Border Health Workshop Literature Review

Literature Review Overview

The following literature review examines two primary challenges to the United States in the realm of public health at the U.S.-Mexico border. The first of these challenges is binational disease surveillance and prevention. For this topic the literature review examines the history of programs aimed at binational disease surveillance and prevention, including animal health programs, and examines the Middle East Consortium on Infectious Disease as a model of a successful organization.

The second portion of this literature review examines public health supply chains. While the majority of the review is focused on pharmaceuticals, there is a recognition of the unique challenges posed by the medical supplies and equipment supply chains, as well as identifying counterfeit medical supplies and pharmaceuticals. Both of these issues are also addressed in the literature review.

Binational Disease Surveillance and Prevention

History of Binational Disease Surveillance and Prevention Agreements and Programs

The first notable collaborative agreement between the United States and Mexico was established in 1963 at the 21st United States Mexico Border Health Association Meeting. The agreement established the Binational Health Councils, which aim to help sister cities along the U.S.-Mexico border work more effectively together. The councils exist in all the major sister cities along the border, but the State of Texas has the most with eight councils (Texas DSHS, 2019). Some of these councils include busy ports of entry such as El Paso/Juarez and Brownsville/Matamoros. While the Binational Health Councils have extensive freedom to develop their own collaboration methods, many aim to meet regularly in order to discuss the most pressing binational health issues in their region.

Following the establishment of the Binational Health Councils along the southern border, little additional action was taken until 1983. At this time the State of California opened its own statewide binational health office, which it named the California Office of Binational Border Health (California Department of Public Health, 2017). Throughout the following decade, the remaining border states open their own border health offices in an effort to better address binational health issues. Most efforts remained at the state-level, however, until October 1994 when the U.S. Congress passed Public Law 103-400 (HHS, 1994). The law, which is titled the United States-Mexico Border Health Commission Act, established a commission to identify, prevent, and evaluate health problems in the border region (HHS, 1994). For the United States' commitment to the U.S.-Mexico Border Health Commission, there are 13 members. This includes the Secretary of Health and Human Services, who serves as the leader of the Commission (HHS, 1994). The other members of the Commission are made up of the health commissioners or their delegates from all of the states along the southern border and at least two individuals from each state that live in the border region (HHS, 1994). Though the law that

established the Commission was passed in 1994, it was not until 2000 that the Commission was formed.

In the time between the passage of the 1994 law and the formation of the U.S-Mexico Border Health Commission, the Binational Border Infectious Disease Surveillance Program (BIDS) was established in 1999. The primary goal of the BIDS program is to improve surveillance and disease response in the border region between the United States and Mexico. In order to do this BIDS has focused on ways to improve communication and information sharing, but it provides a great deal of autonomy to the states regarding the types of programs that are developed and how funds are allocated.

Within its first few years BIDS had several successes, which helped bolster the argument that binational disease surveillance was worth investing in. One such success was the 1999 binational investigation conducted by the Mexico Secretaria de Salud, CDC, and public health officials from both Texas and Tamaulipas (Weinberg et al., 2003). This was the first binational outbreak investigation ever conducted for dengue fever and it set a good model for the cooperating organizations moving forward.

In Texas, money from BIDS has been used to establish mosquito surveillance and to fund community health workers (CHW), but funding from the Centers for Disease Control and Prevention (CDC) has not been consistent (Banicki, 2018). Consistent funding from the CDC is vital to the success of state-level BIDS programs because the CDC Office of Global Migration is responsible for allocating all of the funding to states to run the program. The lack of consistent funding means that the State of Texas was not running any of its BIDS-related programs between 2011 and mid-2013 (Banicki, 2018).

In the early and mid-2000s there was a dramatic increase in development of and funding for binational disease surveillance and prevention programs. With the U.S-Mexico Border Health Commission formally implemented in 2000, they set about putting together the Healthy Borders 2020 Initiative. This initiative laid out the five main priorities of the Commission, which included addressing chronic and degenerative disease, infectious disease, maternal and child health, mental health and addiction, and injury prevention (US-Mexico Border Health Commission, no date). Once these primary objectives were developed, the Binational Technical Workgroup, which is a group created to discuss technical issues of public health such as laboratory diagnostics and epidemiological training, conducted a survey to identify the primary causes of the top public health problems in each category. While each category had different contributing factors, the Binational Technical Workgroup identified poverty has a primary cause in all five of the categories (US-Mexico Border Health Commission, no date).

