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Pharmacy Emergency Preparedness and Response (PEPR): a proposed framework for expanding pharmacy professionals' roles and contributions to emergency preparedness and response during the COVID-19 pandemic and beyond



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ABSTRACT

Background: Pharmacists have long been involved in public health and emergency preparedness and response (EP&R), including through preventive measures such as screening, vaccinations, testing, medical and pharmaceutical countermeasures, as well as ensuring medication safety and access during natural disasters and pandemics. Pharmacy professionals are considered essential partners in response to the ongoing COVID-19 pandemic. Community and hospital pharmacies are expanding services and hours to provide essential services, putting pharmacists and their co-workers at the frontlines for patient care and safety to improve public health. In addition, pharmacy professionals are increasingly integrating into global, national, state and local EP&R efforts, including into interprofessional teams, such as Medical Reserve Corps (MRCs). However, lacunae exist for further integration of pharmacists into public health and safety initiatives. There are increasing opportunities and recommendations that should be expanded upon to provide improved patient care and population health interventions, and to ensure healthcare worker and public health safety.

Objective: Develop a Pharmacy Emergency Preparedness and Response (PEPR) Framework and recommendations for pharmacy professional pathways towards full integration within public health EP&R efforts (such as the COVID-19 pandemic), and enhanced recognition of pharmacists' skills, roles and contributions as integral members of the interprofessional healthcare team.

Methods: This paper draws on the American Society of Health-System Pharmacists (ASHP) 2003 Statement on the Role of Health-System Pharmacists in Emergency Preparedness and lessons learned from previous and current public health emergencies, such as the 2009 H1N1 pandemic and the current COVID-19 pandemic, to provide expanded guidance for pharmacists and pharmacy professionals across all practice settings in EP&R. The proposed PEPR framework also incorporates information and recommendations from The Pharmacy Organizations' Joint Policy Recommendations to Combat the COVID-19 Pandemic (March 2020), CDC-NIOSH, International Pharmaceutical Federation (FIP) Guidance, health departments and emergency preparedness guidance and resources, Boards of Pharmacy, and other pharmacy professional organizations and educational institutions.

Results: Based on methods and resources utilized in developing this proposed PEPR Framework, five key focus areas were identified, as follows:

- 1) Emergency preparedness and response
- 2) Operations management
- 3) Patient care and population health interventions
- 4) Public health pharmacy education and continuing professional education
- 5) Evaluation, research, and dissemination for impact and outcomes

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Conclusion: Pharmacists and pharmacy professionals have been at the frontlines in responding to the COVID-19 pandemic. Yet, challenges remain, such as limited availability of personal protection equipment, high risk of infectious exposures inherent in healthcare professions, and legislative hurdles resulting in lack of provider status and related reimbursements. Recommendations to enhance pharmacy's scope as public health professionals involved in EP&R include targeted training and education on key framework areas and policymaking. Pharmacy professionals should further integrate with interdisciplinary public health teams. Additional research and dissemination on impacts and outcomes of EP&R can enhance recognition of pharmacy professionals' contribution and value during public health emergencies. The proposed PEPR Framework can be utilized to develop, implement, evaluate, and disseminate results in order to strengthen existing efforts and to establish new initiatives in EP&R.

Introduction

In late December of 2019, reports of a new coronavirus infection in Wuhan, China were released. On March 11, 2020 the WHO declared the COVID-19 as a pandemic and asked for enhanced cooperation and collaboration among different nations. On January 21, 2020 the first confirmed case due to the novel SARS-CoV-2 virus was reported in the U.S. in the State of Washington; additional cases led to a national emergency declaration in the U.S. on March 13, 2020. Subsequently, unprecedented measures were taken in the U.S. and worldwide to address the pandemic, including closures of schools and non-essential businesses, restricted travel, social distancing, and other civil limitations and restrictions. ^{1,2}

Challenges in the COVID-19 response include healthcare workers with limited training in emergency preparedness and response (EP&R), lack of adequate supplies of personal protective equipment (PPE) (masks, hand sanitizers), testing kits, ventilators, number of available hospital beds, approved treatments, and a specific SARS-CoV-2 vaccine. These challenges affect pharmacists and pharmacy professionals who are among the frontline healthcare workers.3 During the pandemic, pharmacy professionals have been highly responsive to the crisis. Community pharmacies and hospital pharmacies provide essential services to patients and healthcare teams through continued provision and supply of medicines and treatment. Pharmacies continue to stay open and, in some areas, provide extended hours and services. Pharmaceutical scientists and professionals are engaged in researching vaccines and treatments. Pharmacy professionals often serve as members of state or local Medical Reserve Corps (MRCs) and engage in ensuring continuity-of-care and supplies for communities, while others serve as volunteers and provide additional services to members of their

Pharmacy organizations, both in the U.S. and globally, have issued guidelines and advisories for pharmacy professionals to guide workflow and optimize services in the COVID-19 pandemic. A joint statement was issued by ten (10) U.S. professional pharmacy organizations to support and enhance the roles of pharmacy professionals in the COVID-19 pandemic.4 In yet another joint effort by thirteen (13) pharmacy organizations, a petition addressing pharmacy reimbursements and rapid responses during crises was submitted to a bipartisan group of members of Congress. However, the most recent Coronavirus Aid, Relief, and Economic Security (CARES) Act, signed into legislation on March 27, 2020, did not grant provider status to pharmacists. It is noteworthy how the expansion of pharmacists' scope in the UK and Canada to include prescriptive privileges for certain medical conditions has the potential to contribute to COVID-19 response capabilities, reduce costs, and relieve pressure on other providers such as general practice physicians. This result regarding provider status is unfortunate, but illustrates that pharmacy organizations can work together on a shared vision.

In addition, many of the other articles invited, submitted and curated in this RSAP Special Article Collection: *Pharmacists' Response to and Involvement in the Novel Coronavirus (2019-nCoV) Pandemic* are cited below as they relate to the different sections. This special Article Collection provides an important vehicle to address and disseminate the

impact of the pharmacy profession into public health EP&R, including the role of community pharmacists across the globe, such as those in Macau, China, Columbia, Ireland, the UK, and Canada, ^{6–9} the interesting differences across continents, ⁹ and the importance of pharmacists' provision of accessible, evidence-based drug information, ¹⁰ and the relevance of health beliefs models. ¹¹

Pharmacists in public health

Pharmacists have contributed to improving public health in a variety of ways, including immunizations, health promotion, health education, patient and medication counseling, medication reconciliation, disease self-management training, point-of-care testing, screenings, EP&R, and disaster management.

