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Scaling training facilities for patent and proprietary medicine vendors in Nigeria: insights and lessons learned for policy implication and future partnerships

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Abstract

Patent and proprietary medicine vendors in Nigeria play a very integral role in providing primary health care services and are an important source of care for the poor. They are located close to communities and are often the first source of care for hygiene and family planning (FP) products and treatment of child illnesses. Since 2017, Pharmacy Council of Nigeria (PCN) has partnered with Society for Family Health through the IntegratE project to address the poor quality of services by patent and proprietary medicine vendors (PPMVs) and reposition them for better service delivery through piloting the three-tier accreditation system. The partnership has engendered innovation for human resource for health, and considering the peculiarity of their situation, new emerging methods and arrangements to deliver the training to PPMVs in diverse geographical locations within their catchment areas are developed. In this study, we aimed to discuss the role of patent and proprietary medicine vendors in the provision of quality health delivery and provide key lessons and recommendations which have been learned from the pilot scaling of training facilities for PPMVs in Nigeria through the IntegratE project. From the lessons learnt, we propose that, for a successful scale-up of implementation of the three-tier accreditation of PPMVs, PCN will have to establish a budget line for accreditation. In addition, the government should also consider supporting this training through the Basic Healthcare Provision Fund as a way of strengthening human resources at the primary healthcare level. Other alternative sources of funding include licensing and registration fees and other dues generated internally by PCN.

Keywords Patent and proprietary medicine vendors, Drug shop owners, Health systems, Health policy, Human resource for health, Nigeria

Background

Drug shop owners, also referred to as patent and proprietary medicine vendors (PPMV) in Nigeria, are an important source of care for the poor, located close to

communities, and are often the first source of care for hygiene and family planning (FP) products and treatment of child illnesses [1]. They operate legally in Nigeria and are defined as “persons without formal training in pharmacy who sell orthodox pharmaceutical products on a retail basis for profit” [2]. PPMVs are permitted to sell a limited number of pre-packaged, over-the-counter medicines but are prohibited from selling prescription medications (e.g. antibiotics) or conducting invasive medical procedures (e.g. malaria rapid diagnostic tests)

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[3]. They are estimated to be about 200 000, spreading across urban, peri-urban and rural parts of Nigeria [4]. Despite their scale and patronage, studies show that PPMVs commonly stock poor-quality medicines (e.g. partial or repackaged doses [5] and/or sub-standard formulations) [4]. PPMV shop owners and workers also have poor dispensing practices, influenced by their low health knowledge and improper stocking practices [6], and drug sales do not conform to recommended treatment guidelines [7]. They are regulated by the Pharmacy Council of Nigeria (PCN), a government agency responsible for regulating and controlling pharmacy education, training and practice in all aspects and ramifications, including regulating pharmacy technicians and PPMV operations and practices. According to PCN's guidelines, no formal training is required before a vendor is allowed to operate [8]. A vendor is licensed to operate after meeting the minimum requirements, which include age provision, location, provision of reference of good standing, and payment of statutory fees. A day orientation is arranged by PCN for all the vendors before they are licensed. Little or no formal training in health service provision or handling of medicines is provided to the vendors except the periodic continuous education, which happens after

some years of practice. Since 2017, the Pharmacy Council of Nigeria (PCN) partnered with Society for Family Health (SFH) through the IntegratE project to address the poor quality of services by PPMVs and reposition them for better service delivery through piloting the three-tier accreditation system [9]. This system seeks to classify PPMVs into three tiers per their qualifications in health discipline and set standards for training, supervision and scope of practice appropriate for each tier [Table 1]. The first phase of this accreditation was successfully piloted in Lagos and Kaduna states, where over 206 PPMVs were trained and accredited [8]. Therefore, we discussed and provided key lessons learned from the scaling training facilities for PPMVs in Nigeria through the IntegratE project.

