Chapter One: Introduction

The nation must have the nimble, flexible capability to produce and effectively use MCMs in the face of any attack or threat, whether known or unknown, novel or reemerging, natural or intentional. These capabilities must be communicated to the American public before and during an emergency.

2015 Public Health Emergency Medical Countermeasures Enterprise Strategy and Implementation Plan, p. 7[1]

How FDA and other US government officials convey information about medical countermeasures (MCMs) will affect uptake, compliance, and ultimately survival in the aftermath of a natural disease emergency or a chemical, biological, radiological, or nuclear (CBRN) attack. Moreover, effective communication regarding MCMs has the potential to strengthen psychological resilience as well as engender public trust in science, government, and public health. The purpose of this casebook is to provide FDA and other officials who deliver public health information with "real world" inspired opportunities for reflective learning on the principles of effective MCM communication and on the wider contexts that influence the development, delivery, and consumption of accurate, timely, and meaningful MCM information in an emergency. Communication successes will better enable FDA to fulfill its regulatory role and activities and "facilitate the development of and access to safe, effective, and quality MCMs" to counter CBRN and emerging infectious disease threats (for more on FDA's MCM-related mission, activities, and collaborators, see Appendix A).[2]

This opening chapter previews the casebook findings, and it reviews expert-vetted, model practices in risk and crisis communication in order to provide a self-contained takeaway for FDA users seeking general advice on how to communicate effectively about MCMs in an emergency. In addition, this introduction describes the methods used to develop the casebook including integrating input from the Expert Working Group on MCM Emergency Communication Strategies (Table 1). Each of the 4 chapters that follow represents an in-depth case study of an emergency in which communication regarding MCMs was important: the recent Ebola outbreak, the 2011 Fukushima nuclear accident, the 2009-10 H1N1 influenza pandemic, and the 2001 anthrax letter attacks. The cases are comprised of a background on the emergency, a selection of serious communication challenges faced by FDA and its

Table 1.

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partners, and forward-looking implications, including action items for the FDA to help mitigate comparable issues in the future.

The 4 case studies are snapshots in time to memorialize the lessons learned from the experience, and they are not intended as a comprehensive assessment or history of after action implementation efforts by the FDA and US government in subsequent years. Like much of the leading crisis and risk communication literature, the casebook relies upon real crises to illustrate successful or failed application of model communication practices. Accounts of actual events can accelerate learning: people reason effectively through analog and not just general, abstract principles; contextualization makes broader principles meaningful and memorable; and cases provide reflective thinking and reinforce users' ability to apply that knowledge in future settings.[6-7] Moreover, industry-specific cases can motivate users who see direct, practical relevance to familiar issues and settings (eg, MCMs in emergency contexts).[8]

What Defines Good Stewardship of MCMs in a Public Health Emergency?

MCM stewardship comprises strategies to optimize population wellbeing in an emergency, including reduced morbidity and mortality, enhanced psychological resilience, and preserved faith in the institutions of science, government, and public health.

Medical countermeasures – the drugs, biologics (eg, vaccines), and devices (eg, in vitro diagnostics, respiratory protective devices) used to diagnose, prevent, or treat the human health impacts of CBRN emergencies and emerging infectious disease threats – are an essential part of national health security.[9] Appropriate shepherding of countermeasures in an emergency entails the following objectives:

- Enabling citizens to make smart, informed decisions about MCM uptake;
- Maximizing benefit and minimizing harm, including psychological impacts;
- Getting MCMs to individuals and groups most in need of them;
- Allocating scarce MCMs in ways that preserve public lives and public trust;
- Protecting the public from fraudulent products and false product claims that can be harmful, feed unfounded hope, or waste scarce household money;
- Testing unproven MCMs in a scientifically rigorous way that provides interpretable data;
- Supporting non-pharmaceutical measures that empower people to protect themselves.

Why Do Emergencies Present Special Communication Challenges for Stewards of MCMs?

Public health emergencies are exceptional events, and many of the drugs, vaccines and medical devices now being developed to manage them are also outside the norm.

MCMs, as a class, are often novel products, rare in number, and limited in supply: There are insufficient MCMs for preventive and therapeutic purposes, to match the number and diversity of high-priority threats to US health and security. While the nation's MCM inventory does include large quantities of some well-established products, many CBRN countermeasures are recent innovations, still under development, and/or not scaled for mass production. Some MCMs may be among the first being developed for a specific threat, potentially through innovative ways like recombinant and molecular techniques and the use of flexible, disposable manufacturing component and multiuse facilities.[10]

MCMs target health threats that are themselves extraordinary: MCMs are medical products intended to protect against high-priority threats that have the capacity to affect US national security.[9] Such high-priority threats include agents that can lead to substantial illness and death and, by virtue of their lethality, unfamiliarity, and/or gruesome clinical presentation, can induce significant fear in the population. Among the current high priority threats are anthrax, smallpox, viral hemorrhagic fevers, nerve agents, and radiological agents. Development of a flexible infrastructure to support rapid production of MCMs for future, as-yet unknown threats is also a national goal.

