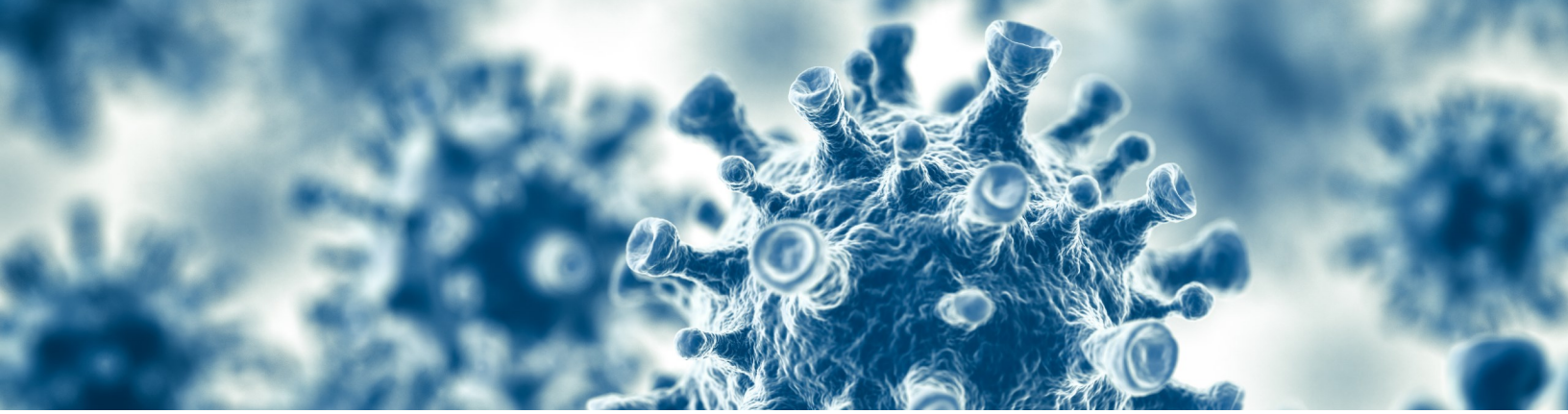

Chapter Four: The H1N1 Influenza Pandemic of 2009-2010

Author's Note: *The analysis and comments regarding the communication efforts described in this case study are solely those of the authors. This analysis does not represent the official position of the FDA. This case was selected because it illustrates MCM communication challenges in the context of an influenza pandemic, including vaccine safety themes. This case study does not provide a comprehensive assessment of all FDA and USG communication efforts. The authors intend to use this case study as a means of highlighting communication challenges strictly within the context of this incident, not to evaluate the success or merit of any changes made as a result of these events. Intensive after-action reports and lessons-learned concerning the H1N1 pandemic influenza response served as the basis for systemic changes, such as the FDA's MCMi.*

Abstract

The H1N1 outbreak of 2009-2010 was the result of a novel flu strain. The response to H1N1 was multifaceted and involved multiple governmental organizations. In particular, at the beginning of the outbreak FDA instituted an H1N1 management system to coordinate a response, which included creating seven teams to address specific public health needs related to H1N1. While FDA's response to H1N1 was thus far-reaching, in relation to communication several components of FDA's response could have been enhanced: communicating about vaccine production including responding to concerns that the vaccine was risky, rushed through production, or untested; being more transparent about the vaccine manufacturing process generally including reasons why vaccine production might be delayed; strengthening collaboration with other health entities to overcome disparities in MCM uptake; and finally, in conjunction with CDC, clarifying the use of new MCMs/new uses of approved MCMs to both healthcare providers and the public.