Methodology and Results

Navigating policy framework support using the scale-up matrix: the scale-up matrix (Fig. 1) describes how the regulatory agency Pharmacy Council of Nigeria (PCN) has been placed in the driver's seat for the PPMV tier accreditation and has helped reduce regulatory challenges. To kickstart the implementation, the project secured waivers from PCN and the States Ministry of

Table 1 PCN three-tier accreditation system for PPMVs

Tier classification	Eligibility criteria	Scope of work in provision of primary care and service delivery
Tier 1 PPMVs (i.e. PPMVs lacking health qualifications and any training)	<ol style="list-style-type: none"> (1) Ability to read and write (2) Attainment of 21 years of age (3) Submission of reference from two referees to PCN (4) Qualified personnel will include those who attempted to obtain a Secondary School Certificate (5) Also in this category are holders of bachelor's degree in biological sciences or any other disciplines (outside of health-related disciplines) 	This tier will be licensed to sell over-the-counter products and manage common illnesses. FP services will include condoms, cycle beads, emergency contraceptives, refill of pills but not initiation, counselling and referrals. However, persons who have training on the use of malaria rapid diagnostic test kits (mRDT) may use the test kits to test patients for malaria
Tier 2 PPMVs (i.e. health-qualified PPMVs)	<ol style="list-style-type: none"> (1) Must fulfil the tier 1 eligibility criteria (ability to read and write and attainment of 21 years of age) (2) In addition, must possess diploma or degree in nursing or midwifery or, community health extension workers (CHEWs), community health officers (CHOs) or any other health qualifications recognized by PCN 	PPMV operators in this tier will be enabled to provide selected PHC services in line with the task shifting and task sharing policy. They will provide tier 1 services as well as use rapid diagnostic test kits (RDTs), administer amoxicillin dispersible tablet (DT), conduct HIV self-testing, sell self-injecting contraceptives and refer patients to PHCs and higher-level facilities for nutrition counselling and treatment of any other common ailment. They will also be allowed to initiate and administer LARC, particularly implants, if they have received training on comprehensive FP services in line with the task shifting and task sharing policy
	<ol style="list-style-type: none"> 1. This category must fulfil the tier 1 eligibility criteria 2. In addition, must be pharmacy technician 	PPMV operators in this tier will be enabled to provide selected PHC services (in line with the task shifting and task sharing policy); they will provide tier 1 services as well as use rapid diagnostic test kits (RDTs), administer amoxicillin DT, conduct HIV self-testing if trained, sell self-injecting contraceptives and refer patients to PHCs and higher-level facilities for nutrition counselling and treatment of any other common ailment