MCMs used in an emergency may have limited prior clinical experience in humans: Many of the high-priority threats for which MCMs are being developed do not occur naturally to an extent that would allow for field efficacy studies in humans, and it is not ethical to conduct human challenge studies with many threat agents. In these situations, efficacy data from animal studies may be used if the results can reasonably be extrapolated to expected human use. MCMs may have been FDA-approved on the basis of efficacy studies in animals, may be unapproved but authorized for use during the crisis, or may not have been previously used in certain populations (eg, pediatric populations).[9] Helping to inform clinical decisions during the public health response requires near real-time monitoring and assessment of MCM performance such as through enhanced adverse event tracking, reporting, analysis, and communication.[9]

Typically time-consuming, product development and review processes can be accelerated for MCMs: FDA applies its rigorous review and approval regulations and policies to MCMs, like all medical products. FDA does have the authority to help speed up MCM development and availability through

processes that include fast track, breakthrough therapy, accelerated approval, priority review, and orphan designation, as well as through the enhanced authorities and resources specifically devoted to MCMs.[9,11]

Prompt emergency access to MCMs may involve atypical procedures: Even with an approved product, rapid distribution and administration to a large affected population may call for an unconventional approach: eg, extending the labeled expiration date; dispensing a product without an individual prescription; allowing deviations in storage temperatures during a response; enabling innovative delivery methods such as postal carriers equipping households with antibiotics in event of an anthrax attack; making available streamlined, easy to understand "emergency use instructions" concerning the product's approved use.[12] In the case of an unapproved, investigational product, or the unapproved use of an approved product, FDA has certain mechanisms to facilitate emergency access (eg, through an Investigational New Drug [IND] or Device Exemption [IDE] process, as well as through Emergency Use Authorization [EUA]).[9]

Liability immunity can exist for a MCM-related claim of loss: The Secretary of Health and Human Services can issue a PREP Act declaration to confer liability protection (absent willful misconduct) in relation to the manufacture, testing, development, distribution, and administration, and use of MCMs for an actual or potential emergency threat. Claimants may have recourse to the Countermeasures Injury Compensation Program.[12]

How will MCM Communication Dynamics Evolve Over the Life Cycle of an Emergency?

People's level of interest, topics of concern, emotional requirements, demand for information, capacity for processing information, and objective public health needs will evolve over the life cycle of an emergency, prompting the need for a phased approach to MCM communication.

Before the Emergency:

1) Health threats are abstract and personally irrelevant. People commonly believe that they are, as a rule, "safe" and that a disaster only happens to "other" people.[13]

2) A person may be unaware of the risks and benefits of a specific MCM; if they are aware, then the risks of MCM use may be the more salient issue given that there is no imminent threat.

3) Communication that enables individuals to personalize a risk, envision how certain actions protect against that risk, and feel a degree of self-efficacy in performing such actions may motivate people

3) (contd.) to take protective measures in advance of an emergency (eg, learn more about a MCM or an entity involved in its distribution and administration).[14-15]

4) On-going, repetitive, and mutually reinforcing messages from diverse sources are necessary to break through everyday background noise and to prompt a desired public behavior (eg, seeking out more information about an agency's role in stewarding MCMs).[16]

5) Engaging in a preparedness behavior (eg, learning about local plans for MCM dissemination) is the end result of many prior steps: ie, thinking about surprise events in advance, seeking out additional information, conferring with others, deciding to do something, and then taking action. A continuous stream of reinforcing messages helps people successfully complete this sequence.[16]

6) Human ties and social dynamics strongly influence preparedness communication and action. Once receiving preparedness messages, people typically confer with others to assess the significance and relevance of the information; conferral could occur in person or via social media. Moreover, a person is more likely to engage in a preparedness behavior when they see others around them doing the same.[16]

7) Community partners (eg, community- and faith-based organizations, health professionals, private industry, schools and universities, social service providers, volunteer groups) can broaden and deepen the reach and reception of official communication on MCMs. By collaborating with diverse partners, officials can better understand specific audiences and tailor messages accordingly, enlist additional spokespersons who are already respected within their own communities, and enable the adoption of preparedness as a group's own social norm.[16]

8) People learn as they interact with the world, developing mental maps along the way that serve as heuristic devices (or shortcuts) for organizing information.[14,17,18] The operating assumptions that individuals hold around health threats and MCMs in advance will shape how they later make sense of these things during an emergency.

