Chapter Three: Fukushima Nuclear Accident of 2011

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 communication around an unneeded medical countermeasure and provides additional insight into the important supportive role FDA may play even if the US government is not the primary responder to the event. This case study does not provide a comprehensive assessment of all FDA 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.*

Abstract

The Tohoku earthquake in Japan caused a series of tragic and cascading disasters in Japan, including the release of radiological materials from the Fukushima Daiichi Nuclear Power Plant. The vast majority of the nuclear release affected only Japan, and as a result, no medical countermeasures were recommended in the US. However, despite messages to the public by health authorities not to purchase, stockpile, or administer potassium Iodide (KI), some consumers still sought out the radiation countermeasure. Additionally, when KI was not available, some consumers attempted to acquire potassium from other sources even though these sources were ineffective and/or not approved by the FDA. The adverse effects of such behaviors were the potential occurrence of negative side effects from taking unnecessary or unapproved products. Additionally, in the event of a future emergency requiring KI for a limited proportion of the population, demand for KI by those who would receive no benefit may prevent those who need KI from accessing it.

To improve public response, a more rapid federal response was necessary in coordination with state and local officials to fill an information vacuum. Specifically, the FDA could have improved its supportive role in this disaster by more actively promoting the messages it was producing about KI. Salient information points included acknowledging people's reasonable desire to protect themselves and outlining the negative impacts of seeking out unwarranted and potentially ineffective or unsafe countermeasures. Additionally, the public required hard data about radiation levels to improve trust of messages about safety.

Background

On March 11, 2011, a 9.0 magnitude earthquake occurred off the Pacific Coast of Japan. Known as the

as the Tohoku earthquake or the Great East Japan Earthquake, this earthquake created 15-meter tsunami waves that quickly reached the Tohoku region of Japan. The waves overwhelmed the protective seawalls of the region and caused one of the worst natural disasters in Japan's history, killing 15,889 people with an additional 2,594 still missing, and injuring 6,152.[1]

When the earthquake struck, 6 nuclear power units were located at the Fukushima Daiichi Nuclear Power Plant, in the Fukushima prefecture of the Tohoku region. Of the 6 reactors located at the site, 3 were in operation. These reactors initiated an emergency shutdown process and external power to the reactors was lost. A short time later, the tsunami breached protective sea walls and flooded the back-up power units at the nuclear power plant. This caused the reactors, as well as spent fuel pools, to lose their cooling capabilities. The next day, on March 12, explosions caused by pressure from hydrogen released from damaged nuclear cores occurred at 3 reactors.[2]

The radiation released by the disaster at the Fukushima Daiichi Nuclear Power Plant was about 5.5% of that of the Chernobyl accident.[3,4] At the time of the accident, prevailing winds blew much of the radiation eastward and out to sea.[2] This event marked the world's most significant radiological accident in 25 years, rating 7 on the International Nuclear Event Scale.[5] While the amount of radiation predicted to reach the United States was small, there was a perceived risk, especially in West Coast communities, that radiological poisoning might occur in the US as a result of the incident. However, during the first few days of the disaster, there was a marked lack of communication from the federal government.[6]

Potassium Iodide (KI) can block absorption of a radioactive isotope of iodine (I-131), which may be absorbed and concentrated in the thyroid in the event of an environmental release. Following the Chernobyl accident, approximately 5,000 cases of thyroid cancer in children were attributed to exposure to I-131.[7] However, the use of KI can decrease the risk of developing thyroid cancer in those exposed to an environmental release of I-131.[8] For this reason, KI is considered a medical countermeasure in the event of nuclear power plant accident. KI is stockpiled and has been distributed to the public in the Emergency

Planning Zones (EPZ) around nuclear power plants in some states, which has likely increased public awareness of this countermeasure.[9]

Although KI can be used as an effective medical countermeasure against I-131, its role is limited. It must be ingested within a few hours of exposure, and its protective abilities are reduced as the time since exposure increases. KI is also ineffective if given more than 48 hours before exposure. Side effects can include nausea, vomiting, diarrhea, and rash. It may also cause short-term underactive thyroid function, especially in infants. Additionally, persons with iodine sensitivity and certain conditions such as dermatitis herpetiformis, hypocomplementemic vasculitis, Graves' disease, and autoimmune thyroiditis should avoid KI or take it with caution.[10] These negative side effects highlight the fact that KI should not be taken if not needed. This balance of risks and benefits is true for other MCMs as well.