Utilizing the data gained by the Workgroup, the Commission set goals that they hoped to achieve by 2020. The United States and Mexico each set individual goals, but the overarching goal remained improved health in the border region. One example of these goals is the United States set a goal to reduce the rate of HIV infections by 50 percent, while Mexico set the goal of keeping their rate of infection stable at 3.1 per 100,000 population (US-Mexico Border Health Commission, no date). When the goals of the Healthy Border 2020 program were evaluated in

2020 -- the report was released in January 2021 -- there were only limited improvements in the priority areas. More concerningly, there were several areas in which health outcomes were worse than they were when the goals were set. These included increases in diabetes and heart disease-related deaths as well as a 140 percent increase in gonorrhea incidence and a 584.3 percent increase in the incidence of congenital syphilis (US-Mexico Border Health Commission, 2021).

Although the Healthy Borders 2020 initiative was not as successful as the Commission had hoped, there was significant progress made between 2001 and 2008 in the development of infectious disease surveillance and prevention programs along the U.S. southern border. In 2002 the Binational Group on Epidemiological Surveillance and Information Exchange was developed to improve collaboration between the United States and Mexico on epidemiologic issues (CDC, no date). In 2004, the Early Warning Infectious Disease Surveillance program was established as part of the Public Health Preparedness and Response for Bioterrorism (Dopson, 2009). This program emerged in the aftermath of 9/11 to strengthen disease surveillance and prevention along both the northern and southern border. Then in 2008, the Memorandum of Understanding (MOU) on Cooperation in Fields of Public Health and Science was established. This MOU was an agreement between the US Department of Health and Human Services and the Secretaria de Salud to establish a framework for binational collaboration (CDC, no date).

Since 2010, the U.S.-Mexico Border Health Commission has continued to work collaboratively on issues of border and binational health. Programs like the Leaders across Borders program have improved the training and professional development of individuals working in the realm of binational health and have improved health outcomes for those living in the border region (Contreras et al., 2017).

Programs to Address Binational Animal and Zoonotic Diseases

In 1993 the Binational Committee for Tuberculosis was founded during the annual meeting of the U.S. Animal Health Association (APHIS, 2020). This original committee was made up of 14 members with one beef producer, one dairy producer, and one general farm representative from each country (APHIS, 2020). Additionally, the Chief Veterinary Officers from each country served as the co-chairs of the Committee. The Committee required that both state interests, federal interests, producers, and the research community be represented. Several years later, brucellosis and cattle fever ticks were added to the list of diseases that the Committee concerned itself with. As the Committee has expanded -- both in number of members and in mission -- the collaborative efforts between the U.S. and Mexico has increased at both the federal and state level (APHIS, 2020). Today the Committee focuses on the eradication of bovine tuberculosis, brucellosis, and cattle fever ticks. Both tuberculosis and brucellosis are bacterial infections, while cattle fever ticks spread a parasitic infection known as bovine babesiosis. While these three diseases are the primary focus of the commission, many viral, bacterial, parasitic, and protozoan zoonotic infections pose a threat in the border region.

Regarding zoonotic disease, vector-borne diseases are of greatest concern, particularly along the portion of the border in the lower Rio Grande Valley of Texas. Some of these vector-

borne zoonotic concerns include Venezuela Equine Encephalitis and Hantavirus. Zoonotic bacteria diseases of concern along the southern border of the U.S. include Lyme disease, Leptospirosis, and Rocky Mountain Spotted Fever. Lastly, protozoan diseases such as Chagas and Leishmaniasis raise additional concerns. Despite these threats, some scholars have argued that we have little understanding of the zoonotic diseases present along the U.S.-Mexico border (Esteve-Gassent et al., 2014).