9) The routine, non-crisis timeframe allows public health entities to be more proactive. The opportunity exists to develop careful messages about threats, MCMs, and regulatory processes as part of a longer-term awareness raising campaign.[19-20]

During the Emergency:

1) A health threat is present and potentially dangerous for the person. However, the perception of personal risk may not match the professional appraisal of risk (whether it is higher or lower).[21-22]

2) Risk/benefit information about a MCM is more salient (ie, personally relevant and significant), and public demand and need for these facts becomes more acute.

3) At the outset of a crisis, an information deficit typically exists – circumstances are still unfolding, facts are few in number, media interest is piqued, the full scope of the problem is uncertain, communication channels may be disrupted, and only partial perspectives are possible.[23]

4) When a threat is present, people are hungry for information, and they rarely if ever get too much information.[24] They want to know as much as they can about potential dangers for which officials have sounded an alarm, and they will turn to the media and sources they consider trustworthy to find out more details before protective actions are started.[25] In contrast, uninformed authorities may hesitate to sound any alarm, out of an unsubstantiated fear regarding the potential for public panic.[16]

5) The urgency of the situation coupled with heavy demand for information, by the media and the public, may be at odds with well-reasoned but protracted government procedures for "clearing" information before it can be shared publicly.[23] The delay can lead to an information vacuum that is potentially filled by unreliable sources and inaccurate information.

6) People who are worried and distressed due to a perceived threat have a reduced capacity to process information effectively and efficiently and to engage in complex decision-making.[14,17,26] Protective action information, however, should not be simplistic and short out of fear people will be overwhelmed or confused; instead, messages should meet style and content criteria proven to prompt the desired public response (points 8-9 below).[24-25]

7) For the public to implement the protective behavior desired by officials, they typically undergo a sequence of perceptual, cognitive, and behavioral steps: hearing the warning, understanding the information, believing the warning is credible and accurate, concluding that the message applies to them (ie, they are at risk if they do not take protective action), confirming the warning is genuine and others are taking heed, deciding to take action, and carrying out that decision to act.[24-27] Also affecting this process is whether the protective action is feasible.[28-29]

8) Five kinds of information are essential to motivate public compliance with official protective actions: what (ie, the actions the public should take), when (ie, by what time the action should be executed), where/who (ie, which people should or should not take the action as described in clear geospatial, age groups, and other everyday terms), why (ie, the threat and how the protective action will reduce its impact), and whose advice (ie, the person or entities providing the information).[16,30]

9) People respond well to messages that are jargon-free and use wording that is specific (ie, precise and non-ambiguous), accurate (ie, free from errors that create confusion), certain (ie, authoritative and confident); and consistent.[30]

10) Government-issued details on MCM risks/benefits and on recommended protective actions will not be the only information available to the public on those topics. Monitoring the "information sea" in which the public is immersed can help reveal if conflicting information is inhibiting the desired response and thus inform necessary corrective actions.[16]

11) Information on MCM benefits/risks may change during an emergency as MCMs are used and clinical information is received and analyzed, which could alter the response. Any change in public information regarding benefits/risks will require forthright explanation.

12) The time urgency and dynamic conditions put public health entities in a more reactive mode. Exigencies may require MCM-related message development on the fly, a focus on short-term problems, and quick delivery of information.[19-20]

After the Emergency:

1) Health concerns can shift from the emergency threat to the unintended and lingering consequences of the public health response, including the long-term effects of MCMs, if any.

2) People are in a state of reflection, as they try to make sense of what has happened and why. They rely on images, narratives, and frames of reference around them to help explain what has been seen, heard, and felt in connection with the calamity, and also to provide a meaningful framework for processes of coping, grieving, and rebounding.[31-32]

3) Themes of causality, responsibility, accountability, and the in-/adequacy of the emergency response can dominate the post-crisis period of retrospection.[19,23,31,33] In a world of instantaneous news and information saturation, the "framing and blaming" that tend to follow epidemics and disasters occur with increasing speed and reach.[33-34]

4) Communal narratives that give people's experience of mass tragedy shared meaning and purpose help facilitate recovery after the event.[35-37] Stories held in common that emphasize capability, adaptability, optimism, collective learning, and a focus on the future can help ease people's experience of distress and restore their sense of well-being.[19,35]

5) When the emergency is no longer front page news, the people who have been most affected continue to require emotional support as their feelings of loss and grief set in.[23] Themes of having

5) (contd.) had access (or not) to a MCM and/or whether the MCM has helped or not may figure prominently in their experiences and personal narratives of the public health emergency.