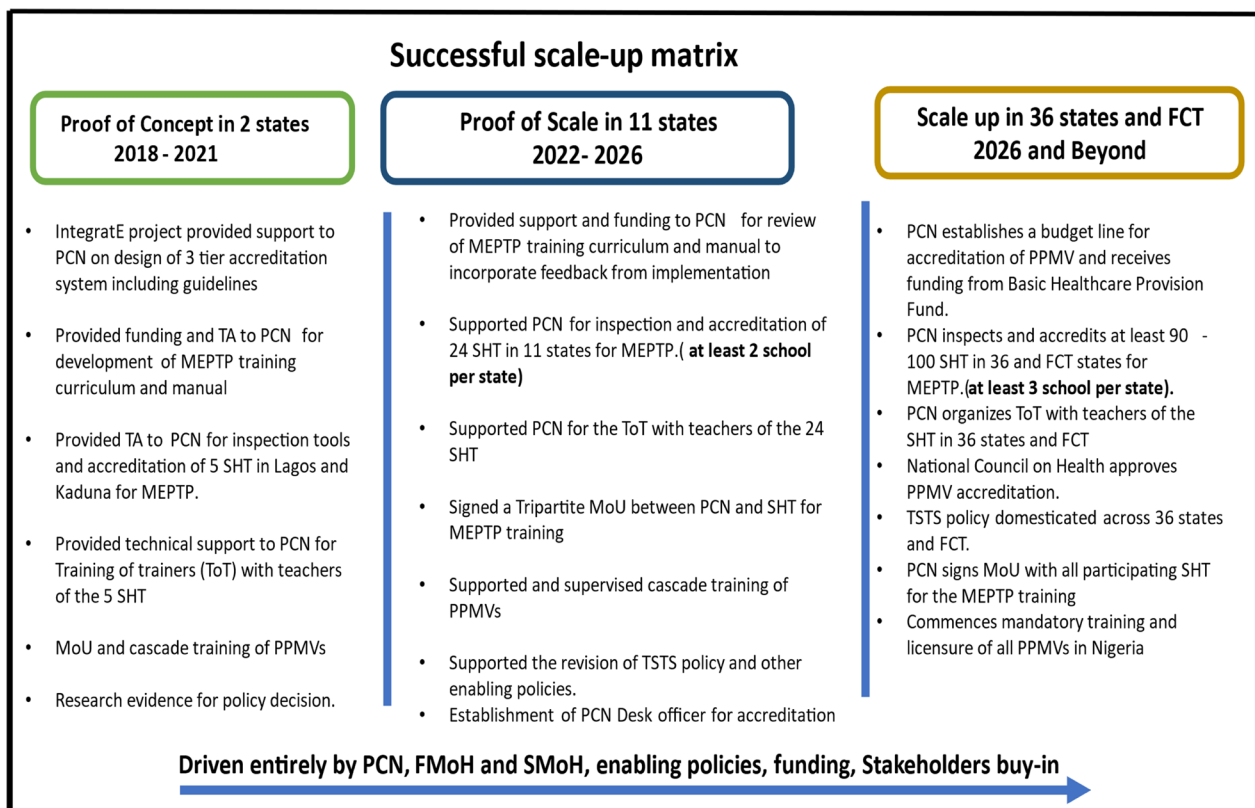


Fig. 1 The IntegratE scale-up matrix

Health (SMOH) from across the 11 implementing states to allow both community pharmacists and health-trained PPMVs (tiers 2 and 3) to provide implant insertion and injectable administration for family planning after achieving competency. This helped surmount some regulatory challenges. Evidence from this implementation informed the revision of the task shifting and task sharing (TSTS) policy of the government. However, to achieve scale, the TSTS policy, which now allows Community Pharmacies (CPs) and health-trained PPMVs to provide injectable contraceptives and implant insertion, will need to be domesticated by each of the states in Nigeria. Before the approval of the TSTS policy in 2014, CPs and PPMVs were not allowed to provide expanded FP services, including the long-acting reversible contraceptive (LARC). At the time, CPs and PPMVs were not authorized to stock or provide any extended FP services, translating to increased strain on the already existing healthcare professionals including doctors and midwives, higher cost, increased waiting time, and LARC not included in the country's treatment guidelines to enable CPs/PPMVVs to have access to it [10]. Only doctors and midwives were authorized to provide any form of injectable contraceptives, which is not the case in many

countries [11]. For example, in Ethiopia, Malawi and Mauritania, the successful implementation of the pilot programme increased the overall health budget for over a decade and increased the demand for family planning, though many countries have faced challenges of training lower-cadre healthcare workers [10]. The engagement of Schools of Health Technology helped to significantly reduce these challenges and the cost of training of PPMVs in the provision of expanded FP services in Nigeria. The schools have quality teachers who can be trained as experts to cascade the training to the PPMVs across Nigeria. The Schools of Health Technology exist in every state in Nigeria, and currently, over 109 have pharmacy technician programmes accredited by PCN where the Mandatory Practitioner Training Programmes (MEPTP) programme can be nested. The majority of the schools are willing to include the MEPTP in their training curriculum and have the facilities for additional training programmes. Almost all the schools providing training of community health extension workers (CHEWs), community health officers (CHOs) and pharmacy technician programmes have partnership agreements with government hospitals for practical training of their students, and this collaboration can also be leveraged for training

