VIEWPOINT



Ethical considerations for mandating food worker vaccination during outbreaks: an analysis of hepatitis A vaccine

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Abstract

A widespread global outbreak of Hepatitis A virus (HAV) has prompted regulations in a few cities in the United States (US) mandating HAV vaccination of food service workers. This Viewpoint considers the global impact of HAV, analyzes ethical issues pertinent to recent mandatory vaccination regulations and the core values of public health. It explores the health and rights of stakeholders and ethical criteria for mandatory vaccination that could be applied globally with the ethical codes of the World Health Organization and the American Public Health Association. The goal is to help create ethical guidance for determining under what conditions, and for what populations, should regulations be created requiring vaccination for a communicable disease.

Keywords Policy · Ethics · Food workers · Foodborne illness · Hepatitis A

Key messages

- Current U.S. regulations mandating Hepatitis A vaccine for food service workers raise ethical issues
- Regulations mandating Hepatitis A vaccine for food service workers must be based in scientific evidence of transmission from workers to consumers, and must apply global ethical guidelines and principles

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Introduction

Each year, hepatitis A virus (HAV) causes 1.4 million cases around the world, with recent outbreaks showing a 294% increase in infections between 2013–2015 and 2016–2018 [1]. Between January 2017 and April 2020, 24 European Union/ European Economic Area (EU/EEA) countries reported 25,032 confirmed HAV cases [2]. Since 2016, thirty-five states in the United States (U.S.) reported over 39,000 HAV cases, almost 24,000 hospitalizations, and over 370 deaths [3].

The outbreak has led to responses from U.S. health departments and city governments, including implementing mandatory HAV vaccination regulations for food workers. The United States Centers for Disease Control and Prevention (CDC) and United States Food and Drug Administration (FDA) have designated five foodborne pathogens that cause severe illness and can be transmitted by food workers as the "Big 5" including Hepatitis A virus (HAV), Norovirus, *Salmonella typhi, Shigella* spp., and *Escherichia coli* (*E. coli*) [4]. This Viewpoint examines whether public health policies and regulations should mandate HAV vaccination for food service workers. I base the arguments and recommendations on a review of the data, and on guidance from the World Health Organization Code of Ethics and Professional Conduct [5] and the America Public Health Association Public Health Code of Ethics [6].

Both symptomatic and asymptomatic people spread HAV, a viral liver disease, through fecal–oral contact via improper handwashing, or from contaminated food, water, or objects [7]. In countries with good sanitation, HAV infections tend to occur in high-risk groups, including people who are substance users, homeless or unstably housed, incarcerated, or men who have sex with men [8]. HAV can be transmitted by asymptomatic people via feces from up to two weeks before and as long as two weeks after the appearance of symptoms. Complications are unusual although fulminant hepatitis, a rare, severe complication, has up to an 80% mortality. The case fatality among all ages ranges from 0.3 to 0.6% is as high as 1.8% for adults over age 50 or those with chronic liver disease [9].

Foodborne illness traceable to a known pathogen in the United States annually causes approximately 9.4 million illnesses, 56,000 hospitalizations, and over 1,300 deaths [10]. *Food Safety News*, a daily update for food policy and public health issues, ranked HAV transmission by food workers as one of the top five food safety issues of 2019 in the U.S., and some experts support mandatory food worker vaccination [11–13]. Of 40,000 adults with HAV reported during 1992–2000, 8%—or over 3,200 people—were food handlers. Just one food handler with HAV can transmit HAV to many people, creating a substantial economic burden on the public health system [14]. Because people are most contagious before symptoms appear, and because children and people with weak immune systems may be contagious for up to 6 months, it is not sufficient to require workers exhibiting symptoms to refrain from working in food service.

