Safety, Quality, and Acceptability of Contraceptive Implant Provision by Community Health Extension Workers versus Nurses and Midwives in Two States in Nigeria

Megan Douthwaite, Olalere Alabi, Kingsley Odogwu, Kate Reiss, Anne Taiwo, Ebere Ubah, Anthony Uko-Udoh, Kayode Afolabi, Kathryn Church, Justin Fenty, and Erik Munroe

Task sharing is a strategy with potential to increase access to effective modern contraceptive methods. This study examines whether community health extension workers (CHEWs) can insert contraceptive implants to the same safety and quality standards as nurse/midwives. We analyze data from 7,691 clients of CHEWs and nurse/midwives who participated in a noninferiority study conducted in Kaduna and Ondo States, Nigeria. Adverse events (AEs) following implant insertions were compared. On the day of insertion AEs were similar among CHEW and nurse/midwife clients—0.5 percent and 0.4 percent, adjusted odds ratio (aOR) 0.92 (95 percent CI 0.38–2.23)—but noninferiority could not be established. At follow-up 6.6 percent of CHEW clients and 2.1 percent of nurse/midwife clients experienced AEs. There was strong evidence of effect modification by State. In the final adjusted model, odds of AEs for CHEW clients in Kaduna was 3.34 (95 percent CI 1.53–7.33) compared to nurse/midwife clients, and 0.72 (95 percent CI 0.19–2.72]) in Ondo. Noninferiority could not be established in either State. Implant expulsions were higher among CHEW clients (142/2987) compared to nurse/midwives (40/3517). Results show the feasibility of training CHEWs to deliver implants in remote rural settings but attention must be given to provider selection, training, supervision, and follow-up to ensure safety and quality of provision.

Megan Douthwaite, Kathryn Church, Justin Fenty, Erik Munroe, MSI Reproductive Choices, London, UK. E-mail: megan.douthwaite@gmail.com. Olalere Alabi, Kingsley Odogwu, Ebere Ubah, MSI Nigeria, Abuja, Nigeria. Kate Reiss, London School of Hygiene and Tropical Medicine, London, UK. Anthony Uko-Udoh, Kayode Afolabi, Federal Ministry of Health Nigeria, Abuja, Nigeria.

INTRODUCTION

Like many countries, Nigeria has a severe shortage of health workers (WHO 2012; Federal Ministry of Health 2014; Akeju et al. 2016) along with inequitable geographic distribution and an imbalance in the range of health worker skills. Physicians and nurses tend to be concentrated in tertiary care facilities, and shortages are most acute in rural and northern parts of the country (Federal Ministry of Health 2014; Awofeso 2010). Task sharing is a potentially cost-effective means to increase access to health services for people living in areas with a shortage of health workers. Essentially it allows a wider range of cadres, including less qualified health workers to offer certain services, when deemed safe and effective (WHO 2017). WHO has endorsed the strategy as a means to increase access to reproductive health services, including access to long acting reversible contraceptives (LARCs) (WHO 2017), defined here as implants and intrauterine contraceptive devices (IUCD). In 2014, lower cadre Community Health Extension Workers (CHEWs) were approved by the Government of Nigeria to insert and remove contraceptive implants and IUCDs after appropriate training (Federal Ministry of Health 2014). Prior to this, provision of LARCs was restricted to midwives, nurses, and physicians.

Senior CHEWs—the focus of this study—make up 27 percent of the workforce in Nigeria's primary health care units (vs. 8 percent nurses and midwives) (Federal Ministry of Health 2014). They are classified as "upper-lower" health staff and undergo three years of training (Evidence to Action Project 2017). They are often located in more remote areas compared to more highly qualified cadres (Federal Ministry of Health 2014). In larger urban centers CHEWs assist nurses and physicians; in rural health centers they work alone or with another CHEW or nurse. Although CHEWs are expected to spend half their time on community-based functions, in reality they spend most of their time in clinics due to shortages of higher cadre staff in many rural areas (Abdul-hadi et al. 2013; Kress, Su, and Wang 2016; Uzondo et al. 2015).

In Nigeria, one in four married women has an unmet need for family planning (Performance Monitoring and Accountability (PMA2020) 2018). Modern contraceptive use, estimated at 12 percent among married women (National Population Commission (NPC) [Nigeria] and ICF 2019), varies significantly by geographic zone (7.8 percent in the North East vs. 24.3 percent in the South West), state (1.7 percent in Yobe State vs. 29.0 percent in Lagos State), residence (18.2 percent in urban areas vs. 7.8 percent in rural areas), socioeconomic status (3.7 percent among the poorest vs. 22.2 percent among the richest), education and religion (National Population Commission (NPC) [Nigeria] and ICF 2019). Short-acting methods predominate (Performance Monitoring and Accountability (PMA2020) 2018), and LARCs are used by 35 percent of modern method users (implants 28.3 percent and IUCDs 6.7 percent) (National Population Commission (NPC) [Nigeria] and ICF 2019).

The Government of Nigeria committed to increasing the prevalence of modern contraceptive use among all women from 15 percent in 2016 to 27 percent by 2020 and to scale up access to modern methods (FP2020 2019; Guttmacher Institute 2019). LARCs offer particular

benefits to women over short-term methods, including higher effectiveness, longer continuation, fewer contraindications, and in some settings, higher cost-effectiveness (Mazza et al. 2016; Mavranezouli 2008; Shoupe 2016; Trussell et al. 2015). Despite several initiatives in Nigeria to increase access to modern methods, including task-sharing provision of LARCs with CHEWs (Charyeva et al. 2015; Blumenthal et al. 2013; Shelton and Finkle 2016), a recent study found method choice and access to LARCs remains limited, slowing increase in modern contraceptive use (Thanel et al. 2018).

WHO recommends that auxiliary nurses (WHO 2014) provide contraceptive implants under close monitoring and evaluation before they fully endorse this cadre for implant provision globally (WHO 2017). CHEWs are the closest equivalent to this cadre, but they have three years of medical training. Studies from several sub-Saharan Africa countries show that provision of contraceptive implants by lower cadre health workers can increase access to and use of LARCs (Thanel et al. 2018; Asnake et al. 2013). Two studies have assessed the acceptability and feasibility of implant provision by CHEWs in Nigeria. The first, a pilot study in rural Sokoto and Bauchi States, tested the feasibility of training CHEWs to provide implants, documenting CHEW knowledge and skills, client acceptability, and effectiveness of supportive supervision mechanisms (Charyeva et al. 2015). The study found CHEWs consistently followed clinical protocols and delivered high-quality services, but observed challenges with low client flow. The second feasibility study, in Kaduna and Cross-River States, observed high-quality implant insertions. The study also investigated effects on contraceptive method mix and found an increase in implant provision overall (Morgan et al. 2017). Neither study evaluated insertion-related clinical outcomes nor compared CHEW provision with higher cadre health workers. In their guidance on task sharing, WHO highlights the lack of studies on the safety and effectiveness of contraceptive implant insertion and removal with lower cadre health staff (Polus et al. 2015; WHO 2012).