The zoonotic disease receiving the most attention is Chagas disease, as its impact on working dogs has been documented for many years. A study conducted in 2015 and 2016 found that Department of Homeland Security (DHS) working dogs are widely exposed to the *Trypanosoma cruzi* parasite that causes Chagas disease (Meyers et al., 2017). Additionally, the study found that 7.4-18.9 percent of the dogs tested positive for antibodies, meaning that they had experienced a previous infection (Meyers et al., 2017). This widespread exposure is important not only because it can lead to heart failure in DHS dogs if they become infected, but because it could also lead to congenital and gastrointestinal consequences for human health.

While Chagas disease is most common in the Texas borderlands, Rocky Mountain spotted fever is prominent along the California border. A 2016-2017 study of dogs in Imperial County, California found that 12.2 percent were seropositive for the spotted fever group rickettsia (Estrada et al. 2019). The authors of the study argue that understanding the prevalence of rickettsial pathogens in the border region is critical to prevent tick-borne disease among humans.

The work undertaken by the US-Mexico Binational Committee for Tuberculosis, Brucellosis, and Cattle Fever Tick, along with academic research into the prevalence of important vector-borne zoonoses is necessary for improving health and disease surveillance along the U.S.-Mexico border.

Gaps in Binational Disease Surveillance and Prevention

Over the course of the last 100 years, Mexico and the United States have collaborated to establish stronger, more resilient binational disease surveillance and prevention. The heart of the modern-day program is the U.S.-Mexico Border Health Commission, which has had some success in improving border health broadly. Despite the successes of this Commission and programs like BIDS, many gaps remain. The remainder of this section will detail some of primary gaps that came to light through this review process.

The first major gap is the substantial structural differences between American public health and Mexican public health. Mexican public health is more centralized and it can become complicated for the singular entity in Mexico to coordinate and collaborate with four different state organizations, many of which have different data systems and conduct public health work differently. It would be useful to consider a standardized public health system for all southern border states to improve collaboration with Mexican public health organizations.

The second major gap is the lack of research and program data for the State of New Mexico. The majority of health data and programs are focused along the California border and

the Texas border, which is logical given that the largest border populations reside in these states, however, there is not sufficient focus on binational disease surveillance and prevention programs along the New Mexico border. In order to strengthen overall binational disease surveillance and prevention, programs must be functioning and collecting data in all states.

The third and final gap is the lack of disease surveillance and prevention of zoonotic disease. Seventy-five percent of emerging diseases are zoonotic and it is believed that this percentage will only continue to climb. Current binational disease surveillance and prevention programs must begin expanding to accommodate the threat of zoonotic disease.

Middle East Consortium on Infectious Disease: An Example of a Successful Binational Disease Surveillance and Prevention Program

The Middle East Consortium on Infectious Disease Surveillance (MECIDS) was founded in 2003 and serves as a framework for surveillance, prevention, and response of infectious disease in Jordan, Palestine, and Israel (MECIDS, 2021). The greatest infectious disease concerns for the three nations are foodborne illnesses, avian influenza, and leishmaniasis, so MECIDS focuses heavily on these disease issues. MECIDS has a number of project areas that include field epidemiology, biosafety and biosecurity, WHO International Health Regulations (IHR), and individual projects within the area of infectious disease (MECIDS, 2021).

Since its establishment in 2003, MECIDS has responded to numerous disease outbreaks. In 2006, the organization stopped a cross-border outbreak of avian influenza in just 10 days (NTI, no date). During the COVID-19 pandemic, MECIDS has been instrumental in developing and implementing pandemic mitigation plans for Jordan, Palestine, and Israel. They have facilitated the exchange of information, developed rapid response strategies, provided training and webinars for public health officials, and launched a public education campaign (MECIDS, 2020).

The success of MECIDS provides a framework from which other states can evaluate the effectiveness of their programs and incorporate elements that have worked well for MECIDS. Such elements should be examined when further developing binational surveillance and prevention programs along the US-Mexico border.

Public Health Supply Chains

The SARS-COV-2 pandemic has made it clear that our nation's public health supply chains are fragile. U.S. health care systems, such as the pharmaceutical and medical supply chain planning and management, do not serve the American people as well as is necessary. There is a notable disconnect between the demands of public health agencies, health-related manufacturing companies, and medical facilities--hospitals and clinics--and the needs of the U.S. population (Regan 2021). Errors on both sides of supply and demand, miscommunication between government agencies and the general population, and widening of existing gaps in the healthcare system have made it possible for substandard and falsified medical supplies and pharmaceuticals to flood the U.S. healthcare system in the midst of a crisis.

