Final Report
Safety and Feasibility of Community-Based Distribution of Depo Provera

Family Health International
Save the Children/USA

June 2005

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Save the Children.

Ministry of Health
THE REPUBLIC OF UGANDA

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Safety and Feasibility of Community-Based Distribution of Depo Provera in Nakasongola, Uganda

Family Health International

John Stanback, PhD, Senior Associate

Uganda Ministry of Health

Dr. Anthony Mbonye, Acting Assistant Commissioner for Reproductive Health

Save the Children / USA

Joyce LeMelle, Country Director
Martha Bekiita, Reproductive Health Advisor

Nakasongola Local Government

Dr. Gerald Ssekito, District Medical Officer
Sister Nakityo Justine Kajura, District Health Educator

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We are grateful to the many people who made this project a success. They are too many to list individually, but we must single out Sereen Thaddeus, Catherine Kennedy, the staff of Save the Children, and the Health Assistants, Nurses, Midwives and Community Reproductive Health Workers of Nakasongola District. We are grateful to the United States Agency for International Development for funding this project. This report is dedicated to the women of Nakasongola who participated in this research.

Family Health International

Family Health International (FHI) is dedicated to improving lives, knowledge and understanding worldwide through a highly diversified program of research, education and services in family health. Since 1971, FHI has worked with governments and communities to meet the public health needs of some of the world's most vulnerable people. FHI has offices in 38 countries and manages research and field activities in more than 70 countries. Working with a wide variety of partners including governmental and nongovernmental organizations, research institutions, community groups, and the private sector, FHI helps countries and communities to:

- Improve people's access to quality reproductive health services, especially safe, effective, and affordable family planning methods
- Prevent the spread of HIV/AIDS and sexually transmitted infections and care for those affected by them
- Improve the health of women and children, especially those who live in resource-constrained settings

Save the Children / USA

Save the Children is a leading independent organization creating real and lasting change for children in need around the world. It is a member of the International Save the Children Alliance, comprising 27 national Save the Children organizations working in more than 100 countries to ensure the well-being of children. The cornerstone of Save the Children's approach is to work with families to define and solve the problems their children and communities face and to utilize a broad array of strategies to ensure self-sufficiency.

In Uganda, Save the Children works in an integrated way to reach these children with a range of programs that compliment and reinforce each other. Save the Children identifies good local practice and builds on it, as well as bringing in new ideas from its international perspective and experience. Community volunteers are trained and supported by Save the Children to provide education and services to community members. Uganda benefits from Save the Children's programs in the following sectors:

Non-formal Primary Education

Youth Protection and Development

Reproductive Health

Maternal and Child Health

Adult Education

Livelihood support for HIV Orphans

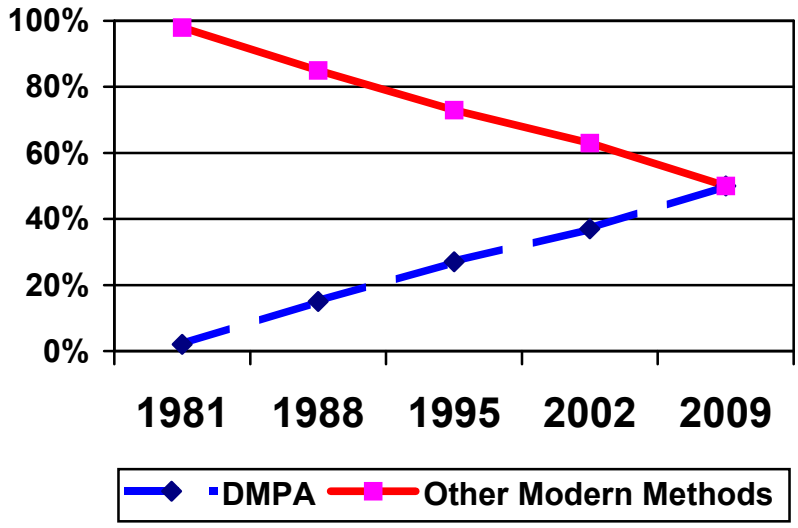
Food for Education

Food Security

INTRODUCTION

Throughout Africa, the popularity of depot medroxy progesterone acetate (DMPA, Depo Provera) has increased dramatically in recent years. From its negligible availability 10 years ago, DMPA now dominates the method mix in dozens of countries worldwide, including Uganda (see Figure 1). Given increases in both the contraceptive prevalence rates and population, the overall demand for DMPA commodities and services in Uganda surpasses even the rapid increase in its share of the method mix depicted below.