International, national and state pharmacy organizations have supported public health pharmacy, including EP&R efforts. The International Pharmaceutical Federation (FIP) recently released an extensive document providing guidance for pharmacy professionals related to COVID-19 measures in the pharmacy workforce, including a list of resources in eight different languages. ¹² As noted by Ung (2020)⁷ and Cadogan & Hughes (2020)⁶; the FIP guidance document can be used to guide pharmacy EP&R during COVID-19.

Major U.S. pharmacy organizations have recognized the value of public health to the profession and, in parallel, a major public health organization has recognized the value of pharmacy to public health. The American Association of Colleges of Pharmacy (AACP) Public Health Special Interest Group (SIG), established in the mid-2000s, has been active in supporting public health pharmacy within pharmacy education, research, practice and service, many of which have included EP&R topics. Several members of the AACP Public Health SIG created an ad-hoc committee to work for recognition of pharmacy within the 25000-member American Public Health Association (APHA). APHA had previously recognized the role of the pharmacist in a 2006 policy statement, 13 but did not have a section or other networking group dedicated to pharmacy. In response to this situation, Dr. Stuart Feldman, a recognized leader in public health pharmacy, led a core group of public health pharmacy academics and leaders to petition the APHA for a special primary interest group (SPIG), subsequently approved by the APHA in November of 2014. In 2016, modifications to the APHA's policy statement were proposed, based on expanding roles of the pharmacist in public health. ¹⁴ In 2018, the APHA promoted the Pharmacy SPIG to become a Section, the first new Section in several years. Currently, the APHA Pharmacy Section has 275 members, including pharmacy professionals across different practice settings such as academics, researchers, students, public health professionals, and others with interest in public health pharmacy. 15 In 2020, the APHA Pharmacy Section will join other organizations in issuing a call for action for pharmacists to gain provider status and recognition as public health professionals. This move to include public health in major pharmacy organizations, and pharmacy in a major public health organization, demonstrates the dynamic and interdisciplinary nature of public health pharmacy, which continues to highlight pharmacists' role and contribution to public health, especially during emergencies such

as the COVID-19 pandemic.

Pharmacists have long been involved in public health EP&R, including prevention through routine vaccinations and ensuring medication access. For example, access to medications, especially for the elderly and disabled, were cited as major issues for individuals during Hurricane Katrina in 2005¹⁶, and the H1N1 pandemic in 2009.¹⁷ Currently, in the U.S. and globally, pharmacists and pharmacy professionals are considered essential personnel in response to the ongoing COVID-19 pandemic. Pharmacies are often the first point-of-contact within the healthcare system. Therefore, pharmacy professionals have a shared responsibility to provide essential services, ensure uninterrupted care, provide reliable and evidence-based information, and promote infection control. 12 while upholding the ethical values and integrity of professional standards. In addition to working in pharmacies, hospitals and clinics, there are other mechanisms by which pharmacists and pharmacy professionals continue to be integrated into global, national, state and local EP&R efforts, including into interprofessional teams such as the MRC. However, lacunae exist for further integration of pharmacists into the public health and safety workforce.

This paper proposes a Pharmacy Emergency Preparedness and Response (PEPR) Framework to outline emergency preparedness and responses by pharmacists across different healthcare sectors and provide recommendations for a robust, sustainable response (Table 1). The proposed PEPR framework draws upon the American Society of Health-System Pharmacists (ASHP) 2003 Statement on the Role of Health-System Pharmacists in Emergency Preparedness, 18 The Pharmacy Organizations' Joint Policy Recommendations to Combat the COVID-19 Pandemic (March 2020)4, the Centers for Disease Control and Prevention (CDC), National Institute of Occupational Safety and Health (NIOSH), health departments and emergency preparedness guidelines and resources, Boards of Pharmacy, the FIP Guidance Document¹², and other pharmacy professional organizations and educational institutions, and lessons learned from previous and current public health emergencies such as the COVID-19 pandemic to provide expanded guidance for pharmacists across all practice settings in EP&R. This Framework identifies five key focus areas: (1) emergency preparedness and response, (2) operations management, (3) patient care and population health interventions, (4) public health pharmacy education and continuing professional education, and (5) evaluation, research and dissemination for impact and outcomes. Each of the focus areas are further described in this document.

Emergency Preparedness and Response (EP&R)

Public health as a field strives to be proactive, but funding is often reactive, and has not often been prioritized in terms of funding or response until an emergency or crisis. Public health EP&R funding and

resources increased after the terrorism attack on September 11, 2001 and the natural disaster of Hurricane Katrina in 2005, and there has been some strengthening of infrastructure for EP&R at the national, state and local levels. For instance, MRCs have expanded and increased recruitment and training for all volunteers, including pharmacists. Pharmacy professionals have joined and serve as members of local and state MRCs. As MRC members, pharmacists work in interdisciplinary teams in a variety of roles including, point-of-dispensing (POD) activities, receiving medications and supplies from the Strategic National Stockpile (SNS), managing inventory, ensuring adequate drugs and supplies, dispensing medications, and providing education for diverse patient populations.

The expanded EP&R roles and opportunities for pharmacy professionals are outlined in the proposed PEPR Framework, along with the existing structures, processes, and anticipated outcomes and contributions of pharmacy professionals (Table 1). At the local and state levels, these include the MRCs, as well as partnerships with county and state health departments, Boards of Pharmacy, professional pharmacy organizations, and EP&R task forces. At the national level, these roles include deployments for officers or employees of the U.S. Public Health Service and the Armed Services, the Food and Drug Administration (FDA), federal agencies, and professional pharmacy organizations.