Background

In early April 2009, reports surfaced of an influenza outbreak in rural Mexico.[1,2] On April 15, a novel flu virus was detected in a child living in southern California.[3] Additional cases of the disease were identified in California and Texas within a week.[4] Subsequent testing indicated the earlier outbreak in Mexico was due to the same virus.4 By June, the disease, classified as 2009 H1N1, was found in all 50 US states and across the world.4 The World Health Organization subsequently declared a pandemic.[5]

By the end of the outbreak in April 2010, it is estimated that there were as many as 60.8 million cases of H1N1 in the US, resulting in 274,304 hospitalizations and 12,469 deaths.[6] Compared to the average seasonal flu virus, H1N1 was typical in regards to morbidity and mortality.[7,8] Unlike typical seasonal flu viruses, however, H1N1 appeared to pose the greatest risk to adults (aged of 25-64 years) with underlying medical conditions.[9,10] Greater rates of morbidity and mortality were also seen among pregnant women, who had compromised immune systems due to pregnancy, and minority populations, who were at greater risk for both underlying medical conditions and a lack of access to healthcare.[11-14]

The Food and Drug Administration (FDA) responded to public health needs throughout the pandemic. At the beginning of the outbreak FDA instituted an H1N1 incident management system to coordinate a response. As a component of this, FDA created seven teams to address public health needs related to H1N1: the vaccine team, the antiviral team, the in vitro diagnostics team, the personal protective equipment team, the blood team, the drug shortage team and the consumer protection team.[13] While FDA's response to H1N1 was thus multifaceted and far-reaching, in regards to communication several components of FDA's response are of particular importance to future communication efforts: vaccine development, vaccine availability, health disparities, and communication of emergency use authorizations (EUAs). This chapter will focus primarily on these issues.

DILEMMA #1

Perceptions of the H1N1 vaccine as "risky," "rushed" through production and/or "untested" motivated some people to shun vaccination.

Vaccine development began in earnest in June 2009.[4] Although lab tests had revealed the H1N1 virus did not have the 1918-like markers associated with severe disease nor the markers associated with the high death rates seen in H5N1 flu strains, H1N1 was still seen as a health concern that warranted a response.[4]

The first doses of H1N1 vaccine were administered in the US on October 5, 2009. Due to production issues, however, vaccine supplies were limited until the end of December.[4] Despite the fact that the H1N1 vaccine was a safe and effective way to prevent the spread of the disease, vaccine uptake in the US was lower than expected; only 24-27% of Americans were vaccinated and tens of millions of doses of vaccine went unused.[14,15] A significant reason for this was perceptions that the H1N1 vaccine was "risky," "rushed" through production and/or "untested." Moreover, by the time that vaccines became widely available, public perception that the pandemic was mild or that there was limited risk also curtailed demand for the vaccine.[16]

Typical of vaccination in the US today, concerns about vaccine additives such as thimerosal and adjuvants were present during the 2009-10 H1N1 pandemic.[17-19] Despite the fact that thimerosal, a organomercury preservative, was only used in one formulation of the H1N1 vaccine (multi-dose vials) and the fact that adjuvants were not used in any of the H1N1 formulations administered in the US, internet reports, primarily from anti-vaccination blogs and news sources, raised concerns about the possible link between these vaccine components and autism, Gulf War Syndrome and other neurological and developmental disorders.[17-19] Consequently, these sources suggested that the public refrain from receiving the H1N1 vaccine.

The related issue of the novelty of the H1N1 vaccine was also raised by the anti-vaccination blogs and news sources, but unlike the additive issue, this topic was reported in the mainstream media as well.[20-21] The underlying perception related to this concern was that the production of the H1N1 vaccine was "rushed;" that because of its accelerated production it was somehow unsafe. Additionally, some sources

suggested that the vaccine had not been sufficiently tested for safety. In reality, the H1N1 vaccine was produced by the same manufacturers and using the same methods as the seasonal flu vaccine and, unlike the 2009 seasonal flu vaccine, the H1N1 vaccine had been tested for safety in clinical trials conducted over the summer.[4] However, confusion about how vaccines are produced and tested persisted, leading to claims that the vaccine was unsafe.