Figure 1. Estimated Trend of DMPA as % of Method Mix in Uganda



Unfortunately, some women, particularly in rural areas, do not have adequate access to clinical service delivery of family planning. Other women are able to attend clinics, but lack the motivation to do so. Finally, some women currently receiving clinic-based services would probably prefer CBD provision of their method of choice, but have such a strong preference for injectable contraception (instead of the pills offered by community-based agents) that they travel to distant clinics for DMPA.

In both Asia and Latin America, community-based health workers have been trained in safe injection techniques and routinely provide injectable contraception. However, the African continent still resists this service delivery mechanism with the rationale that it is unsafe for clients to receive injections from paramedical personnel. This argument is weakening, however, as non-reusable syringes become the norm and with the recent development of a checklist, based on the latest WHO Medical Eligibility Criteria, for safe provision of DMPA

by community-based agents. It will weaken further in coming years as new subcutaneous formulations of Depo Provera become available in easy-to-administer Uniject devices.

Has the time come for community-based provision of DMPA in Africa? Is it safe? Is it feasible? Family Health International, with partners Save the Children/USA, Uganda's Ministry of Health, and Nakasongola District's Local Government, has undertaken a major research project to answer these questions.

OBJECTIVES

The broad goal of this study was to improve access to contraceptive services in Uganda and elsewhere. The primary objective of this study was to assess the safety, quality and feasibility of DMPA provision by community reproductive health workers. This was accomplished via the following sub-objectives, based on a comparison of the clients of community-based reproductive health workers (CRHWs) and clinic-based DMPA clients:

- To compare three month-reacceptance rates, i.e., acceptance of 2nd DMPA injection (key outcome)
- To compare user satisfaction
- To compare client knowledge of key information about DMPA (a proxy for the quality of counseling received)
- To compare reported incidence of injection site morbidities

This report will also discuss elements of the project which bear directly on the safety and feasibility of the intervention:

- Supervision, logistics, and safety (including waste disposal) for CRHWs trained to provide DMPA in Nakasongola, Uganda.
- The MOH district-level DMPA training plan for CRHWs that progressed from classroom training to a clinic-based practicum to remotely-supervised injections in clients' homes.

METHODS

Intervention: CRHW Provision of Depo Provera in Nakasongola

This was one of the first projects in sub-Saharan Africa to train community-based health workers to provide injectable contraception. It took place in Nakasongola, a rural district two hours north of Uganda's capital, Kampala. Nakasongola's population of about 130,000 subsists mainly on agriculture, cattle grazing, and fishing. The total fertility rate of 7 is higher than Uganda's average, while the district's contraceptive prevalence of between 3% and 5% is less than a third of Uganda's average (17%). The population's health needs are served by a sub-district hospital, six health centers, and 11 health posts. Save the Children/USA sponsors health and education efforts throughout the district, including a community based reproductive health / family planning program that complements clinic-based services.

More than 100 CRHWs (half male, half female) work in Nakasongola's 45 parishes, supervised by 15 Save the Children field supervisors. Each CRHW is also affiliated with a health center where (s)he is re-supplied with free contraceptive commodities and refers clients for clinic-based methods. CRHWs are not paid a salary, but are "incentivised" by Save the Children with monthly gifts of useful household items such as raincoats and gumboots that can facilitate their work. Their services and products (condoms, pills, and now Depo Provera) are provided free of charge to clients.

Funding for the intervention was provided by the United States Agency for International Development (USAID), through FHI and Save the Children. Some technical assistance for the intervention was provided by FHI, but the clinical training was conducted primarily by the District Health Educator. Supervision, logistics, and safety systems were developed locally and managed by District Health Officials and local staff of Save the Children.

Clinical Training

Save the Children, Nakasongola District Health Officials, and FHI worked together to develop a comprehensive, phased-in approach for training a cohort of 20 CRHWs in safe provision of DMPA. The training began in March 2004 with classroom training in reproductive physiology, contraceptive technology, counseling, client screening, injection technique, infection prevention, waste disposal and other essential aspects of DMPA provision.

All 20 CRHW trainees successfully completed the classroom training and progressed to a two-stage clinic-based practicum emphasizing safe injection techniques. Stage one took place in the small hospital in Nakasongola Town and in the local Army Barracks Hospital. After five days of training and observation in the hospital setting, the trainees moved to a second week of practical training in the health centers in their home area, where they already had working relationships with local clinic staff. At the health centers, the trainees provided contraceptive injections using FHI's DMPA checklist tool to screen clients under the direct supervision of MOH nurses. Only after this rigorous training did CRHWs begin to give contraceptive injections in their homes and the homes of their clients.

