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PURDUE COLLEGE OF PHARMACY'S RESPONSE TO THE HAND SANITIZER SHORTAGE DURING THE PANDEMIC

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AUTHOR BIO SKETCHES

Alissa M. Freimuth was a PharmD candidate in the Doctor of Pharmacy program at Purdue College of Pharmacy during her involvement in this community outreach project in March 2020. She is currently the Wasson Veterinary Pharmacy Resident at the Purdue University Veterinary Teaching Hospital.

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Jane E. Krause is a Clinical Associate Professor of Pharmacy Practice at Purdue University. She was involved in this community outreach project and served as the writing mentor for this manuscript.

INTRODUCTION

COVID-19 Pandemic

The outbreak of the novel coronavirus [severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)] was first reported in Wuhan, China, in late December 2019

(del Rio & Malani, 2020). On January 31, 2020, a public health emergency was declared by the secretary of Health and Human Services (HHS) (Wang et al., 2020). By late February 2020, more than 82,000 cases of a respiratory disease caused by the novel coronavirus [Coronavirus Disease 2019 (COVID-19)] had been reported, of which about 95% of cases and 97% of deaths were in China

(Wu & McGoogan, 2020). On March 13, 2020, the President of the United States declared a national emergency in response to the outbreak (Chen et al., 2020). That same month, COVID-19 was declared a “pandemic” by the World Health Organization (del Rio & Malani, 2020). Since its start, COVID-19 has been a rapidly unfolding situation (Figure 1).

A “pandemic” is defined as an “epidemic” occurring worldwide or over a very wide area, crossing international boundaries and usually affecting a large number of people (Avera Health, 2020). An “epidemic” is defined

as the occurrence of more cases of disease than expected in a given area or among a specific group of people over a particular period of time. By definition, a pandemic ends when the disease is no longer prevalent throughout the world or in multiple countries/regions. This can happen in two ways: (1) a vaccine or an effective treatment is developed (i.e., polio came to an end with a vaccine) or (2) infection and death rates rapidly decline (i.e., the Spanish flu pandemic of 1918 ended when those infected either died or developed immunity). At the time of this writing (March 2021), COVID-19 remains a global pandemic.

<p>December 31, 2019 Chinese health officials inform the WHO about a cluster of 41 patients with a mysterious pneumonia. Most are connected to Huanan Seafood Wholesale Market (WHO 2020).</p> <p>March 6, 2020 Indiana State Department of Health confirms the first COVID-19 case in Indiana (Montgomery, 2021).</p> <p>March 13, 2020 President Trump declares COVID-19 a national emergency (AJMC, 2021).</p> <p>May 1, 2020 Gov. Eric Holcomb announces a phased reopening plan for the state of Indiana (Montgomery, 2021).</p> <p>December 14, 2020 First vaccination of COVID-19 in Queens, New York (Wetsman, 2020).</p> <p>March 2, 2021 Residents 50 years and older may receive the COVID-19 vaccine in Indiana (Montgomery, 2021).</p>	<p>January 21, 2020 CDC confirms the first COVID-19 case in the United States (WHO, 2020).</p> <p>March 11, 2020 COVID-19 is declared a pandemic by the WHO (WHO, 2020).</p> <p>March 23, 2020 Indiana Gov. Eric Holcomb issues a “stay at home order” for nonessential Hoosiers (Montgomery, 2021). Purdue University begins remote learning (Purdue, 2020).</p> <p>July 27, 2020 Gov. Eric Holcomb’s order to wear face coverings begins (Montgomery, 2021).</p> <p>January 13, 2021 Residents 70 years and older may receive the COVID-19 vaccine in Indiana (Montgomery, 2021).</p>
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Figure 1. COVID-19 timeline.

Viral Disease

A virus is a small collection of genetic code (i.e., DNA or RNA), surrounded by a protein coat (NIH, n.d.). A virus cannot replicate on its own. Instead, viruses invade living cells and use components of those cells to multiply and make new copies of the virus. This process can kill or damage the normal cells and cause illness. Antibiotics are not effective against viruses. For most viral infections, treatment generally involves alleviating symptoms while a person's immune system fights off the virus. With some viral diseases, antiviral medications and/or vaccines have been developed to help eliminate or reduce the severity of the infection.

