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Original Research

Multistate Hepatitis A Outbreak: Vaccination of Food Service Workers as Part of the Kentucky Outbreak Response

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Abstract

Background: In August 2017, a local outbreak of Hepatitis A was identified among homeless individuals in Louisville, Kentucky. This marked the first cases in what has now become recognized as the largest Hepatitis A outbreak in the US. When infection was identified in a Food Service Worker (FSW), vaccination efforts were expanded to target this group.

Objectives: The purpose of this study was to describe: 1) the processes used to provide access to Hepatitis A vaccine for FSWs, 2) results from the immunization activities, and 3) lessons learned from the outcomes.

Methods: Through a partnership between the Louisville Metro Department of Public Health and Wellness (LMDPHW) and the University of Louisville Division of Infectious Diseases (UL), a novel approach to vaccination was implemented. Access to vaccine was provided via on-site immunization in 66 restaurants and subsequent availability in a pop-up vaccination clinic. Data were collected using the LMDPHW data collection form and included demographics, risk factors for Hepatitis A, and vaccine documentation. Results for those vaccinated March-December 2018 were analyzed using descriptive statistics.

Results: On-site vaccination was provided to 1337 FSW at 66 restaurants during the seven (7) week period from March 28-May 15, 2018. This process involved a team of 42 including Advanced Practice Registered Nurses, Registered and Licensed Practical Nurses, Physicians, and UL team members. During the 35 weeks the walk-in clinic has been in operation (May 16-December 31, 2018), 3068 additional FSW were vaccinated for a total of 4405 FSWs vaccinated as part of the outbreak response. Critical partners included the Kentucky Restaurant Association and the Kentucky Nurses Association.

Conclusions: This study demonstrated a successful model for vaccination of a novel population during an infectious disease outbreak and the importance of expanding partnership networks to ensure success. The outcomes emphasized the importance of the resources available in the academic community for reliable and consistent public health emergency response.

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Background

In August 2017, a local outbreak of Hepatitis A was identified among homeless individuals in Louisville, Kentucky. This marked the first cases in what has now become recognized as the largest Hepatitis A outbreak in the US [Warren, 2018]. In the midst of the changing epidemiology of this disease, Kentucky joins a growing number of other states in a larger nationwide public health concern [KDPH, 2018]. Cornerstones in disruption of this outbreak include immunization and education regarding the disease and its transmission opportunities for all at risk.

Hepatitis A is a communicable disease transmitted via ingestion of the organism that is found in feces of an infected individual. Hepatitis A impacts the liver and as the virus replicates, it is shed in the stool. Risk factors for both acquisition and transmission of infection include those who are homeless or housing insecure, persons who use drugs, men who have sex with men, or those who have close contact with these persons described [CDC, 2018a]. Due to various social determinants of care in populations facing homelessness and substance abuse, challenges exist in engaging those at risk to provide vaccination and education regarding transmission and prevention of infectious diseases.

The first confirmed cases of Hepatitis A infection in Kentucky were reported in Louisville, and initial vaccination efforts targeted the homeless and persons who use drugs, but as the outbreak progressed the vaccination outreach efforts broadened. In December, 2017 the first case of Hepatitis A was reported in an individual working in the food service industry in Louisville [KDPH, 2018]. This case highlighted the importance of considering food as a source of transmission as well as those

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who may be handling or preparing food for consumption. Identification of infection in a food service worker (FSW) also brought awareness regarding the ability of this disease to manifest itself more broadly in the general population. This served as motivation to expand vaccination efforts and target those working in the more than 3000 restaurants and food service facilities in Louisville. There was also concern regarding the perception of risk of transmission via food in the wake of planning for the Kentucky Derby, an international event that attracts close to a million visitors to the state during April and May. Typically, hundreds of food trucks and mobile restaurants also enter the Louisville area as part of the Kentucky Derby Festival. This was a driving factor to expand vaccination efforts and garner assistance that could augment traditional public health emergency response operations and the human and material resources necessary to improve vaccination capacity.

Since early 2000, emphasis has been placed on development and training of groups of individuals with expertise in aspects of healthcare emergency response so they could be quickly called into action for assistance. These groups compose the community Medical Reserve Corps and significant resources are devoted to their training. However, response rates among those trained may be inconsistent leaving communities, including Louisville, with unfilled needs in the wake of emergency situations that require rapid and broad response. The Hepatitis A outbreak in Louisville was another demonstration of this gap and, combined with the decreasing capacity within the traditional public health system, resulting in the inability to implement the robust response needed for vaccination and education of the disenfranchised populations at the heart of the outbreak. In response to this capacity need, the Louisville Metro Department of Public Health and Wellness (LMDPHW) reached out to the University of Louisville Global Health Center (UL-GHC) for assistance in planning and implementation of a community-wide vaccination response targeting FSWs.