Supervision and Logistics

CRHWs giving contraceptive injections were supervised as usual by staff from Save the Children and also maintained normal contacts with nearby health center staff. However, because contraceptive injections by paramedical cadres is new to Uganda, district health officials also made special efforts to visit CRHWs in their home areas and ensure quality control.

The logistics of providing Depo and syringes to the CRHWs went smoothly except for a period when autodisable syringes were unavailable. To avoid any risks associated with use of standard disposable syringes, some CRHWs had to suspend new client enrollment for a short time during the course of the project.

Safety and Waste Disposal

The safety of clients was of paramount concern in this project. The risk to clients from intramuscular injections with pre-packaged, sterile syringes is minimal, and the MOH, district health officials, Save the Children, and FHI all believed that the training program was more than adequate to bring the selected CRHWs to acceptable proficiency in both properly screening clients and safe injection technique. In addition, the CRHWs were trained with and used only autodisable syringes to prevent any re-use.

The safety of the CRHWs was also a concern, since the prevalence of HIV/AIDS in Uganda remains high and injection always carries a risk of needle stick to a health worker. To minimize this risk, safe technique was emphasized during the training and providers were supplied with sharps containers and trained in their proper disposal. During the course of the study, no CRHW reported any needle stick injury.

Research Study

After the training of the CRHWs was completed, the research study began in 10 health centers and their catchment areas. All new and re-starting clients accepting Depo Provera either in the 10 clinics or from the trained CRHWs were invited to participate in the research. Enrollment of consenting clients took place between March and December of 2004. Clinic staff and CRHWs enrolled clients using a short, one-page form. Follow-up data collection was conducted by local MOH Health Assistants who attempted to contact each client 13 weeks after the first injection. Thirteen weeks was chosen because it gave clients a one-week "grace period" to be late for their re-injection appointment, yet still allowed good recall of the 12 week re-injection. The timing was also desirable because, without biasing the study results, it allowed clients who might have forgotten their appointment, or who needed slight prompting, to still have a few days to get another shot without having to use a back-up method or prove they weren't pregnant.

The study compared various outcomes between the two groups of women mentioned above, CRHW clients and clinic clients. The follow-up data collected at thirteen weeks included:

- whether the client had a second injection (= six-month continuation of method),
- satisfaction,
- recall of key counseling messages,
- recall of method-related health problems for which medical attention should be sought.
- reported injection site morbidities,
- reported side effects,
- intent to continue contraception later (for abandoners),

RESULTS

Follow-Up

A total of 945 clients were enrolled, among whom 777 (82%) were followed up. Those lost to follow-up included clients who were not located after three home visits and clients who were reported to have moved away, but the largest number lost to follow-up were in certain catchment areas where the study's interviewer left the study and the replacement interviewer failed to make the required follow-up visits. Table 1 shows the number of clients recruited and followed in each health centre catchment area, by the type of provider.

Table 1: Study sites and Enrollment

Parish	Clinic Clients		CRHW Clients		CRHWs in Parish
	No. Enrolled	No. Followed	No. Enrolled	No. Followed	No.
Nakasongola	19	15 (79%)	53	34 (64%)	2
Barracks	60	60 (100%)	59	53 (90%)	2
Nabiswera	49	36 (73%)	61	57 (93%)	2
Nakitoma	43	34 (79%)	59	53 (90%)	2
Lwampanga	22	13 (59%)	52	33 (63%)	2
Kibaalizi	42	35 (83%)	45	9 (20%)	2
Kalungi	51	47 (92%)	57	54 (95%)	2
Bamugolode	34	30 (88%)	56	47 (84%)	2
Kakooge	38	36 (95%)	69	62 (90%)	2
Nakayonza	25	22 (88%)	51	47 (92%)	2
Total	383	328 (86%)	562	449 (80%)	20

Socio-Demographic Characteristics

Researchers analyzed the socio-demographic characteristics of clients to learn more about the study population. Table 2 compares the characteristics of CRHW clients who were followed up to those of clinic-based clients. There were a few differences between the two groups that are likely explained by the fact that CRHWs were recruiting women who had less access to clinic care or were not typical clinic clients. Thus, the CRHW clients had less education and husbands who were less supportive of family planning, and they were more likely to be first time users of Depo Provera. Nearly all the women had children, and most were married.