Coronavirus is a family of viruses that was named based on its appearance and refers to the protein spikes that protrude from the surface of the virus (NIH, n.d.). COVID-19 is a zoonotic disease, which means that it exists in animals but can also infect humans. Therefore, the original source of COVID-19 was an animal, and scientists believe bats are the most likely reservoir as the closest known relative to SARS-CoV-2 is a bat virus that shares 96% of its genome.

It has been determined that COVID-19 spreads through close contact (i.e., being within six feet of each other), coughing, sneezing, talking, or breathing (CDC, 2021). Prevention of respiratory droplet inhalation or deposition on nasal or mouth mucous membranes is important to help avoid the spread of the virus. Touching a surface or object with the respiratory droplets is another possible way to become infected. Therefore, maintaining a distance of six feet from others, staying in properly ventilated spaces, wearing a face mask that covers both the mouth and nose, washing hands, and routinely cleaning and disinfecting surfaces is critical to help prevent the spread of COVID-19.

Hand Hygiene and the Shortage of Hand Sanitizer

Appropriate hand hygiene is an important part of the response to COVID-19 (CDC, 2020). Proper hand hygiene, which includes the use of alcohol-based hand sanitizers or handwashing, is a simple yet effective way to prevent the spread of pathogens and infections. The exact contribution of hand hygiene to the reduction of direct and indirect spread of coronaviruses between people is unknown. However, hand washing mechanically removes pathogens, and laboratory data demonstrate that alcohol-based hand sanitizers inactivate SARS-CoV-2.

Washing hands often with soap and water for at least 20 seconds is essential, especially after using the bathroom, before eating, and after coughing, sneezing, or blowing one's nose (FDA, 2021). If soap and water are not readily available, the Centers for Disease Control and Prevention (CDC) recommends the use of an alcohol-based hand sanitizer containing at least 60% alcohol (i.e., ethanol or ethyl alcohol). Interestingly, unless hands are visibly soiled, an alcohol-based sanitizer is often preferred over soap and water due to evidence of better compliance as compared to soap and water. Hand sanitizers are generally less irritating to hands and are effective in the absence of a sink. Consumers are reminded to keep hand sanitizers out of the reach of young children and to seek medical help if accidentally ingested.

In March 2020, consumers and health care personnel experienced difficulties accessing alcohol-based hand sanitizers. As a result, some consumers started producing hand sanitizer in their homes for personal use (FDA, 2020). This sparked safety concerns as the FDA could not verify the method used to prepare such products and whether the products were safe for use on human skin.

FDA Guidance for Industry

The U.S. Food and Drug Administration (FDA) plays a critical role in protecting the United States from emerging infectious diseases (FDA, 2020). In March 2020, because of the public health emergency, the FDA issued guidance in response to a number of queries from entities (e.g., pharmacies and distilleries) that were not licensed or registered drug manufacturers that wanted to prepare alcohol-based hand sanitizers, either for public distribution or for self-use. In issuing this guidance, the FDA communicated its policy for the temporary preparation of alcohol-based hand sanitizer products by firms that register with the FDA as an over-the-counter drug manufacturer, repackager, or relabeler including pharmacies that repackage or relabel finished hand sanitizer products prepared consistent with FDA policies outlined in this guidance. The FDA allowed such firms to prepare hand sanitizer provided the finished product was manufactured according to a formula consistent with the World Health Organization (WHO) recommendation (FDA, 2020; WHO, 2010) (Figure 2).

<p>Ethyl Alcohol 80% V/V or Isopropyl Alcohol 75% V/V</p> <p>Glycerin (glycerol) 1.45% V/V</p> <p>Hydrogen peroxide 0.125% V/V</p> <p>Sterile distilled water</p>

Figure 2. Hand sanitizer formula (FDA, 2020).

Since this FDA guidance is temporary, a return to using commercial hand sanitizer products should occur once available (FDA, 2020).

In addition, the following were required (FDA, 2020):

- No other active or inactive ingredients (i.e., to improve taste or smell) could be added as different or additional ingredients may impact the quality and potency of the product.
- hand sanitizer is prepared under sanitary conditions and equipment used is well maintained and fit for this purpose.
- Methanol-contaminated alcohol is not used.
- A record is maintained to document key steps and controls to ensure each batch matches the formula.

