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EDITORIAL

Sociocultural dimensions of research on public health roles for community pharmacists in tuberculosis disease control in a developing country

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Community pharmacies are an important addition to public health initiatives in controlling infectious diseases in developing countries.¹ Pharmacists/ pharmacy staff counseling the presenting patients about their disease symptoms and untoward effects of self-medication has a vital role to play in infectious disease control such as Tuberculosis (TB).² Pakistan, which is a lower-middleincome, high-tuberculosis (TB) burden country, has a much higher consumer participation rate in private versus public health care.³ Data collected in 2014 by the Pakistan Bureau of Statistics indicate that pharmacies in Pakistan, for example, are accessed more than the government (public sector) hospitals for healthcare services among households.⁴

Pharmacy case detection service implementation project

Given that the TB incidence reported annually in Pakistan is much lower than the World Health Organization's country prediction, it is clear that some TB cases go undetected.³ To address this problem by using innovative Public-Private Mix (PPM) Health Partnerships, we proposed engaging community pharmacies (as a new private TB referral stakeholder) in Pakistan for conducting TB case detection according to the TB management guidelines developed by the National Tuberculosis Control Program (NTP) Pakistan (i.e., public sector).⁵ The 'innovation' aspect involved utilizing existing PPM partnerships [(Public TB Coordinator and Private Primary Care Physician Model -or PPM-1 -or Private sector physician reporting new TB cases diagnosed in his clinic to district/public TB office]⁶ contained within Pakistan's NTP Framework in three districts in Pakistan through a new PPM partner i.e., private pharmacies. The alignment of existing PPM-1 with private pharmacies was named as PPM-1 Boosted project. Using an implementation science approach, we sequentially progressed this project through the following steps: resource allocation, mapping, recruitment criteria, sampling frame development, training, implementation, and auditing.

Using this systematic program planning approach, we were able to recruit 500 pharmacies into the project (PPM-1 Boosted) from a potential framework of 750 pharmacies in the three project districts. The trained and project 'ready' pharmacies then identified 547 new TB patients in the operational districts within one year. Implementation process data were collected, along with data on patient screening and referral volume per pharmacy.⁵

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Research approaches in designing and modeling pharmacy public health interventions, services, and programs in developing countries

Based on 'implementation barriers/facilitators' identified in this large-scale work on scoping pharmacists' public health roles,⁵ we propose a stepwise guideline (i.e., Fidelity-Advocacy-Consent-Technology-Training -or FACTT) for designing similar interventions, particularly for low- and lower-middle-income countries (such as Pakistan) still battling a high burden of infectious diseases and where private health care such as pharmacy is a high accessed health care venue (Figure 1).

Step 1: Advocating for pharmacy inclusion in national **TB** (or other infectious disease programs): The first step in undertaking such projects should be to engage community pharmacists in the national task force team in policymaking (e.g., National TB programs) and make public health processes within the national program mandatory for community pharmacies. This might prove beneficial in addressing the issue relevant to the resource allocation of pharmacies in such implementation programs. Sociologically, many cultures (and professional practice cultures) respect hierarchy (rather than feel constrained) and are willing to enact roles once they feel these roles are legitimized by a higher authority.⁷

The way forward: In the absence of pharmacy inclusion in national public health initiatives, one way forward may be to use national programs on which potential pharmacy contributions can be piggybacked – this is what we did with the PPM-1 Boosted project cited above.⁵ This also allows enhanced willingness of pharmacist participants to participate in such research projects as well as, in turn, patients who then see the pharmacist's approach as a valid rather than an intrusive one. This is particularly important in nations where populations still view community pharmacies only as a venue for sourcing medicine supplies and the pharmacist as a business owner or drug seller rather than a healthcare professional.⁸

Step 2: Using technology to enhance viable and effective methods of initial recruitment of pharmacies: The advocacy of community pharmacists as national task force members should follow the careful recruitment of existing pharmacies utilizing effective technological scientific tools. In our case, (in the PPM-1 boosted model for pharmacist-boosted TB case detection), we first identified the available range of pharmacies in the operational districts by utilizing Geographic Information Science (GIS) principles. GIS-Based Site Selection Analysis involved visiting the localities all around (the NTP pre-established network) and identifying the population hotspots (slum areas), nearby landmarks, and health facilities (hospitals, general practitioners, and laboratories), not on the panel of the NTP network. GIS data led to the development of a mapping tool for identifying pharmacies that should be invited to participate. In the next step, this mapping tool was updated by hired staff during their pharmacy visits in the locality (three times a week) to observe patient flow at pharmacies, non-prescription use of medicines, and availability of anti-TB medications.

The way forward: GIS-Based Site Selection Analysis should be performed by an expert team with a background in urban planning, and mapping tools/algorithms should be updated by a team with a pharmacy background to ensure sensible development of sampling frameworks. This approach would also be useful for engaging pharmacies to assist with managing epidemics or pandemics;⁹ in other words, these planning-mapping algorithms may be useful in locating disease hotspots, identifying pharmacies in the hotspots, and upgrading them to provide relevant services. A symbiotic relationship between upskilled hospital pharmacies and their application of technological tools (such as natural language processing (NLP) and machine learning) to analyze electronic health records (EHR's) for improving patient care exists in the literature.¹⁰

Therefore, it might be highly encouraging for community pharmacies to be supported and upskilled (by respective NTP's) to adopt artificial intelligence algorithms and big data analytics in exploiting existing TB patient databases either maintained at pharmacy software or referred through pharmacies to the NTP registries in the future. Moreover, organizing three weekly pharmacy visits of hired staff (1-visit each at the start of the week, during the mid-week, and at weekends) would assist in the extensive observation of patient flow at pharmacies, as the flow varies during different times of the week.



