# Contraceptive injections by community health workers in Uganda: a nonrandomized community trial

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**Objective** To compare the safety and quality of contraceptive injections by community-based health workers with those of clinic-based nurses in a rural African setting.

**Methods** A nonrandomized community trial tested provision of injectable Depo Provera (DMPA) by community reproductive health workers and compared it with routine DPMA provision at health units in Nakasongola District, Uganda. The primary outcome measures were safety, acceptability and continuation rates.

**Findings** A total of 945 new DMPA users were recruited by community workers, clinic-based nurses and midwives. Researchers successfully followed 777 (82% follow-up): 449 community worker clients and 328 clinic-based clients. Ninety-five percent of community-worker clients were "satisfied" or "highly satisfied" with services, and 85% reported receiving information on side-effects. There were no serious injection site problems in either group. Similarly, there was no significant difference between continuation to second injection (88% among clients of community-based workers, 85% among clinic-going clients), nor were there significant differences in other measures of safety, acceptability and quality.

**Conclusion** Community-based distribution (CBD) of injectable contraceptives is now routine in some countries in Asia and Latin America, but is practically unknown in Africa, where arguably the need for this practice is greatest. This research reinforces experience from other regions suggesting that well-trained community health workers can safely provide contraceptive injections.

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Une traduction en français de ce résumé figure à la fin de l'article. Al final del artículo se facilita una traducción al español. التجمة العربية لهذه الخلاصة في نهاية النص الكامل لهذه المقالة.

#### Introduction

Africa is home to dozens of programmes for community-based distribution (CBD) of contraceptives. However, the popularity and impact of programmes that use paramedical workers to distribute condoms and oral contraceptive pills may be limited by the fact that none supply the most popular family planning method in sub-Saharan Africa: injectable progestin-only contraceptives such as depot medroxyprogesterone acetate (DMPA, Depo Provera). Though practically unknown on the continent before the 1990s, injectable contraceptives have rapidly become the region's method of choice due to their effectiveness, their simple re-injection schedule (every three months for DMPA) and their suitability for discreet use.

Community health workers routinely provide vaccinations in Africa and give contraceptive injections in some developing regions. Bangladesh, for example, began a programme to provide Depo Provera and other methods in

clients' homes in 1976. The programme was credited with reducing fertility rates by 25% compared with areas where use of DMPA was rare. More recently, community-based family planning programmes in Bolivia, Guatemala, Mexico and Peru successfully added injectable contraceptives to the method mix offered to many of their rural clients. Solid evidence exists that community-based health workers can safely screen for medical contraindications to DMPA, and checklists using WHO eligibility criteria have been created to facilitate CBD provision of injectable contraceptives.

In spite of this evidence base, paramedical provision of injectable contraception remains rare around the world and is unknown in Africa, where clinic access is often poor and the need is greatest. Critics of the practice contend that it is unsafe for women to receive contraceptive injections from non-clinically trained personnel. Other concerns include the possibility that poorly

supervised paramedicals will provide other, perhaps unnecessary, injections or pose as medical personnel. Finally, some health personnel may feel that task shifting to nonclinicians will infringe on their status (or their income), and some policy-makers and managers may dislike the prospect of responsibility for yet another cadre of health workers.

The purpose of this study was to test the hypothesis that the safety and quality of contraceptive injections by community-based reproductive health workers in a rural African setting was not significantly inferior to injections given by local clinic-based workers.

## Participants and intervention

The research took place in Uganda, which has a modern method contraceptive prevalence rate of 18%. Injectables are the most popular contraceptive method in Uganda, accounting for about 57% of all modern methods used.<sup>8</sup>