Table 2: Characteristics of followed clients, by provider

	CRHW Clients (n=449*)	Clinic Clients (n=328*)
Age (mean)	27.6	26.4
Parity (mean)	4.2	3.9
Age youngest child (mean)	1.8	1.6
Marital status		
Married / monogamous	49%	49%
Married / polygamous	26%	31%
Cohabitating	4%	2%
Single / never married	16%	9%
Divorced / separated / widow	2%	8%
Education		
None	8%	16%
Primary	70%	60%
Secondary or higher	21%	23%
Want another child in future?		
Yes	68%	72%
No	27%	16%
Depends on husband/partner	0.2%	1%
Depends on God	2%	4%
Don't know	1%	6%
First time user of Depo Provera	86%	76%
Husband supportive (at start)	41%	52%

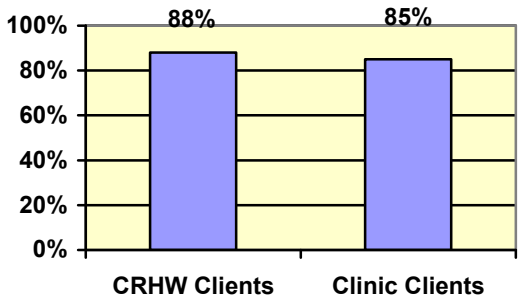
* Columns not adding to 100% have missing values

It is also desirable to compare the characteristics of clients who were followed up with those of clients who were lost to follow-up, in order to rule out the possibility of systematic bias in follow-up. Analysis of these two groups showed no significant differences in socio-demographic indicators such as age, parity, or education (not shown).

Continuation

Some of the most important data collected was information about the client's second injection. Of greatest interest was continuation. Figure 1 below shows the continuation rates in the two groups. Bivariate analysis of the crude proportions showed no significant difference between CRHW clients and clinic clients in the proportion receiving a second injection. Nor was any significant difference found when researchers used exact logistic regression to compare continuation in the two groups, controlling for covariates such as the clinic catchment area, husband's supportiveness, age, parity, education, and desire for more children.

Figure 1: Percent receiving second injection



Researchers also assessed whether the second injection occurred within the MOH-approved "grace period" after the due date, where the injection occurred, and, for those not continuing, why not and whether future use was intended (Table 3).

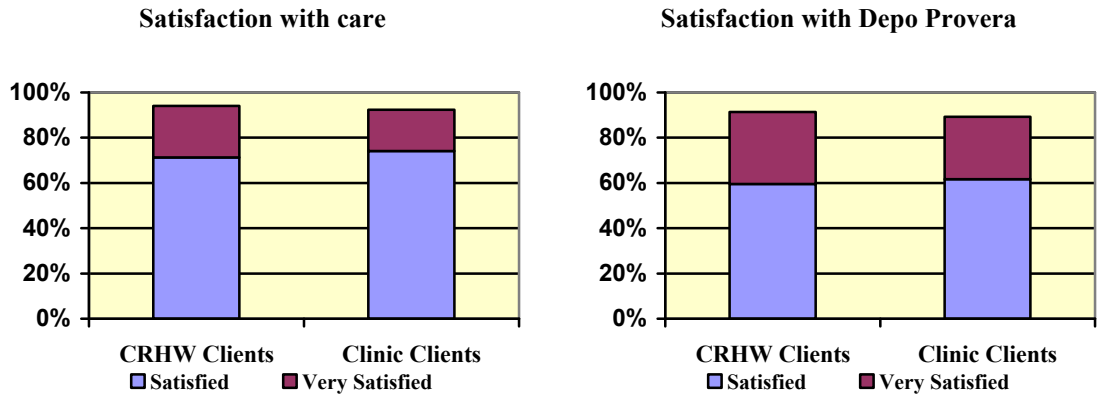
Table 3: Continuation

	CRHW Clients n=449	Clinic Clients n=328
Received 2nd injection	88%	85%
Second injection on time (among continuers)	94%	94%
Where 2nd injection received		
Clinic	5%	96%
Home	35%	2%
CHRW home	56%	1%
Other / unknown	4%	1%
Why not continued? (among non-continuers)		
Plan to get injection soon	52%	37%
Dissatisfied with method	22%	40%
Forgot	2%	19%
Other	24%	5%
Intended future use (among non-continuers)	58%	50%

