Serving the Greater Good:

Public Health & Community Pharmacy Partnerships

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Contents

Executive Summary

The Johns Hopkins Center for Health Security, in the Johns Hopkins Bloomberg School of Public Health, conducted a study to examine how community pharmacy can best bolster public health in the United States. To do this, the study team first assessed the current contributions of community pharmacy in public health.* The study team performed a literature review; held a day-long meeting of experts, including those from state medical associations, preparedness entities, community pharmacies, public health agencies, nonprofit organizations, and academia; and conducted additional consultations with pharmacy, preparedness, and public health experts. To identify pragmatic steps where community pharmacy can contribute in the near term, the study team examined 3 major public health problems as case studies: (1) the current opioid addiction crisis in the United States; (2) antimicrobial resistance, especially due to inappropriate prescribing and overprescribing of antimicrobials, which has diminished the effectiveness of many once-potent antibiotics and which is increasing the morbidity and mortality of once-trivial infections; and (3) pandemic preparedness against influenza and other emerging infectious diseases.

The findings and conclusions reached in this study are those of the Johns Hopkins Center for Health Security and do not necessarily represent the views of the experts consulted. This study was funded through a grant from the National Association of Chain Drug Stores (NACDS).

In the past decade, community pharmacy has often been referred to as an "untapped resource" for public health. Now more than ever, in a time of declining public health budgets, public health should leverage pharmacies to advance community-based priorities.

While community pharmacy is currently supporting public health in myriad ways across the United States, there is considerable room for community pharmacy to have an expanded public health role and deeper integration in the healthcare system. This is particularly the case in medically underserved—typically rural—areas in the United States. Increasing the involvement of community pharmacy in public health has been a 50-state strategy, as the rules and regulations that govern what pharmacists can do are largely controlled at the state level. However, a federal push to increase involvement of and partnership with pharmacists to advance public health could reduce the patchwork of regulation and burden on states (models for consideration include the US Department of Veterans Affairs and the Indian Health Service). These efforts could increase the number of community pharmacies working toward national, state, and local public health goals and could greatly aid in planning for emergencies.

The national opioid addiction crisis presents a critical opportunity for community pharmacy to collaborate with public health entities and make a difference in reducing the number of new addictions, facilitating addiction treatment and other care, and providing access to life-saving medication in the event of an overdose.

Community pharmacy is already doing a great deal to combat opioid abuse and partner with state and federal government agencies to develop and implement collaborative approaches to reduce opioid-related problems. Some states have engaged community pharmacy to prevent new addictions, monitor opioid medication prescriptions, improve access to naloxone (an effective treatment for opioid overdose), and implement "take-back" programs for safe disposal of unused medications. Yet, more should be done to integrate community pharmacy in efforts to slow the opioid crisis with public health, physicians, health systems, health plans,

* For the purpose of this study, "community pharmacy" is defined as the collective group of independent and chain pharmacies (eg, traditional drug stores, grocery stores with pharmacies, mass merchants with pharmacies) in the United States.

and other key stakeholders working together. In particular, issues of access, liability, and payment need to be addressed, especially for naloxone, which is often not made available to individuals addicted to opioids but rather to third parties who may be able to prevent an overdose. Community pharmacy can also take on other essential preventive care services for this subpopulation in order to advance community health, such as immunizations for hepatitis and screenings for HIV and hepatitis C virus infection. Community health can and should improve when pharmacies and public health entities form strong collaborations to counter drug abuse and misuse.

Antimicrobial resistance is a global problem, and many health-related professions must be involved in the responsible stewardship of antibiotics. Community pharmacy can play an important role in providing patient education, performing tests to correctly identify infections so that antibiotic use is appropriate, and helping sufferers manage disease symptoms.

Across the nation, antibiotics are overprescribed and often are not necessary for patient recovery. Patient demand for antibiotic prescriptions, even for nonbacterial infections, further contributes to the problem of antimicrobial resistance. Pharmacists are well-situated to educate patients about the proper use of antibiotics, and they can help patients manage their symptoms, regardless of whether they receive a prescription for antibiotics. The FDA has issued waivers for Clinical Laboratory Improvement Amendments (CLIA) requirements for certain diagnostic tests, which can expand pharmacists' role by authorizing them to perform these tests. For example, many community pharmacies and retail clinics in the United States perform a simple point-of-care test for Group A streptococcal (GAS) or influenza infection and initiate treatment where appropriate. Pharmacists can diminish inappropriate antibiotic use through best practice models so that antibiotic treatment is reserved for when it is deemed clinically appropriate (ie, when diagnostic tests confirm a patient has a disease state that requires an antibiotic).

Public health benefits greatly from repeated successful partnerships with community pharmacy during disease emergencies; however, more can be done in planning so that pharmacies can fulfill valuable public health roles, particularly during a pandemic.

Community pharmacy is well-situated to provide emergency services during a pandemic, including dispensing medication, tracking records, administering vaccinations, and providing extended supplies of routine medications. But planning for these emergency activities has often fallen short, limiting the impact of community pharmacy during a response. For example, it may be legally straightforward to expand the populations that pharmacists are allowed to vaccinate against influenza—for example, from only adults to an expanded population of adults, children, and infants; however, unless requisite policy actions are taken before the onset of a crisis, pharmacists may not be prepared to vaccinate these additional populations. To utilize community pharmacy more broadly as an arm of public health, preparedness activities need to start well in advance of a crisis, such as through statewide protocols that allow pharmacists to prescribe and dispense medications in accordance with medical and public health standards. Community resiliency and access to care increase with integrated public health planning and response that includes community pharmacy.

Purpose of the Study

The Johns Hopkins Center for Health Security (the Center) conducted a study to determine how public health in the United States can best be bolstered by engaging with community pharmacy in the near-term future. To frame the analysis, the Center examined 3 specific areas of growing public health need to determine how community pharmacy could serve the public's health: the national opioid crisis, antibiotic resistance, and pandemic and emergency preparedness and response.

Methods

Review of published literature and previous reports: The Center analyzed and included relevant data from a wealth of scholarly literature focusing on the role of community pharmacy in public health (Appendix C: References).

Invitational meeting: The Center invited experts from academia, government, nonprofit organizations, professional associations, and retail pharmacies to participate in a not-for-attribution meeting on October 25, 2016, at the Center's office in Baltimore, Maryland. The meeting, titled "Innovative Approaches to Collaboration for Public Health and Pharmacy Partners," was intended to convene experts to present and discuss innovative models and opportunities that drive collaboration across public health and community pharmacy partners, specifically around antibiotic stewardship, opioid misuse and naloxone, and pandemic preparedness. Additional meeting information can be found in Appendix A: Agenda for Innovative Approaches to Collaboration for Public Health and Pharmacy Partners Meeting and Appendix B: Meeting Participants and Expert Consultations.