The objectives of this report are to describe: 1) the processes used to provide access to Hepatitis A vaccine for FSWs, 2) results from the immunization activities, and 3) lessons learned from the outcomes

Methods

In late February 2018, LMDPHW and the UL-GHC met to develop a response plan focusing on provision of Hepatitis A vaccine for FSWs. The process involved provision of the vaccine to any individual who self-identified as a food service worker living or working in Jefferson County, Kentucky. A new partnership between LMDPHW, the UL-GHC, and the Kentucky Restaurant Association (KRA) emerged. A communication process was developed that would be used to share information regarding availability of Hepatitis A vaccine and methods to provide immunization to FSWs living or working in Jefferson County. Vaccine and vaccination supplies were provided to the UL-GHC by the LMDPHW. The UL-GHC worked with the KRA to develop a process for providing vaccination and a plan for sharing the costs of vaccination with restaurants and food service establishments wishing their FSWs to be vaccinated. Few restaurants provide health insurance options for FSWs, so access to vaccination was addressed as a public health initiative. An information hotline was established providing specific instructions for participation to restaurant owners and managers. Beginning in March, 2018, an 'early adopters' process for vaccination was introduced where vaccine was taken directly to restaurants, at the request of the owner/manager, and vaccination provided for FSWs on-site. The LMDPHW made vaccine available at a reduced cost of $17 per dose and UL-GHC charged an additional $8 per dose for program management and administration. Restaurant owners/managers were invoiced by the UL-GHC at a cost of $25 per dose of vaccine administered. The 'early adopters" on-site vaccination phase began on March 28, 2018 and continued through May 15, 2018. Response grew rapidly and the FSW vaccination program transitioned away from on-site vaccination to a pop-up walk-in clinic capable of addressing the increasing volume of FSWs requesting vaccination. This clinic was located on the University of Louisville Health Sciences Center Campus and operated by the UL-GHC beginning May 16, 2018. For walk-in vaccination, restaurants were asked to provide lists of their food service workers in the event they agreed to cover the cost for the doses of vaccine administered to their employees. Otherwise, FSW could walk-in to the clinic and self-pay for immunization. FSW less than 18 years of age could be vaccinated if they were accompanied by a parent/guardian or had the signature of the parent/guardian on the data collection form. The LMDPHW had already developed a data collection form for purposes of gathering risk factor information and documentation of vaccination, therefore the process involved use of that same form. The project for immunization and use of the data collection form were submitted to the University of Louisville Institutional Review Board for review and approval. A Research electronic data capture (REDCap™) [Harris, Taylor, Thielke, Payne, Gonzalez, Conde, 2009] database was developed to house information and data collection forms were returned to LMDPHW for entry into the Kentucky Immunization Information System after vaccination was given. Vaccine recipients were provided with a card indicating the vaccine provided, the date, clinic contact information, and information about when to seek the second dose of the Hepatitis A vaccine series.

Results

On-site vaccination was provided to 1337 FSW at 66 restaurants during the seven (7) week period from March 28-May 15, 2018. This process involved a team of 42 including Advanced Practice Registered Nurses, Registered and Licensed Practical Nurses, Physicians, and support staff from the UL-GHC. Team members were responsible for transporting vaccine, supplies, monitoring the cold chain of the vaccine, shepherding completion of the vaccination data collection forms, administration of vaccine, return of the vaccine to the UL-GHC clinic site vaccine refrigerators, return of unused supplies, sharps containers, and trash. The nursing staff consisted of faculty from the University of Louisville, Galen, Bellarmine and Spalding Schools of Nursing and members of the Kentucky Nurses Association. A team of three UL-GHC personnel were responsible for managing the vaccine and supplies and four UL-GHC personnel were responsible for data entry into REDCap™ and review of the data and processes for quality assurance.

During the 35 weeks the walk-in clinic has been in operation (May 16-December 31, 2018), 3068 additional FSW were vaccinated for a total of 4405 FSWs vaccinated as part of the outbreak response. Demographics of the FSWs vaccinated including age, gender, ethnicity, and education level are shown in **Table 1**.