In addition to MRCs, other expanded roles include volunteer opportunities and training with the Red Cross, Association of State and Territorial Health Officials (ASTHO), and National Association of County and City Health Officials (NACCHO) for health departments. Incident Command (IC) training is often required for volunteers and is available online through the Department of Homeland Security. Training guidance documents for the SNS and PODs are available from the CDC and others, and CPE on EP&R through pharmacy and public health organizations. ¹⁹ New volunteers should be aware that before deployment or participation, many organizations require background checks and specialized training. These expanded employment and volunteer roles are enabling the contributions of pharmacy professionals to be incorporated and recognized within the greater public health community.

In response to the COVID-19 pandemic, ten professional pharmacy organizations issued a joint policy recommendation to delineate pharmacists' role in emergency response, with recommendations based on existing structures (e.g. MRCs, partnerships with state and local health departments, and Boards of Pharmacy EP&R task forces). One recommendation is the removal of barriers to address medical product shortages, as applicable, and provide assurances to ensure continuity-of-care. Another recommendation includes easing operational barriers to address workforce and workflow issues for pharmacists during a crisis.

Box 1 State Actions for EUAs in COVID-19

COVID-19 pandemic actions at the state level²¹:

- <u>Maryland</u> Governor's declaration of emergency and provision of executive order including but not limited to the activation of Maryland Responds MRC, which has about 5000 volunteers and allowance of inactive or expired and out-of-state licensed health professionals, including pharmacists, to practice during this emergency.²²
- <u>Alaska</u> eliminated the requirement to complete and pass the Multistate Jurisprudence Pharmacy Examination (MPJE) to expedite pharmacist licensures in the event of an emergency.
- <u>Florida</u> authorized pharmacists currently licensed in good standing in another state to obtain a temporary license if the pharmacist is engaged in a documented relief effort, and is registered or licensed in another state to assist in dispensing prescription drugs.
- <u>Indiana</u> allowed out-of-state licensed health care providers to practice in Indiana.
- Louisiana authorized an extension of the expiration date for certain education requirements.
- West Virginia authorized a pharmacist, pharmacy intern, or pharmacy technician to work in WV with a temporary permit from the Board of Pharmacy. WV further granted leniency for pharmacists by relaxing CE requirements. WV permitted licensed pharmacy professionals (pharmacists, pharmacy interns, and pharmacy technicians/pharmacy technician trainees) to process prescriptions and medication orders from remote locations and authorized exceeding pharmacist: technician ratio if there is actual impact of COVID-19 virus directly on the pharmacy, facility, or staff.

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>	Interdisciplinary EP&R teams are trained and deployed

Table 1 (continued)

Structure	Process	Outcomes
IV. Public Health Pharmacy Education and Continuing Professional Education	nal Education	
Colleges/Schools of Pharmacy and Allied Health Public health agencies and institutions USPHS, Federal/State Agencies Pharmacy Organizations APHA Pharmacy Section APHA Injury Control and Emergency Health Services ACP Public Health Special Interest Group Journals/Organizations/Website Jeducation materials and resources for the public	> Incorporate EP&R into PharmD curricula > Include EP&R topics into ACPE Standards/guidance and CAPE Outcomes > Develop and offer ACPE approved CPE topics to include EP&R > Identify, develop, and promote public health opportunities for pharmacy students, residents and fellows > EP&R training, SNS & POD drills > Identify & disseminate public health education and policy materials developed by pharmacy organizations > Incorporate EP&R into the APHA Pharmacy Section > Collaborate with APHA Section for Injury Control and Emergency Health Services > Reactivate EP&R ad-hoc committee at the AACP Public Health Special Interest Group > Increase open access to EP&R topics in journals/organizations/websites > Prevent or address misinformation	 ✓ EP&R integrated into future ACPE standards & CAPE outcomes ✓ Incentivized/rewarded provision of EP&R education and report on accreditation by Colleges/Schools of pharmacy ✓ # of EP&R related documents, research papers and grants ✓ # Students, residents, fellows receiving awards/scholarships/grants for public health related projects ✓ # of public health projects conducted by pharmacy students, residents or fellows ✓ # of public health projects conducted by pharmacy students, residents or fellows ✓ # pharmacy professionals trained ✓ # pharmacy professionals trained and working in public health ✓ # of EP&R presentations/attendees ✓ Pharmacy organizations' educational materials usage (reads, downloads, citations, tweets, likes, etc.) is documented ✓ EP&R ad-hoc committee established and active ✓ Increased open access provisions to research journals/organizations/websites materials for the general public, students, researchers, and academics ✓ Misinformation/false information identified, corrected, and retracted
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Document preparation and readiness for future emergencies and disasters # of studies conducted on resource utilization/allocation Successful implementation of EP&R projects # of studies conducted in EP&R Document project effectiveness # of funded EP&R projects ➣ Generate evidence to demonstrate value of findings Respond to funding opportunities addressing EP&R ➤ Evaluate resource utilization/allocation ➤ Develop benchmarks and best practices Conduct research and studies on EP&R ➤ Publish and/or disseminate findings Publications (peer-reviewed journals, professional practice journals, newsletters, traditional news sources) Funding mechanisms for EP&R research Case studies and comparisons Implementation research Evaluation studies

Disseminate results and assess impact on websites and social media

Organizational websites

Social media

Feedback mechanisms for documenting benchmarks and best practices in use

Decreased prevalence, morbidity and mortality of targeted populations

of citations, reads, downloads Repository of all lessons learned

Social media: # of users

of publications

of tweets/re-tweets/likes

Association. ASHP: American Society of Health-System Pharmacists. CAPE: Center for the Advancement of Pharmacy Education. CDC: Centers for Disease Control and Prevention. COVID-19: Coronavirus Disease 2019 (infection with SARS CoV-2). CPE: Continuing Professional Education. DHHS: Department of Health and Human Services. EHR: Electronic Health Record. EIS: Epidemic Intelligence Service (CDC). EMT: Emergency Medical Technicians. EP&R: Emergency Preparedness and Response. EUA: Emergency Use Authorization. FDA: Food and Drug Administration. H1N1: Influenza A (H1N1) pdm09 virus. HCW: Healthcare Workers. IC: Incident Command. IPE: Interprofessional Education. MPH: Master of Public Health. MRC: Medical Reserve Corps. NIOSH: National Institute for Occupational Safety and Health. PharmD: Doctor of Pharmacy. PHD: Public Health Department. POD: Point of Dispensing. PPE: Personal Protection Equipment. SNS: Strategic National Stockpile. SARS: Severe Acute Respiratory Syndrome. USPHS: United States Public Health Service. WHO: World Framework Abbreviations: AACP: American Association of Colleges of Pharmacy, ACPE: Accreditation Council for Pharmacy Education. APhA: American Pharmacists Association. APHA: American Public Health Health Organization.