There are safe, effective HAV vaccines. To protect children and boost population-wide herd immunity, 24 US states have mandated HAV vaccination for childcare enrollees, with additional requirements for school age children in some states; the CDC recommends routine vaccination for children and persons at high risk [15, 16]. Public health departments have identified foodservice workers with Hepatitis A in most U.S. states, including California, Florida, Maine, Missouri, Kentucky, New York, and Pennsylvania. In 2019, the U.S. restaurant industry employed 15.3 million people, or about 1 in 10 working Americans, making any disease outbreak likely to affect food workers [17]. In 2019 alone, the following U.S. news stories focused on HAV-infected food workers:

- In Caribou, Maine the health department vaccinated more than 700 potentially exposed customers of a fast-casual restaurant with an HAV infected food service worker [18].
- In Rockport, Massachusetts, the Department of Public Health closed a fish restaurant, tested workers, and warned customers who ate cold or uncooked food possibly prepared by an HAV infected worker [19].
- In Mendham Township, New Jersey, the Health Department considered a food worker the likely source of 25 illnesses and one death [20].
- In Johnson City, Tennessee, a McDonald's employee with hepatitis potentially exposed over 500 customers [21].
- In Newark, Ohio a worker tested HAV positive, prompting the pizza restaurant to close, disinfect, and hold a vaccination clinic for employees [22].
- In Sarasota County, Florida a food service worker at a deli market tested positive, resulting in free vaccines for exposed customers. The restaurant made the vaccine mandatory for all new employees [23].
- In Philadelphia, Pennsylvania a worker in a Chinese restaurant tested positive in July, and in November the public was notified of an infected worker at an upscale Italian restaurant [24].
- In response to a local outbreak, Boyd County and the city of Ashland, Kentucky required vaccination of all food service workers [25].
- Similarly, Franklin Missouri's County Commission passed an ordinance in 2019 requiring HAV immunization for food handlers [26, 27].
- St. Louis County has required HAV vaccination for food handlers continuously since 1999 even though HAV rates declined in the interim [28].

Because HAV disease is the only foodborne illness for which a vaccine is available, and considering that the outbreak is global, should more places around the world develop regulations mandating HAV vaccine for food workers? To answer that question, there are two key ethical issues to address: for what population(s), and under what circumstances, should a jurisdiction mandate vaccination? Analysis of HAV vaccination for food service workers in the U.S. can provide useful guidance.

Core values of public health

The World Health Organization Code of Ethics and Professional Conduct focuses on broad ethical principles such as integrity, accountability, independence and impartiality, respect, and professional commitment and ensuring a fair and respectful workplace [5]. Public health professionals must carefully analyze regulations that mandate vaccinations for a specific group of workers. The American Public Health Association (APHA) Public Health Code of Ethics set forth four components necessary for four components if ethical analysis of a public health issue [6]. These include:

- identifying public health goals
- identifying ethically relevant facts
- analyzing implications for the health and rights of all stakeholders, and
- · determining if the action fits with core values of public health

The core values of public health practice, further elaborated in the APHA document, include safety, justice, equity, civil liberties, solidarity, and inclusivity, underlie ethical decision making in public health. In addition, the APHA advocates considering effectiveness, responsible use of scarce resources, proportionality, accountability, and public engagement [6]. The following sections discuss each of the four components described in the APHA Public Health Code of Ethics to provide guidance for regulations in the US and globally.

The *public health goal* of a regulation mandating vaccines for food handlers is to reduce transmission via food served in commercial establishments. Public health professionals should consider whether there is a legal way to mandate vaccines and whether mandating HAV vaccines for food handlers will meet the public health goal. This, of course, will differ globally.

In 1905 the U.S. Supreme Court upheld states' authority to require vaccination to protect public health and safety during a smallpox epidemic and determined vaccination to be a legitimate use of state 'police power' (the formal legal term, likely unique to the US) during an epidemic. The courts determined some laws to be appropriate for the common good. That is, they explained that people do not have unfettered freedoms, and that a demonstrable health threat warrants state intervention proportionate to the situation. While recent court cases in the U.S. emphasize civil liberties and the important value of *respect*, courts have upheld power of the states to protect public health through mandatory vaccination campaigns [29, 30]. Thus, under certain circumstances, U.S. states or localities within them, may legally require HAV vaccination. A question remains, however, about whether doing so for food service workers is appropriate.

