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Relax Pharmacy Regulations to Help with COVID-19 Testing and Treatment

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One of the most urgent challenges facing policymakers managing the current COVID-19 public health crisis is how to ramp up diagnostic testing on a mass scale. Companies such as Walgreens, CVS, and Target have already started working with the federal government, as their locations are well-suited to become testing sites. As a result, pharmacies and pharmacists themselves are likely to become instrumental in testing for COVID-19 in the coming weeks and months. However, certain regulatory restrictions on pharmacists should be relaxed so that they can practice to the full extent of their training and abilities.

THE IMPORTANCE OF TESTING

The president has declared a national emergency and the federal agencies and state governments overseeing the response to the pandemic have recommended or required that citizens stay at home, practice social distancing, and, in some instances, self-isolate, self-quarantine, or shelter in place. To-date, authorities have offered little guidance as to when these recommendations will expire. Without reliable information about how many people are infected with COVID-19 as well as the rate at which the disease spreading, it is likely that policymakers currently have no clear sense of when to recommend a return to normalcy. Critical data required to inform such decisions will only emerge once large-scale testing is implemented.[1]

Tragically, the federal government botched its early response to the crisis.[2] Among other things, the first COVID-19 tests distributed around the country by the Centers for Disease Control and Prevention (CDC) produced unreliable results.[3] Furthermore, commercial labs and public health officials in the states couldn't get initial approval to perform their own tests (though in some cases,

they tested anyway).[4] These failures, largely a result of inflexible regulations,[5] have contributed to delaying the rollout of testing in the United States. Even now that many legal barriers to testing have been removed, shortages of supplies could be hampering the scaling up of testing.[6]

This is a particularly unfortunate outcome because the experience of other countries suggests that testing on a large scale has been a key ingredient of an effective response to the pandemic. Testing, when combined with practices such as isolating infected individuals and using contact tracing methods to identify who else may have been exposed to the virus, has shown promising results in places such as South Korea and Singapore.[7] Testing to confirm that those who are exhibiting no symptoms or who were previously ill are in good health could also potentially speed the transition back to normalcy.

The effectiveness of mass testing is powerfully illustrated by the experience of Vò, a small town that reported Italy's first death from COVID-19.[8] The town's 3,300 or so residents were tested and retested as part of an experiment rolled out by the University of Padua, with assistance from the government of the Veneto Region and the Red Cross.[9] Residents were tested regardless of whether they were exhibiting symptoms. Those who were confirmed as infected were quarantined. The second round of testing revealed that the number of infected residents had dropped from 3 percent of the population to nearly zero, and Vò eventually reached zero new cases within a few weeks.[10] Notably, this outcome differs dramatically from the experience of other parts of northern Italy, which has been one of the regions of the world most affected by COVID-19.

THE ROLE THAT PHARMACISTS CAN PLAY

At the time this was written, 579,000 COVID-19 tests had been administered in the United States.[11] If the disease continues to spread exponentially, testing will have to keep up with that pace of growth. Meeting that goal is going to be a significant challenge, as laboratories are already facing shortages of testing equipment.[12] Another challenge is going to be finding safe places where potentially infected individuals can be tested without infecting others and healthy individuals can be tested without getting infected themselves. A role for pharmacies is thus quickly becoming apparent.

Massachusetts, for example, set up one of America's first drive-through testing facilities in a pharmacy parking lot.[13] Other states, such as Michigan and Pennsylvania, are following suit.[14] Major drug store chains have publicly committed their support for the fight against COVID-19.[15]

Pharmacies are well positioned to become testing sites because of their geographical coverage across the country. There are more than 309,000 employed licensed pharmacists in the United States and its territories, and 90 percent of Americans live within five miles of a pharmacy.[16] Many pharmacies have adequate parking, which makes them well suited for drive-through testing. Some

pharmacies even have drive-through windows.[17] The familiarity patients have with pharmacists could prove important if sick individuals are more comfortable driving to their local pharmacy than going to a doctor's office or a hospital.

Pharmacists can be of critical assistance in triaging the coming avalanche of patients seeking diagnostics and care. Pharmacists could test patients for COVID-19 and, if the results return positive, give directions for home care if the illness is mild. If the illness is severe, pharmacists could direct patients to designated facilities for their particular area. Even if results were to come back negative, the pharmacist would save the patient from having to visit another venue of care, thereby freeing up time for other medical professionals to focus on more urgent cases. Should patients suffer from other minor ailments, pharmacists could also provide treatment (though this might require legal changes in many jurisdictions; to be discussed later in this brief).