Joint Policy Recommendations by Pharmacy Organizations to Combat the COVID-19 Pandemic (March 20, 2020) 1. Authorize Test-Treat-Immunize: Authorize additional pharmacist-provided services. 2. Ease Operational Barriers: Address workforce and workflow issues that prevent full and effective pharmacist engagement in COVID-19 response.3. Address Shortages and Continuity of Care: Remove barriers for pharmacists to provide continuity of care if a medical product shortage exists. 4. Reimburse for Services: Remove reimbursement barriers that prevent pharmacists from fully and effectively engaging in COVID-19 response.

Expanded roles for pharmacy professionals and pharmacies during the pandemic are also being outlined regarding independent and chain community pharmacies, which are incorporating EP&R resources and education into their websites about COVID-19. These are playing out in the U.S., but also in other countries. Several reports in this RSAP Article Collection note the vital role pharmacies are playing globally and the challenges encountered, including in Macau,7 China,8 the UK and Canada⁶ and Colombia.⁹ Community pharmacy organizations (National Association of Chain Drug Stores and National Community Pharmacists Association) have issued guidelines on pharmacists' response to COVID-19 along with participating in the joint statement put forth by pharmacy organizations and the petition for pharmacists to gain provider status presented to bipartisan members of the Congress, Additionally, there are expanded economic protections for employees such as those provided by the Families First Coronavirus Response Act (FFCRA or Act) which requires that certain employers provide full-time and parttime employees with paid sick leave and expanded family and medical leave for specified reasons related to COVID-19. These provisions will apply from April 1, 2020 through December 31, 2020.

Expanded procedures at the federal and state level include Emergency Use Authorization (EUA) of drugs and devices, but also for workplace restrictions. Restrictions have recently been lifted in many states to allow emergency recall of retired pharmacists or those with expired licenses or lapsed CPE credits. These EUAs are also expanding the use of pharmacy student interns and temporary waivers of licensing exams for recent graduates (Box 1).

Anticipated outcomes for these structures and processes include an increase in the number of pharmacist and student pharmacist volunteers at their state and local MRCs, as well as those who complete registration and receive IC and SNS training. Additional outcomes should include the number of patients and/or communities served during an emergency, response time to emergency, as well as number of EP&R task forces of Boards of Pharmacy. For example, the state of Maryland has strengthened the Medical Reserve Corps; the Maryland Board of Pharmacy established the Bioterrorism Taskforce after September 11, 2001, which evolved into the Emergency Preparedness Task Force that meets monthly with representatives from the Maryland Department of Health Office of Preparedness and Response. Achievements of this Task Force include the recruitment of pharmacists and student pharmacists' volunteers for Maryland Responds MRC and training of student pharmacists using a POD drill as a simulated learning activity annually on emergency preparedness at schools of pharmacy in Maryland.²³

These expanded employment and volunteer roles are enabling the contributions of pharmacy professionals to be recognized within the greater public health community.

Operations Management

Managing operations under emergency circumstances requires preparation and flexibility in accommodating modified protocols and workflows to ensure effective responses and worker safety. The joint policy recommendations by pharmacy organizations calls for the ease of operation barriers, including changing workforce and workflow issues to enable effective pharmacist engagement during COVID-19 response.⁴

The proposed PEPR Framework further divides operations into several components, such as supply chain and inventory management, working conditions and occupational safety, expanded clinics and makeshift field hospitals, routine and supplemental immunizations, compounding, EUAs, and PODs, and shelters, as discussed below.

<u>Supply chain and inventory management:</u> It is essential to ensure an uninterrupted supply chain and accurately forecast inventories for existing medications and supplies, as well as anticipated sales. Additionally, pharmacies could serve as venues for screening symptomatic individuals and conducting rapid testing, provided that adequate PPEs are available to protect workers. Guidelines for screening and testing should be developed and training programs conducted with all workers to ensure adherence and to reduce contagion risk.

During EP&R events, supply chains may rapidly evolve to incorporate drugs and/or devices authorized through EUA mechanisms. On March 28, 2020, the FDA issued an EUA for the use of hydroxychloroquine sulfate and chloroquine phosphate products donated to the Strategic National Stockpile (SNS) to be distributed and used for certain hospitalized patients with COVID-19²⁴, although as of this date, these drugs are not FDA approved for this use. These drugs will be distributed from the SNS to states for providers to prescribe to adolescent and adult patients hospitalized with COVID-19, as appropriate, when a clinical trial is not available or feasible. The EUA requires that fact sheets that provide important information about using chloroquine phosphate and hydroxychloroquine sulfate in treating COVID-19 be made available to health care providers and patients, including the known risks and drug interactions.²⁴ To prevent misuse and hoarding, twenty two (22) states issued guidelines for pharmacists who are being allowed to "use their professional judgment when filling prescriptions for chloroquine and hydroxychloroquine" to ensure adequate supplies for patients with ongoing need for these medications for legitimate and/or pre-existing conditions such as lupus.²⁵ Guidance for remaining states are pending and pharmacy organizations and Boards of Pharmacy in these states should work to ensure that there are adequate measures taken to ensure medications for patients who currently need them. On March 31, 2020, the FDA announced a new program known as the Coronavirus Treatment Acceleration Program (CTAP) to use every tool at the agency's disposal to bring new therapies to patients as quickly as possible, while at the same time supporting research to further evaluate whether these medical countermeasures are safe and effective for treating patients infected with this novel virus.²⁴

Working conditions and occupational safety: During a pandemic or similar infectious disease healthcare crises, there are competing issues for healthcare workers (HCWs) and the settings in which they work: (1) providing public access to essential services and (2) protecting HCWs from infection and other harms.