The meeting served as a forum for not-for-attribution discussion of these pressing areas of public health and the role that community pharmacy can play, particularly in a time of decreasing budgets for public health agencies and services. Diverse views were encouraged in this discussion, and, while there was no requirement for consensus, there was substantial agreement around many findings.

Follow-up expert consultations: After the invitational meeting, the Center performed a small number of additional expert consultations with individuals who were unable to attend the invitational meeting and/or to further discuss topics that there was insufficient time to address during the meeting. These consultations were held over the phone, were not recorded, and were explained to be not for attribution. The experts who were consulted in this process are listed in Appendix B: Meeting Participants and Expert Consultations.

Final report: This final report presents the Center's policy judgment regarding the role of community pharmacy in public health and the areas for which the role of pharmacy should be expanded in the near term. The views expressed do not necessarily reflect the views of the meeting participants, those who were consulted following the meeting, or the sponsor of this study.

Funding: This project was funded through a grant from the National Association of Chain Drug Stores (NACDS).

Analysis

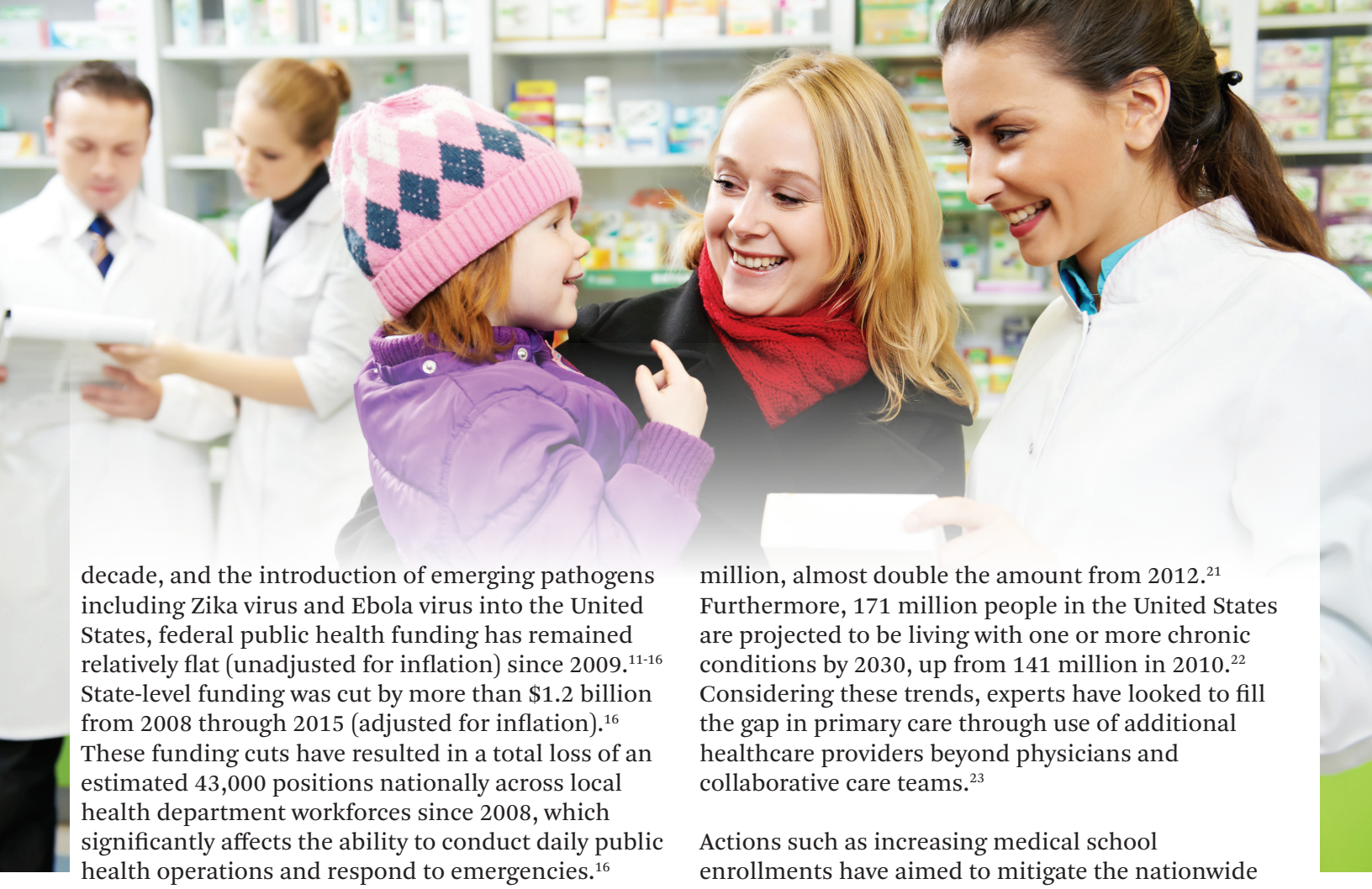
Community Pharmacy as an Untapped Public Health Resource

In the past decade, community pharmacy has often been referred to as an "untapped resource" for public health. Now more than ever, in a time of declining public health budgets, public health should leverage pharmacies to advance community-based priorities.

Community pharmacy has often been called an "untapped resource" for public health.[1-4] Pharmacists are highly trained professionals who are more likely than other healthcare providers to be integrated in their communities, known to patients, accessible for patients' health- and medicine-related questions, and well-situated to provide health monitoring. They are considered among the most trusted of healthcare providers, and they know the medications and their associated side effects perhaps better than any other group of healthcare providers.[5] Given that patients see pharmacists when they pick up prescriptions and refills or household goods in a community pharmacy, pharmacists are well-poised for follow-up health monitoring of patients, education, and monitoring patients' health between primary care visits. Evidence strongly suggests, across a variety of studies, that when pharmacists are integrated into direct patient care in a team with other health professionals, there are positive effects on patient outcomes as well as reduced healthcare costs.[6,7] In many cases, however, more can be done so that these pharmacy professionals can practice at the "top of their license"—that is, at the peak of what they are professionally capable of doing and what their license allows them to do to support public health.[8,9]