An ethical analysis of mandatory vaccination campaigns requires balancing human rights and civil liberties against the seriousness and likelihood of the disease and the effectiveness of the vaccine [31]. Consider two populations, health care workers and food workers. Health care workers are at risk of acquiring some diseases from patients or infectious waste and transmitting the disease to patients and co-workers. U.S. healthcare facilities are increasingly requiring vaccination or proof of immunity to diseases such as Hepatitis B, influenza and Measles/ Mumps/Rubella—although not HAV—with accommodations for people with medical contraindications or religious objections [32, 33]. The rationale for mandating vaccination for some diseases is based on two factors: the likelihood those diseases will spread in the health care setting and the hospital's duty to protect patients and workers [34].

What about risk to foodservice workers? In contrast to healthcare workers, food handlers are no more likely to acquire vaccine-preventable diseases occupationally than other workers in shared indoor spaces, who share tools and interact with people. Unless public health authorities also mandate vaccination for others with similar occupational exposure—such as hairdressers—how can they justify vaccination based on occupational risk to the worker?

What about risk to people who consume the food? Foodborne illness is common, but HAV is often not the culprit. Only 2-3% of HAV cases per year are identified as part of an outbreak transmitted by food or water. Although 50% of reported patients with HAV are unable to identify the source of infection, some cases of HAV, unattributed or attributed to other factors, may have been foodborne. Often it is not possible for health authorities to discern whether or not transmission occurred via food or via some other means. Multiple other organisms cause foodborne illness, including norovirus (58%), nontyphoidal Salmonella (11%), Clostridium perfringens (10%), and Campylobacter (9%) [35]. A study of restaurant associated foodborne disease outbreaks in the United States from 1998–2013 showed that although food workers were a common source of foodborne disease, hepatitis caused just 3% of confirmed or suspected cases, Norovirus caused 48% of outbreaks and outbreak-associated illnesses, and many illnesses could not be attributed to a source [36]. A study of Hepatitis A infections among food handlers in the U.S. from 1993 to 2011 concluded that, of 192 HAV-infected food workers who worked while infectious, just 17% of them transmitted HAV to patrons. It concluded that mandatory vaccination of food handlers is unlikely to be cost-effective [37]. In addition, a multi-state study from 2016 to 2019 that documented 275 cases in food handlers from 18 states, showed secondary infection from food handlers to customers to be less than 1.0%. As the authors state, "Public Health efforts to preemptively vaccinate all food handlers would be ineffective at mitigating the current risk for person-to-person outbreaks [38]."

Also, HAV contamination can occur 'from farm to fork'. Outbreaks have many causes: fruit, fresh and frozen berries, seafood, pomegranate seeds, milk products, sandwiches, and salads. Contamination can occur during cultivation, harvest, processing, or distribution, as happened in a 2016 U.S. outbreak tracked to imported frozen strawberries [39]. In a 2003 U.S. outbreak traced to green onions and for which there was genetic sequencing of the outbreak strain, the editorial notes by the CDC specifically state, "No ill food service worker identified could have been the source of the outbreak. The green onions likely were contaminated with HAV in the distribution system or during growing, harvest, packing, or cooling." Such contamination takes place through contact with HAV-infected field workers during harvesting or by HAV-contaminated water during irrigation or processing [40]. Thus, vaccination of food handlers only addresses the tail end of a long line of possible exposures, potentially including field workers and packers, production workers, transporters, kitchen staff, and servers.

Foodservice workers comprise one of the few controllable points in the transmission continuum, so perhaps public health should target foodservice workers as a flashpoint of transmission? Yet it is not equitable to require food handlers to be vaccinated, yet not require vaccination for farmworkers or food production workers when it is already known that contamination can occur before the food reaches the restaurant. A determination about which populations to vaccinate—crop pickers, production-line workers, packers, or food service workers—must rest on data about likelihood of transmission from that specific source.

Unsurprisingly, the U.S. Centers for Disease Control does not currently recommend vaccinating all food handlers. The CDC points out that transmission from food handlers to customers is rare with practice of good food hygiene. Instead, the CDC advocates vaccination only during community-wide outbreaks and when state or local officials or private employers determine that vaccination will be cost-effective [41, 42]. Consistent with the CDC recommendation, major U.S. cities, such as New York City and Los Angeles, have considered mandatory vaccination for food workers but have not mandated it. Instead, they advocate an approach that addresses other foodborne illness too: proper handwashing, wearing gloves when preparing ready-to-eat food, and not working when sick [43].