Providing essential services and access: The definition of which workplaces are categorized as essential services typically is set by states or localities; these categories can include permission to remain open during lockdown orders, as well as requirements for staff to report to work, despite a shelter-in-place order for non-essential workers. During the current pandemic, pharmacy services have been considered essential services and have remained open to provide critical access to medications, healthcare products and supplies. Many pharmacies also are expanding services, including waiving fees for deliveries, extending hours and extending refill periods.

Protection from serious harm: In parallel with providing access, workplaces must protect employees from serious harm. This is an important issue for pharmacy owners and managers to consider when planning protective measures for their employees. The Occupational Safety and Health Act of 1970, Sec. 5, includes the "General Duty Clause" that requires that each employer "shall furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees."26 This clause directly relates to protecting employees from infection with SARS-CoV-2. According to the CDC, frontline healthcare professionals are at high-risk for infection, therefore safety and other protections such as infection control protocols should be components of planning and managing operations. However, this has been challenging, due to national shortages of personal protective equipment (PPEs), which have put some pharmacists and their co-workers at risk, there are reports of inadequate PPEs and other protections in pharmacies.²⁷

Other factors that contribute to these challenges include workplace categorizations that impact pharmacies. According to the OSHA SIC Division Structure²⁸ (https://www.osha.gov/pls/imis/sic_manual. html), pharmacies are not categorized in "Major Group 80", which includes medical offices and clinics, hospitals and nursing homes. Instead pharmacies are included in "Major Group 59: Miscellaneous Retail", a category that includes liquor stores, second hand stores, bicycle shops, gas stations and convenience stores. ²⁸ In other words, pharmacies are

not included within the category of healthcare professions at the highest risk for exposure to coronavirus. Based on these categories, some employers may be interpreting this to mean that, given pharmacies are *retail* workplaces, there are less stringent requirements for providing masks and gloves for pharmacists and coworkers. However, pharmacists and managers may use their professional judgement, as they know their own professional commitments, as well as that of their co-workers, may put them at high risk of exposure that will require PPE (e.g., vaccinations, medication management services, patient counseling, etc.). When masks are warranted, pharmacists and managers can help their co-workers properly fit the devices, including those with beards, to assure optimal protection at the CDC-NIOSH website.²⁹

It is also important for supervisors to identify and document ill workers to ensure that they are granted sick leave to allow time to rest and recover, as well as to avoid infecting patients, customers or coworkers. Protections for workers should be extended to include interns, students, residents and other temporary or part-time workers. In the event that pharmacies remain open for extended hours, workflow protocols should be in place to effectively limit exposures and provide services including ensuring a safe workplace as delineated by the National Institute for Occupational Safety and Health NIOSH. ^{30–32}

A workplace risk-analysis should be conducted to identify avenues of exposure. Mapping capacity to identify availability of workers and predicting capability to ensure an adequate practitioner-to-patient ratio. Capacity mapping should include proactively identifying workers with illness in the family, childcare or eldercare responsibilities, provision of essential supplies to workers and their families, protecting workers from retaliations who bring their own PPE or if unable to work, predicting capacity outages, and developing protocols for workplace adjustments. Capacity mapping should plan for the post-emergency recovery phase, to return to normal staffing and supply levels, along with resuming previous routines.

Many pharmacies and other businesses experienced panic buying or ran out of PPEs, therefore not only created challenges for crowd control and management, but also increased the possibility of infections. Since pharmacies have smaller areas or workspaces, this presents challenges for social distancing that necessitates additional steps, such as scheduled pick-ups, drive through pickups, clear barriers, and tele pharmacy to reduce risks of contagion. Additional considerations include sanitizing frequently used items such as pens for signing and surfaces (countertops, credit card machines, touch pads, etc.). Three state Boards of Pharmacy (Alabama, Maryland, and Minnesota) have explicitly outlined remote work guidelines for pharmacy workers. Six states (Georgia, Idaho, Kansas, North Carolina, Tennessee, West Virginia) have amended their licensure requirements or practice requirements under the COVID-19 pandemic. The state of Wyoming has set up a virtual support group to help healthcare professionals cope with the stress, anxiety, and trauma of working in the healthcare field during COVID-19.21

The COVID-19 pandemic highlights the importance of also addressing mental health, stress, strain and burnout among healthcare providers in dealing with supply shortages and resource allocations. With increasing numbers of individuals working remotely, panic and fear among the general public regarding COVID-19 pandemic necessitates increased focus and emphasis on mental health. Additionally, all frontline practitioners are themselves at risk for burn-out, stress, trauma and fatigue. Of note, one of the early reported HCW deaths out of Wuhan involved a 28 year-old hospital pharmacist, Dr. Song Yingjie, who died of a heart attack after working double shifts for ten days straight during the COVID-19 outbreak in Wuhan, China.³³ It is important to ensure adequate resources and tools for healthcare providers to take care of their own mental health while they address the physical and mental health needs of their communities.³⁴

<u>Expanded clinics and temporary hospitals:</u> If clinics have expanded hours or pharmacy professionals are deployed to assist at temporary hospitals, including Navy hospital ships³⁵ and the National Guard mobile hospitals, then collaborative agreements should be developed to

address procurements of essential goods and services between local and temporary facilities. As of March 31, 2020, New York is setting up temporary hospitals in Central Park. Pharmacy professionals should be prepared to manage medications and medical supplies while serving on integrated healthcare teams. 36

Routine and Supplemental Immunizations: According to the joint policy recommendations statement issued by ten Pharmacy organizations, 4 most pharmacists are trained to administer a majority of FDA approved vaccinations to all patients. Specifically, pharmacists have contributed greatly to improving influenza vaccination rates. Pharmacists should continue to routinely immunize the public and incorporate additional immunizations in emergencies, as they become available. The joint recommendations also include guidance on immunizations through an authorize-test-treat-immunize protocol to enable pharmacists to order, collect specimens, conduct and interpret tests and, when appropriate, initiate treatment for infectious diseases including COVID-19, influenza, streptococcal infections, as well as interpret and discuss with patients. The recommendations further call for expanding current state pharmacists' immunization authority to include all FDA approved vaccines, including the forthcoming novel vaccine for COVID-19, for all indicated populations.

