Question 1: *How have systems thinking approaches and tools been incorporated in activities to improve health equity? Were these approaches useful in achieving health equity goals? If so, what are the pathways by which these approaches helped to address the root causes of inequity?*

Strengthening Nigeria's Community-Level Health System to Increase Access to Quality-Assured Medicines for Low-Income, Rural Clients

Mopa Esuga, Chinedu Chikwendu, Clement Inyagi, and Antoinette Melnyk, Promoting the Quality of Medicines Plus (PQM+).
Support and direction of USAID, especially Emanuel Ogwuche, USAID Program Manager for PQM+ in Nigeria, is gratefully acknowledged.

HEALTH SYSTEMS STRENGTHENING ACCELERATOR

Context

Nigeria's public health system aims to serve nearly 221 million people but lacks sufficient facilities and resources to meet the country's health needs, including to provide equitable access to quality-assured medicines for all socioeconomic groups. Roughly 65% of Nigerians seek care from the private sector.[1] Many go to community pharmacies (CPs) or proprietary patent medicine vendors (PPMVs) for medicines. PPMVs are not required to complete formal training in medicine or pharmacy and can supply only over-the-counter (OTC) medicines from an approved government list. PPMVs are in semi-urban and rural areas and serve largely lower-income and rural populations.[2] A 2015 systematic review noted that "PPMVs are the first source of care for up to 55% of under-5 child illnesses, and provide services for 35% to 55% of adults seeking malaria treatment."[3] While no one knows how many PPMVs exist, a 2016 study reported that nearly half of Nigeria's states had as many or more PPMVs as formal health facilities.[4]

The U.S. Agency for International Development (USAID), through its Promoting the Quality of Medicines Plus (PQM+) program, surveyed almost 1,300 CPs and PPMVs in five targeted states and the Federal Capital Territory (FCT) to assess their operations and the quality of their medicines and consumables. The surveys found that many PPMVs do not have licenses, do not follow good pharmacy practice, stock prescription drugs in addition to OTC medicines, and obtain medicines from illegal drug markets.[5] A study from 2009 had found that more than half the antimalarials stocked by PPMVs in Anambra State were substandard.[6] Many poor and rural clients who turn to PPMVs do not have reliable access to quality-assured medicines.

The Pharmacy Council of Nigeria (PCN) is the government authority mandated to regulate pharmacy practice, but it lacks the funding, staffing, and capacity to oversee all drug outlets in the country. Some PPMVs are mistrustful of PCN, which they view as heavy-handed and punitive. Many PPMVs fail to register with PCN and fall completely outside PCN's regulatory, monitoring, and supervisory reach. At the same time, many PPMVs are members of the National Association of Patent and Proprietary Medicine Dealers (NAPPMED), which they—mistakenly—feel can protect them from regulatory agencies.

To address inequitable access to quality medicines experienced by PPMV clients, PQM+ worked with stakeholders in the public, civil society, and international development sectors to strengthen and integrate building blocks of the health system related to medicines quality (governance, finance, knowledge and information, medical products, and service delivery) and to strengthen relationships among actors across the health system.

[1] https://ihsprogram.com/pubs/pdf/IFR222/FR222.pdf
[2] Bayeler N, Liu J, Sieverding M. A systematic review of the role of proprietary and patent medicine vendors in healthcare provision in Nigeria. PLoS One. 2015 Jan 28;10(1):e0117165. doi: 10.1371/journal.pone.0117165. PMID: 25629900; PMCID: PMC4309565.
[3] Ibid.
[4] Liu J, Prach LM, Treleaven E, Hansen M, Anyanti J, Jagha T, Seaman V, Ajumobi O, Isiguzo C. The role of drug vendors in improving basic health-care services in Nigeria. Bull World Health Organ. 2016 Apr 1;94(4):267-75. doi: 10.2471/BLT.15.154666. Epub 2016 Feb 3. PMID: 27034520; PMCID: PMC4794299.
[5] PQM+ RQAS assessment reports for FCT and the five states.
[6] Onwujekwe O, Kaur H, Dike N, Shu E. Uzochukwu B, et al. (2009) Quality of anti-malarial drugs provided by public and private healthcare providers in south-east Nigeria. Malar J 8: 22 10.1186/1475-2875-8-22.

Activity Description

The intervention started in Bauchi, Ebonyi, and Sokoto states in 2020 and expanded into Benue, Kebbi, and the FCT (Abuja) in 2022. The ongoing activity has several main components.

