

COMMENTARY

The Roles of Pharmacy Schools in Bridging the Gap Between Law and Practice

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Progressive pharmacy laws do not always lead to progressive pharmacy practice. Progressive laws are necessary, but not sufficient for pharmacy services to take off in practice. Pharmacy schools can play critical roles by working collaboratively with community pharmacies to close the gap between law and practice. Our experiences launching pharmacy-based point-of-care testing services in community pharmacy settings illustrate some of the roles schools can play, including: developing and providing standardized training, developing template protocols, providing workflow support, sparking collaboration across pharmacies, providing policy support, and conducting research.

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It is often noted that pharmacists are educated and trained to perform services that are not yet allowed under their static state laws. Groups will routinely attempt to remedy this gap by advancing “scope of practice” measures in front of their legislative bodies and regulatory boards, often against the objections of other health professions. As bills are signed into law and regulations take effect, the gap between practice and law narrows and pharmacists may provide the newly authorized patient care service. Pharmacists often treat this as the endpoint of a successful campaign; in our experience, this is just the starting point.

We have routinely observed a gap between law and practice, in that, services that are allowed to be performed by pharmacists under state law are not actually provided in practice. A permissive law opens the door; whether or not pharmacists walk through that door is dependent on many market pressures. These pressures include, but are not limited to, patient acceptance and demand, alignment of service to pharmacy mission, facility policies, workflow considerations, payer policies, threat of liability, and pharmacist comfort in providing the service, among other factors.¹

Pharmacy schools have a critical role to play in closing the gap between law and practice and helping pharmacists overcome these market pressures. Our experience

in implementing point-of-care testing (POCT) services for infectious diseases in community pharmacies provides one illustrative example of the role pharmacy schools may play. We first launched POCT services as a small pilot in one store in Michigan. This did not follow the passage of any specific laws or regulations; instead Michigan is a state that generally allows services unless they are specifically prohibited. Over time we scaled this service to 86 pharmacies in seven states that similarly had a permissive legal environment to support the service. Specifically, pharmacists at participating pharmacies used an evidence-based protocol to treat patients with influenza-like illness or Group A *Streptococcal* (GAS) pharyngitis. Eligible patients were offered a CLIA-waived test, and those who tested positive were eligible to receive an appropriate antimicrobial regimen by the pharmacist who had prescriptive authority under a population-specific protocol.² Faculty from the University of Nebraska Medical Center and Ferris State University were instrumental in launching and growing this service. Some of the key areas that faculty from these pharmacy schools played are summarized below.

Develop and Provide Standardized Training. Even when pharmacists have baseline training on a service, a “refresher” training can be beneficial to a pharmacy to ensure fidelity of intervention. Training can further inspire public confidence – and perhaps as importantly, corporate legal counsel confidence – in the service. This presents a significant opportunity for pharmacy schools. For POCT, faculty members developed a 20-hour POCT

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certificate training program (12 hours of self study; 8 hours live) to help pharmacies launch this service.³ Content focused on basic physical assessment, differential diagnosis, use of specific POCTs, and acting on test results. After hosting the initial training sessions, the administrative components of the certificate were taken over by a state pharmacy association and later a national pharmacy association. A train-the-trainer component was added to enable scaling of the certificate training program beyond the reach of the initial faculty.

Develop Template Protocols. POCT works best when pharmacists have the ability to act on the results of the test, specifically prescribing for influenza or Group A *Streptococcal* (GAS) pharyngitis. Albeit not ideal, the primary mechanism available today for pharmacists to prescribe for these conditions is by entering into a population-based Collaborative Practice Agreement (CPA) protocol with a prescriber.² The protocol delineates which patients are eligible for the service by specifying inclusion and exclusion criteria. Further the protocol must specify which treatments may be provided and under what circumstances. While these elements naturally stem from extant clinical guidelines, they often need to be tailored to the unique circumstances of a community pharmacy setting with a goal of directing potentially higher-risk patients to a more appropriate venue of care. Having academic experts develop a template protocol that is reviewed and approved by an Institutional Review Board can go a long way to raising the comfort level of a community pharmacy's legal counsel in the appropriateness of the service. Providing a base template can also help community pharmacies implement services that lead to a consistent patient experience across stores. Few pharmacies have implemented CPAs for services other than immunizations, in part, because of the difficulty in finding a willing collaborator.⁴ Providing a template may lower the activation barrier for starting negotiations with a prescriber over the parameters of a CPA. Still, in our research initiative, three chains were unable to identify a willing collaborating prescriber, and were thus unable to launch POCT in their stores.