PPMVs, especially (tiers 2 and 3) on family planning. The biggest concern of the Nigerian Association of Patent and Proprietary Medicine Dealers (NAPPMED) on the accreditation and curriculum was the fear of losing some of their allowed scope of work. However, involving them in the development of the curriculum and the training manual allowed them to understand the entire process and see the need to tailor training to suit their educational background for better service delivery. From the curriculum development to the stakeholder consultation and the training manual development, the NAPPMED executives were involved, and their opinion was considered. The project relied on them to sensitize their members through their internal mechanisms, and this helped win over their members during implementation. The PCN programme coordinating department (the desk office for accreditation at the head office of PCN) led the first entry meeting in each of the states with a consultative meeting with all NAPPMED state and local government chairmen to sensitize them on the accreditation and the Mandatory Entry Point training programme. This 1-day meeting is used to discuss the benefits of accreditation, address all the concerns the PPMVs may have and explain the process of accreditation. At the state level, PCN state officers also continue these engagements supported by SFH IntegratE staff to constantly sensitize the PPMVs through existing WhatsApp platforms and physical meetings to clarify issues surrounding accreditation and discuss the steps and benefits for achieving accreditation.

For a successful scale-up of implementation of the three-tier accreditation of PPMVs, PCN will have to establish a budget line for accreditation. In addition, the government should also consider supporting this training through the Basic Healthcare Provision Fund (BHCPF) as a way of strengthening human resources at the primary healthcare level. The BHCPF is a component of the National Health Act 2014, designed to provide free minimum basic healthcare to the poorest and most vulnerable Nigerians through accredited primary health centres (PHCs) in each of the 36 states and federal capital territory [12]. It is financed by a 1% statutory deduction from the consolidated revenue fund of the federal government, counterpart funds from the states and other donations, and is a special-purpose protection mechanism for the most vulnerable as well as an attempt to reduce the significant out-of-pocket health expenditure of Nigerians and to deal with the resource gaps in delivering PHC and help to nudge further investment by state government through its counterpart fund mechanism. Its operationalization has not been without its issues, ranging from weakness

of systems and structures that administer the fund and expenditures that are not responsive to the political economic reality of the health sector to dwindling financing for the fund on the back of shrinking public revenue among others [13]. There are concerns by stakeholders on the absorptive capacity of implementing institutions among others, which the training of PPMVs can leverage for sustainability. Other alternative sources of funding include licensing and registration fees and other dues generated internally by PCN. The goal of the project is to fully transition implementation to PCN, SMOH and other partners and donors working with the PPMVs by supporting the creation of an enabling environment, leveraging existing structures for regulation and supervision of the PPMVs and mobilizing support through building a business case for buy-in of the practitioners. Feedback received from the participating Schools of Health Technology has helped enrich the training manual. The project and PCN have reviewed comments and suggestions from the schools in “pause and reflect” sessions organized by the project and identified gaps and concerns in the implementation, and this led to the revision of the MEPTP manual in 2020 and 2022. Some of this feedback was to extend the course completion timelines from the initial 3 weeks to 4 weeks (for tier 1 and 5 weeks for tier 2) and to make appropriate changes to the documents to reflect the PCN new act of 2022. The PCN Act has now empowered the PCN to determine the standards of knowledge and skills to be attained by persons seeking to become a patent medicine vendor and strengthen the regulation of the PPMVs in service delivery [9]. However, while this act has the potential to shape the primary healthcare delivery of care in Nigeria, not much has been explored in terms of strengthening innovations and it will require policy alignment with best practices [14]. For example, while the UK Consumer Value Stores (CVs) or CPs provide immunization coverage and services to citizens to reduce pressure on the healthcare systems, domestication of the TSTS policy has faced challenges on many sub-national levels in Nigeria [15]. Furthermore, there is a low rate of skilled PPMVs in rural areas and fragmented referral pathways to secondary care, low product quality monitoring and oversight management systems [9]. While it is generally agreed that there is paucity of information and limited available data on regulatory oversight and human resources development in many locations, this commentary provides baseline information, lessons learnt and recommendations needed to strengthen regulatory oversight, formulation of coherent policy and legal frameworks, training of human resources for

health and pharmacovigilance for quality delivery of health services.