- The hand sanitizer is produced as an aqueous solution and not as a gel, foam, or aerosol spray.
- Appropriate packaging is used that will seal the bottle sufficiently to prevent evaporation of the alcohol.
- The product is labeled consistent with guidance from the FDA (Figure 3).
- Firms register their facility and ingredients with the FDA Drug Registration and Listing System.
- Firms have a mechanism to accept adverse event reports for any products they manufacture and submit such adverse event reports to FDA.

Of note, FDA issued a warning that a sharp increase in hand sanitizer products that were labeled to contain ethanol tested positive for methanol contamination.

Drug Facts	
Active ingredient[s] Alcohol 80% v/v	Purpose Antiseptic
Use[s] Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
Warnings For external use only. Flammable. Keep away from heat or flame	
Do not use <ul style="list-style-type: none"> • in children less than 2 months of age • on open skin wounds 	
When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away at 1-800-222-1222.	
Directions <ul style="list-style-type: none"> • Place enough product on hands to cover all surfaces. Rub hands together until dry. • Supervise children under 6 years of age when using this product to avoid swallowing. 	
Other information <ul style="list-style-type: none"> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F) 	
Inactive ingredients glycerin, hydrogen peroxide, purified water USP	

Figure 3. Labeling (front and drug facts) for ethanol formulation of hand sanitizer (FDA, 2020).

Methanol, or wood alcohol, is toxic when absorbed through the skin or ingested and can be life-threatening. Methanol exposure can result in nausea, vomiting, headache, blurred vision, permanent blindness, seizures, coma, permanent damage to the nervous system, or death. Individuals using methanol on their hands are at risk. In addition, individuals who drink these hand sanitizer products as an alcohol substitute or children who accidentally ingest these products are at risk for methanol poisoning.

Project Objectives and Community Partner

With this background in mind, the objectives of this community outreach initiative were to (1) describe the hand sanitizer community outreach project in conjunction with the Purdue University Pharmacy as the community partner and to (2) assess the impact on student participants and on the local community. The Purdue University Pharmacy is a full-service community pharmacy located on Purdue University's West Lafayette campus. The pharmacy serves anyone affiliated with the Purdue community, which includes students, faculty, staff, retirees, spouses, and dependents. The pharmacy also serves as an experiential site for students in the Doctor of Pharmacy program. In addition to processing prescriptions, the pharmacy provides immunizations, medication administration services, and contraceptive prescribing. The motivation for the project was to help provide citizens of the local community with hand sanitizer during the early months of the COVID-19 pandemic.

RESULTS

Purdue University Pharmacy's decision to compound hand sanitizer in the beginning of the global pandemic had a large impact on both Purdue University and the surrounding community. In March and April 2020, commercially produced hand sanitizer could not be found anywhere in the community. During this two-month period and in collaboration with the Purdue University Pharmacy, four pharmacists, two pharmacy technicians, and five pharmacy students compounded a total of 831.36 liters of hand sanitizer (approximately 220 gallons). They packaged the hand sanitizer into smaller bottles (i.e., two- or three-ounce bottles) and labeled the bottles according to FDA guidelines (Figure 4). This resulted in over 13,000 bottles of hand sanitizer that was safe and effective for use on human skin and ready for distribution/sale through the Purdue University Pharmacy. As a result, community members, businesses, public safety departments, nonprofit organizations, and the Purdue community had local access to hand sanitizer.

Figure 4. Compounded hand sanitizer (Photo Owner: Jane Krause).

Community Impact

On April 2, 2020, a news story ran on the local television station informing the community of the pharmacy's effort to help with the hand sanitizer shortage. This news story opened the floodgates on requests for hand sanitizer (Figure 5). Individuals living in the local community were able to purchase hand sanitizer from the Purdue University Pharmacy for their personal use (Figure 6). Numerous local businesses, including restaurants, funeral homes, childcare centers, libraries, and retail stores also purchased the compounded preparation to help lessen the risk of transmission for both employees and customers.

Figure 5. WLFI interview (Photo Owner: Jane Krause).

Figure 6. Hand sanitizer available in Purdue Pharmacy (Photo Owner: Jane Krause).

amount requested. The hand sanitizer was picked up at the Purdue pharmacy location. Due to reduced staffing in the pharmacy, a delivery service was not feasible.