Figure 1: Schematic diagram for FACCT guidelines

Step 3: Managing the consent process using a sequential consenting process: In most developed countries, signed written consent is obtained from willing participants (i.e., pharmacies) before project implementation,¹¹ and verbal-only consent is strongly discouraged.¹² However, we used both verbal and written consent from willing pharmacies.⁵ In our project, we used a verbal consent process at the initial stage - verbal consent was followed by providing the pharmacy with research materials. This allowed pharmacies to 'test' the potential for implementation, and in many cases given that health services such as TB screening are not 'normalized/socialized' processes in pharmacy, it allowed pharmacy owners to overcome any initial hesitation, progressing them to readily provide written consent after having tested the water. Written consent was then obtained at regional meetings held to debrief participants about how the project was rolling out and to provide more detailed clinical training and process support. Group debriefing also allowed 'socialization' of the TB case detection process in community pharmacies.

The way forward: Researchers aiming to engage pharmacies in public health initiatives as part of research projects need to have a culturally appropriate process for obtaining consent¹³ –initial consent, immersion, second approach, and full written consent might be better ways of managing the informed consent process. Once engaged, the consented pharmacies, with time, can be utilized as a

valuable and relevant source to debrief non-consenting but potential pharmacies (who are either reluctant or stigmatized to participate for any reason) about the ethical principles involved (beneficence) in referring the TB patients.

Step 4: Strategically constructed training for project participants (capacity building of recruited pharmacies for project implementation): Once consented, a strategic process needs to be developed to strengthen the skills, instincts, and abilities of willing pharmacy participants according to available resources. In our case, two layers of training were adopted; Training-1 (on-spot meeting, before the project implementation) and Training-2 (a didactic presentation during the ongoing project). Training-I focused on TB symptoms, national (i.e., Pakistani) TB treatment guidelines, the process of maintaining the referral register for presumptive patients, and a directory (resource) of GP clinics and private laboratories located near recruited pharmacies. The scope of conducting Training-2 during the project was to have a reminder call for referrals, troubleshooting, and a sign of project sustainability to the pharmacy staff. After comprehensive training, there appeared to be an increasing trend in the proportion of total referrals from 14% to 71% in the three districts.⁵ The training layers also coincided with the twolayer consent process.

The way forward: A pedagogically 'heavy' training at project commencement could be replaced for such research projects (pharmacist roles in public health) by two layers of training where protocol and minimal clinical training are initially provided, and once the implementers are 'immersed' and have experiential learning, the process occurs, leading them to comprehensive clinical training, building a laddered scaffold for knowledge application that bodes well for retention of recruited pharmacists in such research projects. This two-layered training material can be forwarded to the Guidelines and Training Module section of the NTP, which is typically developed and regulated by the Monitoring and Evaluation (M&E) unit. NTP M&E units are already established through PPM intervention at district, province, and national levels in Pakistan to train TB healthcare staff in TB control activities.¹⁴ So, assigning additional responsibilities (with relevance to two-layered training) to existing M&E officers

operating at the aforementioned three levels of the healthcare system or hiring an additional M&E officer (preferably with a background in community pharmacy services) can be employed to monitor the presumptive TB patients' record maintenance, referral, and anti-TB drug sales (with or without prescription) at pharmacies either solely run by pharmacy owners, qualified pharmacists, pharmacy technicians, or in combination with all of them.

Step 5: Using hybrid implementation-effectiveness research designs (implementation and outcome data collected in tandem): Finally, to ensure improved protocol fidelity and sustained engagement of participating pharmacies in the project (in the PPM-1 boosted model), we used a hybrid implementation and impact measurement design. During our study, an implementation science model i.e., COM-B -or ' Behavior system' involving three essential conditions such as Capability, Opportunity, and Motivation,¹⁵ was adopted and used, and we conducted 'behavioral diagnostics' in real-time implementation. The barriers identified were then quickly addressed to maintain engagement with practice change (changing to provide a case detection role and work with primary care physician practices).⁵

The way forward: Utilization of implementation science principles (such as the COM-B model) and likely behavioral barriers (Capability, Motivation, and Opportunity) of pharmacy staff during implementation should be addressed as much as possible, and the use of hybrid research designs is a smart way forward. In general, such a hybrid research design process will not only assist in developing a specific method to improve the intervention design, and facilitate its scientific replication but also develop an understanding of the nature of behavior to be changed with relevance to professionals delivering healthcare and evidence-based public health.^{15,16} Specifically, apart from TB, pharmacists if familiar with implementation science principles¹⁷ and provided with a public health 'Opportunity' towards remaining infectious diseases control based on their 'Capability' along with continuous 'Motivation' by national programs can likely change the Behavior wheel of pharmacists and their contribution in developing countries.

Conclusion

The FACCT stepwise guideline will have implications for pharmacy-based TB case detection (active/passive case finding) in Pakistan, where 81% of initial health seeking is to private providers, and where community pharmacies remain the 2nd highly accessed health care facility across the country. The FACCT steps possibly can also be tested to trace highly stigmatized TB-related comorbidities such as Human Immunodeficiency Virus (HIV)-infected cases presenting at community pharmacies in Pakistan.

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