a bidan presently capable of removals. Given the way implant training is managed (see below), it is unlikely that the density of personnel trained in removal will decline during the coming years. There may be questions about the technical quality of the removing personnel, which we were unable to evaluate; but simple availability of personnel will not be a problem.

Most providers in the study areas consider even low levels of "early removal", i.e., removal prior to 5 years, as a problem, rather than as a normal occurrence, as with other family planning methods. Some providers said they nevertheless removed the implants on demand, attempting only to allay clearly baseless reasons or fears before removing. Others said they try to talk the users out of removal if the reason is not medically valid, but will remove anyway if the woman insists, because otherwise the method will get a bad reputation. Client views of this issue await the implementation of the Use-Dynamics Study. But continuation rates obtained in the follow-up (see below) indicate significant availability of early removals in practice.

Although all clinics were either in their sixth year of implant use or late in their fifth, and thus faced the problem of 5-year removals, only a few in Lebak had prepared a list of clients for removal for the year, and no general directives had been given for a systematic attempt to locate women for removal. Such an effort does not appear difficult. Clinic records, supplemented by fieldworker knowledge, should be sufficient to locate the vast majority of acceptors who have remained in the area. Women were said by the providers to be well aware of the need for removal after 5 years, and were coming in on their own after 5 years had passed; but the proportions are not known. What proportions of 5-year removals will actually be done remains to be seen.

4. Continuation

Of the 120 sampled implant acceptors from 12 clinics, 102 were interviewed. From these, interviewers learned whether the implants were still in place, and if not, when and why they were removed. Of the 17 lost to follow-up, 11 had moved from the area, 3 were not at home during the interview period, and 3 were not known at the address (see below).

With such small numbers, life-table continuation rates were calculated by hand, with standard errors estimated as if estimating for simple proportions (which slightly overestimates standard errors). Events by month are shown in table 5. There were a total of 3,322 woman-months of observation, for an average length of observation per woman of 32.3 months. Continuation rates at 12, 24, 36, and 48 months are as follows:

Ordinal Month	Continuation Probability	Standard Error*
12	.94	.026
24	.90	.037
36	.82	.058
48	.78	.069

In other words, the life-table estimate of the percentage of acceptors who will continue wearing the implants for 12 full months is 94%, with standard error a bit less than 3%, and so on for 24, 36, and 48 months. The probability of continuation until the completion of five years was .72, since the removals at 59 and 60 months were for that reason. Reasons for the 20 removals were as follows (for details, see Table 6):

<u>Reason</u>	<u>W. Sumatra</u>	<u>W. Java</u>	<u>Total</u>
Bleeding problems	. 4	3	7
Complications at insertion site	2	1	3
Other medical **	2	2	4
Personal	1	2	3
Completion of 5 years	3	0	3
Total	12	8	20

* s.e. = sq. rt. $\frac{P_x Q_x}{N_x - W_x}$

** Fever; headache and fever; blurred vision; and lightheaded, loss of appetite, sore throat.

The differences in continuation and removals between West Sumatra and West Java are not statistically significant.

Given the sampling errors, these continuation rates must be taken with considerable caution. However, they suggest that removal prior to 5 years is realistically available (although barriers to removal probably also exist). The fact that three of the four "other medical" removals were probably for medically inappropriate reasons is in this sense reassuring. There is no ideal continuation rate for implants; but a 5-year continuation rate of .72 is not in itself evidence of unavailability of removal.

At the same time, these data also do not support the fear that early removals may seriously reduce the cost-effectiveness of the implants. Overall, about 91% of the total months of protection that the 102 interviewed acceptors would have achieved if they had all continued use to the time of interview, had been achieved. Reduction in cost-effectiveness of the implants due to early discontinuation is thus not an important issue.

Finally, pending more reliable estimates of continuation, the rates above may be used to predict numbers of removals needed in any area by year, given annual acceptor totals.

5. Training

Substantial numbers of providers are inserting and removing implants in the areas visited. All the physicians and bidans interviewed had training and experience with implants; in each center between 2 and 6 providers were said to be capable of inserting and removing.