Reduction of cost of training

Recognizing the need to reduce the cost of training and support PCN to achieve scale through a more sustainable training model, SFH supported PCN in developing a comprehensive training curriculum and manual for the PPMVs called the Mandatory Entry Point training manual [9]. This manual covers a wide range of topics, including family planning, non-communicable diseases, basic childhood illnesses such as malaria, pneumonia and diarrhoea, some neglected tropical diseases, supply chain management and handling of medicines in line with the different scopes of service approved for each tier in the accreditation system. PCN also partnered with some selected Schools of Health Technology in Lagos and Kaduna state to pilot the transitioning of this sustainability training [8]. Through this model, the project reduced the cost of training by over 70%.

The rationale for embedding Mandatory Entry Point training programme (MEPTP) in the Schools of Health Technology

In Nigeria, there are over 110 accredited public and privately owned schools and colleges of health technology. These schools are approved by the Nigeria Board for Technical Education, and they offer certificate and diploma courses in community health extension work (CHEW), junior community health extension work (JCHEW), National Diploma in Health Information Management (NDHIM), Diploma in Health Education and Promotion (DHEP), environmental health technology (EHT), medical laboratory technician (MLT) and the pharmacy technician programme, among others. The PCN regulates the pharmacy technician cadre and accredits the pharmacy technician programme of these schools. Currently, about 109 schools have been accredited for this programme in Nigeria by PCN [9]. The initial sets of training on family planning carried out by the project starting July 2018 were 6 days of residential training for PPMVs with health qualifications and 3 days for PPMVs without health qualifications using the national training manuals for invasive and non-invasive methods of family planning [8].

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Leveraging the facilities and capacities of schools to train health workers and sustainability

SFH partnered with PCN and the Schools of Health Technology to nest the PPMV training within the pharmacy technician department to leverage the facilities, experience and expertise of the schools in training health workers to train the PPMVs with little or no additional burden to the schools. In return, the schools received payment for tuition for every PPMV trained. These Schools of Health Technology are both publicly and privately owned, and they exist in every state in Nigeria. They offer several health-related courses, and they have qualified teachers and non-teaching staff who manage different programmes within the school. They also partner with some Public Health facilities for practicum for their students. Embedding the PPMV training within the schools will ensure the training is carried out in a more formal setting and that the existing training institutions are leveraged for sustainability beyond the life of the project. The project also recognizes that PCN cannot handle this training at scale and will need to build partnerships with training institutions. The project supported PCN in carrying out a training of trainers for the teachers at the selected Schools of Health Technology to prepare them for the cascade to the PPMVs since this is specialized training and must be standardized across schools to achieve the desired results.

Discussion

Insights and lessons learned from scaling-up for policy implication and future partnerships are discussed herein, drawing key themes relating to collaboration, partnerships, scalability, tailoring training curricula, coherent policy framework, regulation and compliance.

- (i) Collaboration and partnership: the IntegratE project has worked in close collaboration with PCN, expanding this training to over 3000 PPMVs across 11 states, partnering with about 24 Schools of Health Technology accredited by PCN. This partnership starts with PCN identifying interested schools and inviting them for a sensitization meeting. During this meeting, the schools are expected

to complete an expression of interest form and will describe facilities available to support such training. PCN eventually visits the school to inspect the facilities. This is very important to ensure that additional PPMV training will not affect existing academic programmes. Thereafter, successful schools are accredited for the PPMV training by PCN, and a tripartite memorandum of understanding (MoU) is signed between PCN, SFH and the participating schools. This MoU clearly states the role each party is expected to play in the partnership. This is in line with recommendations that have discussed on the role of partnership and collaboration between government, partners and regulatory agencies in ensuring the coherence of policies that relate to training healthcare workers for fitness to practice in Nigeria [14, 15].