The proper insertion and removal of implants are essential for clinical efficacy and for the prevention of complications, such as infection, neurovascular injury (Lefebvre et al. 2018), implant migration, or expulsion (Rowlands and Searle 2014). Complications related to insertion and removal procedures, although rare, may include pain, paresthesia, bleeding, hematoma, scarring, or infection. Implant removal may be difficult if the implant is not inserted correctly, inserted too deeply, not palpable, encased in fibrous tissue, or has migrated. Deep insertions may make the implant difficult to locate and may require a surgical procedure in an operating room to remove the implant (Implanon USA 2019). Research is urgently needed to establish whether task-sharing implant insertions with lower level health staff is clinically safe and of acceptable quality.

This study compares insertion-related adverse events (AEs) due to implant insertions by newly trained CHEWs or nurses/midwives. We also compare the quality of implant insertions and client satisfaction. The overall goal is to provide scientific evidence on the safety of this form of task sharing for national and state health authorities. In addition, the study aimed to provide robust data on insertion-related clinical side effects and moderate and severe AEs in a low-income setting.

METHODS

Study Setting

The study was conducted in public health facilities in two Nigerian states, Kaduna in central northwest Nigeria, and Ondo in the southwest. The north and the south differ culturally, socially, and economically, with the south tending to be richer, and with better health and socioeconomic indicators compared to the north, including maternal, infant and child mortality, education, contraceptive prevalence, distribution of medical schools, and availability of health care providers (Makinde et al. 2018; International Organization for Migration (IOM) 2014). Kaduna State is the third most populous state in Nigeria, with an estimated population of 8.25 million, compared to 4.18 million in Ondo State in 2016. Sixty-six percent of the population in Kaduna State is under the age of 25, compared to 59 percent in Ondo State (Nigeria Bureau of Statistics 2019). Forty seven percent of women aged 15–49 years in Kaduna State have no education, compared to 7.9 percent in Ondo State. The total fertility rate (TFR) in Kaduna was 5.9 with a mean ideal number of children of 7.2 children, compared to a TFR of 4.1, and a mean ideal number of children of 4.5 in Ondo. In Kaduna 36.5 percent of households live in the poorest two wealth quintiles compared to 21.2 percent in Ondo (National Population Commission (NPC) [Nigeria] and ICF 2019).

Study Design and Intervention

This was a quasi-experimental noninferiority study that aimed to compare insertion-related moderate and severe AEs resulting from insertion of contraceptive implants by CHEWs with nurses and midwives. Random allocation of clients to intervention groups was not possible in this study because clients access their local area clinics. Also, providers could not be randomized because they work at either CHEW-led or at nurse- or midwife-led public clinics. The methodology and detailed description of the intervention is provided in the published protocol https://doi.org/10.2196/resprot.8721 (Reiss et al. 2018). Briefly, 12 out of 23 local government areas (LGAs) were purposively selected from Kaduna State, and seven of 23 LGAs from Ondo State. LGAs that shared reproductive health interventions funded by the same donor and implemented across several LGAs, as well as those that were geographically hard-to-reach were excluded from the sampling frame.

Facilities in remaining LGAs were eligible for inclusion if they were CHEW or nurse/midwife led; had not previously provided implants; had provided family planning services for at least three years; had a provider interested in participating in the study who expected to remain at the facility for the 12-month client recruitment period; and, finally could offer onsite referral, or were within 20 km of a referral facility in case of implant insertion or removal complications. From 657 facilities operating in these LGAs, 93 were eligible for inclusion in the study. Seventy-seven were primary basic health units (BHUs) or small rural hospitals and 16 were secondary or tertiary centers or hospitals.

We aimed to select 60 providers (30 CHEWs and 30 nurse/midwives) from each state. Providers from the 93 facilities were invited to participate in the study if they met the following criteria: they had no prior implant training or provision experience; were resident in the LGA; expected to remain at the health facility for the 12-month client recruitment

period; and lastly, that they had good verbal and written communication skills. In total 119 providers were included in the study. A single provider was recruited from 67 facilities; and two providers from the remaining 26 facilities. This comprised two CHEWs from 15 facilities and two nurse/midwives from 11 facilities.

Providers comprised 30 nurses/midwives from each state; and 30 CHEWs from Ondo and 29 from Kaduna State. Providers were trained by 13 supervisors, themselves trained by Marie Stopes Nigeria (MSION) in family planning counselling, insertion and removal of implants, management of AEs, and study procedures. For a full description of training and supervision procedures see Reiss et al. (2018).

Two implant brands were initially included in the study: Implanon Classic® (one rod preloaded in trocar) offering three year protection from pregnancy; and Jadelle® (two rods, with separate disposable trocar) offering five year protection. ImplanonNXT® was introduced into Nigeria partway through the study and accounted for 2.6 percent of insertions during the study period. Posttraining, providers went through a facility-based accreditation process, providing implant insertions and removals under supervision. After five successful supervised insertions and two successful supervised removals of both Jadelle® and either Implanon Classic® or ImplanonNXT®, providers were qualified to insert and remove implants without clinical supervision. Postaccreditation, each provider received visits every two to three weeks from their study supervisor, supported by a MSION clinical supervisor, a quarterly visit from the State Ministry of Health, and a bi-annual visit from the Federal Ministry of Health (FMoH) and a study principal investigator. During these visits providers received study updates and, if required, additional training. MSION also implemented demand generation activities around each facility, including advocacy with local stakeholders and engagement of mobilizers (health promoters) to help promote and publicize service availability.

Client Enrolment and Data Collection

Between November 30, 2015 and November 30, 2016, all clients attending the selected facilities, aged 18–49 years, and who voluntarily chose an implant following comprehensive contraceptive counselling were invited to participate in the study. Written informed consent was obtained from all study participants by the provider. This included consent for follow-up at the clinic or by telephone. Immediately following implant insertion, the provider completed a structured questionnaire to record participants' demographic and background characteristics, and experience of any insertion-related clinical AE during and immediately postinsertion (Table 1). All AEs, including those classified as more minor events or side effects were recorded. AEs were categorized into one of three levels: (1) *Minor (side effect)*: The client experiences some level of discomfort that only requires resting or minimum level of medical intervention such as taking pain medication; (2) *Moderate (complication)*: The client experiences frequent or more severe level of discomfort that requires a medical intervention and/or expulsion of implant resulting in risk of unintended pregnancy; (3) *Major/critical (complication)*: Major injury leading to long-term incapacity/disability and requires hospitalization and/or results in fatality, or expulsion of implant resulting in pregnancy.