Health care relies on personal protective equipment (PPE), pharmaceuticals, medical devices, medical supplies, and blood to provide adequate care to those in need (Mirchandani 2020). According to the Food and Drug Administration (FDA), since the start of 2020, there have been over one hundred drugs in short supply nationwide (Johns Hopkins University, 2020). These drugs are not only for emergency use but also used to treat chronic conditions. In light of the pandemic, this has severely affected the safety of the most vulnerable and increased mortality and morbidity of high-risk populations (Miller et al. 2020). A stockpile shortage of PPE in the event of an influenza-like pandemic has been predicted by the National Institute for Occupational Safety and Health since 2006 (Cohen and Rodgers, 2020). Despite this awareness and outbreaks that have occurred since then, like the 2014 Ebola Virus in Dallas, Texas, the standardization of PPE and mandates to require hospitals to provide their healthcare providers with essential PPE has not occurred (Cohen and Rodgers, 2020). A major factor for this lack of preparation is the existing budget model for PPE that incentivizes hospitals to prioritize cost-effective expenses. This risks the safety of healthcare workers because this causes hospitals to use a just-in-time approach with purchasing PPE to sustain their inventory levels (Cohen and Rodgers, 2020). In the pandemic, it has led to high demand for effective PPE and suppliers without the ability to meet that demand. Experts from various public health sectors have pointed out the flaws in these systems over the years and the SARS-COV-2 pandemic continues to exacerbate the vulnerabilities. Building a robust public health infrastructure should take precedence so that the U.S. is prepared for the next pandemic. Improving relationships with North American countries, such as Mexico, will help to ensure that the U.S. has a robust medical pipeline that can help ensure the safety of the population.

The following is an overview of what the current literature recommends to improve the U.S. healthcare supply chain with a specific focus on the pharmaceutical industry. Specifically, to prevent future drug shortages, which impact the U.S. on a health and socioeconomic level—as well as proposed solutions to these issues. A majority of the published literature focuses on the pharmaceutical industry at a nationwide level. This is a gap that requires more research and development of all health care supply chains and health informatics.

U.S. Pharmaceutical Supply Chain

Pharmaceutical drugs have been identified and tracked since 2001, however, this system is not sufficient. It relies on receiving information from manufacturers on a national level instead of gathering detailed information from its consumers at a local and state level. The latter option would give a more accurate depiction of where shortages and gaps exist (Johns Hopkins University, 2020). Additionally, there is a variety of pharmaceutical databases maintained by organizations like the FDA and nonprofit pharmaceutical organizations which update different types of consumers and the systems do not cross-reference one another to ensure accuracy. This is an issue in U.S. healthcare because there are various systems that are overly redundant and do not connect with one another. A system that can track shortages, cater to different types of consumers, alert for counterfeit issues, and provide detailed information of shortages would be

pertinent to the safety and well-being of all, but especially to high-risk communities. This imperfect system needs to pivot to a state of predicting and preventing pharmaceutical shortages in order to thrive and prepare for the next health crisis.

Prior to the pandemic, the FDA did not have the authority to require pharmaceutical companies to report quality metrics and shortages of emergency use medications. This is a flaw in the system and hindered the United States during the COVID-19 pandemic. The FDA's newly granted authority should be used as an opportunity to continue requiring quality metrics in order to build a system that can properly coordinate and provide direct sharing of medications and other health care supplies to varying institutions across all regions of the United States (Johns Hopkins University, 2020).

There are several points in the U.S. pharmaceutical supply chain that lack a failsafe. This can, and has, resulted in drug shortages, but it also resulted in the progression of antimicrobial resistance (AMR) and drug-resistant infections, increased out-of-pocket and U.S. spending on health care, and loss of income to individuals due to prolonged illness (WHO, 2017). AMR is of great concern as a study showed that lack of dispensary regulations and poorly trained pharmacy clerks in over 32 pharmacies located in Ciudad Juárez, which shares a border with El Paso, were overprescribing antibiotics. This correlated to higher rates of drug resistant tuberculosis in patients residing along the U.S.-Mexico border (Homedes and Ugalde, 2012). U.S. border residents, who are commonly low-income and/or uninsured, often go to Mexico in search of affordable pharmaceuticals. It is important that the affordability and accessibility of medications, like antibiotics, is still available while also implementing regulation to curb AMR and other negative impacts.