Concerns about vaccine safety were more common in certain subpopulations. Pregnant women, for example, were more likely than women in general to have concerns about the vaccine and to resist vaccination, in spite of the fact that they were more at risk for complications from H1N1 infections.[11,18,19] Particular concerns of pregnant women centered on the health of their fetuses including the possibilities of miscarriage or autism and other developmental issues. Healthcare providers in some areas were also reluctant about receiving the live attenuated vaccine (LAIV) formulation of the H1N1 vaccine.[22] Their concern was that the live virus in the vaccine could be spread to patients in healthcare settings. While all of these concerns were unfounded, messaging about the safety of vaccines generally, the H1N1 vaccine specifically, and even different formulations of the H1N1 vaccine was not sufficient to overcome doubt. Many pregnant women and healthcare providers remained unvaccinated.

FDA's communication about the H1N1 vaccine included news releases;[23] information for consumers posted on FDA's website,[24] including a Q&A page targeted toward pregnant women;[25] and an update for healthcare providers.[26] Information provided in these sources contained statements that FDA had approved different formulations of the vaccines, the names of the manufacturers of the vaccines, warnings of potential side effects, and specifically for providers: dosage recommendations and contraindications. In all of this communication, however, FDA did little to explain the oversight that went into the manufacturing processes to ensure vaccine safety.

An FDA press release from September 15, 2009,23 for example, provided only the following information on this topic:

> *"The H1N1 vaccines approved today undergo the same rigorous FDA manufacturing oversight, product quality testing and lot release procedures that apply to seasonal influenza vaccines," said Jesse Goodman, M.D., FDA acting chief scientist.*
>
> *Based on preliminary data from adults participating in multiple clinical studies, the 2009 H1N1 vaccines induce a robust immune response in most healthy adults eight to 10 days after a single dose, as occurs with the seasonal influenza vaccine.*
>
> *Clinical studies under way will provide additional information about the optimal dose in children. The recommendations for dosing will be updated if indicated by findings from those studies. The findings are expected in the near future.*

While FDA is limited by confidential commercial information (CCI) protocol from sharing specific information on manufacturing processes, additional information comparing the production of seasonal flu vaccines to H1N1 vaccine production and specific details on steps FDA took to ensure "safe" H1N1 vaccines could have stemmed consumer fears.

Implications for the Future:

To address future lack of interest in medical countermeasures due to unwarranted concerns about safety, including production issues, various strategic and practical communication approaches are necessary. First, FDA should gauge its public credibility periodically as a "safety" gatekeeper for MCMs (ie, within its role to assess product safety), capitalizing upon this reputation when it is strong and relying more heavily on communication partners (who have more sway among certain key audiences) when it is weak. Second, FDA should provide clear explanations about countermeasure components and testing and to do so as early as possible. In fact, pre-disaster preventative messaging, such as regularly communicating the universal and routine steps FDA takes to ensure product safety, including safe vaccine production, could mitigate the need for intensive messaging during a disaster. Third, depending on the nature of the emergency, including the size of subpopulations affected and the nature of the risks they face, it may be necessary to tailor messages for particular groups. In the case of H1N1 vaccines, FDA did this type of tailoring for both pregnant women and healthcare providers. Finally, it is necessary to disseminate

messages in such a way that they will be accessible to members of the targeted groups. In the case of H1N1 vaccines FDA's communication strategies could have been improved in this regard; for example, messages about the safety of the LAIV formulation for health care providers were disseminated through the FDA website and other sources including the American Medical Association. The fact that some healthcare providers remained concerned about the LAIV formulation22 suggests that these efforts could have been more successful.

Action Items for FDA

1) Conduct an initial baseline survey regarding the FDA's standing in the public domain, followed by periodic assessments of the agency's credibility and reputation as gatekeeper for MCM safety. To have credence when speaking about MCM safety in an emergency, the agency must already have public opinion on its side. Between emergencies, the agency can take measures to strengthen its public standing.

2) Develop additional public resources on FDA's role in assuring safety over the lifecycle of a vaccine. In particular, continue to use the FDA Basics Webinar series to represent the agency's commitment to, and specific procedures for assuring vaccine safety; link to CDC materials on influenza vaccine safety, benefiting from the trust people hold in this agency; and supplement "text heavy" public communications about vaccine safety with more readily consumable graphic representations.