Women were invited to return for follow-up two weeks postinsertion. At follow-up, they were reconsented to ensure they remained willing to participate, and providers completed a

TABLE 1 Implant insertion-related AEs recorded on day of insertion and at follow-up

Description of adverse event
Recorded on day of implant insertion
Anaphylactic reaction to the implant
Implant insertion unsuccessful on first or second attempt
Implant breaks
Palpitations resulting from the local anesthetic
Recorded at follow-up
Expulsion of implant
Paresthesia due to neural damage (numbness, tingling, tickling, pricking, or burning sensation at implant site)
Pain post procedure for >1 week and requires further outpatient observation and medical intervention.
Infection: local redness swelling
Infection: Discharge
Infection: Fever
Scarring
Recorded on day of implant insertion and at follow-up
Hematoma / bruising requiring medical intervention
Bleeding around the insertion site
Other adverse reaction requiring medical treatment or resulting in long-term incapacity or fatality

structured questionnaire to record all AEs experienced since insertion. Women who did not return to the clinic were followed-up by phone by the provider, with up to three attempts made.

Clinical supervisors visited every provider within the first month following training (accreditation), then again one, two, three, and six months post-accreditation to assess the quality of implant insertions. Visits lasted one to two days, during which all implant insertions were observed and data on quality recorded (Reiss et al. 2018). They used a 28-item checklist (Online Appendix T1) to record competence in preinsertion counselling, preinsertion preparation, insertion technique, postinsertion procedures, and counselling. An overall score of 28/28 was defined as high quality. Supervisors also conducted client satisfaction exit interviews among a subsample of participants. Women were considered highly satisfied if they rated seven aspects of care as "good" or "very good" (Online Appendix T2).

Outcome Measurement

We had two primary outcomes for this study: (1) insertion-related moderate or severe AEs at the time of insertion, and (2) insertion-related moderate or severe AEs overall, measured at the time of insertion and at follow-up. Secondary outcomes were (1) quality of implant insertions observed by clinic supervisors, and (2) client satisfaction with implant insertion measured through client exit interviews.

Sample Size and Noninferiority

This was a noninferiority study designed to assess whether the proportion of insertion-related moderate/severe AEs among CHEW clients was not higher than a specified amount than the proportion of moderate/sever AEs among nurse/midwife clients. Insertion-related AEs are rare and based on outcome data from clinical trials (Reiss et al. 2018; Meirik et al. 2013), and agreement of the research team, we assumed a base rate of 0.5 percent for moderate/severe AEs among clients of nurse/midwives on the day of insertion. The noninferiority margin, or predetermined benchmark of acceptable difference between the two groups for the day of implant insertion was set at 0.5 percent. In other words, we consider that CHEWs are

noninferior to nurses/midwives if the upper confidence bound of the difference in AE rates (CHEWS – nurse/midwives) is not higher than 0.5 percent.

In the absence of any data on moderate/severe insertion related AEs at follow-up, we assumed a base rate of 1 percent at follow-up, with a noninferiority margin of 1 percent. We combined data from the day of insertion and follow-up to give a total complications score.

The target sample size required to measure moderate/severe AEs on the day of insertion assuming a noninferiority margin of 0.5 percent, 80 percent power, 95 percent confidence, a design effect of 1.5 (for clustering by provider), and 10 percent incomplete records was 8,125. The target sample size for the same outcome at follow-up, assuming a noninferiority margin of 1 percent and a loss to follow-up of 20 percent, was 4,410.

To assess the quality of insertions, we assumed 80 percent would be rated *good* based on Marie Stopes International's (MSI's) previous quality audits with nurses in multiple countries, with a noninferiority margin of 10 percent. We assumed that the noninferiority margin referred to a difference in proportions, meaning that if the lower 95 percent confidence limit for the difference in proportions is −0.10 or greater, then we can conclude that CHEWs are noninferior to nurse/midwives in terms of quality.

Data Analysis

We used Stata software version 15 (StataCorp 2017) for the statistical analyses. All analyses were adjusted for clustering by provider. Outcomes were analyzed using Generalized Estimating Equations (GEE) models where nested models were compared using Wald tests. Covariates were excluded from the models where they were not statistically significant at the 5 percent level and when data were too sparse to support more complicated models. Effect modification was examined for several key covariates (state, facility type, implant type, in-study insertion experience). Due to a large variation in the timing of follow-up visits (which were beyond the study team's direct control), we extended the follow-up interval from two weeks to include data up to 75 days postinsertion.

For the primary outcomes, noninferiority was assessed by modeling odds ratios (OR) rather than risk differences. Since the AEs rates were so low the odds is a very close approximation to the risk difference. Assuming a prevalence of moderate/severe AEs among nurses/midwives of 0.5 percent on the day of insertion, and a risk difference of no more than 0.5 percent, the corresponding noninferiority margin expressed as an odds ratio is 2.01. Assuming prevalence of moderate/severe AEs of 1 percent by day 14 (follow-up), the corresponding odds ratio margin is 2.02. For the secondary outcome—quality of insertions—proportions were within the range where it is reasonable to assume linearity and so difference in proportions was modeled directly using GEE rather than converting to odds ratios.

We examined background characteristics and differences between CHEW clients and nurse/midwife clients among all those with complete primary outcome data for the day of insertion. Simple proportions and frequencies for categorical variables and means for continuous variables are shown. We then compared insertion-related AEs among clients of each provider at the time of insertion, and overall. We present proportions reporting specific AEs as well as an overall AE prevalence for each provider, with unadjusted odds ratios and 95 percent confidence intervals (CIs) for comparison. For the multivariate analysis, we

investigated several potential confounders. Contributions to the model fit were assessed using Wald tests. Variables were included in the model if the *p*-value was <0.05, or if there was evidence of confounding whereby the estimated effect (nurses/midwives vs. CHEWs) changed by 10 percent or more. Provider level co-variates were state, rural location of facility, facility type (BHU/small hospital vs. tertiary hospital), number of in-study insertions conducted by provider, and other provider present at facility. Individual client characteristics were age, number of living children, education, marital status, previous family planning use, brand of implant, distance travelled, residential location, household drinking water source (proxy for household poverty), and employment status. We conducted stratified analyses to assess potential effect modification by selected individual and contextual characteristics listed above. Effect modification was considered statistically significant if the interaction term *p*-value was <0.05. We found some effect modification by state and adjusted the final model. Models were sensitive to choice of variables, likely due to the small number of AEs.

Missing Data

The multivariate analyses to assess insertion-related AEs occurring on (1) the day of insertion and (2) overall, (on the day of insertion and at follow-up), were conducted on all observations with complete data for covariates. On the day of insertion, 98 observations or 1.3 percent of observations from each cadre (53 nurse/midwife clients; 45 CHEW clients) had missing data for at least one of the variables included in the final model (implant brand, number of previous in-study insertions, and employment status) and were excluded from the analysis. Excluded observations did not include any AEs. For the combined outcome, there were no missing observations.

Sensitivity Analyses

We conducted four sensitivity analyses (Online Appendix T4 and T5) by repeating the primary analyses while excluding or including selected subgroups to determine if they had an inordinate effect on the estimated measure of effect, and noninferiority margin. Three of these sensitivity analyses were predetermined, and one was data driven. The latter excluded *outlier* providers, or those with relatively high rates of AEs; defined as a provider with more than 10 AEs, or above the 25 percentile for AEs, with more than five expulsions, or above the 25 percentile for expulsions. We conducted three sensitivity analyses to investigate how best to address issues with missing or incomplete data, and these included (1) exclusion of observations with low-quality insertions; (2) exclusion of observations with low-quality follow-up dates; (3) inclusion of observations with less than half missing outcome components, and inclusion of observations with any missing outcome components.

