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PII: S1544-3191(22)00358-2

DOI: https://doi.org/10.1016/j.japh.2022.10.013

Reference: JAPH 1702

To appear in: *Journal of the American Pharmacists Association*

Received Date: 27 June 2022

Revised Date: 7 October 2022

Accepted Date: 10 October 2022

Please cite this article as: Smith DJ, McGill L, Carranza D, Adeyemo A, Hakim A, Global Engagement of Pharmacists in Test and Treat Initiatives: Bringing Care from Clinics into Communities, *Journal of the American Pharmacists Association* (2022), doi: https://doi.org/10.1016/j.japh.2022.10.013.

Global Engagement of Pharmacists in Test and Treat Initiatives: Bringing Care from Clinics into Communities

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Manuscript Word Count: 2626

Abstract word count: 237

Conceptualization: Dallas Smith, Avi Hakim; Original draft preparation: Dallas Smith, Lily McGill, David Carranza, Adesubomi Adeyemo; Writing- Reviewing and Editing: Dallas Smith, Lily McGill, David Carranza, Adesubomi Adeyemo, Avi Hakim

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors

The authors declare no relevant conflicts of interest or financial relationships

Abstract:

The COVID-19 pandemic has placed substantial strain on the global healthcare workforce, disrupting essential and non-essential services. Task sharing of test and treat services to non-traditional prescribers, like pharmacists, can facilitate more resilient healthcare systems by expanding access to health services while simultaneously decreasing the pressure on traditional healthcare providers. Expansion of pharmacists' scope of work has historically been hindered by socio-political, resourcing, and competency considerations; addressing these challenges will be key to including pharmacists in testing and treatment of priority diseases. Socio-political considerations include migrating to flexible national legislation and scope of practices as well as engagement with other healthcare providers and the public to increase the acceptance of pharmacists participating in test and treat services. Resourcing issues include healthcare financing for test and treat services to parallel established systems or utilize voucher systems and service competition. Also, pharmacists can utilize their training in supply chain management to ease and prevent medication stockouts in test to treat initiatives. Investments in technologies that support disease surveillance, basic reporting, and interoperability with health management information systems can integrate these initiatives into healthcare systems. Competency considerations comprise test and treat specific education for the pharmacy profession to equip them with the knowledge and confidence to execute successfully. Monitoring and evaluating the outcomes of these services can facilitate the scalability of test and treat initiatives. Pharmacists are uniquely positioned to bring testing and treatment from the clinic to the community.

The COVID-19 pandemic has placed considerable pressure on healthcare systems globally. An estimated shortage of 18 million healthcare workers existed before the pandemic and burnout has been rampant during the pandemic.[1,2] These healthcare worker shortages could result in excess morbidity and mortality of communicable and non-communicable diseases (NCDs).[3] Meanwhile, declines in healthcare facility visits have been common during the pandemic and still may not have fully rebounded three years into the pandemic.[3] Task sharing, that is, the redistribution of tasks to healthcare cadres in non-traditional roles, can address these disrupted services and foster more resilient healthcare systems.[4] Pharmacists have the clinical training and medication-use system expertise to help alleviate health system pressures and address acute healthcare needs by providing testing and treatment services for select diseases, including COVID-19.[5,6] Pharmacists are also often the most accessible healthcare provider in many countries, particularly in rural areas.[7,8]

The World Health Organization recommends implementing or expanding task sharing, particularly when certain services are hindered by a shortage of healthcare personnel like physicians or nurses. WHO includes pharmacists as a cadre whose scope of practice could be expanded.[4] Conditions that require point-of-care testing and simple treatment regimens to prevent severe disease and transmission can be well-suited for task sharing. Globally, pharmacists have seen their scope of work expand; albeit, at various rates, from one of pure dispensing to providing testing and treatment for diseases such as urinary tract infections.[9] Similarly, in countries with large HIV epidemics, pharmacists now provide HIV testing and subsequent pre- and post-exposure prophylaxis.[10] Chronic care, like hypertension and diabetes, has seen improvement in outcomes when pharmacists participate in the diagnosis, monitoring of appropriate tests and subsequent drug therapy.[11] Other diseases for which pharmacists trained in disease-based protocols could manage include mild cases of malaria, sexually transmitted diseases, leishmaniasis, influenza, and COVID-19 requiring oral therapies (or topical therapy in the context of leishmaniasis).