Create Sustainable Services. Anyone who has ever proposed a new pharmacy service has been met with the question "how will this fit into the workflow?" or, worse, a declarative statement: "this won't fit in the workflow." While both of these mistakenly believe that pharmacy workflow is currently optimized, pharmacy schools can help overcome this barrier. A time motion study is a great way to evaluate the feasibility of incorporating a service into an actual community pharmacy practice setting. Our POCT time motion study identified that this service would take roughly the same time as an immunization, especially

if well-trained pharmacy technicians were involved.⁵ This study was often the first thing pharmacy operators asked to review before they would give serious consideration to this service.

The long-term sustainability of any service is dependent on its ability to fit seamlessly into workflow, and the cost-benefit conferred to the stakeholders involved. Colleges have a tremendous opportunity to assess the benefits to diverse stakeholders (namely patients and payers) to ensure that services are maximally positioned for long-term success.

Spark Collaboration Across Stakeholders. Delos Cosgrove, chief executive officer of the Cleveland Clinic once noted that he would rather be a fast follower than a pioneer, as "pioneers frequently have high mortality rates."⁶ We found this to be true for many pharmacies in the context of POCT. Several pharmacies that independently launched advanced pharmacy services have found themselves on the receiving end of political pushback from the medical profession.^{7,8} As a result, some pharmacies were hesitant to launch POCT on their own. Pharmacy schools are well-positioned to bring together multiple pharmacies in a collaborative project, insulating each individual party from perceived turf issues and keeping the focus, appropriately, on the public interest. Our initiative involved many different pharmacies, and while it was not immune to the usual and customary pushback, to our knowledge, not a single pharmacy was deterred from continued participation.

In addition, there is a tremendous opportunity for pharmacy schools to work collaboratively, especially in states with multiple pharmacy schools. Individual colleges may have different priorities and/or missions. Working together, colleges can leverage their unique strengths to bridge the gap in order for citizens of their state to receive maximum patient care benefits.

Provide Policy Support. A surprising trend with our research was being called in front of a regulatory board after the project was launched. Regulatory boards often defaulted to saying a new service was not allowed in their state; it was our experience that these regulatory boards were incorrect. In fact, 23 states recently said pharmacy-based POCT was not allowed in their states, which is certain to be a surprise to the 4,107 pharmacies currently doing POCT in those same states.⁹ Pharmacy schools are well-positioned to research state and federal laws, and connect the dots between state laws – in our case, pharmacy and laboratory practice acts. Having an academic expert present on these topics to the regulatory board was very well-received; in no state where we helped pharmacies launch POCT did a regulatory board ultimately ask any pharmacy to cease and desist. Pharmacy schools are

charged with preparing future pharmacists on federal law, state law, and policy issues. It is reasonable that the same faculty members who teach these critical courses should be involved in the creation of policy, both at the association and at the administrative levels. Support for faculty members to participate in these activities is essential to the creation of functional health policy surrounding pharmacy issues with a focus on the public interest.

Conduct Research. This may be the most obvious role of pharmacy schools and also the most important. The type of research needed will vary by the service, but can encompass clinical, economic and humanistic research. By conducting clinical and economic research on a service, the value of the service on patient care outcomes can be demonstrated, acceptance among payers and patients can be facilitated, and potential political and turf tensions can be diffused. For POCT, we published on the patient care outcomes achieved from both the influenza and strep throat testing, the benefits related to enhanced antimicrobial stewardship, the experience and perceptions of patients who received the service, and also the cost-effectiveness.¹⁰⁻¹⁴ The research was disseminated broadly at both state and national meetings and conferences, and generated considerable attention that furthered the movement toward POCT. In addition, research on patient satisfaction of a service, or perceptions of a service (from pharmacists, physicians, public health, etc.) can add to the body of understanding and help develop better pharmacy-based services. For example, we hosted focus groups with public health stakeholders in seven states and these discussions led to valuable insights, such as opportunities for information sharing between pharmacies and public health entities.¹⁵

Progressive laws do not always lead to progressive practice. Progressive laws are thus necessary, but not sufficient for pharmacy services to take off in practice. Pharmacy schools can play critical roles by working collaboratively with community pharmacies and other stakeholders to lower the barrier to launching a service. Our experiences, shared in this commentary, were a result of learning as we went as opposed to a concerted plan from day one. We believe they may serve as a template for roles that pharmacy schools may play in piloting and scaling other advanced pharmacy-based services that have the potential to improve patient care and population health.

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