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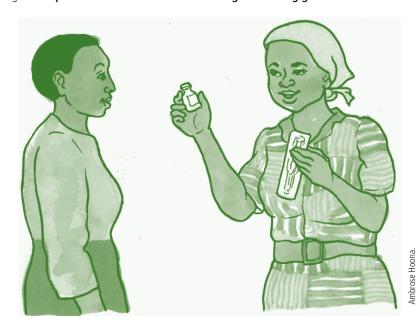
Planning for the study began in 2003, after interest was expressed by Uganda's Ministry of Health and Save the Children/USA, a nongovernmental organization that sponsors Uganda's most active CBD programme in its main focus district, Nakasongola. This large rural district two hours north of Kampala has a population of about 140 000 which subsists mainly on agriculture, cattle grazing and fishing. The district's total fertility rate is about 7, while its contraceptive prevalence is estimated at 9%. There are no sterilization services in the district, nor are implants routinely available. Intrauterine devices (IUDs) are available in theory, though in practice they are almost never provided due to provider concerns about STI risks. For most women, oral contraceptive pills and Depo Provera are the only realistic options for family planning, and reviews of clinic records suggest that Depo Provera is by far the preferred method available.

Although Nakasongola's health needs are served by a subdistrict hospital, five health centres and eight health posts, only 6% of the population live within 5 km of a health services unit. Save the Children/ USA sponsors health and education efforts throughout the district, including a community based reproductive health and family planning programme that complements existing clinic-based services, particularly for those for whom clinic access is problematic.

About 100 community-based reproductive health workers (CRHWs), half males and half females, work in Nakasongola's 45 parishes with 15 Save the Children field supervisors. Each CRHW is also affiliated with a health centre where (s)he is resupplied with free contraceptive commodities and refers clients for clinic-based methods. CRHWs are not paid a salary, but are "incentivized" by Save the Children with periodic gifts of useful items such as raincoats, rubber boots and backpacks that can facilitate their work. Their services and products are provided free to clients.

Save the Children/USA has always worked closely with district health officials in Nakasongola, so researchers worked closely with local health staff in the planning stages of the project, through the research period, and beyond. To that end, it was decided very early that the principal training

Fig. 1. Sample artwork from illustrated training/counselling guide



intervention would be conducted by Nakasongola's District Health Educator, rather than staff from Save the Children or the research sponsor, Family Health International.

In March 2004, twenty CRHWs in Nakasongola were trained to provide DMPA injections to their communities using single-use autodisable syringes. These workers were active providers of pills and condoms for Save the Children/USA. The workers were chosen based on their level of activity and productivity in the Save the Children programme, and also on their geographical location within this large district. Sixteen were female, four were male. All were primary school leavers, but only three had completed secondary school.

A first week of classroom training emphasized counselling, health screening, safe injection technique and proper waste disposal. The CRHWs were provided with an illustrated counselling tool for women in their communities (Fig. 1) and were taught to use a checklist developed for paramedical personnel to screen potential DMPA clients for health problems requiring referral. The community health workers then spent two weeks observing and practicing injections in a small hospital and in their local health centres before starting to provide DMPA to women in their home areas. Sharps containers were provided

to all CRHWs, who were instructed to take full containers to their local clinic for proper disposal.

#### Methods

Shortly after training ended, we began a prospective study to compare the care received by CRHW clients with that received by women getting DMPA injections from the usual source in the district, i.e. nurses and midwives in local health centres. The study protocol was reviewed and approved by the ethical review committees of Uganda's National Council for Science and Technology and Family Health International.

The sample size for the study was based on testing for the noninferiority of services provided by CRHWs as measured by three-month reinjection rates for the clinic-based and CRHW clients. After conversations in the field with key informants and review of the literature describing continuation rates for DMPA in Africa, we assumed a threemonth reinjection proportion of 65% among clinic-based clients. Further, we assumed that no more than a 10% decrease in this proportion (i.e. 55%) in the CHRW clients could be considered as acceptably equivalent. We also assumed 10% loss to follow-up of new clients, a design effect of 2.0 (based on similarly clustered studies), and we made assumptions about recruitment rates in each of the 10 clusters (catchment areas). For a one-sided test with an  $\alpha$  of 0.10 and with 80% power to reject the null hypothesis of a reinjection rate less than 55% among CRHW clients, the required sample size was 600 CRHW clients and 320 clinic-based clients.