The training is sometimes but not always through the formal system. Some had gone for formal courses at regional training centers: Padang for West Sumatra, Bandung and (for bidans) Bogor in West Java. Some were trained locally and more or less formally by trainers trained in those sites. Others, particularly bidans and nurses, were trained informally at the clinics by other clinic personnel, or during mass campaigns. (Whether nurses became involved in implant insertion and/or removal varied by clinic.) There is thus a vigorous process of diffusion of this skill among providers considered appropriate to acquire it. There seemed to be little anxiety about this: at all levels, providers appeared unconcerned about their technical abilities in insertion and removal.

It was not possible to assess directly the quality of training, either through visiting training centers or through observation of implant procedures. The impression from interviews was that training was stronger on medical aspects of insertion and removal than on counselling and client education. On the medical side,

providers generally felt that their training was adequate. However, they did note field problems in two training-related areas: difficult removals as a result of improper insertion technique, and insertion site infections.

Providers expressed concern that their training in counselling was not adequate. There seemed to be a feeling that "counselling" is a highly complex procedure involving long training, and that anything less is not counselling. This may have impeded our assessment of how much counselling is really going on, whether in training or in services.

6. Information

In the centers visited there was a total absence of written information specifically for implants, either for providers or for clients. Although many prototypes of provider and client information materials on NORPLANT® implants have been designed in Indonesia, and several of these have been printed for distribution, none had found its way into any of these twelve centers. In Lebak, instructions for insertion and removal had been distributed to each district (kecamatan), but they had been deposited in the district library and were not readily available to providers.

In West Sumatra, the absence of written information has probably contributed significantly to the declining acceptance rates. Providers generally responded to questions about this decline by citing fears and rumors about the implants in the population, and the providers themselves seemed unsure about what side effects could and could not be expected. In Lebak, such rumors do not seem to pose a similar problem.

Providers in both areas felt that more written materials, especially for clients, is necessary. Two types were mentioned repeatedly: illustrated booklets to share with clients during pre-acceptance counselling; and posters, for clinics, field workers' houses, posyandus, etc. Other types of materials, while welcome, were not mentioned as often.

7. Quality of Services

As with other areas, our perspective on quality of services is limited by the nature of the study. However, some observations can be made.

a. Medical aspects. Providers were concerned about several aspects of the quality of medical care they are able to provide. Ability to perform procedures under proper aseptic conditions was often mentioned as a problem, particularly in non-clinical settings but sometimes in clinics as well. Clearly infection at insertion site

occurs; a few providers were asked about the most serious problems with implants they knew of in their areas, and the reply in each case concerned infections. Three of the twenty removals were because of problems at the insertion site. We cannot infer, however, that infection rates are high; this information is essentially anecdotal. The Use-Dynamics study will provide better information about this.

Providers also noted that removals were sometimes difficult, due to poor placement at insertion. This was not cited as a problem leading to serious complications, nor can we speculate at this time on rates of difficult removal. In two cases we learned of infections and/or spontaneous expulsion years after insertion, perhaps because the implants may have been inserted too close to the skin.

Excessive or prolonged menstrual bleeding was consistently identified by providers to be the most important side effect. Commonly providers treat excess bleeding with estrogens, either in the form of oral contraceptives or, if available, straight estrogen preparations. Vitamins and other drugs also are sometimes used. If the treatment does not work, the implants are generally removed. In the follow-up interviews with acceptors, bleeding problems were the most common cause of removal.

Providers were uncertain about the need for a pelvic examination before acceptance. It is understood that this is policy; but since an important aspect of the implant's popularity is that it does not involve genital touching, they are reluctant to give a pelvic examination, and it was our impression that this is generally not done.

b. Information and counselling. Providers generally felt that they were unable to provide adequate information and counselling, due to a combination of lack of materials, inadequate training, and lack of time during service delivery. It was not clear what priority was given to counselling; our sense was that the providers were interested, but did not quite know how to proceed.

c. Follow-up and continuity. It is not clear how often users return to clinics, since return visits are rarely recorded in clinic records (although they may be recorded on the client's own follow-up card, which she keeps). There are no routine follow-up appointments. When implant users have questions, fears, or complaints, they first are expected to go to satisfied users or fieldworkers, then to the clinic; we did not observe how satisfactory this system is in practice.