Depending on the state and region, pharmacists already perform a wide variety of public health roles, including vaccinations and health screening. A meta-analysis conducted in 2010 of 298 studies of pharmacist-delivered care (eg, medication therapy management services, disease state management, education) demonstrated that pharmacist-provided care has favorable effects with respect to patient outcomes, healthcare settings, and disease states.[6] The limits on what pharmacists can do are set by the states in which they practice. While there are a wide variety of needs and conditions that affect pharmacists' scope of practice, states can further tap into this healthcare resource and expand pharmacists' public health roles. This is particularly important as public health budgets and capabilities are likely to continue to shrink and physicians become increasingly inaccessible, as has been seen in recent years. Numerous reports have highlighted the merits of pharmacists and how they are underutilized in the US health system. For more than 40 years, pharmacists in the US federal government system (eg, Department of Veterans Affairs, Indian Health Service) have collaboratively managed disease through medication and other clinical pharmacy services, yet these models are not fully used outside the federal sector due to policy, legislation, and payment barriers.[8,10]

Public health budgets have precipitously declined, placing greater demands on potential force multipliers to achieve public health goals. Despite the recent re-emergence of vaccine-preventable diseases including measles and pertussis, the first increase in domestic tuberculosis cases in more than a



decade, and the introduction of emerging pathogens including Zika virus and Ebola virus into the United States, federal public health funding has remained relatively flat (unadjusted for inflation) since 2009.[11-16] State-level funding was cut by more than $1.2 billion from 2008 through 2015 (adjusted for inflation).[16] These funding cuts have resulted in a total loss of an estimated 43,000 positions nationally across local health department workforces since 2008, which significantly affects the ability to conduct daily public health operations and respond to emergencies.[16] Additionally, nearly a quarter of local health departments reported budget cuts in 2015.[17]

In addition to declining public health resources, there is a decline in physicians available to see patients, across communities in the United States. The shortage of physicians, particularly in rural areas, is exacerbated by the fact that the US population is aging and requires more health care.[18,19] One study projected a shortfall of between 46,100 and 90,400 physicians by 2025, with demand for physicians going up about 17%.[19] According to that same study, the specific shortage of primary care providers is expected to expand from 12,500 to 31,100 primary care physicians.[19]

Not only is care in the United States more expensive, with paradoxically worse health outcomes (eg, life expectancy and prevalence of chronic conditions) compared to similar countries, but the US population is also becoming older and sicker. Among patients with chronic illness, approximately 50% do not take their medications as prescribed, which leads to increased mortality, morbidity, and costs of approximately $100 billion per year.[20] By 2050, the population aged 65 and older is projected to be 83.7 million, almost double the amount from 2012.[21] Furthermore, 171 million people in the United States are projected to be living with one or more chronic conditions by 2030, up from 141 million in 2010.[22] Considering these trends, experts have looked to fill the gap in primary care through use of additional healthcare providers beyond physicians and collaborative care teams.[23]

Actions such as increasing medical school enrollments have aimed to mitigate the nationwide physician shortage, and there are some who doubt that the shortage will be as severe as projected.[24] However, in rural areas, in the United States and around the world, there is already a clear shortage of physicians and primary care providers.[25] The opportunity to expand the roles of pharmacists offers particular benefits for rural areas, where they can help fill these existing gaps.

There is considerable room for the role of community pharmacy to expand, particularly in medically underserved areas. Rules and regulations that govern what pharmacists can do are generally controlled at the state level; however, increasing the involvement of pharmacists in public health does not necessarily have to be a state-by-state strategy. A federal push to increase involvement of pharmacists in public health could reduce the burden on states to involve physicians directly in efforts to achieve public health goals, including ensuring that they are paid for their services through Medicare. Expanding pharmacists' roles could also benefit the public during an infectious disease crisis—for example, if there is a need to vaccinate the entire population of the country against a new influenza strain.[26]

Community Pharmacy and the Opioid Epidemic

The national opioid addiction crisis presents a critical opportunity for community pharmacies to collaborate with public health entities and make a difference in reducing the number of new addictions, facilitating addiction treatment and other care and providing access to life-saving medication in the event of an overdose.

Community pharmacy is playing an important role in diminishing the national opioid crisis. In many states, pharmacists are working to prevent new addictions, surveil for unlawful prescription drug abuse, provide medications that can reverse overdoses, monitor prescriptions, provide a safe place to dispose of unwanted medications, and educate communities about addiction and prevention. While significant progress has been made, there are policy steps that should be taken so community pharmacy can more readily work to benefit public health, diminish the escalation of new cases, and prevent overdoses.

The abuse of opioid drugs—both prescription drugs like morphine and illicit drugs like heroin—is an epidemic in the United States. Of the 52,404 lethal drug overdoses in 2015, more than 63% involved an opioid.[27] This was an 11% increase over 2014 and included a 23% increase in heroin deaths and a 73% increase in synthetic opioid deaths.[28] Between 1999 and 2008, the rate of overdose deaths in the United States rose by about a factor of 4.[29] Additionally, the rate of substance abuse treatment admissions increased by nearly a factor of 6 over similar periods (1999-2010 and 1999-2009).[29] One of the leading drivers of the opioid epidemic is patients' transition from prescription opiates to illicit drugs. A 2014 study found significant shifts in the populations vulnerable to opioid abuse over the past 50 years.[30] Among heroin users, more than 80% of those who initiated their opioid abuse in the 1960s started with heroin, whereas 75% of those who initiated their opioid abuse in the 2000s started with prescription pain medication and later transitioned to heroin.[30]

Compounding the problem of increased abuse of nonprescription opioids is the introduction of synthetic opioid products and counterfeit drugs. In recent years, illicit drug manufacturers and dealers have responded to the increased opioid demand by "spiking" counterfeit opioid products with synthetic opioid drugs in order to increase already significant profits and make their products more desirable (due to their increased potency). According to the Drug Enforcement Agency, 1 kilogram of fentanyl, which can be purchased for $3,500, is enough to make 1 million pills worth a total of $20 million.[31] Synthetic opioids—including fentanyl and its derivatives as well as novel drugs—are considerably stronger in their effects than morphine, oxycodone, and heroin. Fentanyl has been shown to be 100 times as potent as morphine and multiple times stronger than heroin, and some novel synthetic opioids can be 100 times as strong as fentanyl. Opioid users can unknowingly consume counterfeit products that are orders of magnitude stronger than intended, often resulting in lethal overdoses.[32,33]

In an effort to reduce overdose deaths, there has been a push to increase availability of naloxone, a fast-acting drug that reduces the risk of respiratory failure after overdose. Naloxone, which is also known by a variety of brand names, is not a controlled substance and does not itself carry a risk of causing addiction. It was FDA-approved in 1971, and there have been more than 26,000 overdose reversals documented.[34] Opioid overdose deaths have been demonstrated to decline proportionately to the amount of naloxone available in a community.[35] One barrier to accessing naloxone is cost; despite the availability of generic versions of naloxone since 1985, the cost of the drug has grown rapidly in response to the national opioid epidemic.[36]

Community pharmacy is in a good position to raise awareness about the risks of addiction to prescription drugs, both to the person who has been prescribed opioids and to their contacts and family members.[37] According to one expert consulted in this study, most people do not understand that an opioid abuser may not "look" like they are on drugs—and many people sincerely believe that addiction could never happen to them personally. It was this expert's opinion that naloxone should be considered analogous to an epi-pen: "If you have a peanut allergy, you carry an epi-pen in case you accidentally ingest a peanut and have

an allergic reaction. If you are on a high-dose opioid, you should be carrying a rescue [naloxone]."