- (ii) Successful partnerships with government bodies, educational institutions and PPMV associations: successful partnerships are key in ensuring that the MEPTP programme and training are achieved at scale due to the limited human and material resources available to PCN. One key stakeholder in this partnership, apart from the Schools of Health Technology, is the National Association of Patent and Proprietary Medicines Dealers. (NAPPMED). NAPPMED is a trade association of PPMVs and has a strong membership across the states. The association has a very strong structure at the local, state and national levels. Over the years, NAPPMED has become popular and has built trust and loyalty among its members because of the protection it provides against police and other enforcement agencies. The project also partnered with the state Ministries of Health (SMOH) through the State Primary Health Care development agency (SPHCDA) to use some select Primary Health Care facilities as practicum centres for post-training competency certification for the health-trained PPMVs who are allowed to provide invasive methods of family planning. The health-trained PPMVs upon completion of MEPTP undergo a 3-month post-training competency programme in a PHC or general hospital under the direct supervision of a FP/RH (Reproductive Health) coordinator or a State Master trainer. This will allow them to achieve the required number of insertions of implants and injectable administration necessary to achieve competency.
- (iii) Fostering effective collaboration for scalability: engaging NAPPMED leadership at various levels and selling the business case of accreditation through sensitization meetings helped build own-

ership and support for the programme. In fact, in some states, the NAPPMED executives were involved in distributing the PCN MEPTP registration forms called Form T1 to their members and reminding them of the training through their internal communication mechanisms, including WhatsApp platforms. NAPPMED also used their meeting platforms to sensitize their members to pay for Form T1, which is the application form for enrolment into the MEPTP, and provide PCN with the relevant certificates so they can be classified into the appropriate tier. It is noteworthy to mention here that the provision of health training certificates was not initially a requirement by PCN to register a PPMV. In fact, most of their members were reluctant to provide this initially for fear of being disqualified by the regulator before intervention by NAPPMED. The NAPPMED executives were also engaged as tour guides during the geospatial location mapping of the PPMVs, which was a precursor to the tiered accreditation training. Through this partnership and with internal communication, the data collectors received the full cooperation of their members during the exercise. Engaging the SMOH and SPHCDA in the post-training supervision of the PPMVs helped break some of the barriers to referral for the PPMVs. Since some of the PHC FP coordinators were Master trainers involved in the supervision of the PPMVs, there was trust built, and this facilitated acceptance of referrals by the PPMVs for family planning and other diseases.

- (iv) Tailoring training curricula: the Mandatory Entry Point training programme (MEPTP) recognizes the different educational qualifications of the PPMVs and tailored the training to address the needs of the PPMVs and the scope within which the PPMVs in these categories are allowed to practice by PCN. The tier 1 PPMV training covers health promotion and simple illnesses they can treat while severe cases are referred. The tier 2 and tier 3 PPMVs who are health workers are allowed a slightly wider scope, and the training covers more topics, including family planning injectable administration and implants. Customizing the curriculum of the PPMVs to recognize their qualification and educational backgrounds has helped achieve better knowledge retention. A longitudinal study conducted by the project revealed that most providers retained knowledge of the family planning training received (which was tailored to the tier) even 9 months after the training. We also noticed that tailoring the curriculum of the PPMVs and simplifying contents with a lot of job aids and schemat-

ics help improve their practice and recall. Furthermore, a low-dose high-frequency model of training which is adopted by all 24 Schools of Health Technology that allows the PPMVs to attend training three times a week over 4 weeks helped achieve a high completion rate. This arrangement recognizes that the PPMVs must also go back to their businesses. The first day of the training is usually an orientation/flag-off where PPMVs are allowed to decide the most appropriate days for the training and the information is used by the school to draw up a training calendar.

- (v) Overcoming regulatory and compliance challenges: one of the key regulatory concerns is the issue of the quality of training and compliance with standards. To mitigate this, the project developed standard training slides. This is in addition to the development of a facilitator's guide. The training slides cover all topics in the curriculum and provide relevant examples to ensure that the facilitators remain focused on selecting appropriate examples and case studies in delivering the training. In addition, a 1-week training of trainers (TOT) is conducted for all the teachers at the School of Health Technology upon accreditation by PCN. This is important to fully acquaint the teachers with the content of the curriculum and the teaching methodology and guide them on where to put emphasis during the delivery of the training. Also, a final examination is prepared by the regulator and administered by the Schools of Health Technology to ensure uniformity in standards across the different schools.
- (vi) Ensuring compliance and adherence to standards: one key lesson we have learned is that supervision remains key to ensuring that the schools deliver quality training. PCN state officers and SMOH provide supervisory support to schools throughout the training programme to ensure training was carried out in line with the training plan and content. Some private Schools of Health Technology that do not have permanent teachers were initially seen to replace almost 60–80% of teachers who participated in the TOT, and this affected the quality of some of the training, but this was mitigated by the impromptu random visits by PCN and the SMOH.
- (vii) Critical stakeholder engagement: successful stakeholder engagement across regulators, governments, practitioners, communities and associations remains key to achieving successful training and accreditation of the PPMVs. The project had constant and sustained stakeholder engagement to ensure the buy-in of all those who drive the process or are affected by it. Large stakeholder meet-