Maintaining linkages with users who move from their own clinic's coverage area may be a problem. Of the 120 clients followed up, 11 had moved their residence, 8 of whom were from West Sumatra. Although migrants are expected to register with authorities at

their new residence, this does not in itself establish a linkage with the local health center. How well the migrants adapt to this situation, particularly when removals are needed, is not known.

B. Information for Use-Dynamics Study Planning

1. Record keeping

For all centers, official Provincial totals were clearly based on real local data; official acceptor data are, as far as we could tell, accurate. All centers made significant efforts to keep family planning acceptor records. However, in all centers the records had significant gaps, and there is little attempt to keep follow-up information in the clinics.

All centers keep registration books in official format (which changes occasionally over the years), and acceptor cards (K-IV forms). In addition, health centers in Lebak kept informal "helping books" which kept acceptance records, but no indication of clinic vs. non-clinic source.

In no center was there a complete sequence of registration books dating back to 1986, although some, especially in West Sumatra, were nearly complete. Typically, one or more registration books from past years were missing for unknown reasons. In West Java registration books were particularly incomplete, but there the "helping books" are kept fairly consistently.

Because of these gaps in the record, sample lists will probably need to be drawn from a combination of sources, including registration books, K-IV files, "helping books", and anything else available. Given the variability in record keeping in the 12 centers visited, there will undoubtedly be patterns in other centers which we haven't seen.

All acceptors listed had their village recorded, but no more detailed address information. During the follow-up study, the expectation that fieldworkers would know how to locate sampled women was confirmed. However, in West Sumatra clients give their formal names for the registration books, which may be different from the informal names by which they are known to neighbors and fieldworkers. This may be the reason that 3 of the 60 acceptors in West Sumatra could not be found, as their name was not known in the village; with extra diligence, these could probably be located.

The K-IV cards have acceptance information on the front, and space for follow-up and removal information on the back. Some K-IV forms were misfiled, so that of 118 acceptors sampled for which K-IV forms were sought, 93 (79%) were located, slightly more in West Sumatra than West Java (Table 7. Two acceptors had had their villages, and hence their files, transferred to another clinic.)

Moreover, follow-up information was recorded on the K-IV forms for only 2 of the 93 located acceptors. The only likely use of these forms for the Use-Dynamics Study will be to supplement other sources to obtain a sampling list for implant acceptors.

2. Ability to locate respondents

Of 120 sampled acceptors from the 12 clinics, 103* were successfully located, for a follow-up rate of 86%. The rates differed by province: 47 of 60 (78%) were located in West Sumatra, 56 of 60 (93%) in West Java. Of the 17 lost to follow-up, 11 had moved from place of residence, 3 were not at home during the period of the fieldwork, and 3 were not known in the village, perhaps because of name confusion (see above under record keeping.)

Of the 11 who had moved, 8 (or 13% of sampled acceptors in the Province) were from West Sumatra, a proportion which may hold approximately for the Use-Dynamics Study as well. The dominant ethnic group, the Minangkabao, are known to be a highly mobile population. Moreover, in the West Sumatra component of the WHO-supported NORPLANT® implant surveillance study, about 10% are said to have moved from the area during the first year of recruitment. To keep follow-up rates high, and because implant acceptors who move are a particularly important group to study, funds were set aside in the Use-Dynamics budget for follow-up of migrators.

Since some of those in each category of those lost to follow-up could probably have been located in a more diligent search, it seemed that a follow-up rate of over 90% would be achievable in the main study.

3. Fieldwork

The two areas are different geographically, and different approaches to fieldwork will be necessary. A common feature of both, however, is need for a combination of a centrally trained and supported team of field interviewers, relying locally on the family planning fieldworker for each village. In both provinces this approach was used successfully. It also resulted in the ability to locate more respondents per interviewer per day than was anticipated in study planning, so that the total time for fieldwork might be substantially shortened.

The experience of the follow-up in the Diagnostic Study also suggests that the budget for fieldwork in the Use-Dynamics Study should be approximately accurate.

* One woman died (of suspected tuberculosis) 16 months after NORPLANT® implant acceptance, apparently while still using; she was not included in the life table analysis.