Expanded Compounding Capability: The National Association of State Pharmacy Associations (NASPA) along with the Alliance for Pharmacy Compounding, the American Pharmacists Association, and the National Community Pharmacists Association, sent a letter to the FDA on March 18th requesting clarification and flexibility related to compounding hand sanitizers and anticipating additional health emergency needs. Twenty seven (27) states have provided guidance on compounding hand sanitizer during the COVID-19 pandemic. Turing COVID-19, panic buying of PPEs and other goods set in, leading to a shortage of PPEs for healthcare workers. Compounding sanitizers is well within the realm of compounding pharmacies and can serve to fill the gaps in PPE shortage for healthcare workers.

Emergency Use Authorizations (EUAs) for drugs and devices: Unprecedented times call for unprecedented measures. "Under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the FDA Commissioner may allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by CBRN threat agents when there are no adequate, approved, and available alternatives." (CBRN: Chemical, Biological, Radiological, and Nuclear). Several EUAs have been issued under COVID-19 to address PPE shortages and are available on the FDA website. 24

Point of Dispensing (POD): Points of dispensing (POD) are community locations at which state and local agencies dispense and administer medical countermeasures (MCMs) to the public. MCMs such as vaccines, antiviral drugs, antibiotics, antitoxins, and chemical antidotes are used to effectively prevent, mitigate, or treat adverse health effects of an intentional, accidental, or naturally occurring public health emergency. The CDC and State governments provide guidelines for establishing PODs. Public health staff from local health agencies, MRC members, Community Emergency Response Teams (CERTs) and other sources are essential to fulfill POD surge capacity needs in emergencies. PODs are typically located in designated areas of each community including, local health departments, fairgrounds, schools, arenas, churches, firehouses, and colleges or universities.

Emergency/Disaster Shelters: Similar to PODs, shelters provide essential services to members of the public. The CDC provides an assessment tool to evaluate shelters³⁹ that may be used for a rapid situational analysis. Other facilities, such as the American Red Cross and homeless shelters, emergency quarantine housing sites should be accounted for in the provision of healthcare services and continuity of care. In addition, individuals impacted by shelter closings should have appropriate patient care plans developed and supported.

Patient Care and Population Health Interventions

As noted previously, public health funding is often reactive, therefore patient-centered care and population-based interventions are not often seen through the lens of EP&R or are not prioritized unless an epidemic or pandemic becomes imminent. This section provides the context of micro-level public health, which is individual patient care, and macro-level public health, which includes population and policy levels of public health activities during emergencies.

In response to the COVID-19 pandemic, professional pharmacy organizations collaborated to provide a joint policy statement with several recommendations based on existing structures to enhance processes for pharmacists' role in emergency response. One recommendation is the authorization to test, treat, and immunize patients as expanded pharmacist-provided services. Specific examples include provision of testing for individual patients as well as treating and vaccinating for a community or patient population, especially those in limited access or underserved areas. Pharmacists should continue to monitor and report adverse events for newly approved drugs and vaccines in emergencies. This could occur in the form of expanded collaborative practice or scope of practice under declared emergencies. Another recommendation is the removal of reimbursement barriers and enable pharmacists to respond and contribute effectively to the COVID-19 pandemic.⁴

There are existing structures and processes with anticipated outcomes for pharmacists' role and contributions in enhancing patient care and population health as identified in the proposed PEPR Framework (Table 1). These include hospitals and health-systems, long-term care facilities, outpatient clinics, community pharmacies, drug information centers and tele-pharmacy/call centers working to enhance outcomes such as modified patient care protocols, enhanced workflow to ensure social distancing, facilitated screening and triage for essential medications and patients, mitigated plan for medication use, and ensured delivery of medications and supplies, including availability of essential dispensing and refill of medication. To ensure the achievement of anticipated outcomes, it is important to improve processes such as facilitating continued screening, and/or testing and immunizing services, enabling medication dispensing, pick-up and delivery services, procuring essential medications and supplies, and notifying and addressing at-risk and disabled patients. Another element of the framework is the provision of quality patient education and guided access to evidence-based sources. In addition, it is important to address misinformation and unhelpful views during emergencies using communication and education approaches such as those described in the validated Health Belief Model (HBM).¹¹

In terms of population health intervention, the framework identifies the structure including state and local health departments and its integration and communication with pharmacists in a variety of practice settings for sharing of information and resources to enable outcomes such as updated software systems and integrated workflows and protocols. Another population-based intervention example is the existing structure such as State Poison Control Centers that should enhance answering services and poison prevention education (e.g. potentially inappropriate or overuse of hydroxychloroquine for self-treatment and without provider consultation for COVID-19 leading to potential toxicity). This will ensure the anticipated outcomes for patients and the public to receive accurate and high-quality information regarding medication use safety, as well as documentation of the number of calls and reports for toxicity. Another example of population health emergency preparedness and response teams is that there is a supportive structure for preparing fully trained interdisciplinary professionals ready to serve as described in the first element of the proposed PEPR framework as described earlier in EP&R.

Public Health Pharmacy Education and Continuing Professional Education
Education is a key mechanism to ensure the integration, value and
sustainability of pharmacy professionals in EP&R efforts. Pharmacy
education pathways encompass traditional and nontraditional PharmD
programs, Bachelor's in Pharmaceutical Sciences, continuing

professional education (CPE), post graduate residencies and fellowships, and interprofessional education (IPE). Public health education and training, including EP&R topics, should be valued and embedded into these pathways, including maximizing opportunities for IPE between pharmacy and public health professionals.