3) Tailor FDA's communication strategies to match the information consumption patterns and behaviors of subpopulations of interest.

    a) Use surveys to investigate how particular groups (eg, HCWs, pregnant women) receive and consume messages pre-emergency, and build outreach mechanisms accordingly; poll subgroups of interest during an emergency to check whether or not FDA messages have been received, and if not, the mechanisms necessary to make them accessible.

    b) Enlist strategic communication partners to convey FDA messages, including those about vaccine safety, to key subgroups. Maternity care providers and childbirth educators (reachable through their respective professional societies), for instance, are the top 2 sources pregnant women consult for information about pregnancy, with government agency websites following in sixth place.[27]

DILEMMA #2

Unmet public expectations about when and how a newly manufactured vaccine would become available during the H1N1 pandemic had an adverse impact on its uptake.

To maximize the amount of available vaccine, the US government contracted with 5 pharmaceutical companies.[22] Four of these companies were contracted to produce different formulations of inactivated vaccine that would be administered via injection, while the fifth company was contracted to develop a LAIV formulation that would be administered via nasal inhalation. Early production estimates suggested that approximately 45 million doses of vaccine would be available in early to mid-October.[15]

While the H1N1 vaccine was being prepared, the CDC developed plans to distribute it across the country. The CDC contracted with a logistics company to establish a centralized distribution network that would distribute the vaccine to state and local health departments based on population estimates.[14] State health departments, in turn, worked with local health departments to develop plans to distribute and administer the vaccine.[28] Many of these state and local efforts were covered by state and local media.

The first doses of the H1N1 vaccine were administered in early October 2009.[4] Due to various manufacturing issues, however, the amount of vaccine available by the end of October, 23.2 million doses, was less than anticipated (CDC 4, CDC 5).[14,29] As a consequence, many healthcare providers, including hospitals and clinics, received less vaccine than expected.[22,30,31] In addition, vaccine deliveries were sporadic. Often healthcare providers were given only a few days' notice that a vaccine shipment was arriving.[22] Both of these conditions made it difficult for healthcare providers to schedule vaccination appointments with their patients and to give answers to the patients who were calling their offices asking when they could come in to be vaccinated.[31]

The situation was further complicated by the availability, or lack of availability, of the different vaccine formulations and the co-messaging about the seasonal flu vaccine. The LAIV nasal spray, for example, was the first vaccine available, but it was contraindicated for both pregnant women and persons with underlying medical conditions like asthma.[29] For members of these groups, this meant that even though they had repeatedly been told they were in a priority group for vaccination, and even though they had

planned on being vaccinated as soon as possible, that they had to wait until the correct formulation was available. This situation and related communication dilemmas including how vaccination distribution programs were implemented in different areas (discussed below) led to reduced vaccine uptake across the country.

Due to the limited supply of vaccine, the availability of different formulations, and on-the-ground exigencies, local public health departments and organizations opted to implement the vaccination guidelines in different ways.[16,22] Some, like Group Health Cooperative in Seattle, used a strict interpretation of the CDC Advisory Committee on Immunization Practice (ACIP) guidelines and only gave vaccines to people in the priority groups.[16] Others like the Chicago Department of Health, focused vaccination efforts on people in the priority groups but did not turn away anyone who came to mass vaccination clinics.[16] Such differences, especially when they occurred in close geographic proximity, led to some people to wonder why one jurisdiction was vaccinating a certain subset of its population and another was not.

Some of the distribution programs themselves became controversial. In New York City (NYC), for example, the local public health department opted to provide H1N1 vaccine to occupational clinics, including clinics for Wall Street firms such as Goldman Sachs and Citibank.[31-34] While vaccine distribution through occupational clinics was a well-established practice for the NYC health department, under the particular conditions of H1N1 vaccine scarcity, it was widely interpreted as a form of favoritism and prompted public outcry.[31,32,35] Amidst these and other complexities of vaccine supply and demand, many people became discouraged in their search for vaccination.