Supervision and Safety Monitoring

During study implementation supervisors visited all providers every two to three weeks to provide study and clinical support. Study participants were encouraged to return to the facility if they had concerns or experienced any AEs. The study followed standard FMoH/MSION management and reporting protocols requiring immediate reporting to the clinical services manager of severe and moderate AEs, and within 24 hours for minor events. The clinical

services manager was responsible for ensuring effective management of AEs, and that all AEs were reported to the study manager. Severe AEs were reported to MSI's Medical Development Team in London within 24 hours.

Ethics

Ethical approval was obtained from MSI's Ethics Committee, National Health Research Ethics Committee of Nigeria and the Population Council Institutional Review Board. This study is registered with ClinicalTrials.gov, number NCT03088722.

RESULTS

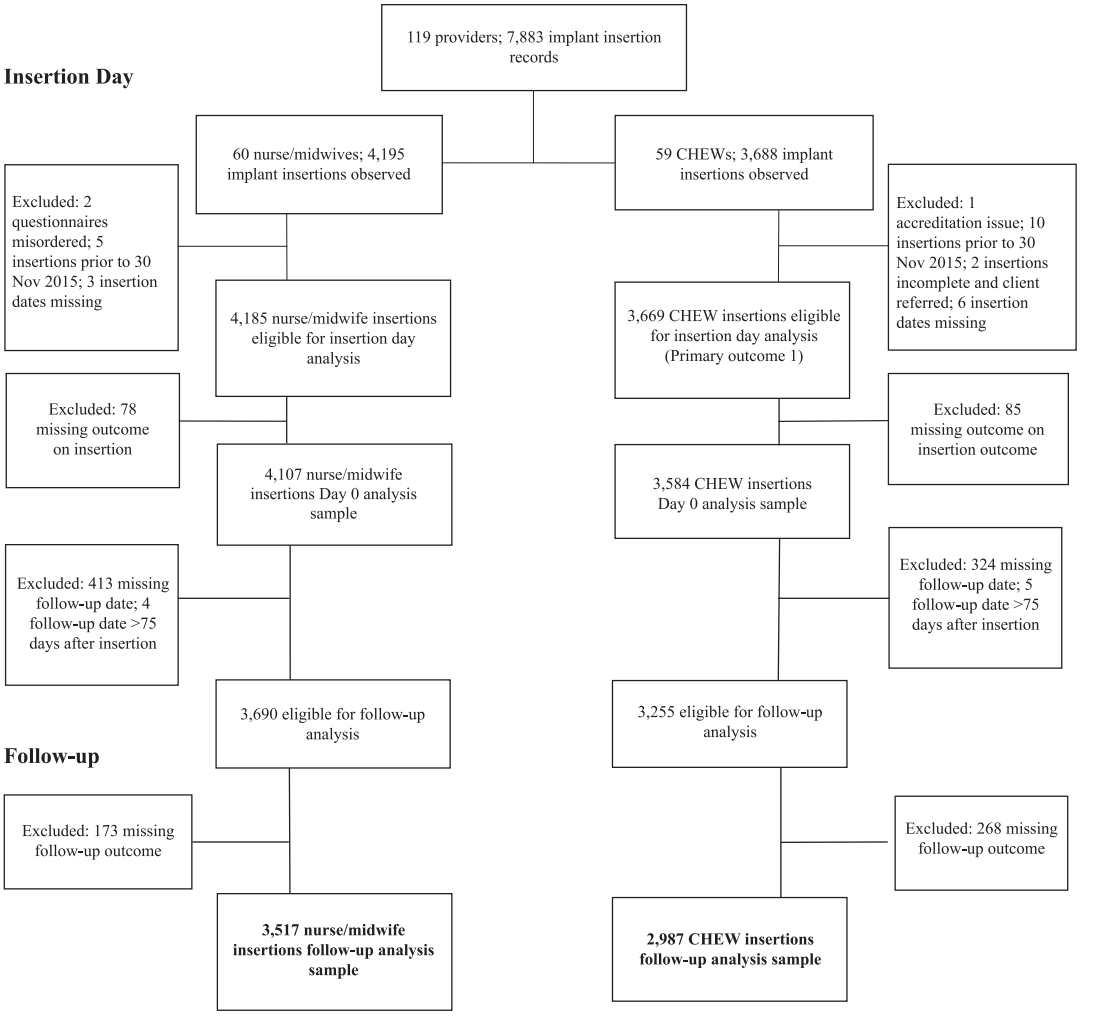
One hundred and nineteen providers (60 nurse/midwives; and 59 CHEWs) across 93 health facilities took part in the study between November 30, 2015 and November 30, 2016. In total, they inserted 7,883 implants (4,195 nurse/midwife clients; and 3,688 CHEW clients). Figure 1 shows the flow of insertion clients by provider included in this analysis. Of the total number of clients, 2.1 percent nurse/midwife clients and 2.8 percent CHEW clients were excluded from analysis of AEs occurring on the day of insertion, mostly due to missing information on the primary outcome. Complete data on AEs occurring on the day of procedure were available for 4,107 nurse/midwife clients and 3,584 CHEW clients ($N = 7{,}691$). Of these 3,517, or 85.6 percent of nurse/midwife clients and 2,987, or 83.3 percent of CHEW clients were successfully followed up within 75 days ($N = 6{,}504$). In total 15.5 percent of respondents included in analysis of AEs at the time of insertion were lost to follow-up due to problematic follow-up dates or missing AE outcome at follow-up (see Figure 1). This included a total of 590 (14.4 percent) of nurse/midwife clients and 597 (16.7 percent) of CHEW clients. Of those lost to follow-up due to problematic follow-up dates ($N = 746$), there were 11 AEs: two among nurse/midwife clients and nine among CHEW clients. Those lost to follow-up were significantly more likely to be CHEW clients compared to nurse/midwife ($p = 0.001$); urban compared to rural (19.3 percent vs. 11.9 percent; $p \leq 0.001$); from Ondo compared to Kaduna State (20.0 percent vs. 10.8 percent; $p \leq 0.001$); primary educated compared to secondary (17.1 percent vs. 13.8 percent; $p \leq 0.001$); employed compared to unemployed (16.4 percent vs. 13.3 percent; $p \leq 0.001$); and had chosen to use Implanon® compared to Jadelle® (16.4 percent vs. 14.3 percent; $p \leq 0.05$). Loss to follow-up did not vary significantly by distance to facility, age of respondent, or type of facility.