In short, using KI carries potential risks that should be avoided in the absence of any potential benefit from the drug. Furthermore, in the event of a future emergency requiring KI for a limited proportion of the population, demand for KI by those who would receive no benefit may prevent those who need KI from accessing it.[11,12]

DILEMMA #1

Despite the vast distance between the US and the Fukushima accident, Americans still had strong interest in self-protection against the dread-inducing threat of radiation.

Because of KI's limited role as a medical countermeasure in this instance, due to low levels of exposure, it was not recommended for use in the US following the accident in Japan.[13,14] However, some US consumers chose to ignore these recommendations and US KI consumption increased.11 For example, one online company was receiving a new order every 30 seconds.[15,16] Much of this demand for KI was concentrated in western parts of the country, although similar concerns were echoed across the nation on a smaller scale (informant interview completed for this project, public health official). Many consumers attempted to acquire KI from KI manufacturers and pharmacies, which quickly sold out or never stocked it in the first place.

Between March 11 and April 16, 2011, poison control centers in the United States captured 340 requests for information and 60 potential exposures to KI, iodine or iodide product ingestions, or radiological exposures related to the nuclear power plant incident in Japan. There were 38 reported exposures specifically related to KI, iodine or iodide products.17 These incidents likely represent only a portion of actual exposures since not all were reported to poison control centers.

Implications for the future

Individuals will actively search out information on self-protection when they perceive risks, even if their heightened sense of risk is unfounded from a professional viewpoint. Radiation is one of several hazards that evoke an increased perception of risk from the public. Other hazards that often trigger more pronounced reactions are those that are not directly observable, unknown to those exposed, new or unknown to science, uncontrollable, catastrophic, fatal, not equitable, risky to future generations, not easily reduced, increasing in risk, or involuntary, or those that have delayed effects.[18] In the context of these dread hazards, the FDA should be prepared for intense reactions as well as enhanced public demand for information and potential MCMs. Officials, including those at the FDA, can most effectively counter inappropriate MCM-seeking behaviors by acknowledging the desire of individuals to protect themselves, reframing personal health concerns in proportion to objective risk, specifying the negative impacts of using

using potentially ineffective or unsafe products, and redirecting the impetus to take protective action in a more positive direction.

Action Items for FDA

1) Be prepared to communicate about potential MCMs even if the USG has a limited or non-existent role in an international incident, especially one involving a dread hazard like radiation. The public does not limit its concerns or questions because the USG is not an official responder to an incident.

2) Pre-emergency, engage radioation-related groups [eg, National Alliance for Radiation Readiness (NARR) and Conference of Radiation Control Program Directors (CRCPD)] to build up working relationships and familiarity with FDA's emergency roles and responsibilities. These entities can help communicate in a radiological incident about the risks/benefits of specific MCMs and/or redirect inquiries to FDA.

3) To deter the public from using unnecessary and/or potentially harmful countermeasures, coordinate at interagency level to draft and deliver common warning messages that motivate people to take appropriate actions, based on evidence regarding content and style (see Table 1).

Table 1.
Sample Public Warning about Potassium Iodide in the Fukushima Context: Content and Style Tips

NOTE: The following public statement illustrates communication best practices, using a specific example to demonstrate in concrete fashion the more general content and style principles recommended. It is not intended to represent an actual public warning issued by the FDA. In actuality, any FDA and/or interagency statement would have to be adjusted for different threats, MCMs, and the specific communication goals of the FDA and its interagency collaborators.

CONTENT:

- Specify who is issuing the warning, invoking a chorus of credible sources.
- Describe exactly what action people should take and explain why.
- Note the timeframe for when to engage in the behavior.
- Single out who should take action and explain why.
- Outline the consequences of taking the action.
- Indicate if the recommendations have changed or may change in the future.
- Channel concerns about potential risk to productive behaviors.