It has been demonstrated repeatedly that community pharmacy can do a great deal to curb misuse of opioids. For example, one traditional chain pharmacy started programs to dispose of prescription opioid medication, educate about opioid risks and overdose, and expand access to naloxone; as a result, they have collected and disposed of more than 10 tons of medication across 35 states and Washington, DC.[38,39] Similar efforts have been made by a number of other national and regional chains as well.[40-45]

Implementing standing orders, prescription drug monitoring programs (PDMPs), and drug disposal programs as well as serving as an education resource are just a few of the strategies that have been used to increase pharmacists' public health role in preventing or mitigating opioid misuse. It is important that these strategies be adopted more broadly across the country, particularly revising pharmacist standing orders to permit pharmacists to dispense naloxone without a prescription from a physician or nurse practitioner. In a method similar to the way pharmacists are able to provide flu vaccines without a physician consultation, some states have instituted standing orders—or statewide protocols[46]—so that pharmacists can provide naloxone without a physician consultation. The standing orders vary from state to state,[47] but these programs have proven effective at overdose rescues. Some states limit naloxone prescriptions to the individual who is at personal risk of overdose, while others permit dispensing to a third party. Additionally, some states require a doctor's signature to dispense to a third party, while others do not.[48] The use of a statewide protocol helps to reduce confusion over regulations as well. As of August 2016, 44 states allow a third party to be prescribed naloxone, and 5 states permit pharmacists to prescribe naloxone on their own authority.[49] Twenty-three states do not require a person to have a prescription for naloxone in order to purchase it at a pharmacy.[39] There are also community programs that have been demonstrated to be effective in which naloxone kits are distributed to laypeople.[34]

Pharmacies have also been involved in other areas to support public health's efforts to address the opioid crisis. For example, PDMPs are electronic databases that document controlled substance prescriptions, and they can be used to identify and track inappropriate patient and prescriber behavior and cut down on unlawful misuse. State PDMPs lack uniformity and interconnectivity, and a nationwide PDMP effort could provide a more comprehensive monitoring capability for opioid prescriptions to curb abuse and prevent new addictions.

Pharmacists are also ideally positioned to offer education to potential victims and their families. They can educate those who are at risk of addiction and overdose about the potential for serious consequences as well as their options for treatment, and they can provide overdose response training for professionals and laypeople. Pharmacies and other stakeholders can also reduce the supply of opioids available by partnering to implement a 7-day supply for minor acute care and to support local safe disposal of unwanted or unused prescription medications. As families are counseled on medication, community pharmacy can start to create a new social norm around restricting opioid access for minor acute care (eg, wisdom tooth extraction).

While a great deal of progress has been made, community pharmacy remains the "untapped resource" for the national opioid epidemic, and policies need to be developed so that they can fully engage in this public health crisis. Issues of liability, payment, and legality continue to be a barrier to community pharmacy's engaging as a resource for public health. This is particularly the case for a drug like naloxone, which is often not made available to individuals addicted to opioids, but rather only to third parties who may be able to prevent an overdose. There is also the challenge of legality in prescribing for a third party or caregiver. As of August 2016, 36 states provide protection from civil liability for naloxone dispensing, and 32 states provide protection from criminal action for the prescription of naloxone.[49] To be in a position to educate about the potential for addiction and to be able to dispense naloxone effectively, pharmacists needs to be trained as well. Some states—like Kentucky, which has exceeded 1,000 deaths per year from overdoses—have put forward live and webinar-based training programs for pharmacists so that they can become certified to dispense naloxone.[50] Good Samaritan laws (also called medical amnesty laws) are also critically important, so that people who witness overdoses are not punished for seeking or providing help.[51]

Community Pharmacy and Antimicrobial Stewardship

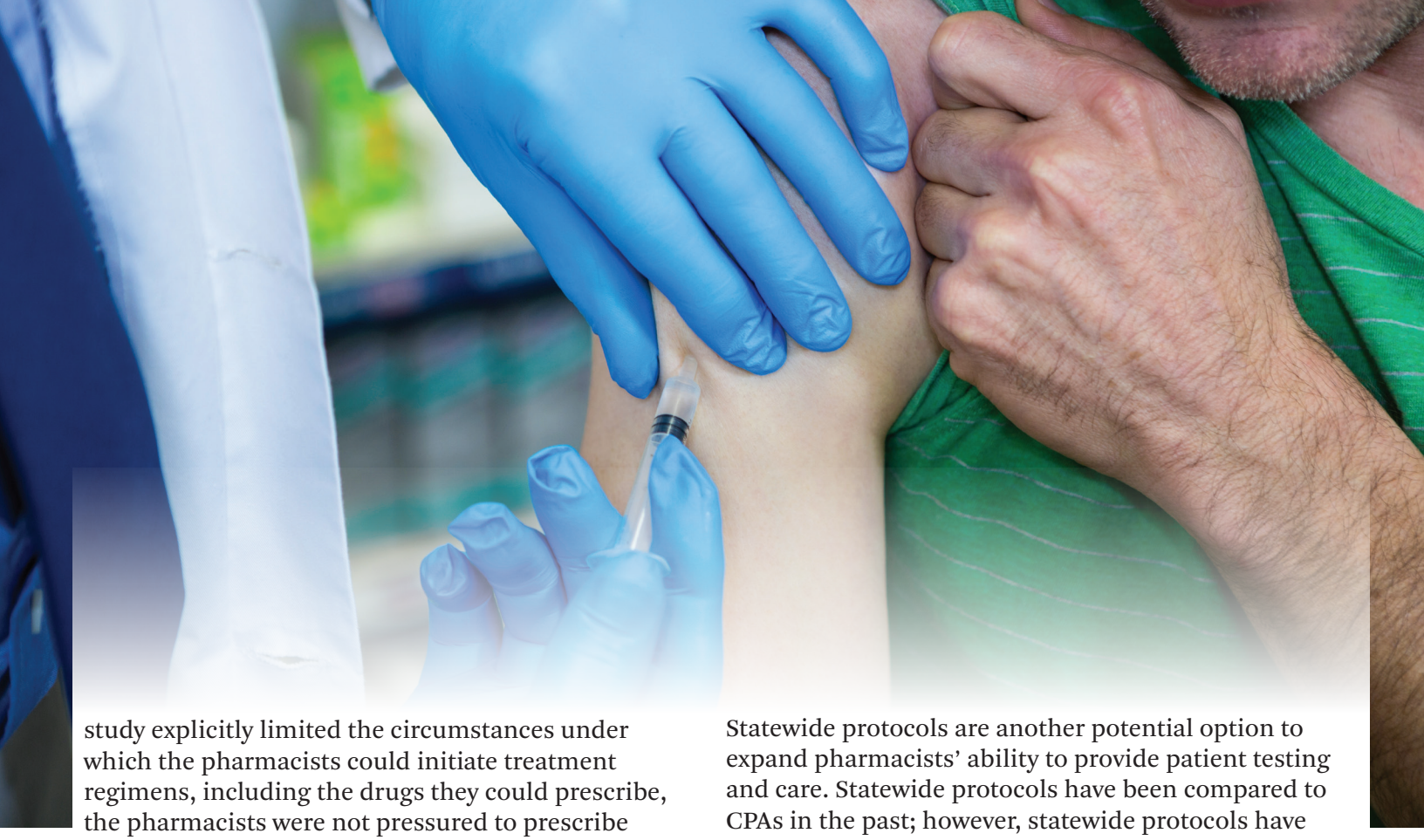
Antimicrobial resistance is a global problem, and many health-related professions must be involved in the responsible stewardship of antibiotics. Community pharmacy can play an important role in providing patient education, performing tests to correctly identify infections so that antibiotic use is appropriate, and helping sufferers manage disease symptoms.