Further issues in the pharmaceutical supply chain can arise because of the lack of available raw materials, too few North American-based manufacturing facilities, the quality of the final product, or a manufacturer's choice to stop production of a generic drug or active pharmaceutical ingredients (API) altogether (Schondelmeyer et al., 2020).

Disruptions to any of these points in the drug production supply chain can be brought on by: natural disasters, such as hurricanes or a polar vortex; a population's response to rumored or actual shortages, such as hoarding; human-made disasters, such as intentional or unintentional cross-contamination of drugs. Disruptions occurred between 2018-2020 and nearly occurred when China suggested it would stop exporting life-saving drugs to the U.S. in March 2020, but, fortunately, did not. It did occur when India stopped exporting 26 drugs and 13 APIs in order to ensure it had enough supplies for its citizens during the early months of the COVID-19 pandemic (Schondelmeyer et al., 2020) (Johns Hopkins University, 2020).

The United States' overdependence on other countries' abilities to produce APIs, injectable drugs, biologics, and specialty drugs puts the U.S. pharmaceutical supply chain at high risk of falling victim to any of the disruptions previously mentioned (Schondelmeyer et al., 2020). For instance, "in 2019, two-thirds of the US drug supply (by $ value) [was] imported, while about 72% of the manufacturers of APIs that used to make pharmaceuticals [were] located out of the country. Also, about 55% (based $ value) of biologics and specialty drugs [were]

imported" (Schondelmeyer et al., 2020). This has already caused product quality and economic issues, and without reliable and sufficient data we are most likely underestimating the burden this has had on communities who rely on such resources.

Substandard, Unregistered, and Falsified Medical Products

Often the words "fake" or "counterfeit" are used interchangeably to describe ineffective products. It is important to note that currently, there is no consensus on which word to use in which context. In exchange for goods and services, it would be worthwhile to have a mutual understanding of these definitions amongst countries in order to properly regulate and identify ineffective medical products. For the purposes of this review, we use the WHO's recommended definitions to refer to inadequate medical products. Substandard: "authorized medical products that fail to meet either their quality standards or their specifications, or both" (WHO, 2017). Unregistered: "medical products that have not undergone evaluation and/or approval by the national or regional regulatory authority for the market in which they are marketed/distributed or used, subject to permitted conditions under national or regional regulation and legislation" (WHO, 2017). Falsified: "medical products that deliberately/fraudulently misrepresent their identity, composition or source" (WHO, 2017). Counterfeit: "medicines that infringed patents or other intellectual property rights" (WHO, 2017).

Pharmaceutical shortages in the U.S. have been an ongoing issue and are not something new in light of the SARS-COV-2 pandemic. However, because of the SARS-COV-2 pandemic there has been a dramatic increase in demand for life-supporting medications, disruptions to the pharmaceutical supply chain due to shortage of APIs, raw materials, closed off borders, insufficient human capital, and delayed inspection and review procedures (Johns Hopkins University, 2020). These gaps in the pharmaceutical production and distribution chain in conjunction with exponential growth in e-commerce have allowed for these vulnerabilities in the supply chain to be exploited.