Student Impact

Pharmacy students found the experience to be rewarding both personally and professionally. For example, Alicia Cheng, who was involved with compounding the hand sanitizers, reflected, “I have been impacted by the amount of love and support I received from others when they found out that I compounded hand sanitizers for them. I felt a huge sense of accomplishment and became more motivated to continue practicing pharmacy and advocating for public health for the purpose of improving the health of the community.” In addition, Peyton Randolph, who was also a hand sanitizer compounder, observed, “Working on the project provided an avenue to leverage my education and background, as supported by Purdue Pharmacy, to give back to our community in crisis.”

Alissa Freimuth was involved in developing the hand sanitizer recipe from the guidelines, helping compile the ingredients, compounding the hand sanitizer, and assisting in the distribution not only in the Purdue University Pharmacy, but also in direct deliveries to high-risk patients and outreach to other medical facilities. She wrote, “I became involved in the hand sanitizer project during my Advanced Pharmacy Practice Experience (APPE) rotation at Purdue University Pharmacy when COVID-19 was beginning to impact our community. Sanitization products were in high demand and hand sanitizer was nearly impossible to find. Dr. Eric Barker, Dean of Purdue College of Pharmacy, approached my preceptor, Dr. Nicole Noel and I about the new release in the ability of pharmacists to compound hand sanitizer during the pandemic with the idea to compound it for our own community.”

In the future, Cheng commented, “I can apply this information to my career as a pharmacist by remembering the impact I can make on the community. I realize that pharmacists are heroes that are there to support others when resources are scarce. I will remember to be resourceful and practice to the top of my license just to make sure one patient receives the service and care they deserve.” In agreement, Freimuth commented, “I will use this experience to continue to think outside of the box on the impact I can make on the health of my patients and my community.”

Regarding project refinement, Freimuth noted that starting this project sooner could have led to a bigger

In terms of public safety departments and local government offices, the pharmacy was able to provide hand sanitizer to local fire departments, police departments, and first responders in Tippecanoe County. The Indiana Department of Transportation and the city sanitation department also had a great need. Some requests even came from areas outside of Tippecanoe County, where Purdue University Pharmacy is located.

A portion of the compounded hand sanitizer was provided to local nonprofit organizations that requested donations. On campus, one such recipient was the ACE Campus Food Pantry. In the greater Lafayette community, the pharmacy donated hand sanitizer to Lafayette Transitional Housing, Lafayette Urban Ministry, and Food Finders Food Bank. These nonprofit organizations are essential to the community as they serve some of the most at-risk and vulnerable populations who needed food and housing during the pandemic. Providing hand sanitizer to these organizations helped improve the safety and health of both essential workers and the populations they serve. In general, the quantity donated to the nonprofit organizations was consistent with the

impact on the community. Cheng too wished to make a bigger impact and mentioned, "I would want to increase the amount of involvement I had in this project. I felt like I could have done more outside of compounding the hand sanitizers such as distributing them to others or providing education on the hand sanitizer (e.g., how they are made and how they are slightly different than the ones sold regularly). This would have given me a chance to really interact with patients and see the impact we made on them." Additionally, Cheng states, "I felt like more students could have been involved with the project. Only a few students had the opportunity to do so due to COVID-19 restrictions at the time. However, if the opportunity arises again, it should involve student pharmacists. Students involved with compounding hand sanitizer experienced a huge sense of community which motivated them to continue to do their best as future pharmacists."

CONCLUSION

This project illustrates how pharmacists and pharmacy students can play a significant role in the public health arena, which is a role they have traditionally not filled. Corresponding to this, pharmacists are now largely responsible for COVID-19 vaccination distribution and many also provide COVID-19 testing at their various pharmacies and clinic locations. With this project, the FDA Guidance for Industry provided the Purdue University Pharmacy the opportunity to provide the service of compounding hand sanitizer for the Purdue and local community during a public health emergency. Compounding the scarce resource of hand sanitizer was a sense of pride for the students, staff, and faculty involved. It allowed for collaboration and provided a sense of purpose during a challenging and fearful time. As Alissa Freimuth summarized, "This community outreach initiative helped to protect community members and allowed the pharmacy students to contribute and continue to learn during an uncertain time. It was a tremendous honor to be involved in this initiative."

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