From March to November 2004, CRHWs recruited 562 clients, and nurses and midwives in 10 health centres recruited 383 clients. In the first short interview, each client gave a verbal informed consent and answered several questions. Thirteen weeks after their first injection, study staff attempted follow-up interviews in the clients' homes or preferred location. Thirteen weeks was chosen because it gave clients a one-week "grace period" to be late for their reinjection appointment, yet still allowed good recall of the care received at the time of the 12 week reinjection. The timing was also advantageous 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 injection without having to use a back-up method or prove they weren't pregnant. (Such clients were not counted as continuers since standard practice in Nakasongola at the time of the study was to give late DMPA clients a oneweek grace period beyond the 12 week reinjection schedule.) Three attempts were made to interview each recruited client before she was considered lost to follow-up.

The data collected at thirteen weeks included:

- whether the client had a second injection
- reasons for discontinuation (among abandoners)
- satisfaction
- recall of key counselling messages
- recall of method-related health problems for which medical attention should be sought
- reported injection site morbidities
- reported side-effects.

The data were screened and entered at the Save the Children office in Nakasongola using EpiInfo (v.6) software. The data were cleaned by Family Health International (FHI) researchers in the field and in North Carolina, USA. For the final analyses, FHI researchers used

Table 1. Background characteristics of clients, by provider type

	CRHW clients (n=449 <sup>a</sup> )	Clinic clients (n=328°)
Age (mean)	28	26
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%
Don't know/other	3%	11%
First-time user of Depo Provera	86%	76%
Husband supportive (at start)	41%	52%

CRHW, community-based reproductive health workers.

both bivariate and multivariate methods to compare various outcomes between the CRHW clients and clinic clients.

#### Results

Of the 945 clients recruited, 777 clients (82%) were followed up. (Many of the lost-to-follow-up clients were from the catchment area of a particular interviewer who left the study and whose replacement failed to interview his assigned clients.) Table 1 compares the characteristics of CRHW clients with those of clinic-based clients. There were a few differences between the two groups that are likely to be explained by the fact that CRHWs might naturally recruit women with less access to clinic care or who might otherwise be less likely to attend clinics. CRHW clients were less likely to have used Depo Provera previously, and they had spouses who were less supportive of family planning. Nearly all the women had children and most were married.

There was no significant difference in continuation between the two groups; 88% of CRHW clients and 85% of clinic clients received the second injection. Exact logistic regression controlling for clustering of responses within

provider catchment areas confirmed no difference in the odds of CRHW clients continuing use compared to clinic-based clients (odds ratio, OR = 1.2; 95% confidence interval: CI = 0.8–1.9). Given the nonrandomized design of the study, we also tested other regression models controlling for covariates such as age, parity, education, husband's supportiveness and desire for more children, none of which showed significant differences in continuation between the two groups of clients.

Among the CRHW clients, 56% received their first injection in the home of their CRHW, 35% received the injection in their own home, 5% went to the clinic and 4% received their injection in another location (some CRHWs reported meeting with clients in the home of mutual friends or in the bush). When noncontinuers in both groups were asked why they did not receive a second injection, it was notable that clinic clients were nearly twice as likely as CRHW clients to report dissatisfaction with the method (40% versus 22%) and 10 times as likely to report that they had forgotten to continue (20% versus 2%).

We also assessed several measures of acceptability and service quality

<sup>&</sup>lt;sup>a</sup> Maximum *n* for followed CRHW and clinic clients; some cells have non-response missing values.

(Table 2). There were no significant differences between the two groups in our measures of satisfaction or quality of care provided, but clinic-based clients were more likely to recall weight gain and spotting as side-effects and to recall being told about clinical family planning methods such as Norplant, IUD and female sterilization. CRHW clients, on the other hand, were more likely to recall headache as a side effect and being told about condom use for family planning. When asked about problems related to their injections, neither group of women reported any infections or abscesses. However, women in the CRHW group were more likely to report very painful injections or temporary numbness, though such reports were rare (< 1%) and became rarer over time as CRHW workers gained experience. Given Uganda's female HIV prevalence of 7.5% 10 needle-stick injuries were a concern, but none were reported by CRHW workers queried at monthly supervision meetings.

