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Feasibility of patent and proprietary medicine vendor provision of injectable contraceptives: preliminary results from implementation science research in Oyo and Nasarawa, Nigeria

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ABSTRACT

Background: Nigerian policymakers are debating task-shifting injectable contraceptive services to Patent and Proprietary Medicine Vendors (PPMVs).
Methodology: One hundred fifty-two PPMVs were trained to provide injectable contraceptives in Oyo and Nasarawa states. Data were collected before and 1, 3 and 9 months posttraining. χ^2 tests were conducted to assess associations between survey time points.
Main findings: Few PPMVs had the necessary knowledge to provide injectables pretraining. A majority demonstrated increased knowledge after the training. Knowledge required for screening and counseling clients was lower than knowledge on administration.
Conclusion: PPMVs should be trained before providing injectable services. Additional research is needed on the benefits of job aids for screening and counseling.

1. Introduction

Only 10% of married women age 15–49 use modern contraceptives in Nigeria [1]. To increase access to family planning (FP), policymakers are debating task-shifting injectable contraceptive services to Patent and Proprietary Medicine Vendors (PPMVs). PPMVs sell prepackaged, over-the-counter medications and are widespread throughout rural and urban Nigeria [2]. PPMVs are not pharmacists but must be 21 years or older, obtain two references, and read and write in English [3]. Thirty-eight percent of modern contraceptive users obtain their method from PPMVs [1] because of their convenient locations, consistent drug stocks, extended operational hours, personable interactions and the lack of consultation fees [4,5].

Nigerian law restricts PPMVs from selling and administering all forms of injectable contraceptives, including intramuscular and subcutaneous forms of DMPA (DMPA-IM and DMPA-SC), and yet 13% of injectable users obtain their method from them [1]. The Federal Ministry of Health recognizes the important role PPMVs can play in improving access to contraceptive methods and added them as a distribution point of sale for DMPA-SC in the Strategic Plan for DMPA-SC Introduction and Scale-Up [6]. This plan seeks to scale-up access to DMPA-SC in all 36 states by 2021 [6]. Policy change allowing PPMVs to sell and administer injectable contraceptives could increase access to FP, especially in rural areas and for underserved populations [2,7]. Though opponents to policy change cite PPMVs' low education and lack of training, proponents argue that PPMVs, like community health workers, could administer all types of progestin-only injectables with training and support [7–9]. This paper presents preliminary results from Phase I of a longitudinal study to assess the feasibility of PPMV provision of progestin-only injectable contraceptives and client acceptability of these services. Phase II is ongoing in four additional states.

1.1. Methodology and interventions

In November 2015, 152 PPMVs from two rural and two urban local government areas in each of Oyo and Nasarawa states participated in a 5-day training facilitated by two certified FP trainers in Nigeria. The curriculum was based on validated materials developed by PATH (2014) and FHI 360 (2015) [10]. Topics included FP counseling, injectable client screening and counseling, intramuscular and subcutaneous administration of injectable contraceptives (including the reinjection grace period), commodity storage, sharps disposal, infection prevention practices and pharmacovigilance. Enrolled PPMVs were authorized to administer injectable contraceptives during the study.

Trained data collectors administered a pretraining survey at the start of the training and in-person follow-up surveys at the PPMVs' shops 1, 3 and 9 months posttraining. The follow-up surveys were identical and

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included knowledge questions from the pretraining survey and additional questions on injectable services provided since the training. Knowledge questions focused on DMPA-IM. A monitoring team comprised of the research team and federal, state and local Ministry of Health representatives visited PPMVs 1, 3 and 9 months posttraining, independent of data collection visits. The monitoring visits generally occurred before data collection visits, not on the same day. The team used a monitoring form to identify knowledge gaps and challenges and to offer feedback to PPMVs (PPMV–client interactions were not observed). PPMVs were informed when the monitoring visit would take place.

Descriptive statistics were calculated for respondent characteristics and the monitoring data. Pearson χ^2 tests were conducted to assess associations among those who had and who had not administered an injectable in their shop, and between survey time points. Data were collected on paper forms and then entered in SPSS. Data were analyzed using Stata 14 software. Ethical approval was received from the Population Council's Institutional Review Board and the Ethical Committee, College of Medicine, University of Ibadan.

2. Results

PPMVs were between 20 and 72 years old (Table 1), with a median age of 38. Most were male (69%) and had secondary education or more (90%). Fifty-four percent had administered injectables in their shop before the training and 26% previously worked in a health facility.

PPMVs' knowledge on key injectable characteristics was low before the training (Table 2). Only 33% of PPMVs named 3 or more of the 7 common side effects, and 13% named 4 or more of the 11 exclusionary health conditions for progestin-only injectable contraceptives. Forty-one percent named the five key DMPA-IM administration steps. Only 5% had heard of DMPA-SC, 3% correctly reported 13 weeks as the reinjection frequency, and 3% reported Uniject™ as the injection device for DMPA-SC. Knowledge was higher on all key indicators (p value≤.05) for those who had administered injectables before the training except for the DMPA-SC indicators and identifying four or more of the exclusionary health conditions (data not shown).

Statistically significant increases were observed in knowledge from the pretraining to 1-month survey (Table 2). Over 90% of PPMVs correctly identified the administration route and reinjection frequency for DMPA-IM and DMPA-SC. Knowledge also increased for the five key steps to ensure safe DMPA-IM administration. For instance, the proportion of PPMVs who identified "check label for expiration date" increased from 40% to 88% (p value≤.01). Significantly more PPMVs could name three or more side effects at the 1-month survey compared to pretraining (67% to 33%, respectively). Similarly, more PPMVs could recall four or more exclusionary health conditions at the 1-month survey compared to pretraining (47% to 13%, respectively).