Antimicrobial resistance (AMR) is currently a grave concern, and it is getting worse. The US Centers for Disease Control and Prevention (CDC) estimates that more than 2 million people are infected with antibiotic-resistant bacteria every year and that resistant bacteria are directly responsible for more than 23,000 deaths annually.[52] The European CDC reported significant increases in resistance to multiple classes of antimicrobials across multiple pathogens from 2008 through 2015, including to last-line drugs like carbapenems.[53,54] Additionally, multiple countries have reported large numbers of isolates resistant to colistin, an important drug for combating multidrug resistant organisms, which potentially signals the emergence of even greater AMR threats.[53] In fact, the United States identified its first case of pan-resistant bacterial infection—resistant to every single available antibiotic—in August 2016.[55,56] While antimicrobial resistance is traditionally viewed as an issue for hospitals, most antimicrobials for human use are dispensed in outpatient settings, including primary care offices and community pharmacies, potentially leading to an increased risk of antimicrobial resistance developing outside of hospitals as well.[57]

Pharmacists are in an excellent position to educate the public about the appropriate use of antibiotics. As many community pharmacies are conveniently located, have expanded operating hours compared to primary care physicians, and provide services and products beyond those of the pharmacy itself (eg, groceries), more potential patients visit pharmacies more regularly than they visit doctors' offices or outpatient clinics.[57,58] This additional foot traffic, combined with pharmacists' expertise and experience, provide community pharmacies with an opportunity to educate patients and the public about the proper use of antibiotics. One expert in AMR consulted for this study observed that "people need to see antimicrobial resistance messaging when they pick up their blood pressure medication" in order for pharmacies to be effective in educating about AMR. Constant exposure to public messaging about antimicrobial resistance and the appropriate use of antibiotics can reinforce antimicrobial stewardship programs and build AMR awareness in the broader community.[58]

Antibiotics are lifesaving drugs, but they are often overused and inappropriately prescribed, contributing to the global antibiotic resistance crisis. Historically, community pharmacists have not played a major role in diagnosing patients or initiating treatment regimens. Steps in the past 20 years to expand pharmacists' role in patient care, such as providing immunizations and more recently diagnostic tests for tuberculosis and HIV infection, signal a shift in this mentality.[59-61] One option that seems to be gaining attention in the United States is the use of Collaborative Practice Agreements (CPAs). CPAs are agreements between specific pharmacists and physicians under which pharmacists are authorized to conduct specified screening and physical examinations (eg, temperature, blood pressure), perform certain Clinical Laboratories Improvement Act (CLIA)–waived point-of-care diagnostic tests, and immediately initiate designated medication regimens based on those test results for certain specified populations. As direct consultation with a physician is not required, the treatment can begin immediately.[57] Although CPAs are typically narrower partnerships between pharmacists and local physicians (compared to statewide protocols, discussed below), they still can be effective tools in combating antimicrobial resistance.

Two small pilot studies for seasonal influenza and group A Streptococcus conducted in the United States suggest that these partnerships could potentially reduce the frequency of inappropriate antimicrobial prescriptions.[62,63] Both pilot studies exhibited lower rates of antimicrobial prescriptions—often cited as an expectation by many patients—compared to historical averages. These studies also found high rates of customer satisfaction. Because the CPAs for this



study explicitly limited the circumstances under which the pharmacists could initiate treatment regimens, including the drugs they could prescribe, the pharmacists were not pressured to prescribe antibiotics unnecessarily. One theory posited for the high rate of satisfaction is that community pharmacists can also provide appropriate symptom management options—immediately available from the pharmacy in the form of over-the-counter products—for patients who may not warrant antimicrobial prescriptions.[62,63] As one AMR expert consulted for this study observed, "Not prescribing an antibiotic is different than not treating a patient."

By treating patients with over-the-counter drugs to address their symptoms, pharmacists could also indirectly reduce downstream opportunities for the development of antimicrobial resistance. Addressing a patient's suffering or discomfort may provide sufficient relief and avert unnecessary primary care or emergency department visits and, in turn, subsequent requests for and prescriptions of antimicrobials.[58] Reductions in unnecessary antimicrobial prescriptions could also potentially reduce the development of resistance in hospital settings that can be associated with individuals' prior exposure to certain antibiotics.[57] These programs demonstrate the potential for community pharmacy to engage further in antimicrobial stewardship efforts, but dedicated efforts are required in many places to make these programs widely available.[57,59]

Statewide protocols are another potential option to expand pharmacists' ability to provide patient testing and care. Statewide protocols have been compared to CPAs in the past; however, statewide protocols have a much broader scope of eligible participants. While CPAs are agreements between specific individuals or groups of prescribers and pharmacists, statewide protocols are implemented by state regulatory authorities and apply to all eligible pharmacists across the state. Statewide protocols have broader public health impact, because they allow all licensed pharmacists in the state who meet the specified qualifications to implement the protocol.