Client Satisfaction and Preferences

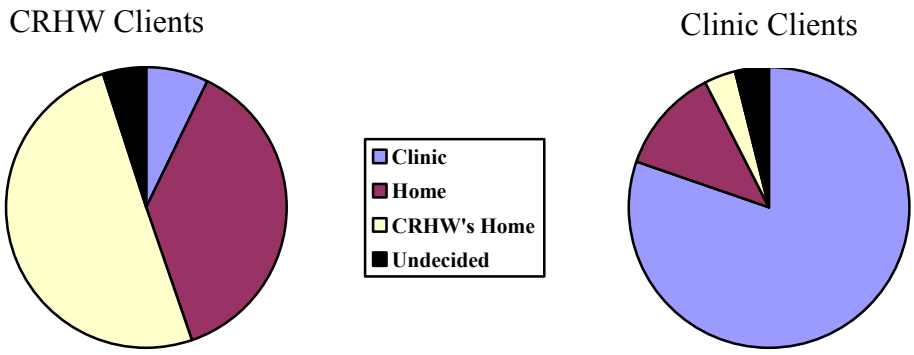
Because community-based health workers live and work closer to their clients and have more flexibility in meeting with them, clients may be more satisfied with such services. On the other hand, clients know that clinic-based providers have more clinical expertise. Researchers, therefore, were interested in several indicators of client satisfaction and preferences for services. Figure 2 compares clinic and CRHW clients' satisfaction with the services and with Depo Provera. In each instance, CRHW clients were at least as satisfied (and have more clients reporting "very satisfied") than clinic-based clients.

Figure 2: Client Satisfaction



Clients were also asked where they prefer to receive their Depo injections. Since this study was not randomized, and clients therefore "self-selected" into their group, it was not surprising to see stark differences in preferences shown in Figure 3.

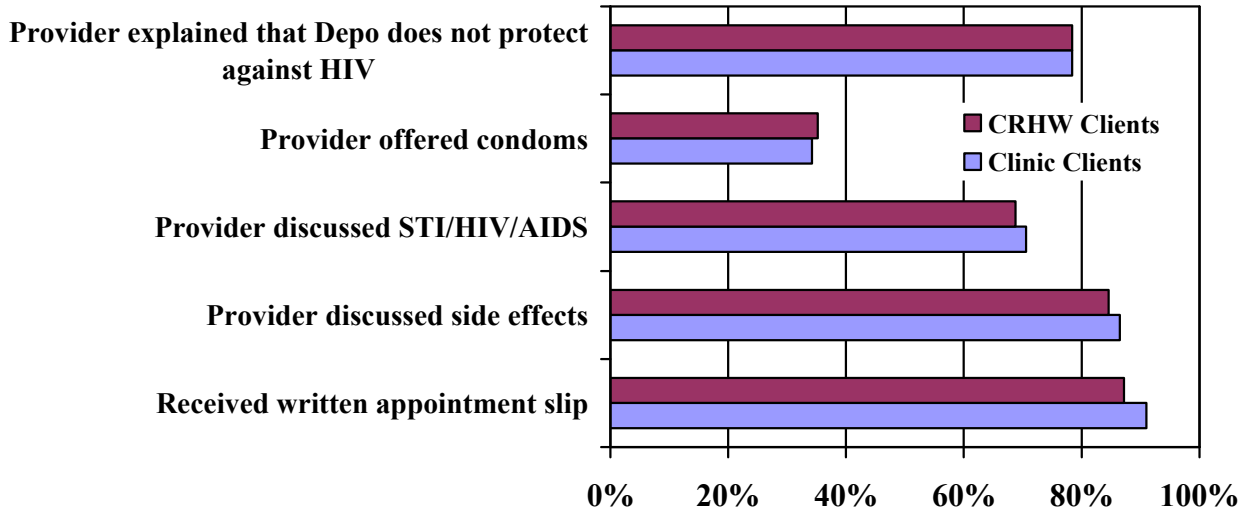
Figure 3: Preference of Where to Receive Depo Injections?



Quality of Care

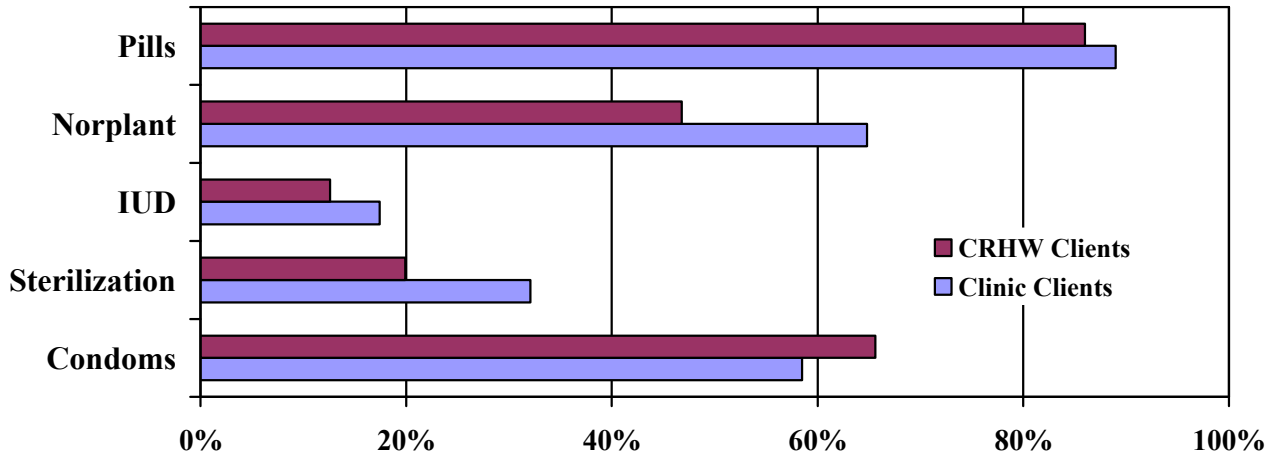
For similar reasons, researchers looked at client reports of the quality of care received. Figure 4 compares CRHW client versus clinic client reports of several standard indicators of quality. Overall, the results were good, but the main finding was that there was little difference between client reports of care received from nurses and that CRHWs.