As for most professional programs, pharmacy education is pulled in many directions by a range of forces. Pharmacy education often assigns emphasis to public health and EP&R topics based, in part, on factors outside the Academy, including national healthcare initiatives, funding and healthcare emergencies. Public health EP&R funding often increases only in response to natural disasters, civil defense threats, and healthcare emergencies, including pandemics. ⁴⁰ DeGuire, Fjortoft, and Duncan reflected on these fluctuations in the American Association of Colleges of Pharmacy (AACP) *Report of the 2009–2010 Standing Committee on Advocacy*: "The public health pendulum continues to swing back and forth on the issue of public health preparedness". ⁴⁰

Background and recent history of infectious disease public health emergencies. In recent decades, several public health crises have elevated the role of pharmacy professionals in EP&R. The HIV and Ebola virus outbreaks date from the 1980's and 1990's, but the recent focus on viral pneumonias date to the Asian highly pathogenic avian influenza A H5N1 virus (H5N1 Asian HPAI) outbreak in 1997, with cases reported in Hong Kong, China and elsewhere. 41 The H5N1 Asian HPAI re-focus news media attention on previous deadly pandemics, including the oft-forgotten 1918 H1N1 influenza pandemic. 42 Similarly, DeGuire, Fjortoft and Duncan⁴⁰ noted how the terrorist attacks on 11 September 2001 on the World Trade Centers and Pentagon resulted in increased federal funding for EP&R through the Health Resources Services Administration (HRSA). The associated October 2001 postal anthrax attacks targeting Congress also highlighted the importance of EP&R countermeasures. Anthrax response plans included the integration of pharmacies. 43 Pharmacists and pharmacy educators were included in CDC-led training programs in Atlanta for anthrax prophylaxis for the Strategic National Stockpile (SNS). Participants were encouraged to return home and further disseminate training information at the state and county level, which in turn involved pharmacy students and practitioners in POD exercises. The 2002/2003 global outbreak of SARS alerted the medical and scientific community of the virulence and potential impact of SARS.⁴⁴ The resurgence of H1N1 in the 2009 pandemic illustrated the value of the SNS to stockpile and distribute antiviral agents, including EUAs for special uses, 45 as well as implementing restrictions to limit hoarding of antivirals. This further served to highlight the importance of pharmacists in EP&R response during pandemics as effective team members and gatekeepers, as well as increased integration of pharmacies and pharmacists into EP &R^{17,45} However, as noted by Gudi and Tiwari (2020)⁴⁶, despite the contagiousness of H1N1 and the virulence of the 2003 SARS and more recent Middle Eastern Respiratory Syndrome (MERS) outbreaks, these outbreaks did not spur maintenance of vibrant EP&R structures or rapidly deployable resources for public responses in preparation for the current pandemic. Thus, hard lessons were unlearned, and there is an impaired response capability to public health emergencies such as the current pandemic.47

These healthcare crises were occurring against the background of increased scope of practice for pharmacists. Starting in the 1990s, pharmacists and pharmacy interns were gaining vaccination administration privileges, which greatly expanded the national capacity to provide vaccines to the public: in 1990, 2 states allowed pharmacists to deliver vaccines, whereas by 2016, the converse was true; all but 2 states allowed vaccinations by pharmacists ⁴⁸ from all states, the District of Columbia, and Puerto Rico can vaccinate.

EP&R in *Pharmacy Education*. The fluctuations in national public health emphasis and funding are paralleled in academic pharmacy. The relative importance of different topics in PharmD education is driven by several

factors, including the Center for the Advancement of Pharmacy Education (CAPE) 2013 educational outcomes and the Accreditation Council for Pharmacy Education (ACPE) 2016 accreditation standards. CAPE educational outcomes were published in 1992, 1998, 2004 and 2013. CAPE 2004, published shortly after September 11, 2001, granted prominence to public health, where it was one of the three major domains. ⁴⁹ This provided a clear incentive for PharmD programs to build on or add curricular and co-curricular elements of public health, including EP&R. In contrast, as noted by Covey et al. (2017)⁵⁰, in the CAPE 2013 outcomes, the term public health was replaced with the narrower term population health. Furthermore, public health related topics were given reduced prominence in CAPE 2013, with no mention of EP&R nor related topics such as disaster or emergency preparedness, pandemic planning, or civil defense. ⁵¹

The ACPE 2016 Standards Appendix 1 includes a subsection labeled "Public Health" as a required element of the didactic curriculum. Although there are no specific mentions of EP&R or related topics in the Appendix, the associated "Guidance for Standards 2016" includes one bullet point related to EP&R: "Describe the role of a pharmacist in emergency management." in Appendix B (p.33) under the public health subheading. Immunizations are also discussed under this subheading.

Even in the face of fluctuating emphasis and funding, public health EP &R is valued and taught by many in pharmacy education. DeGuire, Fjortoft, and Duncan⁴⁰ reported in 2010 how pharmacy education aligned with six goals of the strategic plan of the Health Resources and Services Administration (HRSA) as part of their charge on the AACP Standing Committee on Advocacy. They surveyed 51 Colleges/Schools of Pharmacy in the US and captured outcomes related to the six goals assessed. This included Goal #6, which most directly related to EP&R: "Enhance the Ability of the Health Care System to Respond to Public Health Emergencies". Of the 35 responding Colleges/Schools, 22 of them reported activities related to EP&R. Many of the 35 listed immunizations as the sole outcome for Goal 6, but others included membership in MRCs, disaster preparedness, PODs, and collaborations with public health departments.

Despite the fluctuations in emphasis on public health and EP&R training in the CAPE Outcomes and ACPE Standards, pharmacy educators have studied and reported on EP&R education and initiatives across the time period discussed. For example, PharmD students and pharmacists have been incorporated into emergency preparedness drills, ⁵² and reports have been published on pharmacists' roles in assisting in emergency preparedness in long-term care facilities, ⁵³ table-top exercises, ⁵⁴ and in interprofessional education CPE/CE programs with public health professionals. ⁵⁵ Other outcomes that can be assessed include the number of students, residents, fellows, and pharmacy professionals receiving awards/scholarships/grants for public health related projects, the number of public health projects conducted by pharmacy students, residents or fellows, and the dissemination of scholarly activity.

Public health pharmacy textbooks and resources. Educational resources pertinent to pharmacy professionals in EP&R include textbooks focused on public health in pharmacy, which include chapters on EP&R. ^{56–58} The American Society of Health-System Pharmacists (ASHP) published a textbook focused on pharmacy preparedness for biological and chemical terrorism. ⁵⁹

Continuing Professional Education (CPE). Pharmacy CPE is an important component of ensuring that practitioner knowledge is up to date and applicable to emerging topics and trends in pharmacy practice. In response to COVID-19, the Accreditation Council for Pharmacy Education (ACPE) has expedited the CPE process for coronavirus-related programming and as of March 31, 2020, has over fifty (50) programs listed between March and July 2020 (see the link listed in the coronavirus notice on the homepage: https://www.acpe-accredit.org/). There should be additional opportunities for pharmacy professionals to engage and develop interdisciplinary skills, particularly in the areas of EP&R and disaster management. This will enhance and support

pharmacy professionals roles in public health upon receiving targeted training and education on key Framework areas and policy-making recommendations.