For the secondary outcome (quality of implant insertion), all providers were observed at least once. This comprised observations of 1,064 nurse/midwife clients and 781 CHEW clients. The analysis sample comprised 883 (83 percent) observations from 54 nurse/midwives and 537 (69 percent) observations from 50 CHEWs across 86 facilities (see Figure 2). Incorrect date of implant observations was the main reason for exclusion of observations from the analysis (164 nurse/midwife clients and 210 CHEW clients).

Background Characteristics

Table 2 presents data at the provider level. Providers were equally distributed by state and urban/rural location, but CHEWs were significantly more likely to be based at a BHU than

FIGURE 1 Study flow chart for AEs (primary outcome)



nurse/midwives (93.3 percent vs. 64.4 percent; $p \leq 0.001$) and less likely to work alone (53.3 percent vs. 61.0 percent; $p \leq 0.001$). The mean number of insertions conducted during the study was significantly lower among CHEWs compared to nurse/midwives (54.3 vs. 62.5; $p = 0.040$). Table 3 presents data on client's background, by provider. The mean age of clients was 30 years with little difference between CHEW and nurse/midwife clients; they had four children on average (4.1 for CHEW vs. 3.7 for nurse/midwife clients; $p \leq 0.001$); and almost all were married. Compared to nurse/midwife clients, CHEW clients were less educated (57.6 percent had primary or less vs. 47.6 percent; $p \leq 0.001$), more likely to be unemployed (38.6 percent vs. 29.8 percent; $p \leq 0.001$) and to live in a household without access to treated water (31.9 percent vs. 17.3 percent; $p \leq 0.001$). CHEW clients were also less likely to want to limit their number of children (26.4 percent vs 34.8 percent; $p \leq 0.001$), and significantly more likely to be nonusers of modern contraceptive methods in the previous three months (70.8

FIGURE 2 Study flow chart for insertion quality

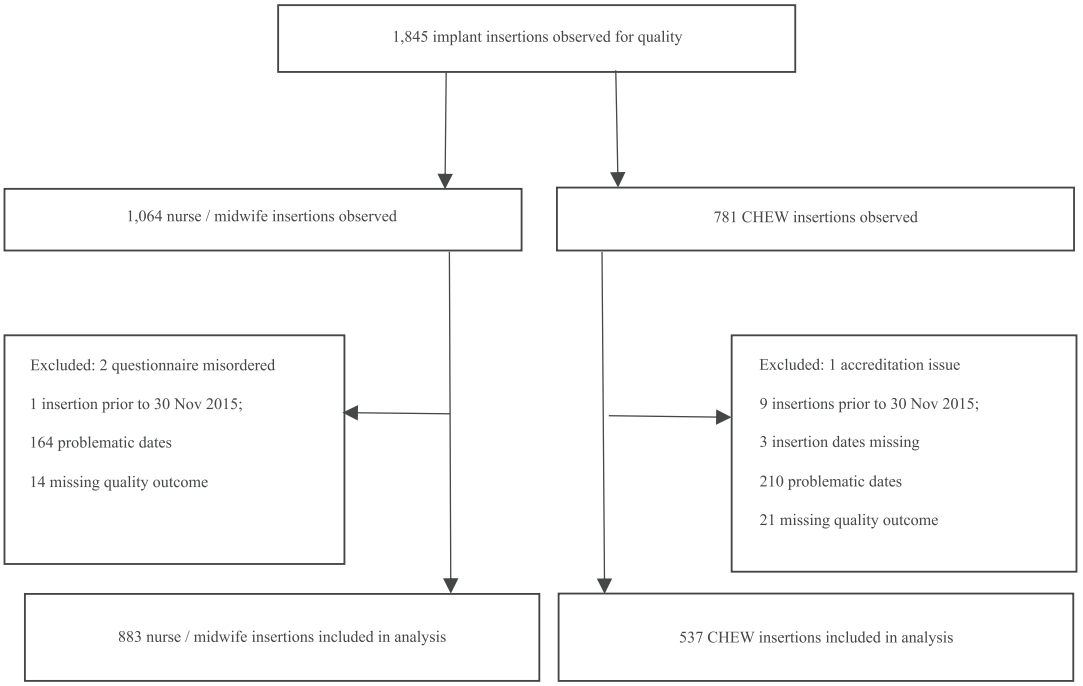


TABLE 2 Characteristics of newly trained providers and facilities included in the study in Kaduna and Ondo States, Nigeria

Characteristic of facility and provider	Total (%) ($N = 119$)	Nurse/midwife clients (%) ($N = 60$)	CHEW clients (%) ($N = 59$)	*p*-value
State (% in Kaduna)	49.6	49.2	50.0	0.926
Facility location (% rural)	51.3	50.9	51.7	0.929
Facility type (% basic health unit)	79.0	64.4	93.3	≤0.001
Other providers on site (% working alone)	57.4	61.0	53.3	≤0.001
Implant insertions during study (mean & range)	58.4	62.5 (6-189)	54.3(3-107)	0.040

percent vs. 62.9 percent; $p \leq 0.001$). They were also less likely to receive the longer-acting Jadelle® implant (43.0 percent vs. 50.8 percent; $p \leq 0.001$) compared to nurse/midwife clients.

Primary Outcome: Insertion-Related AEs

No major/critical complications were recorded during the study. Table 4 shows moderate and severe AEs on the day of insertion were rare. Overall 40 clients reported 48 specific AEs occurring on the day of insertion. All results are adjusted for clustering by provider, showing an overall percentage of 0.46, and 0.51 percent among CHEW clients' vs. 0.41 percent among nurse/midwife clients. In the crude analysis, the odds ratio is 1.27 (95 percent CI 0.31-5.14). After adjustment for provider's previous in-study insertion experience, implant brand, and

TABLE 3 Client background characteristics by cadre (nurse/midwife or CHEW) among those with complete primary outcome data for insertion-related AEs occurring on day of insertion in Kaduna and Ondo States, Nigeria

Client characteristics	Total (%) ($N = 7,691$)	Nurse/midwife clients (%) ($N = 4,107$)	CHEW clients (%) ($N = 3,584$)	*p*-value
Age (mean years)	30.1	30.4	29.8	0.008
Missing (*n*)	(*43*)	(*22*)	(*21*)	
Marital status (% married)	97.6	97.3	98.0	0.040
Missing (*n*)	(*26*)	(*13*)	(*13*)	
Number of children (mean)	3.9	3.7	4.1	≤0.001
Missing (*n*)	(*84*)	(*49*)	(*35*)	
Fertility intentions (% limiting)	31.1	34.9	26.8	≤0.001
Missing (*n*)	(*92*)	(*42*)	(*50*)	
Education (% primary or less)	51.2	46.3	56.8	≤0.001
Missing (*n*)	(*65*)	(*46*)	(*19*)	
Occupation (% unemployed)	33.0	28.5	38.2	≤0.001
Occupation (% manual/agricultural)	30.8	33.5	27.8	≤0.001
Occupation (% sales/services/clerical)	25.6	26.7	24.4	0.024
Occupation (% professional/student)	10.5	11.3	9.5	0.012
Missing (*n*)	(*76*)	(*42*)	(*34*)	
Wealth (% without treated water source)	24.1	17.3	31.9	≤0.001
Missing (*n*)	(*60*)	(*33*)	(*27*)	
Modern FP use (% not using in last 3 months)	66.5	62.9	70.8	≤0.001
Missing (*n*)	(*110*)	(*51*)	(*59*)	
Implant brand inserted (% Jadelle®)	47.2	50.8	43.0	≤0.001
Missing (*n*)	(*30*)	(*42*)	(*50*)	

client's employment status (unemployed vs. employed) the odds ratio falls to 0.92 (95 percent CI 0.38-2.23). (Table 5). Other potential confounders mentioned in the methods were explored during the analysis and were found to have no or negligible effect on estimates. These included rural location of facility, facility type (BHU/small hospital vs. tertiary hospital), and individual client characteristics such as age, number of living children, education, marital status, previous family planning use, brand of implant, distance travelled, household drinking water source (proxy for household poverty), and employment status.