Clients in both groups reported similarly low levels – generally less than 20% – of side-effects normally associated with DMPA use: irregular bleeding, heavy bleeding, spotting and amenorrhoea (Fig. 2). Well-informed clients should also know warning signs that require immediate medical intervention. As an indicator of quality counselling, Fig. 3 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 knew this condition than did clinic-based clients.

#### **Discussion**

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

Table 2. Continuation and client reports of care received

	CRHW % (n = 449) <sup>a</sup>	Clinic % (n = 328) <sup>a</sup>	<i>P</i> -value <sup>b</sup>
Client received 2nd injection	88	85	0.38
Satisfied or highly satisfied with:			
provider care	95	93	0.27
DMPA as contraceptive method	93	90	0.15
Standard quality indicators:			
provider discussed side-effects	85	86	0.49
client received written appointment slip	87	91	0.10
provider discussed STI/HIV/AIDS	69	71	0.58
provider offered condoms	36	34	0.64
provider explained that DMPA does not protect against HIV	80	81	0.75
Spontaneous recall of other methods mentioned by family planning provider:			
pills	86	89	0.21
Norplant	47	65	< 0.01
IUD	13	17	0.06
female sterilization	20	32	< 0.01
condoms	66	59	0.04
Spontaneous recall of common side- effects:			
irregular bleeding	55	54	0.74
heavy bleeding	49	49	0.97
spotting	25	33	0.03
amenorrhoea	15	20	0.08
headache	40	32	0.02
weight gain	26	32	0.04
Injection-related problems reported: c			
infections/abscesses	0.0	0.0	-
very painful injection	0.7	0.0	0.27
temporary numbness	0.7	0.3	0.64

CRHW, community-based reproductive health workers; IUV, intrauterine device.

- <sup>a</sup> Maximum *n* for followed CRHW and clinic clients; some cells have non-response missing values.
- <sup>b</sup> *P*-values based on Mantel-Haenszel chi-square test, unless otherwise noted.
- P-values based on Fisher's exact test.

This success does not mean that provision of injectables by both CRHWs and nurses could not be improved. For instance, clients of CRHWs reported slightly more injection site problems than clients of nurses, though that difference diminished over time. And the data suggest that both CRHWs and nurses could do a better job of counselling their clients. That only about half of the clients in either group could report bleeding irregularities as a common side effect of Depo Provera is lamentable.

Equally lamentable is the fact that women in rural Uganda (and elsewhere in Africa) have so few choices among effective contraceptive methods. For women in Nakasongola, sterilization and implant services require long journeys, typically to Uganda's capital, Kampala. The IUD, which is highly effective, safe and inexpensive, is not provided due to providers' exaggerated fears about the method's risks. Oral contraceptives are widely available in Nakasongola but not very popular, in part because keeping pills in the home and taking them daily is a threat to their covert use, a practice many women in our sample found necessary. Thus, for many women in our rural study area, Depo Provera was the only realistic contraceptive option. Although the method is relatively costly to donors at about US\$ 1 per three-month dose and has other disadvantages, we do not advocate withholding it from

poor, rural women who want to delay or limit future childbearing. DMPA commonly has discontinuation rates higher than most other family planning methods. There has also been concern that use of DMPA may predispose women to HIV transmission. However, a recent National Institutes of Health (NIH)funded study concluded that use of DMPA and other hormonal methods does not appear to increase women's overall risk of infection with the AIDS virus.11 Expanding the use of injectables in this rural area will save lives, and given the fact that the ongoing CBD programme uses the same donated products used throughout Uganda, adding injectables to the method mix will probably increase the programme's cost-effectiveness by allowing existing workers to provide the contraceptive method favoured by local women.