Interprofessional education (IPE). ACPE Standards require IPE for PharmD students, and public health topics can be included in IPE opportunities for Pharmacy education, 60 including interprofessional CPE. 55 In addition, public health professionals and students serve as valuable members of an IPE team, as they bring a unique perspective for students. In addition, public health professionals include individuals with a range of educational backgrounds, including Master of Public Health (MPH) degrees, epidemiologists, nurses, physicians, social workers, and others. IPE programs and events with these individuals can also increase their awareness of the skills and competencies of pharmacy students and professionals.

Evaluation, research and dissemination for impact and outcomes

Research and dissemination on impacts and outcomes of EP&R can enhance recognition of pharmacy professionals' contribution and value during public health emergencies. Actions taken during the COVID-19 pandemic have varied by sector, organization, and state in improving patient care and health outcomes, as well as population-based interventions. Lessons learned from this pandemic should be documented, studied and disseminated to evaluate existing or new systems, policies and procedures, and intermediate and final outcomes. Researchers are encouraged to study the implementation and successes of various EP&R policies and guidelines, evaluate protocols for efficiency, report case studies, and seek funding for EP&R related projects. Results should be published in a range of venues for a variety of audiences. Benchmarks and best practices should be highlighted to close the loop on the policies and original aims to optimally plan future directions. A list of additional outcomes is listed in Section V of the proposed PEPR Framework (Table 1).

A repository of pharmacy-related resources, similar to the FIP coronavirus pharmacy guidance document would be valuable for future training and studies by educators and researchers. This resource could enable design of improved systems and procedures based on lessons learned from the COVID-19 pandemic. Curating social media for pharmacy related work would be worthwhile to understand pharmacy-led communications, specific concerns, and additional services that pharmacies have provided, especially services beyond their current scope.

The dissemination of studies, resources and lessons learned would be significant in educating future generations of students, pharmacy professionals, and others to learn from countries or communities that followed public health best-practices to reduce exposures and deaths in the COVID-19 pandemic.

Conclusion

In response to the COVID-19 pandemic, pharmacy professionals have acted promptly to provide essential services. They have worked in collaboration with other HCWs, federal health agencies, local and state health departments, professional organizations, Boards of Pharmacy, non-profit organizations and the private sector. Services provided include continuing access to medications and supplies, supporting healthcare needs and services, educating the public, developing modified workplace protocols, adjusting to critical PPE shortages, and serving as trustworthy drug information sources. During the early phase of the COVID-19 pandemic, pharmacy professionals have demonstrated their commitment to being the most accessible healthcare professionals. The actions above exemplify the role of the pharmacist in public health, as called for in the APHA 2006 policy statement, ¹³ especially in times of public health emergencies such as the COVID-19 pandemic.

Yet, there are additional opportunities for enhancing the roles of pharmacy professionals and recognition in public health, specifically with regards to EP&R as further outlined in the proposed PEPR Framework (Table 1). This Framework can be utilized to develop,

Box 2

Recommendations for Action.

1 EP&R

- a. Volunteer with MRCs to register and be trained in EP&R.
- b. Develop a national registry of MRC volunteers.
- c. Conduct SNS and POD drills for pharmacy students and professionals.
- d. Formalize partnerships with health departments.
- e. Strengthen or create EP&R task forces on boards of pharmacy in collaboration with state health departments.
- f. Cross-train with other healthcare professionals and first responders on EP&R.
- g. Enable and facilitate pharmacists and trainees to step in during emergencies and to incentivize EP&R participation by employers or institutions.

2. Operations management

- a. Ensure adequate resources and tools for pharmacy professionals to provide patient care and protect their own health and safety during emergencies.
- b. Develop and share best practices for emergencies through adequate planning and deliberation to ensure an optimal response during emergencies.
- c. Develop plans to address the mental health challenges and impacts on pharmacists and other HCWs with regard to burnout, stress and PTSD.
- 3. Patient care and population health
 - a. Ensure adequate resources and tools for pharmacy professionals to provide patient care and population health interventions during emergencies.
 - b. Continue to serve as highly accessible drug information experts and provide evidence-based information and education about and during emergencies.
 - c. Identify, serve and evaluate evolving community health needs during and after emergencies.
 - d. Implement and evaluate community-based initiatives in EP&R for effectiveness.

4. Education and CPE

- a. Incorporate EP&R into pharmacy curricula, CPE, IPE, CAPE Educational Outcomes, and ACPE accreditation standards.
- b. Incorporate EP&R content on the NAPLEX and State Boards of Pharmacy licensure exams.
- c. Identify and promote the utilization of EP&R educational and training opportunities outside of the Academy or traditional pharmacy education platforms.
- 5. Evaluation, research and dissemination
 - a. Study, evaluate, and disseminate the impacts and outcomes of the pharmacy profession's response to the COVID-19 pandemic and other emergencies.
 - b. Conduct interdisciplinary research on EP&R.

6. Policymaking

- a. Seek elected and appointed positions on influential policy-making boards, committees and task forces.
- b. Work together to support pharmacists for elected legislative or appointed positions on impactful community, state, federal, or international boards, committees, and task forces.
- c. Support the "Pharmacy Organizations' Joint Policy Recommendations to Combat the COVID-19 Pandemic" statement.
- d. Continue to advocate for provider status to ensure that pharmacy professionals are duly recognized and reimbursed for cognitive services.

implement, evaluate, and disseminate results in order to strengthen existing efforts and to establish new initiatives in EP&R. The Framework provides recommendations for six specific areas (see Box 2) of individual or collective actions for pharmacy researchers, educators, professionals, organizations and allies to further prepare and respond to the current COVID-19 pandemic and future public health emergencies.

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