Of those followed up ($N = 6,504$), 255 clients experienced at least one AE at insertion and/or follow-up (overall prevalence of 4.27 percent) (Table 4). These 255 reported 317 AEs in total occurring between insertion and follow-up. The most common was implant expulsion (overall prevalence of 3.15 percent; 5.24 percent among CHEW clients; 1.15 percent among nurse/midwife clients). CHEW clients were more likely to report all types of AEs, except scarring, and reported an overall higher prevalence of AEs than nurse/midwife clients (6.6 percent vs 2.1 percent; crude odds ratio [cOR] 3.17, 95 percent CI 1.32-7.57, $p = 0.010$) (Table 4).

Further analysis of the combined AEs outcome showed some evidence of effect modification by state. Results in Table 5 show the striking difference in AEs by provider in each state. Of the total 255 AEs reported, 203 occurred in Kaduna State, of which 160 occurred among CHEW clients. In the final adjusted model stratified by state, CHEW clients in Kaduna experienced an elevated odds of AEs compared to nurse/midwife clients (adjusted

TABLE 4 Comparison of implant insertion-related AEs by cadre among clients with complete primary outcome data for day of insertion, and insertion-related AEs occurring on day of insertion and up to 75 days later, Kaduna and Ondo States, Nigeria[a]

	Total ($N = 7,691$)		Nurse/midwife clients ($N = 4,107$)		CHEW clients ($N = 3,584$)			
Moderate or Severe AE[b]	**AEs**	**%**	**AEs**	**%**	**AEs**	**%**	**cOR**	**95% CI**
At least one AE occurring on day of insertion	**40**	**0.46**	**19**	**0.41**	**21**	**0.51**	**1.27**	**0.31–5.14**
Specific AEs occurring at insertion								
Bruising or hematoma	27	0.30	15	0.30	12	0.30	0.97	0.15–6.40
Bleeding around insertion area	19	0.24	8	0.18	11	0.31	1.69	0.45–6.40
Implant breaks	1	0.01	0	0.0	1	0.03	–	–
(Other) Oedema	1	0.01	0	0.0	1	0.03	–	–
Implant insertion with follow-up	**($N = 6,504$)**		**($N = 3,517$)**		**($N = 2,987$)**			
At least one AE occurring on day of insertion	**32**	**0.42**	**18**	**0.44**	**14**	**0.40**	**0.90**	**0.20–4.07**
Specific AEs occurring at insertion								
Bruising or hematoma	22	0.27	14	0.32	8	0.22	0.69	0.08–5.69
Bleeding around insertion area	14	0.21	7	0.19	7	0.23	1.23	0.33-4.58
Implant breaks	1	0.02	0	0.0	1	0.03	–	–
(Other) Oedema	1	0.02	0	0.0	1	0.03	–	–
At least one AE occurring up to 75 days after insertion	**233**	**3.98**	**64**	**1.77**	**169**	**6.31**	**3.57**	**1.41–9.07**
Specific AE occurring up to 75 days after insertion								
Pain around insertion site	31	0.46	14	0.34	17	0.59	1.74	0.38–8.03
Bruising or hematoma	6	0.10	4	0.05	2	0.16	3.42	0.27–42.93
Post insertion bleeding	4	0.07	1	0.03	3	0.11	3.95	0.30–52.27
Infection	13	0.22	3	0.09	10	0.36	3.85	0.79–18.55
Paraesthesia	9	0.15	3	0.09	6	0.21	2.24	0.43–11.88
Scarring	23	0.35	16	0.45	7	0.25	0.56	0.19-1.70
Expulsion	182	3.15	40	1.15	142	5.24	4.54	1.41–14.58
Occurring on day of insertion or follow-up	**255**	**4.27**	**76**	**2.08**	**179**	**6.58**	**3.17**	**1.32–7.57**
Bruising or hematoma	24	0.31	10	0.32	14	0.30	0.95	0.14–6.56

[a] All results are adjusted for clustering by provider
[b] None of the following AEs were reported, anaphylactic reaction, palpitations.

odds ratio [aOR] 3.34, 95 percent CI 1.53-7.33). In Ondo State, CHEWs compare favorably with nurse/midwives (cOR 0.79, 95 percent CI 0.37–1.68), but after adjustment for previous in-study insertion experience, and other providers at the facility, there was no evidence that CHEWs were noninferior to nurse/midwives (aOR = 0.72, 95 percent CI 0.19–2.72) as the upper bounds of the 95 percent confidence limit exceeded the noninferiority margin of aOR 2.02 (Table 5). Further analysis showed AEs fell with increased in-study insertion experience for both providers in both states (Figure 3).

Sensitivity Analyses

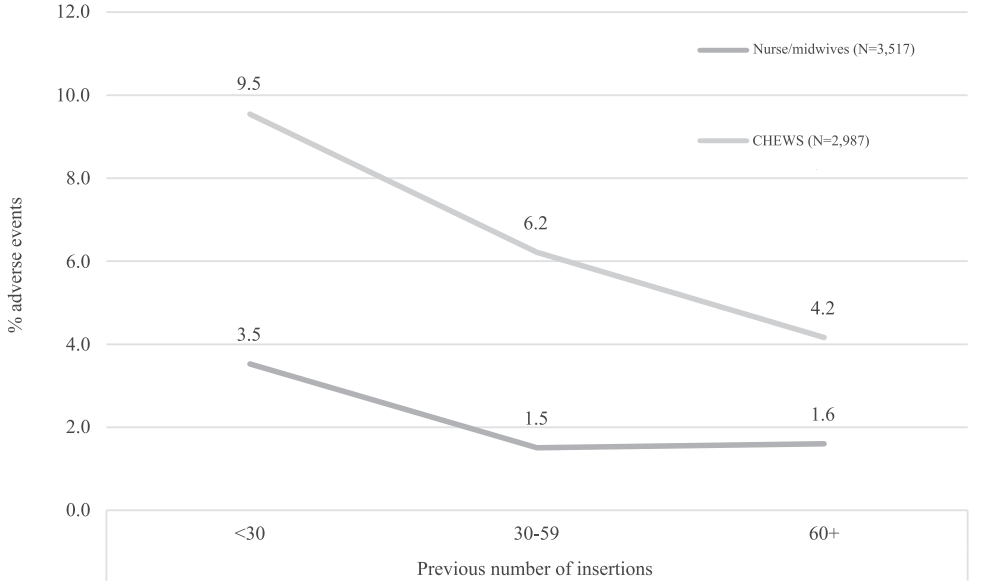
Several individual CHEWs in Kaduna were associated with relatively high rates of moderate or severe AEs (see Online Appendix T3). Elevated levels of AEs are defined earlier in the methods section. To determine whether providers with elevated levels of AEs had an inordinate effect on the estimated measure of effect, we repeated the primary analyses for both outcomes, excluding providers with elevated levels of AEs, and stratifying by state for both primary outcomes (see Online Appendix T4 and T5) In most scenarios when providers with elevated AEs were excluded from the analysis, there remained no evidence that CHEWs were