4. Questionnaire design

The experience of the Diagnostic Study was used to revise the original draft questionnaire for the Use-Dynamics Study. It was possible to expand and sharpen the questions on implant knowledge, on interactions with providers, on services at the time of acceptance, and on subsequent side effects. It was decided to check if the acceptor cards were present, and, if so, to transcribe information from those cards. In important but less definable ways, the experience of the Diagnostic Study made it possible to prepare a more precise and relevant questionnaire.

V. CONCLUSIONS AND RECOMMENDATIONS

A. Conclusions

The Diagnostic Study was not in any way definitive, nor given its intrinsic limitations could it have been. It fulfilled its basic purposes: to provide some quick, early insights into the implant program at the health center level, and to guide detailed planning for the Use-dynamics Study.

Some initial fears were not confirmed: in the following areas where concerns had been expressed, there was, at least, partial reassurance:

- * The potential of the system to manage the projected load of 5-year removals seems clear.
- * Users are able to get implants removed prior to five years in significant numbers.
- * Clinic records on acceptors are generally kept, for safari as well as clinic acceptors.
- * Most implant users can be located and contacted relatively easily.
- * Numbers of providers with experience in insertion and removal are sufficient to handle existing and foreseeable demand.

On the other hand, the program needs improvement in a number of areas. Information for clients and providers and improved training standards seem to particularly require early attention. It is important for the BKKBN to address these issues quickly but carefully, taking necessary action where possible and seeking additional information where necessary.

B. Recommendations

1. BKKBN should immediately print up NORPLANT® implants acceptor registers, one for each puskesmas, with name, serial no., address, date of insertion, date of removal, reason for removal. This should be done retrospectively, to facilitate locating clients for removal, and prospectively, to maintain better contact and follow-up.

2. A series of actions should be begun immediately to improve the information base available in health centers and in the community.
 - a. Determination of how many of which materials have been printed, and sent where.
 - b. Investigation into the development of the materials and the nature of testing for target populations.
 - c. Investigation into the availability of funding for substantial printing and distribution of an appropriate set of IEC materials.
 - d. A set of OR studies to determine an appropriate mix of IEC materials for health centers and communities, with cost alternatives.
3. The recent prohibition on insertions by non-physicians and insertions in non-clinical settings should be reviewed, to consider allowing implant services by trained non-physicians and services outside clinics, within appropriate standards for training and clinical management.
4. Steps should be taken to improve the training of providers for implants, including priority to (a) proper use of information/counselling; (b) clear guidelines for removal prior to 5 years; and (c) aseptic technique.
5. A program should be considered to send implant specialists on a brief visit to each kabupaten to improve implant services by teaching and exhorting the implementation of a few key procedures, such as:
 - a. Keeping and using a log for NORPLANT® implant acceptors;
 - b. Ensuring availability and appropriate use of IEC materials;
 - c. Clarifying policy on removals;
 - d. Clarifying appropriate treatment for prolonged bleeding;
 - e. Improving training procedures, including proper guidelines for training and how to match supply and demand for insertions and removals.

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TABLE 1

Implant Acceptors by Province and Year, Indonesia, 1985/86-1991 (May)