Figure 4: Indicators of Quality of Care



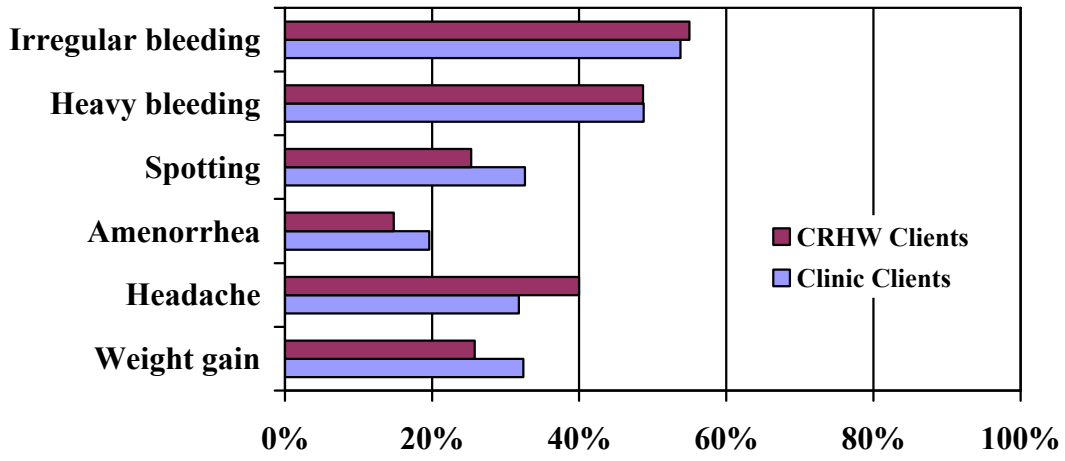
Another standard indicator of quality is the number of family planning methods discussed with the client. Although CRHWs supply only a limited range of methods, it is important that they discuss all available methods in case the client wants a referral. Similarly, nurses and midwives working in rural health centers should inform clients about referral methods such as Norplant, IUD, and sterilization. Figure 5 shows that clinic-based clients heard about more methods than the CRHW clients, most of whom only heard about condoms and pills.

Figure 5: Quality of Services: Methods Mentioned by Provider



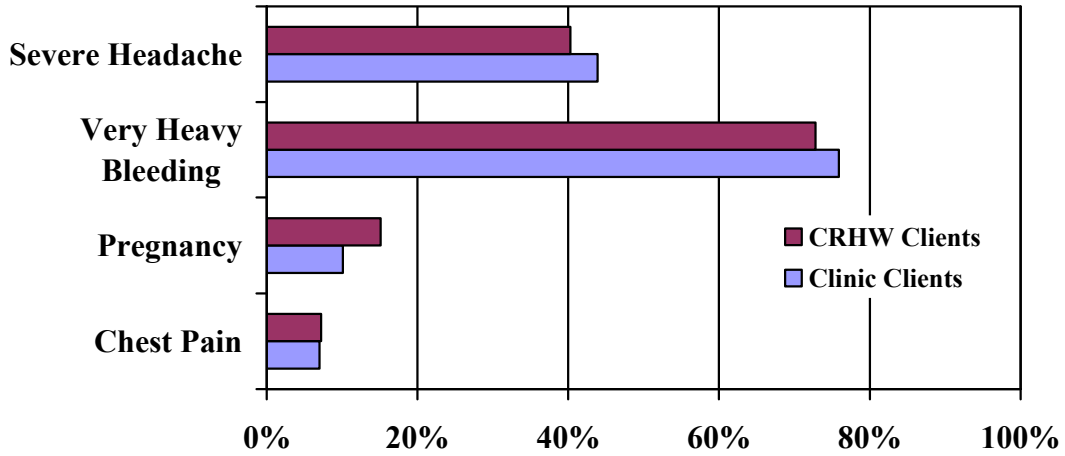
The quality of counseling can help determine whether a client continues. For instance, if clients using DMPA know that they may experience temporary menstrual irregularities, they may tolerate them better and be more likely to continue contraceptive use if these problems occur. As a proxy measure for good counseling, researchers measured client knowledge of common side effects and compared knowledge between the two groups of clients studied. In Figure 6, clinic-based clients were significantly more likely to report spotting and weight gain as common side effects, and CRHW clients were significantly more likely to know that headaches are a side effect. Overall, knowledge was quite low, particularly knowledge of the common bleeding side effects that cause so much discontinuation among Depo clients.