Table 1 Vaccinated FSW Demographics March-December 2018 (On-site vaccinations 1,337 and Walk-in clinic vaccinations 3,068)

Variable	Frequency (%)
First Dose	4,405 (100%)
Return for Second Dose	115 (3%)
Age (Median, IQR*)	31 [24-43]
Sex	
Male	1,977 (45%)
Female	2,166 (49%)
Declined to Answer	262 (6%)
Race	
Asian	105 (2%)
Black	818 (19%)
White	2,339 (53%)
Other	469 (11%)
Decline to Answer	674 (15%)
Hispanic	
Yes	618 (14%)
No	2,563 (58%)
Decline to Answer	1,224 (28%)

*Interquartile range

Table 2 Food Service Workers' Self-reported Risk Factors for Hepatitis A

Variable	Frequency (%)
Housing Insecure or Homeless	
Yes	94 (2%)
No	3,964 (90%)
Decline to Answer	347 (8%)
Active Drug User	
Yes	98 (2%)
No	3,978 (90%)
Decline to Answer	329 (8%)
IV Drug User	
Yes	33 (1%)
No	4,033 (92%)
Decline to Answer	339 (7%)
MSM*	
Yes	79 (4%)
No	1,756 (89%)
Decline to Answer	142 (7%)
Direct Contact with anyone having the above risk factors	
Yes	255 (6%)
No	3,561 (81%)
Decline to Answer	589 (13%)

* Men who have sex with men, among males

The clinic operated Monday-Friday 0830-1600, and one certified medical assistant, one receptionist, and one Advanced Practice Registered Nurse (APRN) provided the staffing. One clerical and one finance manager were responsible for billing restaurants for vaccinations given and not self-paid. Two research personnel were responsible for data entry into REDCap™ and quality assurance of the process and data as well as communication with LMDPHW regarding vaccine, supplies, and the data collection forms.

One section of the data collection form requested information regarding risk factors for Hepatitis A. FSWs were provided the data collection form to complete prior to vaccination and all information was self-reported. Risk factor information responses are shown in **Table 2**. Among those responding to the risk factor questions, 2% indicated homelessness and/or drug use as risk factor and 4% of the responding males indicated MSM (men having sex with men) as a risk factor. A consistent 8% declined to respond to questions about drug use, homelessness, and MSM activity. However, 13% declined to respond to the risk factor question asking if they had contact with any in those groups.

Conclusion

This project demonstrated the successes and operational challenges of immunizing a targeted population during an outbreak. The primary goal in addressing the outbreak was to make Hepatitis A vaccine immediately available to food service workers. Accomplishing that required planning and development of new partnerships and approaches with respect to: 1) available and trained staff competent to administer vaccine, 2) access to sufficient quantities of vaccine and supplies, 3) affordability for the targeted workforce, 4) acceptance of vaccination by the targeted workforce, 5) documentation of those vaccinated, and 6) a tracking process to identify FSWs sent by their restaurant employer as well as those walking in independently for vaccination. The community outreach and immunization expertise present in the UL-GHC made the partnership with the Louisville Metro Department of Public Health and Wellness (LMDPHW) vital in the outbreak response.

Available and Competent Staff to Administer Vaccine

Historically, the UL-GHC has planned and implemented a number of non-traditional approaches to community mass vaccination including drive-through programs and large scale on-site vaccination events [Carrico, 2002; Carrico, McKinney, Watson, Wiemken, Myers, 2012; Carrico, Bosson, Koch, Raghuram, Peyrani, Ford, Pauly, et al, 2015]. Success for this project hinged upon those skills including: 1) identifying and engaging immediately available and competent workers capable of assessing patients, administering vaccine, and providing patient and community education, and 2) engaging the support of a recognized and trusted resource who could link with the food service community. Two key partner groups were engaged to augment the existing UL-GHC staff vaccination capacity including the Kentucky Nurses Association and local Schools of Nursing. Although vaccine administration and the elements of safe injection practice are part of nursing practice, it is not a skill set that is consistently present among licensed (RN/LPN) or certified (MA) healthcare workers. Consequently, it was important to use a competency-based approach for skill validation prior to participation for all administering vaccine [Carrico, Garrett, Balcom, Glowicz, 2018]

The third key partner was the Kentucky Restaurant Association (KRA). The KRA encouraged participation among local restaurants and helped organize several local events that brought together FSW from multiple establishments for vaccination. Their partnership was a critical conduit between the health department, the UL-GHC, restaurant owners and managers, and FSWs eligible for vaccination.

Access to Sufficient Quantities of Vaccine and Supplies

Access to vaccine was a pivotal element in the success of the FSW immunization program. Therefore, success of the vaccination effort involved access to sufficient and reliable quantities of vaccine and supplies. LMDPHW obtained vaccine through a variety of grants and focused funding and provided it to UL-GHC. Typically, batches of vaccine all with the same lot number were provided to the UL-GHC and transported in temperature controlled and monitored refrigerators. Adult and pediatric doses were provided in either prefilled syringes or single dose vials. Vaccine was maintained in pharmaceutical grade refrigerators with continuous temperature monitoring. All vaccine transport was done in temperature monitored vaccine transport coolers adherent with the CDC guidelines [CDC, 2018b]. Needles, syringes, alcohol swabs, bandaids, sharps containers, environmental disinfectant wipes, alcohol-based hand rubs, Vaccine Information Statements (VIS), data collection forms, and patient education sheets in English and Spanish were provided and used solely for these vaccination efforts.