STYLE:

- Aim for clarity, by using simply worded messages and avoiding technical jargon.
- Be as concrete as possible and use familiar landmarks when telling people what to do.
- Project confidence and certainty, while preparing people for dynamic conditions.
- Employ accurate information; avoid any misunderstanding.
- Maintain consistency; avoid "mixed messages." Explain when advice differs or evolves.

This is a public advisory from the US government informed by experts from the Centers for Disease Control, the Environmental Protection Agency, the Department of Health and Human Services, the Food and Drug Administration, and the Nuclear Regulatory Commission.

The Tohoku earthquake in Japan damaged the Fukushima Daiichi nuclear power plant, causing a release of radiological materials that began March 12, 2011.

According to the US Nuclear Regulatory Commission, harmful levels of radioactivity are not expected in Hawaii, Alaska, the US Territories, the US West Coast, or the rest of the country, based on data that is regularly updated.

If you are in Alaska, Hawaii, a US territory, or the continental US, there is no reason for you to take any protective actions at this time. You will be notified if conditions should change, but experts agree that this is not likely.

Do not take potassium iodide, even as a preventative measure. Harmful levels of radioactivity are not expected, so potassium iodide is not needed. Potassium iodide has potential negative side effects, and it should not be taken if not needed.

Side effects can include nausea, vomiting, diarrhea, and rash. Potassium iodide may also temporarily interfere with the thyroid's functioning. People at higher risk of these side negative effects are infants and persons with iodine sensitivity and certain medical conditions involving the thyroid and heart.

Do not seek out substitutes for potassium iodide, as they are not needed and may cause you harm. Be wary of internet sites and stores that promote products falsely claiming to prevent or treat the effects of radiation. Avoid products that are not FDA-approved. Fraudulent products come in all shapes such as dietary supplements, food items, or products said to be drugs, devices or vaccines.

Actions that you can take include the following:

1) Go the FDA website to learn more about potassium iodide and when this drug is and is not useful to protect against the effects of radiation.
2) Go to the EPA Rad Net website to track up-to-date monitoring of radiation levels associated with the recent events in Japan.
3) Learn how to make smarter choices when buying medical products on line. Visit the webpage Buying Medicines and Medical Products Online, and check The Orange Book or Drugs@FDA to confirm if a particular drug is FDA approved.

DILEMMA #2

Amidst an information void and inadequate government coordination, people actively sought out a countermeasure (KI) that held no benefit and posed some risks.

Given that radiation levels in the US were very low and there was little potential for the public to benefit from KI, official recommendations advised against purchasing, stockpiling, and administering KI. Despite this public messaging, there was significant demand for KI.[19] The desire to take personal protective measures, a perception that the Japanese government was not being transparent about the disaster, confusion about what "low" meant, and delays in guidance from trusted officials in the US negatively affected public perception of the disaster and likely spurred interest in KI.[20,21] The mismatch between US government recommendations and rising demand for KI suggests that some people did not receive the government messaging, did not trust these recommendations, or were ignoring these messages in favor of other information sources.

A several day delay in the overall US government communication response coupled with an acute demand for knowledge about personal protective measures created an information vacuum. Unfortunately, this information vacuum was filled by people, such as "experts" used in news media reports or internet bloggers, who provided inaccurate information.[22] Social media allowed for rapid and widespread dissemination of information but this platform allowed inaccurate information to go "viral" quickly.[23] Although most eventual public messages regarding potential countermeasures noted that no countermeasures were necessary, mixed messaging from the federal government also complicated the issue. When asked about the demand for KI in an interview, Surgeon General Regina Benjamin supported KI purchases as a worthy "precaution."[24] Health officials needed to maintain unified health messaging across multiple agencies, which did not occur until after public concerns had already grown.