This study was the first rigorous evaluation of provision of injectable contraception by paramedicals in Africa. As a result of this research, Save the Children/USA was given permission by Uganda's Ministry of Health not only to continue CRHW provision of injectables in Nakasongola, but to expand the practice into new districts where poor access to clinical services limits family planning.

This practice should be scaled up in Africa and elsewhere. In doing so, programme managers should promote both quality and access through training, use of job-aids and solid logistical support systems.

Fig. 2. Side-effects reported by clients

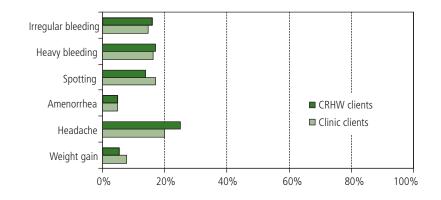
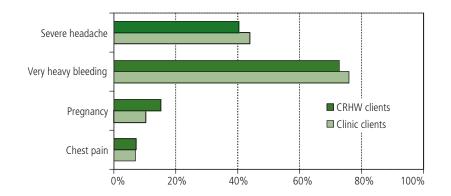


Fig. 3. Client knowledge: serious side-effects requiring medical care



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**Competing interests:** None declared.

#### Résumé

### Injections contraceptives par des agents de santé communautaires en Ouganda : essai en communauté non randomisé

**Objectif** Comparer l'innocuité et la qualité d'injections contraceptives effectuées par des agents de santé communautaires avec celles d'injections réalisées par du personnel infirmier en milieu clinique dans des zones rurales africaines.

**Méthodes** Dans le cadre d'un essai en communauté non randomisé, on a étudié la délivrance de Depo Provera injectable (DMPA) par des agents communautaires formés à la santé génésique et on l'a comparée avec la délivrance habituelle de ce contraceptif dans les établissements sanitaires de district de Nakasongola en Ouganda. Les principales mesures de performance étaient l'innocuité, l'acceptabilité et le taux de continuation de la contraception.

**Résultats** Des agents de santé communautaires, ainsi que du personnel infirmier et des sages-femmes exerçant en milieu clinique, ont recruté au total 945 nouvelles utilisatrices de DMPA. Les chercheurs ont réussi à suivre 777 (soit 82 %) d'entre elles, dont 449 clientes d'agents de santé communautaires et 328 clientes d'établissements cliniques. 95 % des clientes d'agents

communautaires se sont déclarées « satisfaites » ou « très satisfaites » de la prestation et 85 % ont signalé avoir reçu des informations sur les effets secondaires. Aucun problème grave lié au site d'injection n'est apparu dans aucun des groupes. De même, aucune différence notable en termes de continuation avec la deuxième injection (88 % chez les clientes des agents de santé communautaires et 85 % chez les clientes d'établissements cliniques), ou d'innocuité, d'acceptabilité et de qualité, n'a été relevée.

**Conclusion** La délivrance dans le cadre communautaire (CBD) de contraceptifs injectables est maintenant courante dans certains pays d'Asie et d'Amérique latine, mais pratiquement inconue en Afrique, où cette pratique est peut être la plus nécessaire. La présente étude confirme l'expérience acquise dans d'autres régions, qui laisse à penser que des agents de santé communautaires convenablement formés peuvent pratiquer sans risque des injections contraceptives.

#### Resumen

### Administración de anticonceptivos inyectables por agentes de salud comunitarios en Uganda: ensayo comunitario no aleatorizado

**Objetivo** Comparar la seguridad y calidad de las inyecciones anticonceptivas administradas por agentes de salud comunitarios con la de las administradas por personal de enfermería de dispensario en un entorno rural de África.

**Métodos** Se llevó a cabo un ensayo comunitario no aleatorizado para analizar la administración de Depo Provera (DMPA) inyectable por agentes de salud reproductiva comunitarios y compararla con la administración ordinaria de DPMA en unidades de salud del distrito de Nakasongola en Uganda. Las medidas de resultado principales fueron la seguridad, la aceptabilidad y las tasas de continuación.