Affordability for the Targeted FSW Workforce

Cost and complexities involved in provision and acceptance of health insurance plans among owners and workers in the food service industry have resulted in few FSWs with health insurance that pays the full price of vaccination.

Some restaurants reportedly sent FSW to local pharmacies for vaccination, but there are no available data to indicate numbers of FSWs who received vaccination via that method. The FSW vaccination process was made available to anyone indicating they worked in the food service industry with employment and/or residence in Jefferson County. If their restaurant employer had agreed to pay for the vaccine, the FSW was vaccinated following completion and review of the data collection form and a review of the Hepatitis A VIS. Copies of the VIS were also made available, although few FSW took those copies with them after vaccination. If the restaurant employer had not agreed to pay for the vaccine, the FSW was charged $25 and given a receipt to show to their employer. All vaccine recipients were provided with a card indicating the vaccine administered (Hepatitis A) date of vaccination, contact information for the UL-GHC, and a statement encouraging the recipient to seek a second dose of Hepatitis A vaccine in 6-18 months, in accordance with current ACIP recommendations [CDC, 2018c].

Acceptance of Vaccination by the Targeted FSW Workforce

The highest vaccination rates occurred when vaccines were at the employment site. Prior to our arrival at the restaurant, manager(s) were asked to discussed the importance of vaccination with their employees. When the manager was vaccinated as part of the process, usually the rest of the workers would be vaccinated, too. Lower vaccination rates were observed when the manager(s) were not involved in the process. For those vaccinated in the walk-in UL-GHC site, workers were seen quickly and the process was completed within minutes with a space to wait 15 or more minutes following vaccination. A major public bus stop is directly outside the UL-GHC and designated free parking was also available. During the height of the vaccination program in the weeks prior to the Kentucky Derby, a number of restaurants brought FSWs in vans and buses facilitating vaccination of large groups at a single time. It has been estimated that the 3000 restaurants in Jefferson County employ approximately 50,000 workers, but it is not known how many of those work in multiple restaurants or how many were vaccinated and no longer work in the industry. Therefore, the true number of targeted workers is not known. However, as of December 31, 2018 there have been no documented cases of Hepatitis A transmission linked with eating in a restaurant in Jefferson County.

Documentation of Those Vaccinated

Each vaccine recipient completed a data collection form that included demographic and risk factor information, consent for vaccination, questions assessing knowledge regarding Hepatitis A infection and infection control, and an area to document date and site (anatomic) of vaccination, vaccine brand, lot number and expiration date. Information from the data collection form was entered into REDCap™ then checked for data quality using a quality assurance team process. This allowed for access to information regarding prior doses of vaccine received in the event the restaurants sent their FSWs back to the UL-GHC for the second dose of vaccine. A majority of the FSWs seen for vaccination indicated they had no primary care provider, so the state immunization information system provided the only consistent and reliable way of communicating vaccination status with other potential healthcare providers.

Tracking of those Vaccinated and Those Eligible for Vaccination

Use of REDCap™ as a data repository for FSW vaccination provided an ability to verify vaccination status and quickly provide individual FSWs and their employers with vaccination information. The focus of the outbreak response involved the goal of providing the first dose of Hepatitis A vaccine to as many at-risk and eligible individuals as possible. After six months, a number of restaurants indicated a desire to provide their FSWs with the second dose of vaccine. Having the data readily available in REDCap™ helped prevent inappropriate spacing of the vaccine as well as vaccine errors.

As the outbreak continues to move across the US, the UL-GHC and the Kentucky Nurses Association have continued to share practices, successes, challenges, and lessons learned with other states. There are limitations with the generalizability of these processes as the experiences involve only FSWs and an unknown proportion of that targeted population. Information, including risk factors for Hepatitis A was self-reported. FSWs would often come in groups with others from their same restaurant, so it is conceivable that there may have been hesitance to document information that the FSW perceived as potentially available for review by their employer or seen by their co-workers. Privacy of the data was stressed with every vaccine recipient, but it is unknown how that information was perceived.

The Kentucky Restaurant Association was a major partner and it is unknown how that same association functions within other states and what other methods for encouraging vaccination may have been used, or may be able to be used, in response to the outbreak. We learned that having access to nurse leaders, nurses and other healthcare personnel who are competent in vaccine administration and mass vaccination is critical to a rapid and safe community response. Further, establishing and maintaining broad community partnerships that are continuously nurtured is important for future responses as we continue to see gaps in access to preventive care for the entire United States population.

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