Figure 6: Client Knowledge: Common Side Effects



Well-informed clients should also know warning signs that require immediate medical intervention. As an indicator of quality counseling, Figure 7 reports on client recall of these usually rare conditions. The only serious condition for which a significant difference was noted was pregnancy; significantly more CRHW clients reported this condition than did clinic-based clients.

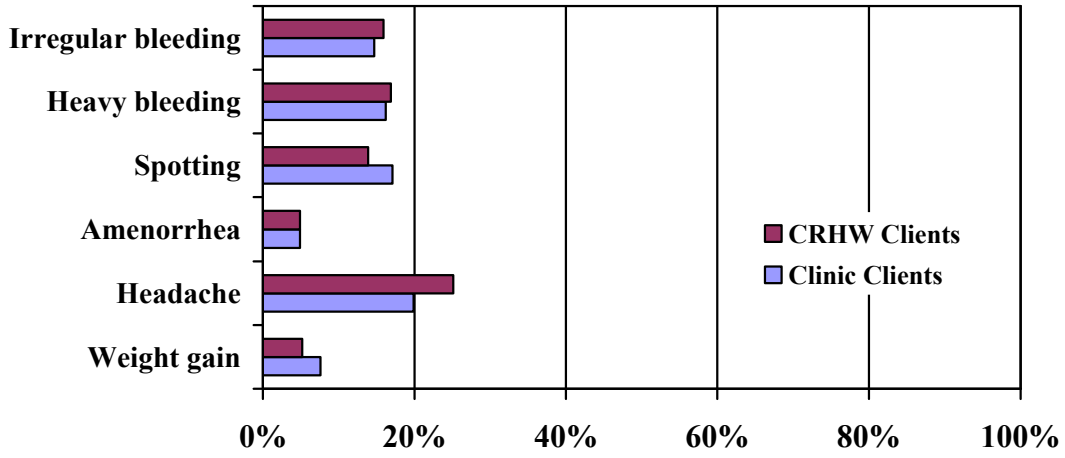
Figure 7: Client Knowledge: Serious Side Effects Requiring Medical Care



Side Effects

Depo Provera has become quite common in spite of the numerous bothersome side effects it causes. Most of these are menstrual-related. The clients followed in this study exhibited the normal range of side effects, with only minor differences in rates between the two groups studied (Figure 5). Amenorrhea is normally quite low in the early months, but becomes nearly universal with long use.

Figure 8: Side Effects Experienced



Injection Safety

Intramuscular injection with new, sterile syringes is rarely dangerous, but because community-based health workers such as CRHWs have less formal training than their clinic-based counterparts, this research included an assessment of injection safety. Besides asking CRHWs to report any needle sticks they may have suffered (there were none), researchers also asked clients about any problems resulting from the first injection. ("After the first injection, did you have any problem with the spot on your body where you got the injection?") If clients answered "yes," they were asked to describe the problem in detail. Of the 748 clients followed and asked this question, 32 (4%) answered "yes," but 10 did not specify any problem. Of the 22 who did describe their problem, eight (1%) described minor problems such as:

- "felt dizzy"
- "little pain"
- "very minor after the prick"

A further five (0.6%) gave descriptions which were vague (e.g., "pain," "almost turned into a wound") and four (0.5%) referred to "paralysis." Researchers were particularly concerned with reports of paralysis and, following up, found that it was a mistranslation for "numbness." Fortunately, the problem was temporary in all cases, but it might indicate a problem with poor injection technique among both CRHWs and nurses. Finally, four CRHW clients (0.5%)

reported "severe" pain at the injection site. Three of these clients received their injections from the same CRHW and all four were interviewed by the same interviewer, so researchers had difficulty determining whether one provider had poor technique or whether one interviewer might have exaggerated problems. For the sake of safety, the provider who gave those injections was asked to cease giving Depo shots until he could receive a training update. Table 4 shows the types of problems reported, by provider. CRHW clients reported a slightly higher percentage of problems, but the difference was never greater than 1%.