In collaboration with NAPPMED, PCN and PQM+ held sensitization workshops in all five states and FCT for registered and unregistered PPMVs. During the workshops, they informed PPMVs about PCN's function and registration and licensing requirements and procedures. PPMVs received many incentives to register—business support, training, and supportive supervision from PCN; recognition in their communities—and additional training and free family planning products from other donors and USAID implementing partners (IPs) that are exclusively for registered PPMVs. They also were cautioned about the penalties for not registering, including shop closure and seizure of inventory. These efforts aimed to incentivize unregistered PPMVs to register with PCN and to build trust between PPMVs and PCN.


A PPMV inspection

Following sensitization workshops, PPMVs received training in good procurement, storage, inventory management, and recordkeeping practices. The intent was to motivate PPMVs to buy medicines from reputable sources and improve their storage and other practices to ensure the quality of the medicines they sell. PCN and PQM+ disseminated job aids and information, education, and communication (IEC) materials on how to identify quality medicines and best medicine practices. These seek to assist PPMVs in their work and to influence attitudes, awareness, and behavior of PPMVs and customers. PQM+ helped link registered PPMVs to other IPs and donors working in the states.

Inspectors, who are members of PCN's state-level PPMV License Committees (PPMVLC), are responsible for overseeing the PPMVs. PQM+ trained PCN trainers on how to train state-level inspectors, helped revise PCN's Pharmaceutical Inspector's Manual, and created new forms to use during inspections to standardize those inspections and better document findings. PCN and PQM+ then trained pharmaceutical inspectors in the five states and FCT. State inspectors received training to check PPMVs' registration status, whether the PPMV stocked only approved and registered OTC medicines, basic aspects of the medicines' quality (e.g., expiration date, discoloration, unacceptable moisture), and storage conditions. Further, to address PPMVs' negative perception of PCN as faultfinders, PCN and PQM+ trained inspectors on the qualities of a good regulator/inspector relationship and how to communicate clearly and manage their relationships with PPMVs.

PPMV training covered the same topics to facilitate transparency during inspections. Both inspectors and PPMVs now know what to expect from inspections, and PPMVs know how to prepare for them.

Under the state PPMVLCs, PQM+ is helping establish new medicines quality assurance committees (QACs) comprising the state head of pharmaceutical services and representatives of PCN and IPs. The QAC, which serves as the quality arm of the PPMVLC, sends a member with inspectors on visits to PPMVs to identify and document the root causes of quality issues. They then report those issues to the PPMVLC, recommend ways to help PPMVs address them, and develop mitigation measures and quality assurance training for PPMVs.

At the national level, PQM+ strengthened PCN's quality assurance and regulatory systems, as gaps in state systems and processes were traced to gaps at PCN headquarters. Thus, PQM+ supported PCN in attaining a functional quality management system (ISO 9001:2015 certification) and WHO maturity level 3 (ML3) for its facility inspection and licensing functions. Both signal that PCN meets international standards and can provide high-quality, consistent services in its effort to regulate the pharmaceutical sector.

PCN and PQM+ anticipate that:

(a) Advocacy and sensitization efforts with NAPPMED and PPMVs will persuade PPMVs to register/re-register with PCN.
(b) Training PPMVs will improve their knowledge of good medicine handling and thus the quality of the product they sell to their clients.
(c) Strengthened inspection and quality assurance systems at the national and state levels will improve the effectiveness of PCN's supervisory and monitoring functions.

Incentives, transparent inspections, and QAC support will improve PPMV relationships with PCN and increase registration. As more PPMVs register with PCN, they will learn about and apply good pharmacy and medicine practices. These will improve the quality of medicines sold by PPMVs and will improve access to quality medicines by low-income and rural populations.

Activity Impact

This activity helped address the most immediate structural causes of inequitable availability of quality medicines by: (1) increasing the number of PPMVs that register with PCN and therefore benefit from regulatory oversight and support; (2) improving the number and quality of state inspections; (3) instituting new or strengthening existing quality assurance systems at PCN's national and state levels; (4) increasing PPMVs' knowledge of good drug management; and (5) reinforcing quality assurance at the community level by providing PPMVs with job aids and IEC materials to assist them in applying the new knowledge in their work.

PCN and PQM+ were able to effect behavioral change among PPMVs (see evidence section). If sustained, this will give predominantly poor and rural patrons better access to safe and effective medicines and medical products.

The PCN/PQM+ activity strengthened several components and levels of Nigeria's health system as well as improved collaboration among key actors.

Community level: Knowledge/information transfers (through training, job aids, and IEC materials) to PPMVs helped improve their knowledge, attitudes, and practices with respect to the quality of the medicines they sell. In the future, PCN and/or NAPPMED could provide the trainings PQM+ conducted. PPMV awareness of substandard, falsified, and degraded medicines and the practices that would safeguard against them directly affects the quality of medicines available to low-income and rural Nigerians at the community level of the health system.