Despite evidence that the scope of work of pharmacists can be successfully expanded, proposals for expansion are often stymied by systemic and regulatory barriers. Efforts to expand the scope of practice of pharmacists have been met with socio-political, resourcing, and competency challenges.[12] The United States, for example, has struggled with the idea of giving pharmacists the right to treat COVID-19 with oral antivirals despite pharmacists testing for it, with national physician organization's hesitancy and lack of reimbursement impacting the decision.[13] Addressing these considerations will be critical for task sharing of test and treat initiatives with pharmacists.

Socio-political context

Engagement with government officials, healthcare professionals, and professional associations to transition to a regulatory system that provides flexibility, decentralization, overlapping, and non-exclusiveness for pharmacists' scope of practice is critical for task sharing. Existing pharmacy practice legislation may limit engagement of pharmacists in test and treat programs namely through restrictions on prescribing rights and billing for pharmacy clinical services.[14–16] Centralized pharmacy legislation can be rigid and unable to be adapted to specific local needs; successful decentralized models such as boards of pharmacy or pharmacy-determined may provide a more efficient route to enacting test and treat services.[17] For example, several states in the United States have proceeded with a decentralized approach to allow pharmacists to prescribe hormonal contraceptives.[18]

Legislation and national guidelines that are broad can allow pharmacists to test for and treat emerging diseases immediately. Temporary waivers and expanded scope of practice during public health

emergencies such as the COVID-19 pandemic can empower pharmacists to provide test and treat services. In Europe, several countries relaxed regulation on controlled substances, and increased pharmacist prescribing authority and medication substitution rights during the COVID-19 pandemic.[19]

Medications or diagnostic tests that are approved by regulatory agencies for emergency use could include pharmacists in authorization to prevent legal hurdles. In the United States, for example, the COVID-19 Public Readiness and Emergency Preparedness (PREP) Act allowed pharmacists to test and treat COVID-19 at the same time as restrictions on oral antiviral's initial emergency use authorization excluded pharmacists as viable prescribers for these agents.[20] More inclusive regulatory policies can facilitate collaboration between healthcare professionals and can enhance participation of pharmacists in task sharing initiatives.

Traditional healthcare prescribers' acceptance and confidence in shifting testing and treatment services to pharmacist can impact the rollout of such efforts. Providing clarity for the role of pharmacists in a certain healthcare program and how they can benefit other healthcare workers can help garner buy-in.[21,22] Positive interprofessional relationships and ease of disease management are two factors to consider in execution.[22,23] Strong partnerships with pharmacists may encourage other health care providers to consider the benefit of referring patients with priority diseases to pharmacists for testing and treatment. Community attitudes towards expanding pharmacy services in country-specific contexts will also need to be explored to encourage use of testing and treatment from pharmacists. In countries where pharmacists only dispense medications, starting task sharing with initiatives such as providing medication refills for chronic diseases after appropriate biomarker monitoring by pharmacists and treatment of minor ailments may facilitate the transition to more involved diagnosis and treatment initiation.[24]

Global, national, and local pharmacy associations can play a critical role advocating for test and treat services. These professional bodies may influence aspects of task sharing through partnerships with regulatory agencies, pharmacy education accreditation councils, and other healthcare professional organizations. Pharmacy organizations can conduct needs assessments and outline priorities for test and treat initiatives. The Commonwealth Pharmacists Association organized virtual interviews with national pharmacy associations to frame themes and subthemes of priorities, including the expansion of pharmacy roles, to achieve sustainable development goals and universal health coverage.[25]

Pharmacy associations can also leverage data or support the development of data systems for the inclusion or effective use of pharmacists. The American Pharmacists Association (APhA) examined federal test and treat locations in socially vulnerable communities and found a dearth of pharmacists in these neighborhoods that were being underutilized and could be used to fill Paxlovid access gaps. APhA communicated this data to the Food and Drug Administration which played a role in the approval of pharmacists to prescribe Paxlovid in July, 2022.[26,27] Pharmacists in Québec, Canada were authorized to prescribe Paxlovid in May 2022. In Canada, the Pharmacists' Association of Newfoundland and Labrador have long advocated for expansion of pharmacists, giving them a large degree of autonomy to prescribe and allowing a quick adjustment to prescribe upon introduction of new agents during a pandemic.[28] International pharmacy bodies, like the International Pharmaceutical Federation, can share best regulatory practices between countries with established test to treat services and those in their infancy.[29]