Members of the public were eager to know radiation levels to put their perceived risk and need for self-protection in context, but this data was slow to emerge, unevenly available, and difficult to interpret. The Federal Radiological Monitoring and Assessment Center (FRMAC), which is typically activated for an event occurring in the US, was not activated (although a limited deployment to Japan occurred); a centralized source for radiation monitoring data was thus absent.[12] The EPA did develop a website to

provide public data from EPA's RadNet monitors.[25] Nonetheless, state health officials still felt that they were left to answer the public's questions and concerns with little data to support the idea that there was no need to take protective actions against radiation from Japan, including taking a countermeasure like KI.[6,19] Federal release of radiological readings occasionally occurred before state and local officials were aware of them (informant interview, public health official), which led to confusion when concerned citizens called local public health officials. This situation was particularly difficult because health officials needed to "prove a negative" (informant interview for this project, public health official). Furthermore, no official public health definition of a safe radiation dose existed.[26] Moreover, when hard data was available, it was often difficult for the public to interpret due to the different units of measurement used for radiation.[12]

Some states were able to generate their own radiation readings, but these data releases often got stuck in wordsmithing cycles with higher level but less radiation-informed officials (informant interview for this project, public health official). Without hard data, it was easy for the public to dismiss claims that there were no public health effects of concern. The ability of frontline health officials to refer to specific readings and put them in context for the public was important in persuading concerned citizens that KI was not necessary. Experts noted the importance of creating effective public messages around the fact that KI was not necessary but also that KI could cause negative health impacts for certain subpopulations. For example, California's Department of Public Health and Emergency Management Agency on Risk of Radiation Exposure issued a statement urging Californians not to take KI, stating that it was unnecessary and could present a danger to some people, especially if taken inappropriately.[27] States also attempted to address the unwarranted public desire to access KI by engaging pharmacies and healthcare providers as spokespersons on the issue.

In the Fukushima disaster, the FDA played a supportive role, utilizing its expertise to advise other agencies and provide relevant information to the public. To disseminate information to the public, the agency relied heavily on the internet and developed its own website. Using a "frequently asked questions" (FAQ) format, the agency addressed issues about the Fukushima disaster relevant to the agency's mission. Topics included the safety of Japanese drug and food imports (eg, dairy products, seafood) and information regarding medical products to treat internal contamination with radioactive materials.[14]

Implications for the future

In general, public health officials should be prepared to support claims about a lack of threat (and thus, the lack of need for a MCM) with concrete evidence. However, in the case of the Fukushima disaster, not all of

the necessary information for the disaster fell under the purview of one organization. A more rapid, visible, and unified federal response to public concerns about radiation and demand for KI, was needed and would likely have reduced early fears, increased the credibility of messaging, and buttressed the communication efforts at the state and local level. Due to the international nature of the event, interagency coordination and information sharing with locals was a challenge. Since the Fukushima accident occurred, work has been done to improve coordination of the federal and local response to such events including pre-developed messages for radiological incidents and joint message development between the National Alliance for Radiation Readiness and the Centers for Disease Control and Prevention.[12]

During the Fukushima emergency, the FDA played a critical supportive role in helping to assure that the public was accurately informed about the potential threat of radiation (i.e., negligible) and any need for protective actions (i.e., none, including potassium iodide). While FDA's regulatory responsibilities may be broader during an event like Fukushima, as in safety screening of drugs from Japan, the agency is nonetheless part of the larger public health emergency response system that has a priority interest in appropriate public use of medical countermeasures. The agency has an essential supportive role in communicating the science behind the need or lack of need for KI and other radiation MCMs, and it remains a key information source for the public on MCMs even when MCMs are not necessary.

Action Items for FDA

1) In the health emergency context, embrace the supportive role in helping to deliver a clear and obvious signal to the public about the desired protective behavior in the context of a specific threat and recommended MCM(s), if any. Even when the FDA is not a primary responder, it can still provide important science-based messages that provide greater legitimacy to information and directives put out by other agencies.

2) Improve the ability of Internet users to find FDA's webpage easily, which is the central archive for its key messages and to which the agency drives consumers via Twitter and other social media. During an emergency, FDA should work to ensure that the rank of its website in Internet search engines is high so that it is a "go-to" site for information on risks and benefits of KI and other radiological MCMs.