Implications for the Future:

While FDA's role in vaccine distribution was limited – the majority of decisions about distribution and communication about these decisions came from the CDC and state/local public health – there is one aspect in which greater transparency from FDA may have made a difference: clearer communication about vaccine manufacturing generally, including reasons that vaccine manufacturing may take longer than anticipated. While CCI laws may limit the amount of specific detail FDA can provide, FDA could either provide a generic overview of a manufacturing process, or work with countermeasure manufacturers to develop and disseminate specific details of manufacturing processes of relevance to the public. Along with this information, FDA can continue to reassure the public about the role FDA plays in ensuring the production of safe countermeasures.

Action Item for FDA

In cases where countermeasures are developed during an emergency, FDA should provide either generic details on the countermeasure manufacturing process or work with the countermeasure manufacturers to develop and disseminate specific details of their manufacturing processes as this is relevant to the public. If delays in the manufacturing process are possible, then these messages should also include reasons production may be slower than anticipated.

DILEMMA #3

In the absence of trustworthy and culturally appropriate information, certain groups were less likely to seek out vaccination against the H1N1 virus.

Disparities in vaccine uptake particularly among different subpopulations in the US represented another communication dilemma of the H1N1 pandemic.[36-40] In some cases, these disparities were the result of how people within the subpopulations accessed available information. In others, they were the result of community beliefs about such things as healthcare, the significance of particular vaccine components, and the trustworthiness of the US government.

In general, marginalized subpopulations, like many poor, racial/ethnic minorities in the US, have less access to authoritative public health information than non-marginalized populations.[20,41] For example, post-pandemic research has suggested that, for H1N1 and the H1N1 vaccine, higher educated people relied primarily on the internet (a primary platform for FDA's public communication); in contrast, for that same information, lower educated individuals were more likely to rely on television.[41-43] In addition, in some poorer communities, personal and community social networks, including faith-based organizations and radio stations, were key sources of information during the H1N1 pandemic.[20,41] When misinformation was spread through these social networks, additional communication from public health agencies and others was needed.

Among poor, African American subpopulations in Los Angeles County, CA, for example, longstanding distrust in the US government stemming from the Tuskegee experiment led local faith-based leaders to urge their congregants not to accept the H1N1 vaccine, local disc jockeys from stations with predominantly African American audiences to advise their listeners to not be vaccinated, and community members to forward chain emails and like Facebook posts with anti-vaccination messages.[20] Subsequently, vaccination rates for African Americans in Los Angeles County were lower than rates for all other racial/ethnic groups in that area.

To address this issue during the pandemic, the Los Angeles County Public Health Department expanded their outreach to the African American community and actively sought to develop partnerships with faith-based leaders.[20] The public health department also sought to provide consistent messaging through

community leaders focusing on increasing understanding of the health risks of H1N1 for African Americans. Combined with increasing the number of public vaccination clinics, these steps were somewhat successful in addressing disparities in H1N1 vaccine uptake among African Americans living in Los Angeles County.

Public Health-Seattle & King County took a similar approach to address concerns within the county's Somali population. In addition to varying understandings of preventative medicine and vaccines, many in the Somali community in Seattle had concerns about porcine gelatin as a vaccine component.[44] As Muslims, members of this community believed that taking any pork-related products into their bodies was a violation of their faith. To address this issue, Public Health-Seattle & King County attempted to work with local Somali leaders during the H1N1 pandemic with varying degrees of success (informant interview, public health official).

Implications for the Future:

To help mitigate against differential rates of morbidity and mortality in future health emergencies, it is critical that the entire US public, including specific subgroups, have access to credible, accessible, and meaningful information that enables them to make appropriate use of potentially life-saving MCMs. Local public health agencies are well-positioned to understand the populations they serve, to develop close relationships with faith-based leaders and other trusted intermediaries to reach specific communities, and to elicit greater understanding as to the health knowledge-needs of diverse constituent groups.[45] Through its own Office of Minority Health, the FDA can reach out to state offices of minority health to solicit ideas about how the agency can better support those on the frontlines of MCM administration and communication. In addition, prior to any emergency, the FDA can establish ties with national non-governmental organizations that represent the health interests of minority populations to have them serve as potential conduits for targeted messages that the regulatory agency may need to disseminate about MCMs in an emergency.