Resourcing Allocation

Pharmacists providing test and treat services will need to be compensated for the services they provide. To realize the potential of task sharing to pharmacists, funding mechanisms must cover the broad network of pharmacies embedded in local communities. Test and treat payments to pharmacists could be covered in a manner consistent with how care is already funded. Broadly, healthcare is funded through four different mechanisms, with each major mechanism having its own defining features. First, many people gain access to healthcare services through government sponsored universal health coverage (UHC). In countries that offer UHC, government pays healthcare providers, directly or indirectly, to serve the population. This type of funding is considered public health insurance. In addition to, or in place of, public insurance, private health insurance is another mechanism. In countries that depend in little or part on private health insurance, individuals or employers purchase insurance through premiums to help pay for future care. In many countries, patients pay for all or select health services at the point of care. These are often referred to as out-of-pocket payments or user fees. Finally, in some countries, nongovernmental organizations (NGOs) or faith-based organizations provide resources to run or supplement healthcare facilities. These funding mechanisms may co-exist in a country.

Given these funding mechanisms, test and treat payments to pharmacists could parallel or be integrated into current health payment systems. Governments could rollout test and treat services in public pharmacies to expedite service expansion while developing mechanisms for government-subsidized service provision in private pharmacies. In countries with public or private health insurance, payors could extend payments to community-based private pharmacies in the same way that it pays for covered medications dispensed locally, for example, by submitting a claim with identifiable patient information while billing for their clinical services. The rapid increase in the number of urgent care and community clinics in the United States highlights the potential for profits in this arena as well as unmet healthcare needs.[30] New Zealand transitioned COVID-19 oral antivirals to advance prescriptions, allowed pharmacists to prescribe them, and then ensured funding for these pharmacy services from previously agreed upon national COVID-19 healthcare provider service's rates.[31] In countries where pharmacy services are primarily funded by out-of-pocket payments two approaches may exist. In the first, pharmacists who procure their own commodities may charge for testing and treatment services. In this scenario, an additional benefit of expanding pharmacy services is that patients may pay lower fees due to the increased competition and potentially lower cost for offering services in this setting of care. In the second, private pharmacists who receive subsidized testing and treatment commodities from the government or donors could in turn provide these services for free or at a subsidized rate. Fraud and overcharging could be prevented by requiring pharmacists to submit proof of services provided and results to the appropriate agency to be reimbursed. Alternatively, governments and NGOs could implement a voucher-like system, in which 1) community health workers or an NGO distribute vouchers to patients, 2) patients surrender vouchers to pharmacists providing test and treat services as specified by the voucher, and 3) pharmacists submit vouchers for payment after services are rendered.[32] Voucher distribution could be targeted or broad depending on the disease.

While not unique to the pharmacy profession, gaps in the pharmaceutical global supply chain can limit the effectiveness of test and treat programs. Pharmacists may not have access to the appropriate antimicrobial agent or a chronic NCD therapeutic modality. The COVID-19 pandemic has exacerbated medication stock-outs stemming from large distribution hubs being locked down or a shortage of workers.[33] Healthcare systems can protect themselves from supply chain disruptions through dual sourcing, diversifying importation location, promoting supply chain transparency, investing in local supply companies, and digitalizing supply chain management.[33] If supply chain disruptions are not adequately addressed, the distribution and use of counterfeit and substandard medications (CSM) could

increase, imperiling patient health and weakening the global supply chain further. In a review of drug products from low- and middle-income countries, WHO found that more than one-third of the hypertension, cancer, epilepsy, and analgesic medications were either falsified or substandard.[34] CSM have led to increased mortality from absence of active ingredients or harmful substances present in the final product.[35,36] Additionally, theft and resale of approved medications threaten the supply chain's integrity.[37] Internet pharmacies that operate outside of the traditional supply chain can also introduce CSMs. Pharmacists, often the leads of supply chain management in health facilities globally, have been identified as competent professionals within the medication supply chain and recognized as experts in safe and legitimate medication procurement, handling, storage, and administration.[38] Pharmacists can serve as stewards of high-standard medications and diagnostic test procurement in test and treat initiatives through their connections with the pharmaceutical industry, educating patients and other healthcare providers about the black market, examining and reporting suspicious medications to the authorities, and monitoring counterfeit product alerts.[39]