TABLE 5 Comparison of implant insertion-related AEs by cadre among clients with complete primary outcome data for day of insertion, and overall (day of insertion and at follow-up), in Kaduna and Ondo States, Nigeria

		Unadjusted[a]					Adjusted		
		N	AEs	%	OR	95% CI	*N*	OR	95% CI
Day of insertion									
	Nurse/midwives	4,107	19	0.41	1.00		4,054	1.00[b]	–
	CHEWs	3,584	21	0.51	1.27	0.31-5.14	3,539	0.92	0.38–2.23
Day of insertion and at follow-up combined									
Ondo state	Nurse/midwives	1,786	33	1.85	1.00	–	–	1.00[c]	–
	CHEWs	1,314	19	1.46	0.79	0.37–1.68	–	0.72	0.19–2.72
Kaduna state	Nurse/midwives	1,731	43	2.39	1.00	–	–	1.00[c]	–
	CHEWs	1673	160	12.01	5.03	1.53–16.54	–	3.34	1.53–7.33

[a] Adjusted for clustering by provider.
[b] Multivariate model adjusts for clustering by provide, implant brand, previous in-study insertion experience, employed status
[c] Multivariate model adjusts for clustering by provider, previous in-study insertion experience, other provider at facility and CHEW##state interaction

FIGURE 3 Comparison of implant insertion-related AEs by in-study implant insertion experience, by provider among clients with complete primary outcome data for day of insertion & follow-up



noninferior to nurse/midwives—in other words, the upper bounds of the 95 percent confidence limit remained greater than the noninferiority margin of 2.01 or 2.02. The exception to this was for the combined outcome in Ondo State where the upper bound of the 95 percent confidence limit decreased to 1.95 for CHEWs versus nurses/midwives, when provider 2109 was excluded (see Online Appendix T5 Primary outcome 2, Sensitivity Analysis 1). This is accompanied by a reduction in aOR in Kaduna State, from OR = 3.34 to OR = 2.70, which is expected because the excluded provider was a CHEW from Kaduna. This analysis provides some (weak) evidence that CHEWs could be considered noninferior to nurses/midwives in Ondo State. Several additional sensitivity analyses were conducted for both primary

outcomes. In every scenario, the upper confidence limits remained greater than the noninferiority margin of 2.01 or 2.02 (see Online Appendix T4 and T5) implying that the results are robust to the methods for dealing with missing/incomplete data because the upper 95 percent CI remains above the threshold.

Secondary Outcomes

Quality of Implant Insertion and Client Satisfaction

Table 6 shows the results for the secondary outcomes—quality of insertions observed by the clinic supervisors (see Online Appendix T1 for quality checklist), and client satisfaction, measured through client exit interviews (see Online Appendix T2). Unadjusted results are adjusted for clustering on provider. Overall 70 percent of insertions scored 28 out of 28 in quality assessments defined here as good quality (67 percent among CHEWs and 73 percent among nurse/midwives). Providers in Ondo—both CHEWs and nurse/midwives—were more likely to score 28 out of 28 in quality assessments compared to providers in Kaduna. In the crude analysis, the proportion of CHEWs rated good was 6.2 percent lower than nurse/midwives, with a 95 percent confidence interval of −21.6 percent to 9.3 percent. In the adjusted analysis the difference in proportion of good quality CHEWs compared to nurses/midwives fell to 4.8 percent with a 95 percent confidence interval of −15.2 percent to 5.5 percent, but the lower bounds of the 95 percent confidence interval was below the noninferiority margin of −10 percent, so we cannot conclude that insertion quality for CHEWs was noninferior to nurses/midwives.

Sixty-three percent of nurse/midwife clients were highly satisfied with the experience of implant insertion compared to 56.2 percent of CHEW clients (Table 6), meaning that they rated all seven satisfaction components as "good" or "very good" (see Online Appendix T2). After adjusting for state, other provider at facility, urban/rural location, and type of facility, there was insufficient evidence of a difference in the proportion of highly satisfied CHEW clients vs. nurse/midwife clients (0.15 percent, 95 percent CI −0.160 to 0.163; $p = 0.985$) (Table 6). We did not assess noninferiority for satisfaction. Almost all clients (99.3 percent) said they would recommend the service to a friend.

DISCUSSION

This analysis, using data from 7,691 women, assessed whether CHEWs can insert implants to the same safety and quality standards as nurses and midwives in Kaduna and Ondo States in Nigeria. The primary outcome focused on insertion-related moderate and severe AEs during or shortly after implant insertion. Although moderate and severe AEs were rare, we were unable to conclude that CHEWs were noninferior to nurse/midwives because the upper limit of the adjusted 95 percent confidence interval exceeded the noninferiority margin of 2.01 (aOR 0.92; 95 percent CI 0.38–2.23), although the difference between the two groups overall was not statistically significant. While AEs were rare, CHEW clients experienced an increased odds ratio of AEs by the time of their follow-up visit, the main driver of which was high expulsion rates. The observed expulsion rate of 3.15 percent overall and 5.24 percent among CHEW clients is far higher than rates reported elsewhere: a rate of 0.0 percent–0.6 percent

TABLE 6 Secondary outcomes: Comparison of "good quality" implant insertions as observed by supervisors, by cadre, stratified by state, and "highly" satisfied clients by cadre

		Unadjusted[a]			Adjusted[b]		
Quality of implant insertion	***N***	**Good quality**	**Proportion**	**Difference in proportions[c]**	**95% CI**	**Difference in proportions[c]**	**95% CI**
Combined							
Nurse/midwives	883	703	0.73	0.00	–	0.00	–
CHEWs	537	366	0.67	−0.06	−0.216 to 0.093	-0.05	−0.152 to 0.055
Ondo State							
Nurse/midwives	612	576	0.94	0.00	–		
CHEWs	338	291	0.83	−0.10	−0.211 to 0.005		
Kaduna State							
Nurse/midwives	271	127	0.47	0.00	–		
CHEWs	199	75	0.45	−0.02	−0.289 to 0.249		
Client satisfaction		Highly satisfied				Adjusted[d]	
Nurse/midwives	383	246	0.63	0.00	–	0.00	–
CHEWs	366	197	0.56	-0.07	−0.235 to 0.105	0.002	−0.160 to 0.163

[a] Adjusted for clustering by provider.
[b] Adjusted for state and in-study insertion experience.
[c] Difference = (CHEWs – nurse/midwives) where a positive value corresponds to a higher proportion for CHEWs
[d] Adjusted for state, other provider at facility and urban/rural location and facility type.

of spontaneous expulsion without infection (Brache et al. 2002; Ramdhan et al. 2018). While infection can lead to implant expulsion (Ramdhan et al. 2018), we found little evidence of this in our study, with infection rates of 0.36 percent among CHEW clients and 0.09 percent among nurse/midwife clients, in line with rates of 0.2–1.4 percent reported elsewhere for Jadelle® (Brache et al. 2002).