Finally, even though HAV has increased dramatically, and HAV is the only foodborne illness for which a vaccine is available, vaccinating food handlers against HAV protects consumers against only one nasty bug; it does not protect against other, more common, foodborne diseases. It may, instead, provide a false sense of security. Consistent with the CDC, the U.S. Food and Drug Administration's Food Code continues to recommend sanitizing of surfaces, hand washing, and glove use as protection against multiple illnesses [44]. In short, mandatory vaccination for food workers does not meet the criterion of *effectiveness* as it is unlikely to achieve the desired goals. A renewed focus on handwashing and wearing gloves when touching any raw or ready-to-eat food, plus an emphasis on these behaviors in inspections by health authorities, would have more far-reaching impact on foodborne disease without requiring vaccination.

What are ethically relevant facts?

Ethically relevant facts include those relevant to rights and preferences of all stakeholders, including consumers, proprietors, and workers

Reciprocity requires public health practitioners to relieve burdens of complying with a public health campaign. If states were to require immunization for food handlers, issues to consider include costs and who should bear the burden of these, ease of access for the target population, and the inconvenience and time required for vaccination. Should food handlers be required to pay for their own vaccines? Proprietors? City, county or state public health departments? Insurance companies?

Concerns about *responsible use of scarce resources* requires consideration of several factors. Foodborne HAV outbreaks cause less than 10% of reported HAV cases in the U.S., yet the cost to affected businesses, the cost to affected patrons, the impact on workers, and the expense of retroactive public health interventions is considerable. A highly publicized outbreak can negatively impact a restaurant's reputation and income. Workers may be unable to work after exposure if the workers

self-isolate. Responses to outbreaks cost health departments thousands of dollars. In Colorado in 1992, reactive mass-prophylaxis clinics administrating immune globulin (IG) to potentially exposed customers for 16,293 people cost over \$800,000 USD, and again in 2002, at a cost of \$48,300. The Advisory Committee on Immunization Practices (ACIP) investigators concluded that an employee had worked while infectious, had frequent and direct contact with ready-to-eat food without wearing gloves, and had not practiced proper handwashing [45]. The public health department determined that immunoprophylaxis was the best strategy and had just a single day to prepare a clinic to serve 900 potentially exposed patrons. Public health authorities offered each restaurant employee IG and prohibited those who did not receive IG from working in food handling for 50 days.

A 2001 study concluded that "vaccinating restaurant employees is unlikely to be economical from either the restaurant owner or the societal perspective, even during Hepatitis A epidemics" [46]. Using Monte Carlo simulation models for both a restaurant-owner perspective and that of society, the researchers calculated loss of business after publicity from an outbreak and reduction in costs of food handler cases. They found that vaccination is cost saving for society if done only during epidemics and if the cost is less than \$20 per employee. They concluded that public health measures should focus on handwashing, consistent glove use, hygiene, and not handling food when sick.

Health and rights of stakeholders

The implications for health and rights of all stakeholders align closely with permissibility of mandating vaccines. The *permissibility* criterion calls for consideration of whether mandatory HAV vaccination for food handlers would be wrong even if the outcome were good.

As J.S. Mill stated in 1869 in his classic treatise, On Liberty,

the sole end for which mankind are warranted, individually or collectively, in interfering with the liberty of action of any of their number, is self-protection. That the only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others. His own good, either physical or moral, is not a sufficient warrant [47].

Mill's reasoning applies even today, as considerations of *respect* and *proportionality* require individuals be allowed maximal freedom that is compatible with others' continued well-being. Although public health practitioners have the duty to protect public safety, those protections must be proportionate—taking into consideration the truncated personal liberties and costs of a mandated HAV vaccination program that focuses on food service workers.