ings were held at the inception of the accreditation across all the states with participation from key government functionaries, religious and traditional rules, community gatekeepers, NAPPMED, Association of Community Pharmacists (ACPN), PCN, National Drug Law Enforcement Agencies (NDLEA) National Drug Food Administration and Control (NAFDAC), Civil Society Organizations and the media. These meetings provided a platform to explain the accreditation and the role each party is expected to play for a successful implementation. The communities were also sensitized to the “new scope” of practice of some of the PPMVs, especially around family planning injectables and implants. Law enforcement agencies were also sensitized regularly to reduce harassment of PPMVs, especially those that have been approved for a wider scope of family planning services. While these lessons learnt and recommendations provide a baseline information for policymakers, government and partners, the Nigerian population is increasing with lesser healthcare professionals to meet the needs and wants of Nigerians. Challenges also continue to impact negatively on the resilience and functionality of the health systems, thereby necessitating the need for partnerships and regulatory oversight to deliver quality health workforce, as well as equitable distribution of existing ones at various levels [10, 16]. The TSTS policy has provided improvement in training through partnership building and enhanced regulatory oversight on the activities of PPMVs and lower-cadre health workers not only in Nigeria but also in other African countries [17]. Until this is fully achieved, the required skills, knowledge and competence needed to guarantee quality service delivery will be shortchanged.

Conclusion

Leveraging the SHT to train PPMVs by PCN has brought efficiency, scale, cost-effectiveness and sustainability to the conduct of the Mandatory Entry Point training programme, which forms a key pillar of the three-tier PPMV model currently implemented by IntegratE on a pilot basis in 11 states. PCN, working with the FMOH and SMOH in the states, leveraged the revised task shifting and task sharing policy to spearhead the categorization of PPMVs into three tiers according to the operator's qualification states. The system aims to drive and promote quality health service delivery through this class of informal health providers. The tiered accreditation system is expected to strengthen the regulation and control

of PPMV practice and improve the overall quality of services they render.

In scaling the MEPTP, SMOH and SHT, PCN partnered with key stakeholders including the management of the schools, SMOH, SPHCDA and the self-regulatory body for PPMVs (NAPPMED) etc. to develop a long-term strategy around PCN's goal and vision for the tiered accreditation system that focuses on the outcome to be achieved, an action plan for key priorities and a coordinated working programme including activities and measures that will contribute to the attainment of the outcomes. These were all detailed in the tripartite MoU/agreement entered into with the schools. PCN and IntegratE project also entered a unique collaborative arrangement with the SMOH/SPHCDA for proficiency training and referrals. Through these partnerships, PCN successfully enhanced the impact and effectiveness of the training through combined and more efficient use of resources. The partnership also engendered innovation as SHT, considering the peculiarity of their situation, developed new methods and arrangements to deliver the training to PPMVs in diverse geographical locations within their catchment areas. Finally, there was also a shared commitment to implement the system and arrangements for monitoring and reporting progress by PCN, including periodic visits to the schools to supervise training and administer examinations.

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Author contributions

The paper was conceived and designed by E.O., D.Y. and M.A. The data collection was supervised by E.O., O.I., J.A., D.Y. and M.A. E.O., D.Y. and Y.H.W. prepared the first draft of the manuscript; O.I., J.A., D.Y., M.A. and R.D. carried out substantive revisions to subsequent drafts. All the authors read and approved the submitted version.

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Declarations

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Not applicable.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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