Experts have developed guidance and best practices for state legislative bodies and regulatory authorities to implement statewide protocols, but further effort is required to take advantage of the broader scope and impact they can have over CPAs. Statewide protocols have been implemented for services and products such as certain vaccinations, naloxone, contraceptives, and tobacco cessation, but they are also promising as a potential mechanism to facilitate antimicrobial stewardship.[46] For example, New Mexico experimented with an expanded scope of practice for pharmacists to allow them to prescribe, administer, and read tuberculosis tests, so that patients could be referred to follow-up treatment, with valuable documented public health benefits.[60] Similarly, statewide standing orders and statewide CPAs are also potential options to provide expanded capabilities to pharmacists; however, they may be subject to additional restrictions and limitations compared to statewide protocols.[46]

The Role of Community Pharmacy in Emergency Preparedness and Response

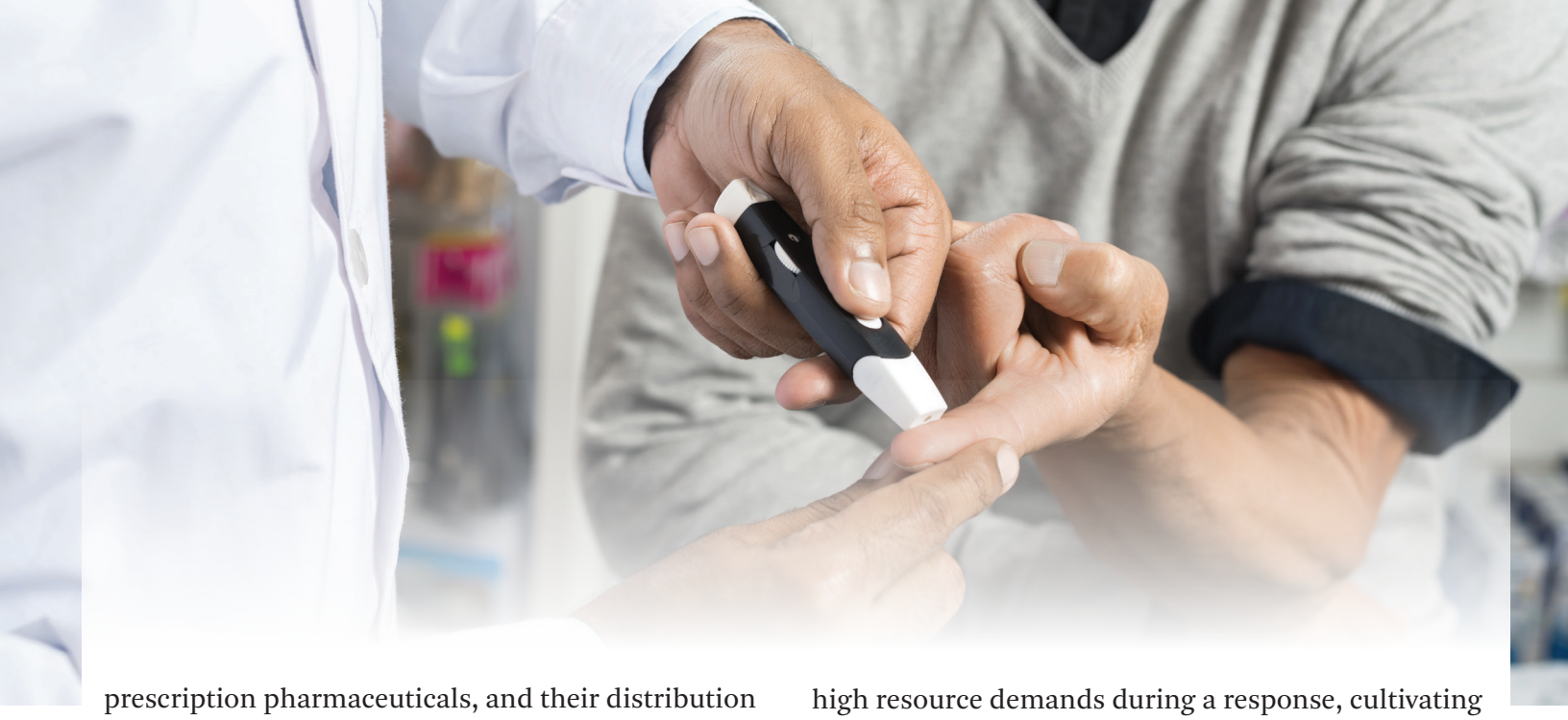
Public health benefits greatly from repeated successful partnerships with community pharmacy during disease emergencies; however, more can be done in planning so that pharmacies can fulfill valuable public health roles, particularly during a pandemic.

Public health benefits from pharmacists and pharmacies that are well-positioned to substantially reduce morbidity and mortality during a disease emergency. Though there exists already a long track record of pharmacies contributing to emergency responses, there remain opportunities to further expand their roles to benefit public health.[26] Community members interact directly with pharmacies far more often than they do with their local health department, and individuals may be more comfortable—or find it more convenient—to access a pharmacy during an emergency than a local health department. Easy access to pharmacies also makes them ideal sources of preparedness information and supplies. Because of the range of products offered at pharmacies (and, in some cases, their physical location within larger stores), they are an excellent one-stop shop for everything from first-aid supplies to food and water. Pharmacies may also be able to provide customers with emergency supplies of prescription medications in the days leading up to a hurricane, snowstorm, or other forecasted emergencies, decreasing the postevent burden on the local pharmacy network and improving individuals' health during the response and recovery from a disaster.

Public health entities partner with pharmacies that can offer a wide range of services and products—both medical and nonmedical—to support an infectious disease emergency response, which will benefit their customers, staff, and the broader community. Given the breadth and depth of the existing supply chain network, pharmacy is well positioned to support public health–led efforts that directly bring medication and care services to communities in disasters. One service that pharmacies can provide is dispensing medical countermeasures, such as vaccines, prophylaxis, and treatments. Based, in part, on pharmacies' national distribution networks, models that forecast the effect of vaccine administration by retail pharmacies project that pharmacists can increase the number of pandemic influenza vaccine doses administered and reduce the time required to achieve adequate coverage.[64] Pharmacies already have extensive experience in dispensing medications as well as managing patient data, and many are already able to administer a wide range of vaccinations, which could facilitate implementation of emergency medical countermeasure (MCM) dispensing protocols.

Pharmacies can also serve as standalone points of dispensing (PODs), provide medical personnel to support other open and closed PODs, or even deploy mobile pharmacy units that can also serve as PODs. In fact, mobile pharmacies can support many types of disasters, providing medication dispensing capacity to supplement local pharmacies that may be unavailable to provide their normal services due to structural or flood damage or loss of electricity. They can also supply additional resources, such as replacing lost or destroyed prescription medication or accessing electronic patient records in response to increased demand on the local pharmacy system. Electronic patient records are also helpful in the event that an emergency requires the displacement or evacuation of affected populations; however, active effort is required to ensure that individual data networks are integrated so that patients can obtain their required medication, even if their regular pharmacy is not available.