In 2017 and 2018, Texas was the number one state to trade with Mexico, and in 2019 Mexico became the United States' number one trading partner and as of 2020, the U.S purchased 80% of Mexico's imports (Wayne 2018; Wayne 2020). This strong interdependence between the U.S. and Mexico was not met with robust supply chains or open lines of communication as the world grappled with the COVID-19 pandemic. The shutdown of essential manufacturers based in Mexico caused issues for the U.S. manufacturers like 3M, an N95 mask manufacturing company. This has undoubtedly led to substandard, unregistered, and falsified medical products flooding the U.S. healthcare system (Sganga, 2021; Rodriguez, 2020). For instance, U.S. Customs and Border Protection seized 12.7+ million counterfeit masks, 180,000 unapproved COVID-19 test kits, and 38,000+ prohibited chloroquine tablets (CBP, 2020). In February 2021 the FDA issued an alert on all hand sanitizers coming from Mexico, which was the first time they issued a country-wide alert. The alert notified the public that the hand sanitizers were testing "positive for methanol which is toxic when absorbed and life-threatening if ingested" (FDA, p.1, 2021). The FDA March Global Update Report stated that a majority of the alcohol-based hand sanitizers

from Mexico were substandard from April to December 2020 (p. 6, 2020). Scare resources and an increase in demand have resulted in the production of substandard and falsified drugs and medical supplies. This has consequences medically and socioeconomically, but often affecting those with the least amount of social and financial resources to understand the risks of using substandard or falsified medical products (WHO, 2017).

A majority of the current literature uses previously published data in addition to probability models to assist in estimating the potential impact of using substandard and falsified medical products. For example, there is a high prevalence of substandard and falsified antimalarial drugs that are imported to sub-Saharan Africa. To understand the impact these substandard antimalarial drugs have on a health and economic level WHO commissioned a team from the London School of Hygiene and Tropical Medicine to use probability models to demonstrate the potential impact. The models predicted an additional 72,000-267,000 deaths per year and $12.1-44.7 million when using substandard pharmaceutical treatment (WHO, 2017). The data on the amount of substandard, unregistered, and falsified medical products along the U.S.-Mexico border primarily focuses on the opioid crisis (DEA 2018). Substandard and falsified medication found along the southern border is commonly lifestyle medications, such as Adderall or Viagra that are laced with synthetic opioids (DEA 2018). Comprehensive research and development on health care supply chains along the southern border need to be conducted to understand the true burden and impact substandard, falsified, and unregistered medical products are having on the U.S. population.

Proposed Solutions

The gaps in the pharmaceutical supply chain cannot be ignored and it will take a binational effort to build a sustainable supply chain that can detect and prevent medical and pharmaceutical supply shortages. Fortunately, there are systems and resources already in place that can be built and improved upon in order to make these necessary changes. In fact, some policy changes have already been implemented since the pandemic spread across the United States and should be used to further the agenda of building a regulated and sustainable set of public health supply chains.

Making changes to the upstream phases, such as where the raw materials are produced and sourced or creating opportunities to produce APIs in the U.S. could result in tremendous improvements that would benefit the downstream supply chain outcomes and relationship with Mexico (Schondelmeyer et al., 2020). While there are a lot of errors that can occur in the upstream pharmaceutical supply chain or downstream pharmaceutical supply chain have resulted during the upstream because of its set up as a ripple effect. In order to mitigate this issue, there needs to be an improvement in the transparency of pharmaceutical supply chains. For instance, the FDA and American Society of Health-System pharmacists maintain a database of current and past drug shortages however this is only on a nationwide basis. These systems could possibly be combined and used for analyzing, predicting, managing, and preventing shortages of critical medications at local, state, and national levels (Ulrich et al., 2020). Since the FDA already

manages and has oversight on the pharmaceutical supply chain it would be wise if they continue to do so in order to avoid further confusion or miscommunication with established pharmaceutical companies and organizations. The FDA's responsibilities and authorization could be expanded so that they could enforce new rules and regulations on pharmaceutical manufacturers and wholesalers. Additionally, an up-to-date map of the U.S. drug supply chain would be pertinent to help with the upkeep of the nationwide system and emergency management plan. The map would inform its consumers of where each of the drug products in the U.S. market was produced—from raw materials to APIs, and packaging and prescription drug profiles for each product should be made available on a user-friendly website. A logo or identification mark should be placed on the pharmaceutical products and websites to ensure their legitimacy to the consumer.

To manage all of these solutions and to keep the transparency of the pharmaceutical supply chain accountable a committee should be formed within the FDA. The committee would do so by continually publishing data on each drug's supply chain, acquiring and analyzing prescription drug spending data, evaluating the consequences of failing to mitigate drug shortage issues, and developing binational policies to regulate supply chains.

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