Action Items for FDA

1) Strengthen the Office of Minority Health's role in the Medical Countermeasures Initiative (MCMi) to uncover, understand, and meet the communication needs of a diverse US populace, particularly underserved communities.

2) In the pre-crisis period, build working relationships with national non-governmental organizations that represent the health interests of minority populations. Rely on these partners to help disseminate any targeted MCM-related messages in an emergency.

DILEMMA #4

Difficult-to-access and hard-to-understand information undermined efforts to make non-vaccine MCMs, including antivirals and N95 respirators, available to healthcare workers and the public.

Efforts to contain the H1N1 virus were not limited to the development, production and dissemination of the H1N1 vaccine. In fact, the first lines of defense centered on providing antivirals to affected individuals and personal protective equipment (PPE) to healthcare workers and other front line responders.

Shortly after the first case of H1N1 in the US was confirmed through laboratory testing, the Secretary of Health and Human Services determined that a public health emergency existed. As a result of this, FDA issued a series of emergency use authorizations (EUA). On April 27, 2009, FDA issued an EUA for oseltamivir (Tamiflu) and zanamivir (Relenza) to expand the age and patient populations these previously approved antivirals could be used to treat.[46] Four days later FDA issued an EUA for certain disposable respirators, known collectively as N95 respirators, in order to permit the distribution of these products to the general public, and particularly people performing work-related duties who were not under OSHA regulations.[47-49] Over the course of the pandemic FDA would issue additional EUAs including one for an unapproved IV antiviral (Peramivir) and eighteen for different diagnostic tests.[50,51]

Since the H1N1 pandemic, reviews of EUA protocols have led to a series of changes in policy, and along with other factors, influenced the passage of the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA) in 2013.[52-53] These statutory changes have had a direct impact on how FDA responds to future public health emergencies. In particular, FDA now has the authority to authorize the emergency use of certain approved MCMs without issuing a EUA. Regardless of the procedural changes (ie, PAHPRA's MCM emergency use authorities for approved MCMs) since the 2009 H1N1 experience, the issue of what constitutes an adequate MCM communication, according to known standards, is still relevant. A communication is considered adequate if it equips a person with information essential to making an effective health decision (ie, it is material), it reaches a person via their normal information channels and gathering practices (ie, it is accessible), and it is readily digestible so that a person can apply it to make a sound choice (ie, it is comprehensible).[54] Inadequacies with respect to these standards were evident in relation to EUAs issued for antivirals during the H1N1 pandemic.

On April 27, 2009, FDA issued an EUA expanding the use of Tamiflu and Relenza, at the request of CDC; the issuance was timely as a result of enhanced FDA-CDC coordination afforded by earlier pandemic planning.[56] Under this EUA, Tamiflu was allowed in for use in children under one year of age (previously it was limited to patients one year of age and older) and both Tamiflu and Relenza were allowed to treat patients beyond two days of symptom onset (which was the previous requirement).[55] FDA, in concert with ther governmental organizations including the CDC, released this EUA through traditional channels including FDA's website. While the EUA had a direct impact on healthcare providers and pharmacists, the information was not communicated effectively, resulting in delayed distribution of these drugs.[56] Specifically, on local levels some healthcare providers and pharmacists did not receive information about the EUA (a break down in accessibility), and in other cases when they did, they did not understand the language of the message being provided (a breakdown in comprehensibility).[56] Implementation of the EUA provisions would have been more timely and effective, if information on the expanded use of Tamiflu and Relenza had been clearer and more concise, and if it had been communicated through mechanisms routinely used by healthcare providers and pharmacists, such as an official federal letter to state pharmacy boards.[56] Confusion resulting from a lack of clear communication was also seen in relation to information on compounding oral suspensions of Tamiflu capsules for pediatric use; the information provided was complicated and difficult for many pharmacists to understand.[56] A consequence of the confusion was an insufficient supply of pediatric doses of the medication during the pandemic.