Intra-donor: PQM+ linked registered PPMVs with other USAID IPs and donors working in the communities. IPs and non-USAID donors seek to work with registered PPMVs that have received training in quality medicine practices and receive regulatory oversight before integrating them into their community health programs. This incentivizes PPMVs to register with PCN and, through integration into these other programs, will further improve the quality of PPMVs' products and services.

State level: Building state inspectors' knowledge of good inspection practices improved both their own inspection practice and PPMVs' pharmacy practice. Good inspection provides an opportunity to give supportive supervision to help vendors improve their practices and to monitor PPMVs' compliance with regulations and standards.

State level: Building state inspectors' capacity to communicate and manage relationships with PPMVs was specifically designed to reduce the antagonism PPMVs have toward PCN. Better people management skills on the part of inspectors will help build trust with PPMVs.

National level: Quality management systems at the national and state levels strengthened PCN as a regulator. Now ISO 9001 certified, PCN has demonstrated that it consistently implements procedures and processes in conformance with regulatory requirements and has processes in place for continuous improvement. This should enhance confidence and trust in PCN and improve its ability to govern the pharmacy sector. PCN is now working to extend ISO 9001 certification to its zonal offices, and will bear the costs of this and subsequent renewals of the certification.

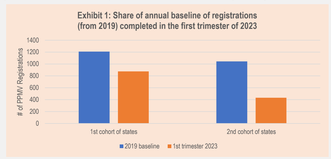
Cross-sectoral: Stronger linkages among the public, private, and civil society sectors created synergies and increased reach and effectiveness of regulatory activities.

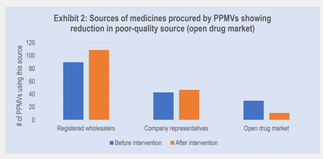
a) **Public sector/civil society –** PCN's and NAPPMED's former relationship was somewhat antagonistic. This activity increased NAPPMED's support for PCN's regulatory goals, which was key to getting more PPMVs to register with PCN.
b) **Civil society/private sector –** The relationship between NAPPMED and PPMVs is strong. NAPPMED's demonstration of support for PCN's registration goal (by explaining PCN rules and why regulatory compliance is important at the sensitization workshops) garnered PPMV interest in registering with PCN.
c) **Public-private sectors –** Bringing more PPMVs under PCN's regulatory umbrella, engaging PPMVs via supportive supervision, and providing other training and benefits effectively strengthened the linkage in the health system between the public regulator (PCN) and private regulated entities (the PPMVs).
d) **National and state –** Better coordination among PCN headquarters and state PPMVLCs through the QACs is helping identify, document, and more expeditiously address quality issues in PPMVs.

Evidence

These exhibits show program impact on intermediate outcomes. Exhibit 1 shows the **increase in the number of PPMV registrations** in the **first trimester** of 2023 compared to the **annual baseline** (2019). Results for the first cohort of states are much greater than for the second cohort of states (minus the FCT, which receives atypical support) where the intervention was too new to have impacted the number of registrations. (Data source: PCN)

Exhibits 2 and 3 show **changed PPMV knowledge and practices**, namely a shift in sources away from the open drug markets to more reliable sources of quality-assured medicines (i.e., registered wholesalers and company representatives) and current PPMV ability to identify quality attributes of medicines when making procurement decisions. (Data source: PQM+ follow-up survey of 120 PPMVs – 20 in each state – in March 2023)



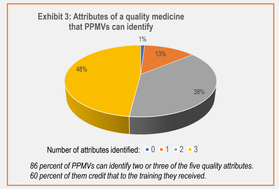


On the integration of PPMVs into integrated community case management (ICCM) activities:

"PQM+ played a vital role in identifying the registered PPMVs and CPs. This helped us enroll more than 400 premises to participate in the ICCM training. At this time, more than 90% of the premises report data in CHMIS* across 20 [local government areas] in Bauchi State, one of the pilot states to test CHMIS in the private sector."

— Pharmacist Ibrahim Yahaya
Project Manager, Center for Comprehensive Promotion of Reproductive Health

*CHMIS: community health management information system



86 percent of PPMVs can identify two or three of the five quality attributes. 60 percent of them credit that to the training they received.


"We look for pharmaceutical outfits, because we believe that any pharmaceutical company or chemist must deal with quality. When you go outside that, you cannot guarantee quality."
— PPMV in FCT

Facilitators

National and state-level stakeholders: This activity benefitted from the considerable buy-in and full support of PCN registrars and directors, state ministry of health commissioners and permanent health secretaries, state directors of pharmaceutical services (who are members of PCN's governing council and chairs of state PPMVLCs), and the primary health care development agency. These stakeholders facilitated efforts to address structural problems and their approval legitimized the work, gave the program access to some of their resources, and facilitated involvement of their staff.