The causes of the high expulsion rates are not fully understood. Poor surgical technique, superficial implant insertion, and/or poor counselling may have played a role. Anecdotal evidence from early on in the study linked implant expulsion to heavy lifting, and increased attention was given to counselling women to avoid heavy lifting in the first 48 hours after insertion. We could not conclude that the quality of CHEW care was noninferior to nurses/midwives, although the difference in quality between the two groups overall was not statistically significant. With fewer years of training, and less overall clinical experience, CHEWs may well be less skilled compared to nurse/midwives. The expulsion problem was concentrated in seven poor performing CHEWs (see Online Appendix T3). The AE models were sensitive to the inclusion or exclusion of CHEWs with elevated rates of AEs, but exclusion of providers with elevated AEs did not change our overall conclusions. While all providers completed an accreditation process prior to initiating study enrolment, our data show that in-study insertion experience played a critical role, since the expulsion rate fell with increased insertion experience through the study (Figure 3). While implant expulsion does not constitute a serious clinical complication, it is potentially unpleasant or painful, puts the client at renewed risk for pregnancy and is likely to require additional visits with a health provider. This result indicates that greater attention to provider accreditation and supervision is essential to ensure the safety of this service delivery mechanism. Screening may also be needed to ensure only those with sufficient clinical competency are selected to undergo training on this method.

The poorer quality of care observed in Kaduna versus Ondo State is also of concern. Kaduna is more rural and economically poorer than Ondo, and like many of Nigeria's more northern states may benefit from the new LARC task-sharing policy. It is therefore imperative that future expansion of implant provision by CHEWs in these states is adequately supervised and quality assured. Failure to adequately assure quality in such services may also have longer-term detrimental effects on efforts to promote and sustain family planning in these settings: fears about the health impacts of contraception are a well-evidenced barrier to uptake (Ajayi, Adeniyi, and Akpan 2018), and studies indicate that certain elements of quality can influence contraceptive behavior (Jain et al. 2014; Fruhauf et al. 2018; RamaRao et al. 2003).

This is, to our knowledge, the largest clinical study to-date of implant provision conducted in a *real-life* service provision context in a low-income setting, albeit with additional supervision and monitoring activities in place. Study findings shed light on the challenges of both training through a cascade approach, and in assuring quality, particularly in remote regions. Findings have important implications for wider quality improvement processes throughout public and private service delivery networks and demonstrate the need to regularly follow-up women postservice delivery to monitor clinical outcomes, including implant or IUCD expulsions. Observing our outcomes in remote locations, however, meant restrictions on study design and consequent limitations which must be considered. First, the observational design implies potential selection bias; while we attempted to control for

confounding between groups, there is likely still unmeasured confounding in the sample, particularly because the CHEW and nurse/midwife cadres are designed to reach different areas and client types. For example, we lacked poverty probability index data and relied on a proxy measure of wealth—source of household drinking water—when assessing the effects of wealth in our models. Second, the CHEWs included in our study were not representative of all CHEWs in these states. They were required to have three years training, were a senior CHEW cadre, and were selected based on communication competency. Third, reporting bias is likely since AE data were collected by providers themselves. It is likely that CHEWs could have reported events differentially to nurses/midwives—overestimating events if less skilled or experienced to deal with AEs, or underestimating due to fear of negative consequences. Fourth, the attrition of providers through the research process may have led to underreporting of AEs because those with the poor data quality may have also experienced elevated AEs. Fifth, quality data collected by supervisors may have been biased by the fact that the groups of supervisor observers differed by state; since the indicators included were partially subjective, this may also help to explain why scores were so different in the two states. Finally, the calculation of noninferiority margins assumed a "true" prevalence of AEs among nurse/midwives of 0.5 percent at insertion. In our sample, the prevalence was closer to 0.4 percent. This prevalence would imply in turn a noninferiority margin of OR = 2.26 (vs. the 2.01 assessed). While this would not affect conclusions from the primary analysis for all AEs, this revised upper margin would lead to a different conclusion, that is, that there is evidence that CHEWs are noninferior to nurse/midwives on the day of insertion (aOR: 0.92; 95 percent CI 0.37–2.23; $p = 0.848$). Since the "true" prevalence among nurses/midwives remains unknown, we could not justify basing our conclusions on the higher margin of OR 2.26 rather than OR 2.01.

In conclusion, our study shows the feasibility of training CHEWs to deliver LARCs in remote, rural regions in low-income countries, but family planning programs must pay greater attention to provider selection, accreditation, training, and supervision procedures to ensure quality and safety of provision. The challenges identified in this study may also be exacerbated in situations where other health programs are also using task sharing as a scale-up mechanism, and there remains an important risk that CHEWs (or equivalent) become overburdened with increasing complexity of work at the primary care level (Schaefer 2015). Also, successful task sharing of implants requires enough client demand for providers to maintain competency and confidence (Schaefer 2015) —a possible challenge in remote, rural settings, such as northern Nigeria. Our intervention involved substantive demand generation activities that provided sufficient client flow for the study, and the fact that quality improved with insertion experience demonstrates that task sharing and demand generation must go hand in hand. The study also importantly demonstrates the need for programs to conduct regular postservice follow-up of implant provision to assess postservice outcomes such as expulsion, in particular in rural regions with known quality concerns. This is also likely to be recommended for IUCD provision too, where expulsion is known to be a common clinical outcome (Jatlaoui, Riley, and Curtis 2017; Madden et al. 2014), yet understudied in low-income settings. If these types of quality assurance are followed, task sharing of implant provision to clinically trained community health workers can still be a powerful intervention to support national governments achieve scale in delivery of LARCs in settings with high unmet need for family planning.

CONFLICT OF INTEREST

MD, OA, KO, AT, EU, KC, JF, KR, are EM are or have been employed by MSI Reproductive Choices or MSI Nigeria. MSI Nigeria receives contracts from international donors to deliver implant training to public sector providers in Nigeria. KA and AUU are or were employed by the Federal Ministry of Health of Nigeria, and have responsibility for the delivery of contraceptives within the national health system.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publically available due to privacy and/or ethical restrictions.

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