**Resultados** Agentes comunitarios, enfermeras de ambulatorio y parteras reclutaron en total a 945 nuevas usuarias de DMPA. Los investigadores siguieron con éxito a 777 de ellas (82%): 449 mujeres atendidas por agentes comunitarios y 328 tratadas en dispensarios. El 95% de las mujeres atendidas por los primeros declararon estar «satisfechas» o «muy satisfechas» con los

servicios, y el 85% dijeron que habían recibido información sobre los efectos secundarios. No se registraron problemas graves relacionados con el punto de inyección en ninguno de los grupos. De forma similar, no se observaron diferencias importantes ni en lo tocante a la continuación hasta la segunda inyección (88% de las mujeres atendidas por agentes comunitarios, 85% de las que acudieron a un dispensario) ni en otras medidas de la seguridad, aceptabilidad y calidad.

**Conclusión** La distribución comunitaria de anticonceptivos inyectables es hoy día algo corriente en algunos países de Asia y América Latina, pero es prácticamente desconocida en África, precisamente donde se diría que más necesaria es dicha práctica. Esta investigación confirma la experiencia de otras regiones y parece indicar que los agentes de salud comunitarios debidamente adiestrados para ello pueden administrar de manera segura las inyecciones anticonceptivas.

#### ملخص

# إعطاء موانع الحمل بالحَقْن من قبَل العاملين في صحة المحتمع في أوغندا: تجربة مجتمعية غير معشاة

الغرض: استهدفت هذه الدراسة المقارنة بين مأمونية وجودة عمليات حَقْن موانع الحمل التي يقوم بها العاملون في صحة المجتمع وبين العمليات المماثلة التي تقوم بها ممرضات العيادات في موقع ريفي في أفريقيا.

الطريقة: تم إجراء تجربة مجتمعية غير معشاة لاختبار عملية إعطاء مانع الحمل ديبو بروفيرا Depo Provera من قبَل العاملين في الصحة الإنجابية في المجتمع، ومقارنتها مع الإعطاء الروتيني لنفس مانع الحمل في الوحدات الصحية في منطقة ناكاسونغولا، بأوغندا. وشملت المقاييس الأولية للنتائج كلاً من المأمونية، والمقبولية، ومعدلات الاستمرار.

الموجودات: شارك في الدراسة 945 من المستخدمات الجدد لمانع الحمل ديبو بروفيرا من المتعاملات مع العاملين في صحة المجتمع، وممرضات العيادات، والقابلات. ونجح الباحثون في متابعة 777 من هؤلاء العميلات (نسبة المتابعة 82%): منهن 449 عميلة للعاملين في صحة المجتمع، و328 عميلة للعيادات. وأعربت 95% من المتعاملات مع العاملين في صحة المجتمع عن للعيادات. وأعربت 95% من المتعاملات مع العاملين في صحة المجتمع عن

رضائهن أو رضائهن البالغ عن الخدمات، في حين أبلغت 85% منهن عن تعرضهن لتأثيرات جانبية. ولم تُلاحظ أي مشكلات خطيرة في موقع الحَقْن في أي من المجموعتين. وبالمثل، لم يلاحظ أي اختلاف ملموس في ما يتعلق بالانتقال إلى مرحلة الحَقْن الثانية (كانت النسبة 88% بين المتعاملات مع العاملين في صحة المجتمع، و85% بين عميلات العيادات)، ولم تلاحظ أيضاً فروق ملموسة في سائر مقاييس المأمونية والمقبولية والجودة.

الاستنتاج: أصبح توزيع موانع الحمل المأخوذة بالحَقْن في المجتمع أمراً ووتينياً في بعض بلدان آسيا وأمريكا اللاتينية، ولكنه غير معروف عملياً في أفريقيا حيث يتعاظم الجدل حول مدى الحاجة إلى هذه الممارسة. ويقوي هذا البحث الخبرات المكتسبة من أقاليم أخرى، والتي تشير إلى أن العاملين في صحة المجتمع المدربين جيداً يمكنهم إعطاء موانع الحمل المأخوذة بالحَقْن بطريقة مأمونة.

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