In addition to being accessible and comprehensible, MCM communications must also provide end users (such as healthcare providers, pharmacists, and consumers) with relevant information that enables them to make quality decisions. Some evidence suggests that this may not have been the case with antivirals during the H1N1 pandemic. A national study conducted during the pandemic,[38] for example, showed that given the information provided on the EUA Fact Sheet for Tamiflu that only 54.4% of respondents were willing to take the drug and only 48.8% would allow their children to take the drug. Moreover, 29.9% of respondents stated that they were moderately concerned about taking Tamiflu based on the information provided on the Fact Sheet and 21.0% stated that they were worried or extremely worried about taking the drug based on the information they received. This overabundance of caution with regard to Tamiflu use, despite the fact that the antiviral had undergone extensive testing and was already approved by the FDA, suggests that the Fact Sheet may not have successfully delivered the information that many people required to meet their own goal of personal health protection during the pandemic.

Implications for the future

EUA requesters – like CDC in the case of Tamiflu and Relenza – bear the major share of responsibility for MCM communication (eg, Fact Sheets) during an emergency. Nonetheless, the FDA can draw important "best practice" inferences from the overall H1N1 experience with antiviral EUAs and enhance its own communication practice in the future accordingly. In particular, it is important that MCM communication to end users (ie, healthcare providers, pharmacists, and the public) meet the 3 standards of adequacy: communicating through means that ensure populations of interest are being reached, providing users with information they consider material to making quality decisions about their health (and/or that of their patients or dependents), and delivering information that is readily comprehended and integrated into a person's decision making. Each of these qualities is amenable to research that takes into account the user's perspective and needs.

While FDA is not the only organization charged with communicating about topics that during H1N1 were EUA-related issues, FDA has a unique opportunity to reassure the public in regards to government oversight and product safety. In the future, FDA should leverage this role in their communication with the public, for example, by providing explanations of the steps FDA has taken to assure public safety in regards to particular MCMs.

Action Items for FDA

1) Leverage the agency's role as 'guardian of the public's interests' to increase the public's confidence in MCMs during an emergency. As part of this communicate, in a general sense, how FDA approves and authorizes MCMs and consequently how MCMs can be trusted, in a general sense, in the current crisis.
2) Assess the adequacy of FDA communication concerning an MCM in terms of the 3 standards of materiality, accessibility, and comprehensibility. For instance, survey intended audiences regarding their routine information gathering behaviors (including sources on which they rely) and materials for salience and understandability with end-users before these are disseminated.

Conclusion

The H1N1 outbreak of 2009-2010 exemplified significant public health accomplishments. In less than a year a novel pathogen was identified and an effective countermeasure was developed, produced and delivered to 81 million people in the US alone. At the same time, the public health outcome was less than optimal. Less than half of the US population was vaccinated and vaccination rates were significantly lower in certain subpopulations including some racial/ethnic minorities and pregnant women.

The cause of this poor public health outcome was multifaceted and due in part to the actions of multiple governmental agencies. In regards to FDA, several communication-related issues were of particular importance: concerns about the safety of the H1N1 vaccine, confusion about countermeasure availability, unevenness in uptake, and a lack of understanding about new MCMs/new uses of approved MCMs. To address these issues we recommend: tailoring messages for particular groups and disseminating these messages in such ways that they will be seen/read by members of these groups; providing more transparent explanations of how MCMs are tested to assure public safety; and leveraging FDA's role as 'guardians of the public interest' in order to reassure the public about MCM use.

All of these steps can be done during a public health emergency, but we also suggest that FDA preemptively take the following steps: provide pre-disaster preventative messaging relating to common MCMs, such as routinely communicating the steps FDA takes to ensure product safety in regards to vaccine and drug production; investigate how commonly communicated with groups, like healthcare providers and pharmacists, receive messages and, based on the information received, modify FDA communication methods as necessary; and finally improve the comprehensibility of existing communications, from which future communications can be modeled, by either testing messages for understandability with end users, including the general public, and/or working more closely with social scientists and other communication experts to refine old messages and develop new ones.

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