Provinces	1985/1986	1986/1987	1987/1988	1988/1989	1989/1990	1990/1991	1991 (Apr,May)	Total
1. Jakarta	3,428	2,180	2,649	6,352	5,750	4,511	972	25,842
2. West Java	2,631	3,550	29,945	49,717	75,893	65,381	5,761	232,878
3. Central Java	5,758	12,382	22,951	43,729	83,611	70,705	5,320	244,456
4. Yogyakarta	417	457	1,031	2,213	2,238	1,632	245	8,233
5. East Java	8,028	13,651	37,962	30,307	87,965	68,177	3,802	249,892
6. Bali	330	878	592	636	556	460	115	3,567
7. DI Aceh	598	143	365	1,680	8,928	6,598	138	18,450
8. North Sumatra	2,262	578	4,246	4,910	18,342	12,136	893	43,367
9. West Sumatra	532	3,675	19,830	12,733	8,020	7,997	591	53,378
10. South Sumatra	4,283	2,654	6,711	12,174	26,626	27,024	720	80,192
11. Lampung	1,313	251	993	5,123	10,580	9,855	556	28,671
12. West Nusa Tenggara	348	188	1,038	6,949	10,031	12,094	372	31,020
13. West Kalimantan	1,868	62	203	2,292	3,936	8,507	49	16,917
14. South Kalimantan	506	242	962	1,193	2,355	4,369	220	9,847
15. North Sulawesi	670	1,231	3,540	6,466	5,058	9,858	430	27,253
16. South Sulawesi	1,146	844	1,235	2,948	13,708	9,763	244	29,888
17. Riau	59	247	3,626	4,233	8,802	18,289	127	35,383
18. Jambi	939	51	1,520	3,388	4,044	11,109	844	21,895
19. Bengkulu	210	74	248	725	1,673	2,917	332	6,179
20. East Nusa Tenggara	233	0	3,689	2,713	5,780	5,251	62	17,728
21. Central Kalimantan	499	7	270	684	2,889	7,037	30	11,416
22. East Kalimantan	444	291	467	733	1,664	2,890	440	6,929
23. Central Sulawesi	351	0	646	481	3,941	5,484	138	11,041
24. Southeast Sulawesi	27	1	240	2,497	2,465	4,218	34	9,482
25. Maluku	586	987	396	1,786	1,204	2,751	161	7,871
26. Irian Jaya	24	79	50	544	1,102	2,535	21	4,355
27. East Timor	94	0	421	737	898	1,095	22	3,267
Indonesia	37,584	44,703	145,826	207,943	398,059	382,643	22,639	1,239,397

- Note: Each of the years 1985/86, 1986/87, etc. covers the period April 1 to March 31.

- Source: BKKBN Monthly Service Statistics and other records.

TABLE 2

Numbers of Implant Acceptors by Year for Sampled
Health Centers, From BKKBN Provincial Data

Program Year						
Puskesmas	86-87	87-88	88-89	89-90	90-91	Total
West Sumatra						
Lubuk Alung (Periaman)	155	129	28	23	21	356
Bungus (Padang Mun.)	101	169	28	3	38	339
Kuranji (Padang Mun.)	-	294	65	9	7	375
Bayang Usang (Periaman)	72	123	36	8	2	241
Duku (Periaman)	33	45	3	4	34	119
	40	59	11	36	57	203
West Java						
Rangkasbitung	93	257	194	105	143	792
Cibadak	105	105	87	209	187	693
Cimarga	130	146	120	310	230	936
Leuwidamar	91	291	161	93	68	704
Sajira	259	193	147	150	126	875
Cipanas	117	339	165	364	194	1179
Total	795	1331	874	1231	948	5179

* Program year is from 4/1 to 3/31

TABLE 3

**Implant Acceptors by Year, Center, and
Type of Service, 1986-87 to 1990-91**

	<u>Program Year</u>											
	86-87		87-88		88-89		89-90		90-91		Total	
Puskesmas	C	NC	C	NC	C	NC	C	NC	C	NC	C	NC
West Sumatra												
Lubuk Alung	0	155	6	90	-	-	-	-	-	-	6	245
Bungus	-	-	-	-	-	-	56	0	2	0	58	0
Kuranji	-	-	-	-	-	-	8	0	-	-	8	0
Bayang	13	39	23	95	-	-	-	-	-	-	36	134
Pasar Usang	13	20	13	28	1	2	1	3	4	30	32	83
Duku	0	46	-	-	-	-	-	-	17	41	29*	102*
West Java												
Rangkasbitung	-	-	108	157	-	-	-	-	-	-	108	157
Cibadak	-	-	45	39	-	-	-	-	-	-	45	39
Cimaraga	-	-	4	24	-	-	11	270	-	-	15	294
Leuwidamar	-	-	-	-	71	36	-	55	4	77	75	168
Sajira	-	-	-	-	-	-	1	85	18	92	19	177
Cipanas	-	-	-	-	-	-	1	-	4	6	5	6
Total	26	260	199	433	72	38	78	413	49	246	436	1420

* Includes 12 clinic and 15 non-clinic acceptors from 4/91 to date.

Note: Years do not always correspond to BKKBN fiscal year;
reviews are not always complete.