In addition to supplying medications or medical services, pharmacies can provide nonpharmaceutical products like potable water and food. The logistics systems in place to support daily pharmacy operations—particularly large regional or national chains—can be repurposed to deliver much-needed supplies to disaster areas. Pharmacies routinely offer over-the-counter medications and products, first-aid materiel, and food and drink in addition to



prescription pharmaceuticals, and their distribution networks are specifically designed to handle an array of products and keep individual stores stocked using sophisticated, just-in-time deliveries designed to minimize on-site storage requirements. These systems can play a vital role during an emergency response, identifying needs and rapidly delivering a variety of high-demand products to support response activities and community health.

In order to facilitate these types of response activities, pharmacies need to coordinate with public health, emergency response, and elected officials to identify the types of products and services that may be required—as well as what services are already available—and exercise the mechanisms required to integrate with official response activities. Pharmacies may be able to maintain or return to normal operations independent of the formal emergency response, but engaging with responders and local officials can help identify and fill response gaps, enabling the combined response to be greater than the sum of the individual efforts.

During emergencies for which the Emergency Prescription Assistance Program (EPAP) is activated, enrolled pharmacies can process claims and provide prescription medication, specific medical supplies, vaccines, and some forms of durable medical equipment for eligible individuals—largely the uninsured—in federally identified disaster areas. EPAP allows those who are unable to access necessary medication and medical supplies to receive 30-day supplies, renewed every 30 days, as long EPAP is active.[65] Due to the inherent chaos, uncertainty, and high resource demands during a response, cultivating the relationships and networks necessary to engage with response activities in the midst of a response can be difficult or resource-prohibitive. Establishing and exercising these protocols before the onset of an emergency can allow a smoother integration of pharmacies into response operations and improve overall response capabilities.

Challenges remain for pharmacies to play a more active role in public health emergencies, especially with respect to licensing and scope of practice. One of the most important challenges for pharmacies engaging with local responders is determining what services pharmacists are legally authorized to provide. While pharmacists perform an extensive range of services in their daily duties, some special populations (eg, children, pregnant women) may fall outside the scope of their licensing for some services. For example, pharmacists may be authorized to administer certain vaccinations or expand the authorized age range via a straightforward executive order; however, they must still be trained in pediatric vaccinations and have the appropriate pediatric syringes available, both of which require foresight to address in advance of an emergency.[66,67] Pharmacists can obtain the appropriate training and certification and stockpile emergency supplies of specialized material in preparation for emergencies, especially through collaboration with the local public health and healthcare systems.

Another major challenge is handling displaced populations. As mentioned above, electronic medical records can help pharmacies determine what

prescriptions an individual has in order to replace lost or destroyed medications; however, pharmacies may run into issues with dispensing prescription medications across state lines. If a displaced population must leave the state, as was seen after Hurricane Katrina, regulatory issues may delay the dispensing of vital medications. Pharmacy networks, particularly those near state borders and those with larger geographical networks, need to understand how differences in state regulations and prescription authority could affect emergency response operations, especially near state borders. Active engagement with regulatory agencies in each state to establish emergency protocols in advance of an event can alleviate response issues and allow healthcare personnel from other states to support the response, including the deployment of mobile pharmacy units.

In the wake of Hurricane Katrina, obtaining prescription medications was a major medical problem among displaced populations.[68-70] In fact, emergency departments along the Gulf Coast and in other areas of the country saw substantial spikes in the number of individuals seeking care to replace prescription medication. For example, emergency departments in Alabama served evacuated populations from Alabama, Mississippi, and Louisiana in the days leading up to Hurricane Katrina's landfall. In response, Alabama expanded an existing provision that permitted emergency refills from a 3-day supply to a 30-day supply of prescription drugs.[69] Similar challenges were also faced in Illinois, as the Chicago Department of Public Health provided care for evacuated Katrina victims. Challenges related to obtaining medical and prescription history posed barriers to obtaining required prescriptions; however, an ad hoc partnership with a major chain pharmacy helped to alleviate some of these issues.[68]

While community pharmacy can provide myriad services that benefit public health in an infectious disease crisis, their effect can be diminished by poor planning. While pharmacists are well-situated to provide emergency services during a pandemic, including dispensing medication, tracking records, and vaccinating, local planning for these activities has sometimes fallen short and diminished their impact in a crisis. For example, it may be a simple executive order to allow pharmacists to ease the burden on public health by allowing them to vaccinate children against influenza, but pharmacists will be unable to do so unless they have the right syringes and vaccine formulations on hand and their state pharmacy board has provided them with the appropriate guidance and permissions. In order to use pharmacists more extensively as an arm of public health, state and local preparedness efforts need to be initiated and implemented well in advance of a crisis.[71]

Because community pharmacy may not be viewed as a traditional public health partner by other healthcare providers, it may be difficult to initiate collaboration with local public health or response agencies. A narrow vision of public health likely includes local health departments; hospitals, primary care offices, and clinics; emergency medical services; emergency management (if external to public health); and other first responders. Because pharmacies can offer such a wide variety of products and services, it is vital that both public health officials and pharmacy representatives make an active, concerted effort to integrate their emergency operations.

Beyond the challenges involved with actual response activities, pharmacies may experience financial burdens resulting from their response operations, which need to be addressed if pharmacies are to reach their full potential as public health partners. Some pharmacies have reported that they have been unable to obtain reimbursement from insurance companies for some services provided during emergency responses, particularly if those services are outside the scope of their normal authorized operations. Pharmacies have cited early prescription refills—for example, in advance of an impending emergency—as a specific issue that requires special coordination with insurers to resolve. In order to combat this, an expert who participated in the meeting mentioned that some pharmacies have sought external funding to supplement their response activities, including through cost-sharing measures for public health emergencies or under Stafford Act disaster declarations. This may not always be an option, however, as many emergencies are not formally declared to be disasters. While pharmacies and pharmacists are often willing to assist in a crisis, working out financial and liability issues ahead of a crisis will assist in planning and enable pharmacies to reach their full potential in the service of public health.

Conclusion

In the past decade, community pharmacy has been called an "untapped resource" for public health. Forging more robust partnerships with pharmacies would be beneficial for all communities, and maximizing the delivery of care by pharmacists in both public and private sectors should improve the nation's public health. Now, in a time of declining public health budgets, the continuous threat of disease emergencies, and the growing effects of the national opioid epidemic, it is clear that community pharmacy is a resource that states and the federal government cannot afford to leave underutilized. Pharmacies are already providing several important services that supplement public health efforts around vaccination, such as for hepatitis B, point-of-care testing for HIV and hepatitis C, and screening of those who may be misusing drugs (SBIRT: screening, brief intervention, and referral to treatment). They can diminish the overuse of antibiotics and help people get the right treatment for their diseases, whether it is influenza or a bacterial infection. They are referral points for treatment programs and good connectors between other health providers and the community, and they have excellent reach into rural and other medically underserved areas. With regard to opiates, they can provide information, treatment for overdoses, and referral program information as well as prescription monitoring and take-back programs for unwanted pills. Yet, while community pharmacy can be a force multiplier for public health and promote community resiliency in the face of crises, state and federal government agencies and officials need to make a proactive effort to make community pharmacy a fully integrated part of the overall health response.