Table 4: Reported Problems at Injection Site

	CRHW Clients (n=435)	% Clinic Clients (n=313)	% Total (n=748)
Unspecified problems	1.6% (7)	0.9% (3)	1.3% (10)
Minor problems (e.g., dizziness, minor pain, headache)	1.6% (7)	0.6% (2)	1.2% (9)
Vague problems (e.g., "almost wound" "pain at spot")	0.6% (3)	0.6% (2)	0.6% (5)
"Paralysis" (numbness)	0.6% (3)	0.3% (1)	0.5% (4)
"Severe" pain	0.9% (4)	0.0% (0)	0.5% (4)

DISCUSSION

It is ironic that until now provision of contraceptive injections by community based health workers has been unknown in Africa where, arguably, the practice is most needed. The findings from this research reinforce the wealth of experience from other regions suggesting that well-trained community health workers can safely provide contraceptive injections. Several findings stood out. CHRW clients were just as likely to receive their second injection as were clinic clients. There were just as satisfied with the care given and with their method, and the quality of care they received was, in most respects, equivalent to that received by clients attending clinics.

That is not to say that their work could not be improved. For instance, clients of CRHWs reported slightly more injection site problems that clients of nurses, though that difference diminished over time. And the data suggest that both CRHWs and nurses could do a much better job counseling their clients. That only half the clients followed up knew that bleeding irregularities were a common side effect of Depo Provera is a sad state of affairs.

RECOMMENDATIONS

The following recommendations are based on the results of this research, and also upon the positive global experience with community based distribution of injectable contraception and on paramedical provision of vaccines, tetanus toxoid, and other lifesaving injections.

- Appropriately trained Community Reproductive Health Workers (CRHWs) in Nakasongola District should continue to provide contraceptive injections to both continuing and new clients. Uganda's Ministry of Health and donors such as USAID should ensure CRHWs a continuing, routine supply of both Depo Provera and auto-disable syringes.

- Given current shortages of qualified medical personal and the *de facto* practice of allowing paramedical cadres to assist in vaccination campaigns, Uganda's Ministry of Health should amend national policies and norms so that eligibility to provide injections is based upon appropriate training and demonstrated skill, not upon job title.

- Community-based family planning programs in Uganda and other sub-Saharan African countries should be encouraged to embrace innovations such as paramedical provision of injectable contraception by appropriately trained cadres.

- Donors should continue to invest in community-based distribution of family planning where access to services is lacking. When new technologies appear, such as Uniject and subcutaneous depo provera, donors should facilitate their rapid transfer to the field.

Checklist for Clients Who Want to Initiate DMPA (or NET-EN)

Please ask the client all of these questions and check the correct box.

NO		YES
	1. Is your menstrual period late *and* do you think you could be pregnant now?	
	2. Have you ever had a stroke, blood clot in your legs or lungs, or heart attack?	
	3. Do you have diabetes (sugar in your blood)?	
	4. Do you have or have you had breast cancer?	
	5. Do you have a serious liver disease or jaundice (yellow skin or eyes)?	

If the client answers NO to all the above questions, continue with question 6.

If the client answers YES to any of the above questions, *refer her to a clinic/physician.*

6. **Do you have bleeding between menstrual periods, which is unusual for you, or bleeding after intercourse (sex)?**

If the client answers NO to all the questions, she can use DMPA, *but to find out*

If the client answers YES, she can be given DMPA now, *but refer her to clinic/physician for further*

7. Are you currently breastfeeding?

If client answers NO, go to

If the client answers YES, go

8. Is your baby less than 6 weeks old?

NO. If client is breastfeeding a baby *6 weeks old or older and her menstrual periods have not returned,* she can be given DMPA now. If her menstrual periods have returned, go to question 9.

YES. If client is breastfeeding a baby less than *6 weeks old,* instruct her to return for DMPA as soon as possible after the baby is 6 weeks old.

9. Has it been more than 7 days since the beginning of your last menstrual period?

NO. If the client began her last menstrual period *within the past 7 days,* she can be given DMPA now.

YES. If the client started her menstrual period *more than 7*

- **She *has been using an effective method of contraception* (including abstinence), she can be given DMPA now, but instruct her that she must use condoms or abstain from sex for the next 7 days. Give her condoms.**

OR

- **She *has not been using an effective method of contraception* (including abstinence), she must wait until her next period to be given DMPA. Give her condoms to use in the meantime.**

Source: Stang A, Schwingl P, Rivera R. New contraceptive eligibility checklists for provision of combined oral contraceptives and depot-medroxyprogesterone acetate in community-based programmes. *Bull World Health Organ* 2000;78(8):1015-23.