Investments in technologies that support disease surveillance, basic reporting, and interoperability with health management information systems can support the expansion of test and treat services to pharmacists. Certain diseases and conditions are of public health concern and may be required to be reported to health authorities; reporting could also highlight diseases that are increasing which may need expanded pharmacy support. Pharmacists who provide test and treatment services can be trained to report their work into national reporting systems, providing critical data to inform public health monitoring. Modernizing institutional infrastructure like health management information systems can facilitate pharmacist inclusion. Dispensing systems in pharmacies often cannot provide reports about medications given, therapeutic updates or even adherence rates back to other providers or to national reporting systems. For patients with chronic conditions, a seamless stream of communication through platforms like electronic health records or mobile paper health passports can improve continuity of care and promote collaboration with other healthcare professionals.[14] Having access to medical records can also improve pharmacists' confidence in participating in test and treat initiatives by obtaining relevant past medical history and current drug therapy.[40]

Pharmacist competence

Assuring high competence among the pharmacy profession to participate in test and treat initiatives is key to implement task sharing. Preparation of pharmacists include building on practicing pharmacists' skillsets and embedding training for diagnostic tests and treatment algorithms for relevant diseases into pharmacy degree curricula. Governments and health sector partners can build upon licensed pharmacist's foundational knowledge of pharmaceuticals through targeted continuing education programs. These programs can be administered virtually or in-person with didactic and case-based learning and can be modeled off of established content like the American Pharmacist Association's Pharmacy-Based Test And Treat Training Program or the UK's Centre for Pharmacy Postgraduate Education's disease-specific test and treat modules.[41,42] The International Pharmaceutical Federation (FIP) and the pharmacist code of ethics in the United States and other countries express the shared professional obligation that pharmacists have to maintain competency through life-long learning.[29,43,44] This commitment to life-long learning allows pharmacists to function as effective resources for the communities that they serve and supports the capacity for pharmacists to be effective in test and treat initiatives. .

Accreditation bodies could also establish standards to ensure the competency of outgoing pharmacy students.[45] Pharmacy school curriculums could entrench test and treat principles for various diseases.

The expansion of the testing component through experiential, hands-on learning may improve pharmacist's knowledge and confidence in using assays of different types to diagnose patients, complementing their medication-use knowledge. Outlined modules, topics, and standards that have been proposed in the United States or implemented in Australia and New Zealand can serve as templates for pharmacy accreditation bodies globally.[46,47] Didactic learning topics could include good laboratory practices, clinical laboratory improvement amendments, business planning, quality control, disease surveillance, supply chain management, and public health disease reporting.[45] The National Alliance of State Pharmacy Associations has created a Pharmacy-based Point-of-Care Test & Treat Program which includes many of the aforementioned topics and may be used as a platform to design curricula around.[48] Pharmacy rotations can provide venues to incorporate both the hands-on diagnostic training and didactic knowledge to improve competence and prepare students to enter test and treat programs directly after graduation. They can further build pharmacist confidence.

Conclusion

As healthcare systems continue to recover from the COVID-19 pandemic, task sharing to increase the scope of pharmacists to include testing and treatment for communicable and NCDs can enhance access to health services and foster a more resilient health system. The socio-political context, key resources, and pharmacists' competence, if adequately addressed, can facilitate an expanding role of the pharmacy profession. Participating pharmacists would be given more opportunities to utilize their pharmaceutical training, be adequately compensated, and expand their contribution to improve population-level health. Scaling task sharing initiatives for pharmacists starting with in-house tests like lateral flow assays and expanding to more complex diagnostics like send-out tests may improve acceptance from other healthcare professionals and the public. Pilot test and treat services can be modeled after successful programs such as the Diabetes Ten City Challenge by utilizing community-based pharmacist coaching, evidenced-based guidelines, and patient self-management strategies.[49] Monitoring the reach of test and treat strategies and the public health outcomes can provide critical evidence to support additional expansion of pharmacists' scope of practice. COVID-19 has opened new avenues for task sharing; pharmacists are uniquely positioned to bring testing and treatment from the clinic to the community.

Disclaimer

The findings and conclusions of this paper are those of the authors and do not necessarily represent the official position of the US Centers for Disease Control and Prevention (CDC).

Acknowledgments:

The authors would like to thank Jeremy Gold, MD, MPH and Faisal Minhaj, PharmD, Centers for Disease Control and Prevention for their review and comments on the manuscript.

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