Pharmacists' training makes them capable of providing this kind of basic medical care. It takes about eight years to obtain a doctor of pharmacy degree,[18] a regular requirement for a pharmacist license. This time includes three to four years of undergraduate prerequisite work and four years of additional professional study. The COVID-19 test is relatively simple and usually involves taking swabs from a patient's nose or throat.[19] This is a task well within the capabilities of a pharmacist to perform. Although for now the analysis of the swab is likely to take place off site at a lab, in the future this work could potentially be done on site. Indeed, rapid-turnaround COVID-19 tests are currently being developed and, in some cases, undergoing FDA approval.[20] Moreover, pharmacists themselves stand ready to assist, as identified by a recent call by the American Pharmacists Association for expanded pharmacist services to combat COVID-19.[21]

POLICY RECOMMENDATIONS

Fortunately, there are not many laws standing in the way of pharmacists and pharmacies immediately assisting in testing efforts for COVID-19. Personnel working at testing sites set up near pharmacies should be able to collect specimens from patients and send those specimens to laboratories for analysis without facing significant legal hurdles. These laboratories, however, do need government approval to operate, and indeed this has been one of the central bureaucratic hurdles that has hampered the US government's response to the crisis.[22]

These same restrictions also affect pharmacists with respect to performing laboratory testing for other ailments. For several decades, many pharmacies have been allowed to perform low-risk health tests thanks to the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Even in ordinary times, pharmacies can obtain CLIA waivers and perform tests related to such ailments as influenza, strep throat, human immunodeficiency virus, and other medical conditions.[23]

Currently, however, the percentage of pharmacies holding CLIA waivers varies enormously across states. One study finds the percentage of pharmacies possessing CLIA waivers to be between 0 and 60 percent, depending on the state, with a median percentage of 19.56 percent.[24] One reason for the disparity across states is varying state and local regulations, which include restrictions related to testing procedures, licensure of the personnel conducting tests or overseeing a lab, phlebotomy requirements, and waste disposal requirements.[25]

Allowing pharmacists to perform tests in ordinary times would better prepare them for crises like the current pandemic. Moreover, as CLIA waivers have increased, pharmacists and lab technicians have been able to incorporate basic testing into their existing workload without needing to work more hours.[26] Pharmacist testing has an additional benefit of potentially reducing the time between symptom development and treatment. Thus, ensuring that CLIA-waived COVID-19 tests quickly become available should be a top priority of the US Department of Health and Human Services.

When pharmacists are testing for an ailment, they are usually qualified to treat similar conditions as well. Florida recently passed a law that allows pharmacists to test and treat for influenza and strep throat.[27] These kinds of changes are likely to alleviate some of the stress on the medical system as pharmacists take on the burden of handling some of the more routine cases. However, Florida's reform remains far from ideal, in part because it requires a licensed pharmacist to have in place a collaborative agreement with a supervising physician, which can act as a disincentive for many pharmacists.

Idaho is perhaps the model state in this regard, as Idaho allows pharmacists to prescribe autonomously if a pharmacist identifies a medical condition as a result of a CLIA-waived test,[28] as well as under a number of other routine situations,[29] all without a collaborative agreement with a physician in place. Idaho also allows for substitution of therapeutically equivalent drugs without express physician authorization (but with notification to the physician). As more states like Idaho and Florida allow for basic testing and prescribing authority for pharmacists, colleges of pharmacy are likely to respond by updating curricula, thereby enhancing preparedness for future pandemics.

Many states are relaxing other kinds of regulations as a result of the COVID-19 pandemic.[30] Massachusetts has allowed pharmacies to produce hand sanitizer and mandated that insurers cover certain telehealth services.[31] Some states are now accepting out-of-state medical licenses or embarking in reciprocity agreements with other states with regard to medical licenses.[32] Again, Idaho has a reciprocity law for pharmacists that could serve as a model in this regard.[33]

Relaxing restrictions on telepharmacy could also yield beneficial outcomes. Currently, most tests for COVID-19 have a relatively long turnaround time,[34] often requiring patients to wait at home for results. When results become available, tested individuals could have a consultation with the pharmacist on the phone or via video conferencing platforms such as Skype or Zoom. Not only is this convenient for the patient, it also encourages social distancing. Currently, there is a debate

taking place about take-at-home COVID-19 tests.[35] If these tests become common, relaxing telepharmacy rules could enable pharmacists to provide remote instructions to patients administering their own tests. Telepharmacy reforms have also been known to increase access to pharmacies among underserved populations, such as rural populations.[36]

Importantly, as pharmacists take on additional responsibilities, they will likely need to rely more on pharmacy technicians to pick up more routine tasks. However, many states have restrictions in place that mandate a maximum ratio of technicians that can work with each pharmacist. Notably, many states have no ratio requirements,[37] and some states even have provisions in place that allow technicians to work remotely,[38] suggesting that some restrictions on pharmacy technicians can be relaxed or lifted altogether.

In short, pharmacists could readily play a role in ramping up COVID-19 testing and treatment, and eventually, when available, providing the vaccine. Relaxing state phlebotomy laws could yield additional benefits, as drawing blood may be necessary in efforts to search for antibodies for COVID-19. Any restrictions on the ability of pharmacists to immunize using FDA approved vaccines should also be reconsidered.

CONCLUSION

As pharmacies and pharmacists become instrumental in COVID-19 testing, any related regulatory restrictions at the state and federal level should be reconsidered. States should make it easier for pharmacies to obtain CLIA waivers, pharmacists should have the ability to prescribe in low-risk situations, regulations should be amended to make it easier for pharmacists licensed in one state to practice in another state, and the use of telepharmacy should be encouraged. Restrictions on pharmacy technicians and the ability of pharmacists to vaccinate are also areas where liberalization could prove beneficial. Combined, these reforms are likely to improve the public's access to testing and treatment for COVID-19 as well as a variety of other medical conditions. Equally important, these reforms can enhance preparedness for future pandemics.

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