At the 9-month survey, 83% of PPMVs had administered an injectable contraceptive to at least one client in the past 30 days: 68% had administered DMPA-IM, 45% had administered DMPA-SC, and 34% had administered Noristerat. During the 9-month monitoring visit, 99% of PPMVs were observed having a sharps disposal box. Overall, knowledge of the key injectable indicators either increased at the 9-month survey or remained the same (Table 2). There was a slight decrease of PPMVs who identified the frequency of DMPA-SC injections (99% to 92%, p value≤.05) and "wash hands" as a key administration step (84% to 50%, p value≤.01).

Table 1
Respondent characteristics pretraining (n=152)

	%
State	
Oyo	52.0
Nasarawa	48.0
Sex	
Female	30.9
Male	69.1
Age	
20–29	11.2
30–39	42.1
40–49	31.6
50+	15.3
Ethnic group	
Yoruba	52.6
Igbo	34.2
Other	13.2
Religion	
Christian	71.8
Muslim	27.0
Other	0.7
Highest educational level	
Primary school	9.9
Secondary school	57.9
More than secondary education	32.2
Previously worked in a health facility	
No	74.3
Nurse/midwife	7.0
Community health extension/worker	4.4
Auxiliary nurse/staff	2.5
Other	11.8
Years working as a PPMV	
Less than 1	2.6
1–5	19.7
6–15	44.8
16–25	26.3
More than 25	6.6

3. Discussion

Consistent with previous studies, results from Phase I showed that PPMVs are a diverse group and that many had worked in a health facility [9,11]. Half of the PPMVs had administered injectables before the training, demonstrating a demand for injectable contraceptive services from drug shops (PPMVs) that was also seen in a Nigerian [1] and Ugandan study [8]. As in another study [11], few PPMVs had the necessary knowledge to provide injectable counseling and services, although knowledge was higher among those who were already providing injectables to clients in their shop before the training. Most PPMVs gained knowledge on the key injection characteristics and DMPA-IM administration steps after the training, suggesting that training is necessary and one standardized curriculum can be used when modeled after validated materials designed for lower-level providers. While the proportion of PPMVs who correctly identified the frequency DMPA-SC decreased by seven percentage points between the 1- and 9-month surveys, most PPMVs (92%) correctly identified the frequency of DMPA-SC at the 9-month survey. In Phase II, additional analyses will look at PPMV knowledge and demonstration of the key steps for DMPA-SC safe administration.

Counseling (side effects) and screening (exclusionary health conditions) knowledge was lower than other indicators, suggesting a need for standard job aids such as FHI 360's injectable screening checklist, the World Health Organization's Medical Eligibility Criteria and the Balanced Counseling Strategy+. Job aids have been identified as effective tools to help providers remember and adhere to guidelines when used [12]. PPMVs' use of job aids is being explored in Phase II. Results from all six states will provide Nigerian policymakers with evidence to inform policy change. Further analyses will explore differences in knowledge and injectable administration by health facility experience, education and client load.

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Table 2
PPMVs' responses on administering progestin-only injectables and knowledge of injectable characteristics

	Pretraining (n=152)	1-month survey (n=152)	9-month survey (n=149)
	% of PPMVs		
Have you ever administered injectable family planning methods in your shop?	54.0	91.5**[a]	98.7**
Have administered an injectable to a client in the past 30 days?	-	70.4*	83.6*
Have administered:			
DMPA-IM	-	57.9	68.5
DMPA-SC	-	32.2*	45.0*
Noristerat	-	21.1*	33.6*
What type of injection is used to administer Depo-Provera?			
Intramuscular injection	62.5	91.5**	100.0**
What is the frequency of DMPA-IM (Depo-Provera) injections?			
13 weeks (3 months)	75.0	97.4**	100.0*
What type of injection device is used to administer DMPA-SC			
Uniject	2.6	92.1**	99.3*
What is the frequency of DMPA-SC injections?			
13 weeks (3 months)	2.6	99.3**	92.0**
Describe the steps you take when administering Depo-Provera (DMPA-IM)			
Check label for expiration date	40.1	87.5**	90.6
Wash hands	38.2	84.2**	49.7**
Expel air from syringe	27.6	52.6**	87.9**
Clean injection site with cotton soaked in methylated spirit	33.6	88.8**	100.0**
Inject drug slowly	30.0	86.8**	99.3**
What are the common side effects of progestin-only injectable contraceptives (change in menstruation, headaches, dizziness, weight gain, delayed return to fertility, decrease in sex drive, skin irritation)?			
Can name 3 or more (out of 7)	32.9	67.1**	83.2**
Can name 4 or more (out of 7)	13.8	41.5	39.6
Under what health conditions should a woman not be provided a progestin-only injectable (deep vein thrombosis, liver tumor, breastfeeding up to 6 weeks postpartum,[a] high blood pressure, diabetes with vascular complications, unexplained vaginal bleeding, multiple risk factors for cardiovascular disease, history of stroke, worsening migraines, rheumatic disease such as lupus, history of breast cancer, history of stroke)?			
Can name 4 or more (out of 11)	13.2	47.4**	50.3
Can name 5 or more (out of 11)	9.21	35.5**	32.2

* p value≤.05.
** p value≤.01.
[a] Training materials were developed prior to the release WHO 2015 recommendations that injectables can be used by breastfeeding women from 4 weeks postpartum.

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