The data are clear that community pharmacy provides valuable services for public health, but further planning and preparedness are required in order to take full advantage of this resource. For community pharmacy to be useful in emergencies, whatever their nature, planning and forethought are required so that the necessary scope of practice, training, and resources are available in a timely manner. Planning for these emergencies has sometimes fallen short. For example, it may be a legally simple action to expand the populations that pharmacists are allowed to vaccinate against influenza, from an adult population only to adults and children. Unless requisite policy actions are taken before the crisis, however, pharmacists may not be prepared to vaccinate children, particularly

Community pharmacy can be a force multiplier for public health and promote community resiliency.

if they are not routinely allowed to do so in everyday practice. Statewide protocols are being put into place to enable pharmacists to prescribe and dispense medications in accordance with medical and public health standards, increasing pharmacists' impact on patient care every day and during an emergency. In short, preparedness efforts need to be started well in advance of a crisis. For everyday practice, it is important to have community pharmacy integrated into public health services—public health needs all the resources that can be made available, and, in an emergency, those resources need to be in place.

Appendix A

Tuesday, October 25, 2016

Agenda

9:00 – 9:30am	**Coffee and continental breakfast**
9:30 – 9:45am	**Welcome, Meeting Overview, and Introductions** • Gigi Kwik Gronvall, Senior Associate, UPMC, Center for Health Security • Lisa Koonin, Director (Acting), Influenza Coordination Unit, CDC
9:45 – 10:45am	**Discussion #1: Antibiotic Stewardship in Outpatient Settings** *Panelists:* • Kathy Talkington, Project Director, Government Performance, The Pew Charitable Trusts • Jeffrey Linder, Director, Brigham and Women's Primary Care Practice Based Research Network, Brigham and Women's Hospital, and Associate Professor of Medicine, Harvard Medical School
10:45 – 11:45am	**Discussion #2: Opioid Misuse and Naloxone** *Panelists:* • Rahul Gupta, President, WV State Medical Association • Jan Pringle, Professor, University of Pittsburgh, School of Pharmacy • Amanda Glover, Vice President Regulatory Affairs, Rite Aid
11:45 – 12:45pm	**Working Lunch – Facilitated Discussion** • Gigi Kwik Gronvall, Senior Associate, UPMC Center for Health Security
12:45 – 1:45pm	**Discussion #3: Challenges and Barriers to Innovative Efforts** *Panelists*: • Rebecca Snead, Executive Vice President & CEO, National Alliance of State Pharmacy Associations • Emily Lord, Executive Director, Healthcare Ready
1:45 – 2:00pm	**Break**
2:00 – 3:00pm	**Discussion #4: The Future of Public Health & Pharmacy Partnership** *Panelists*: • Lisa Koonin, Director (Acting), Influenza Coordination Unit, CDC • Umair Shah, Executive Director, Harris County Public Health
3:00 – 3:30pm	**Facilitated Discussion and Concluding Remarks**

Meeting Participants and Expert Consultations

Participants

Brian J. Bobby, PharmD, Vice President, Clinical Services, Rite Aid Corporation

Lisa Brown, MPH, Program Officer, Board on Health Sciences Policy, Health and Medicine Division, National Academies of Sciences, Engineering, and Medicine

Mary Casey-Lockyer, MHS, BSN, RN, CCRN, Disaster Health Services, American Red Cross

Andi Lane Clark, PharmD, Rite Aid Corporation Director of Clinical Services

Chas Eby, MA, Branch Manager, External Outreach, Maryland Emergency Management Agency

Amanda Glover, PharmD, VP, Regulatory Affairs, DMEPOS Compliance Officer

Rahul Gupta, MD, MPH, FACP, President, WV State Medical Association

Tom Inglesby, MD, Chief Executive Officer and Director, Johns Hopkins Center for Health Security

Kathleen Jaeger, JD, Senior Vice President, Pharmacy Care and Patient Advocacy, National Association of Chain Drug Stores

Lisa M. Koonin, DrPH, MN, MPH, Director (Acting), Influenza Coordination Unit, National Center for Immunization and Respiratory Diseases (NCIRD), Centers for Disease Control and Prevention

Jeffrey A. Linder, MD, MPH, FACP, Associate Professor of Medicine, Division of General Internal Medicine and Primary Care, Brigham and Women's Hospital/Harvard Medical School

Emily St. Martin Lord, MPA, Executive Director of Healthcare Ready (formerly Rx Response)

Justin Manning, PharmD, Pharmacy Supervisor NW Region, Hy-Vee, Inc.

Meghan McGinty, PhD, MPH, MBA, Deputy Director, Big Cities Health Coalition, NACCHO

Jan Pringle, PhD, Professor, University of Pittsburgh, School of Pharmacy, Director, Program Evaluation and Research Unit (PERU)

Andrew Roszak, JD, MPA, Senior Director of Emergency Preparedness, Child Care Aware of America

Sara E. Roszak, MPH, MA, Director, Research, National Association of Chain Drug Stores (NACDS)

Mitchel C. Rothholz, RPh, MBA, Chief Strategy Officer, American Pharmacists Association

Umair A. Shah, MD, MPH, Executive Director, Harris County (TX) Public Health

Rebecca P. Snead, RPh, Executive Vice President & CEO, National Alliance of State Pharmacy Associations

Kathy Talkington, MPA, Project Director, Government Performance, The Pew Charitable Trusts

Eric Toner, MD, Senior Associate, Johns Hopkins Center for Health Security

Appendix B

Expert Consultations

Kevin Barton, PharmD, Senior Manager, Walmart Health & Wellness

JoLynn Coleman, Director of Clinical Services, Walmart Health & Wellness

Mike Duteau, RPh, Vice President of Business Development and Strategic Relations, Kinney Drugs, Inc.

Brian Hille, VP, Patient, Specialty and Wellness Services, Albertsons Companies

Lisa M. Koonin, DrPH, MN, MPH, Director (Acting), Influenza Coordination Unit, National Center for Immunization and Respiratory Diseases (NCIRD), Centers for Disease Control and Prevention

Michael Loehr, MCRP, Chief of Emergency Preparedness and Response, Public Health Operations, Washington State Department of Health

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