TABLE 4

Estimated Current Users by Method and Year, Lebak, 1985-1991

Method

Program Year	IUD	MS •	FS	Implant	Inj.	Pills	Con.	Total
85-86	1744		35*	-	21,119	3,260	-	25,148
87-88	2032		781*	4,955	53,002	31,628	105	92,506
88-89	3147		582*	5,588	27,549	14,529	108	51,503
89-90	2842		1378*	11,529	33,922	21,764	6	71,441
90-91	3552	1846	577	14,505	48,456	22,536	78	91,550

* Male and female sterilizations combined.

Note: Data for 1986-87 were unavailable during our visit. Method of estimation is not known.

TABLE 5

Life Table Event Data from Sampled Acceptors, Combined Provinces

<u>x</u>	<u>N*(x)</u>	<u>W(x)</u>	<u>T(x)</u>	<u>P(x)</u>	<u>x</u>	<u>N*(x)</u>	<u>W(x)</u>	<u>T(x)</u>	<u>P(x)</u>
0	102.0			1.000	31	47.0			.838
1	101.5	1	1	.990	32	47.0			.838
2	100.0		1	.980	33	47.0		1	.820
3	99.0		1	.970	34	45.0	2		.820
4	97.0	2		.970	35	43.5	1		.820
5	96.0			.970	36	43.0	1		.820
6	95.5	1		.970	37	43.0		1	.801
7	95.0			.970	38	41.5	1		.801
8	95.0		2	.950	39	41.0			.801
9	92.5	1	1	.940	40	40.5	1		.801
10	90.0	2		.940	41	39.5	1	1	.781
11	87.5	3		.940	42	38.0			.781
12	85.5	1		.940	43	38.0			.781
13	83.5	3		.940	44	37.5	1		.781
14	81.0	2		.940	45	36.5	1		.781
15	79.0	2		.940	46	36.0			.781
16	76.5	3		.940	47	36.0			.781
17	74.5	1		.940	48	36.0			.781
18	74.0			.940	49	35.0	2		.781
19	74.0			.940	50	29.5	9		.781
20	73.5	1	1	.927	51	21.0	8		.781
21	72.0			.927	52	17.0			.781
22	70.5	3		.927	53	14.5	5		.781
23	68.0	2	1	.913	54	12.0			.781
24	65.0	2	1	.899	55	12.0		1	.716
25	61.0	4	1	.884	56	9.5	3		.716
26	58.0		2	.854	57	7.5	1		.716
27	56.0			.854	58	7.0			.716
28	54.5	3	1	.838	59	6.0	2	1	.597
29	49.5	5		.838	60	3.0	2	2	.199
30	47.0			.838					
					TOTALS		82	20	

X = Ordinal month of observation

N*(x) = No. of woman/months of observation during month x

W(x) = No. withdrawn from observation during month x

T(x) = No. terminating (implants removed) during month x

P(x) = Cumulative estimated probability of retaining the implants from insertion through the end of month x

TABLE 6

Implant Removals by Time Since Insertion and Cause

	Months Since Insertion	Cause of Removal
West Sumatra	1	Allergy at insertion site
	2	Pain/swelling at insertion site
	3	Headache, fever
	8	Heavy menstrual bleeding
	8	Fever
	9	Menstrual bleeding problems
	20	Afraid, heard rumors
	33	Menstrual bleeding problems
	37	Prolonged menstrual bleeding
	59	5 years
60	5 years	
60	5 years	
West Java	23	Vasectomy for husband
	24	Bleeding in insertion site (self-removal)
	25	Blurred vision
	26	Divorce; also lightheadedness
	26	Prolonged menstrual bleeding
	28	Lightheadedness, loss of appetite, sore throat
	41	Menstrual bleeding problems
55	Menstrual bleeding problems; also wants another child	

TABLE 7

**Numbers of K-IV Forms Sampled and Located, by Center,
During the Diagnostic Study**

Center	Forms Sampled	Forms Found
West Sumatra		
Lubuk Alung	8*	5
Bungus	10	10
Kuranji	10	8
Bayang	10	8
Pasar Usang	10	8
Duku	10	9
West Java		
Rangkasbitung	10	10
Cibadak	10	4
Cimarga	10	4
Leuwidamar	10	7
Sajira	10	10
Cipanas	10	10
All Clinics	118	93

* K-IV forms for 2 acceptors from the registration book had apparently been transferred to another clinic.