Core values of public health include justice and *equity*, thus respect for all stakeholders. Does mandating HAV vaccination conform to those values? Public health professionals know that some food service workers are, or have been, in the highrisk groups of people experiencing homelessness, substance abuse, or men who have sex with men. Should employers inquire about whether food service workers are in a high-risk group, and require vaccination of those who are? Encouraging employers to inquire about current or previous homelessness, drug use, or sexual activity violates privacy and may make food service workers feel stigmatized. Workers may believe that if they disclose any history of higher risk experiences to a potential employer they will not be hired because the potential employer will not want to assume the additional risk or pay for immunization. Safeguarding worker's privacy and dignity requires employers to focus on good hygiene by all workers, not discriminatory treatment against a select few. Operators of vaccination programs need to take special care with marginalized groups and ensure respect and equity, especially for stigmatized groups.

Some workers in the food industry work when ill. An online survey in the United States of over 1200 food workers found that 51% of food workers work when sick, while another U.S. study found 11% worked while experiencing vomiting or diarrhea—both of which place the worker at high risk of transmitting infections to coworkers and consumers [48]. Common reasons for working when sick include helping coworkers and avoiding loss of pay [49]. Taking time off is expensive and, because in the United States only 14.4 receive health insurance from their employer, getting diagnosed and paying for treatment can be onerous [50].

To address the values of inclusivity and solidarity, it is important to consider public participation. HAV vaccine stakeholders include public health experts, workers, insurers, trade organizations (such as the National Restaurant Association), nonprofit advocacy groups (such as Restaurant Opportunities Centers United), proprietors, and people who eat in restaurants—especially people from medically vulnerable populations. It is only through stakeholder engagement and public participation that society will be able to arrive at science-based, equitable plan for vaccination when outbreaks of foodborne illness occur.

Ethical analysis, and careful review of transmissibility data, show that mandatory HAV vaccination for food service workers is not ethically supportable currently in the U.S. Of course, foodservice workers and others can choose vaccination based on their risk factors. The Advisory Committee on Immunization Practices (ACIP) Evidence Based Recommendations and model for shared clinical decision-making provide useful guidance [51, 52]. Concerns about the likelihood of contracting the disease and the disease's spread by the population under discussion (foodservice workers), with the international ethics guidelines and core values of public health, support the following recommendations.

Recommendations

These recommendations are consistent with the data and with the principles and values of public health ethics:

- 1. Expand public health education for children and adults about proper handwashing and hygiene to decrease all foodborne illnesses across the population.
- 2. Educate about and encourage HAV vaccination for everyone, including—but not targeting—food workers.



- 3. Recalibrate health department hygiene inspections of food establishments toward weighting heavily proper handwashing, glove use, and hygiene in their calculations–and suspending operation of restaurants that exhibit violations in any of those areas.
- 4. Advocate for requiring written policies for all food production facilities—from farm to fork—to prevent workers from working when ill, to create plans for testing and isolation if positive, and to provide for paid sick days.
- 5. Require food producers and proprietors to provide safe working environments for workers and hygienic environments for food preparation, including gloves and other personal protective equipment.
- 6. Expand mandatory HAV vaccination for school attendance, thereby protecting all who can be immunized while developing herd immunity for those who cannot. Handle religious and philosophical objections to vaccination using existing state or local regulations.
- 7. Continue to require HAV vaccination for children in higher risk areas and offer HAV vaccination to high-risk groups, including men who have sex with men, homeless people, substance users, and health care workers, especially during outbreaks.

Conclusion

Core public health values of safety, justice, equity, civil liberties, solidarity, and inclusivity, and the pertinent components of the American Public Health Association Public Health Code of Ethics, along with global ethics guidance from the World Health Organization, together lead to the conclusion that mandating HAV vaccines for food service workers—in the absence of evidence of increased risk to the workers themselves or significant transmission via food—is not ethically justifiable. This analysis of mandatory vaccination of food workers for HAV can provide ethical guidance for decisions about regulations mandating other vaccines too, focusing on a data-driven approach with consideration of ethical guidelines as important factors to weigh against scientifically documented potential harm to people who consume the food the workers prepare. Vaccinations are essential for population health and there is no place for uninformed rejection of vaccines. Even so, there is no ethical justification.

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