3) When publishing resources for the public on the Web during an emergency, take steps to enhance the prominence of information about the health risk and appropriate protective actions (including MCM use). Take steps to call out this information, for example, by sharing it first or layering information in ways that make this kind of information readily accessible.

DILEMMA #3

With limited access to KI, some people sought out substitutes such as home remedies, fake potassium iodide, and other fraudulent products, prompting the need for another critical line of public health messages.

As KI stocks dwindled, home remedies or alternative sources of potassium iodide were also in high demand. Further complicating the issue, fake KI and other products claiming to protect against radiation were being marketed and sold in the US following the disaster in Japan.[28] In the US and around the world, salt and other dietary supplements were used as potential remedies for perceived risks from the radiation from the nuclear power plant accident in Japan.[28,29,30] Even if a countermeasure for radiation exposure had been necessary in the US following the accident, these alternative sources of KI would not have been able to provide protection.

While their wares were unnecessary, online retailers still promoted a wide array of products and practices to counter supposed radiation exposure. These included foods that supposedly supported detoxification, supplements and natural products purported to protect against free radicals created during radiation exposure, and topical treatments to treat potential effects of radiation sickness. Several companies received warning letters from the FDA about marketing and labeling violations, highlighting the possibility of regulatory action.[14] In addition, several fraudulent products were noted on the FDA webpage dedicated to Fukushima, along with detailed instructions to consumers on how to spot and avoid buying suspicious products.

Via its website, the FDA provided helpful information about the lack of need for KI and about fraudulent products. Nonetheless, certain design and content elements potentially reduced the accessibility and salience of the information for the user:

- Critical information about MCMs was relegated to the end of a long, scrolling, text-heavy webpage that lacked hyperlinked questions at the top of the page to improve interactivity and navigability;

- Details about radiation contamination MCMs were mixed in with information about imported

- (contd.) drug safety, under the heading of "questions about medical products." This generic title failed to signal the public's dominant concern – protection against the effects of radiation.

- Prior to noting the lack of need for any countermeasure (ie, "Does FDA recommend that consumers purchase potassium iodide as a protective step?"), the website first discussed radiation countermeasures (ie, "Hypothetically, if they were needed, what are the FDA-approved products for treatment of internal contamination with radioactive iodine?"). This created a potential inconsistency for those reading these messages, undermining the bottom-line that no countermeasure was necessary due to Fukushima for people on American soil.[31]

- Finally, the website failed to link to FDA's more detailed FAQ webpage regarding potassium iodide.[10]

Implications for the future

The agency could have strengthened its messages by more explicitly acknowledging and prioritizing potential concerns about radiation, the dominant issue for the public as evidenced by their demands for this information from local public health officials and less trustworthy sources. Communicating about unnecessary and ineffective countermeasures requires that communicators acknowledge potential concerns and then provide consistent and transparent messages about the lack of any health benefit from these products. Additionally, as occurred in the case of the Fukushima disaster, actions should be undertaken directly with the companies advertising these products.

Action Items for FDA

1) Design webpages from the viewpoint of the target audience, using state-of-the-art virtual design principles. For instance, users should be able to easily access important information through navigational tools and hotlinks, without having to scroll through and search a long, text-heavy webpage.

2) Use social media such as Twitter, Facebook and YouTube rapidly and repeatedly to support the response to public concerns and preempt dissemination of inaccurate information. Employ plain and consistent language, convey accurate and up-to-date information, and maintain transparency.

3) Extend beyond traditional messaging allies and optimize message accessibility through search engine providers and "debunking" websites to ensure that FDA messages are high ranking in internet search results and that opposing messages do not go unchallenged. A sufficiently important public safety issue may require the FDA to purchase placement with leading internet search engines.

Conclusion

The dilemmas highlighted in this case study focus around public demand for a countermeasure that is unnecessary but also in limited quantity. Although much attention is paid to convincing the public to use or accept a medical countermeasure during an emergency situation, it is equally important to ensure good communication when the appropriate public action requires the public to forgo a potential medical countermeasure. In this case, more rapid and visible communication, data to back up messages informing the public that countermeasures were unnecessary, and united messaging were strategies that could have reduced public concerns and resolved these dilemmas.

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