Trade association: PCN and PQM+ conducted extensive advocacy with NAPPMED to address its members' fears of and grievances with PCN and to persuade the association to partner for the common good. NAPPMED eventually concurred and sent letters inviting PPMVs to the sensitization workshops and persuaded more members to register with PCN. Without NAPPMED, PCN would not have been able to reach more PPMVs, much less persuade them to register.

External partners: Other partners working in the states—UNICEF Nutrition, USAID's Integrated Health Program, Nutrition International, and USAID's Global Health Supply Chain Program-Procurement and Supply Management (GHSC-PSM) program —complemented this work by planning to integrate registered PPMVs into their own programs. These other partners' programming and support provided added incentives (training and free family planning commodities) for PPMVs to register with PCN.

Local evidence: A survey of PPMV knowledge, practices, and challenges preceded and informed detailed planning of the intervention and trainings. Additionally, the QACs continue to learn about PPMV issues and challenges as QAC members join inspections and use this information to shape new training and support to meet PPMV needs.

Challenges

PPMVs' distrust of PCN was deeply rooted. PCN and PQM+ worked closely with NAPPMED to reach PPMVs to help build new trust. PQM+ trained the pharmaceutical inspectors to adopt a supportive supervision rather than punitive approach when dealing with PPMVs. This enabled a shift in the agency's reputation from faultfinder to helper.

PCN's funding is inadequate to carry out its inspection, monitoring, and enforcement activities on the scale required. PQM+ worked with PCN and NAPPMED to persuade more PPMVs to register and acquire licenses with PCN. Only part of the licensing fees, which are nominal for PPMVs, actually go to PCN, but if the many PPMVs did pay their fees, it would constitute a major source of revenue for PCN.

An inadequate system for obtaining data from PCN's state offices hinders PCN's ability to make timely policy decisions. PQM+ identified skills and knowledge gaps in information and data management and trained PCN headquarters staff on monitoring, evaluation, and learning fundamentals. The training covered the need for accurate and timely data and how PCN could use the data to inform management decisions and advocate for funding. PQM+ is helping PCN establish indicators for its activities and operationalize a functional monitoring, evaluation, and learning system. This system will support data collection, analysis and reporting, learning, continuous improvement, and advocacy.


A patent medicines shop

Lessons Learned

Collaboration with NAPPMED was essential to the success of this activity. NAPPMED knows where even the most remote PPMVs are situated. Working with and through NAPPMED is perhaps the best way for PCN to reach most of the PPMVs, therefore sensitization efforts should continue to include NAPPMED. Going forward, PCN must strike a balance between working through a mediating agency such as NAPPMED and getting NAPPMED members (i.e., PPMVs) to understand how they can interact directly with PCN.

Sensitization of PPMVs should be ongoing. More trust between PCN and PPMVs will lead to more registrations, more revenue generated to allow PCN to fulfill its oversight function, and more effective oversight by PCN.

The QACs turned out to be an effective mechanism for identifying quality issues in PPMVs and enable corrective—not punitive—measures. This emphasis on supportive supervision will go a long way in fomenting trust between PPMVs and PCN. Complementing PNC's inspection activities with the QACs' explicit efforts to learn about PPMV needs and design ways to meet them allows the regulatory activity (inspection) to flow seamlessly into efforts to build PPMV capacity.

Better coordination with the other relevant regulatory agencies (i.e., the National Agency for Food and Drug Administration and Control [NAFDAC] and the National Drug Laws Enforcement Agency, which regulates the distribution, sale, and use of narcotics) could facilitate more effective monitoring of the large contingent of PPMVs. PCN's lean resources do not permit extensive travel or follow-up with shops, particularly in more remote areas, where it has identified problems. Collaboration among regulatory agencies could extend PCN's reach and improve enforcement. As part of its own routine monitoring, NAFDAC could target areas with clusters of outlets closed by PCN. Monitoring could include enforcing PCN decisions and reporting violators for appropriate penalties.

PCN could stretch its limited budget by scheduling activities to coincide with those of other implementing partners, and leverage partners' logistics to carry out its own activities.

Ultimately, improving health equity goals on a broader scale will require state and national governments to increase funding for PCN, enabling the regulatory authority to carry out more inspection visits, provide supervisory supervision, and provide training and other support. Without expanded PCN capacity to oversee and support such a sizeable number of shops, many PPMVs will fall through the cracks, with ongoing consequences for low-income and rural patrons' access to quality medicines.

USAID FROM THE AMERICAN PEOPLE
RESULTS FOR DEVELOPMENT
HEALTH STRATEGY AND DELIVERY FOUNDATION
ICF
BILL & MELINDA GATES foundation