6) In the aftermath of an extreme event, a "window of opportunity" opens for moving messages that are otherwise ignored (eg, explanations of FDA processes to ensure MCM safety and efficacy before and during an emergency). Officials have people's rapt attention.[38-39]

What MCM Communication Strategies Should FDA Prioritize for Each Phase of an Emergency?

The impacts of effective MCM emergency communication are largely seen during the crisis. Nonetheless, to be optimal, MCM communication requires groundwork before an emergency ever unfolds. Critical self-reflection and organizational retooling afterward also pre-position an agency like FDA for success during future emergencies.

FDA, in collaboration with its federal partners, is encouraged to implement broadly recommended "best practice" guidance (Table 2) when communicating about MCMs in the emergency context. At the same time, the following represent suggested priorities for FDA tackle in order to strengthen its emergency MCM communication. The action items derive from an analysis of MCM communication concerns emerging during recent emergencies covered at length in the casebook (Tables 3-6) and a larger typology of foreseeable communication dilemmas based upon prior experiences and best professional judgment (Table 7). Under-resourced and heavily burdened agencies like FDA are often forced to communicate in an emergency from a reactive position, rather than a proactive one. Nonetheless, FDA is strongly encouraged to implement as many pre-crisis, preparatory steps as possible so that it can be a nimble and influential communicator in moments of widespread distress.

Before the Emergency:

1) Build Up FDA's Reputation and Credibility: As part of everyday activities, enhance public familiarity with how the FDA regulatory mission applies in an emergency and what legal and administrative tools the agency can facilitate public access to MCMs in a crisis.

   Repetitious messaging and readily-digestible publications concerning FDA's "brand" and its response "toolkit" (eg, EUA) can prime people for the agency's emergency role and help reduce the element of surprise. When a crisis arises, such materials can also be available for people to access without delay. Advance communication materials cannot anticipate every threat and MCM scenario or individual public concern. That is, a pre-prepared playbook of messages for every eventuality is not feasible (although development of high-stakes, audience-tested messages as

Table 2.

Best Practices for Communicating Risk in an Emergency[20,40-43]

1) Incorporate communication experts, insights, and goals at the outset when developing emergency management policies. Embrace communication as an essential part of "front-end" decision-making rather than the mere function of sharing policy decisions at the "back-end."

2) Conduct pre-event communication planning that identifies potential threats or hazards, outlines risk reduction approaches, recognizes the resources needed to implement them, and spells out the responsibilities of principal actors.

3) Build pre-crisis partnerships and alliances with other stakeholder entities to coordinate communication resources and activities, enlist their help in better understanding and reaching target audiences, and establish trusted links that can be activated during the crisis period.

4) Accept the public as a legitimate partner in managing an emergency. Recognize the public's right to know the risks that it faces as well as protective actions that it can take, and plan for the prompt sharing of this information so that people can freely carry out their own informed decisions.

5) Listen to the public before and during the emergency. Find out what people know, think, or want done about risks, and use this to inform communication and emergency response planning. Acknowledge people's concerns, even if they do not conform to scientific risk assessments. Put yourself in their place and adapt messages.

6) Communicate with honesty, candor, and openness. Be truthful to foster credibility with the public and the media. Relate the truth as it is known, even if it may reflect poorly on the agency, and be frank about the potential severity of any crisis. Promptly make information accessible. Convey information uncertainties, strengths, and weaknesses.

7) Accept uncertainty and ambiguity. In an emergency, acknowledge the dynamism of the situation and the potential need to act before all the facts are known. Be prepared to explain the fluidity of conditions and the measures being taken to fill in the knowledge gaps. Address differing scientific perspectives and international variances as needed.

8) Communicate with compassion, concern, and empathy. Recognize the human dimensions of the emergency, acknowledge people's distress and extend genuine sympathy and understanding.

9) Respect the unique communication needs of diverse audiences. Be mindful of differences in cultural background, immigrant status, education, technological adeptness, hearing and seeing abilities, and other factors that influence information uptake and processing. Use clear, non-technical language along with graphics to clarify messages; employ multiple language translations where appropriate.

10) Meet the needs of the media and remain accessible. Plan to work diligently with the media before and during an incident knowing that members of the public often rely on news outlets to learn about a crisis or risk.

11) Convey messages of self-efficacy. Provide specific information to the public on how to reduce any potential harm and what can be done to help others. Protective messages can reduce material harm as well as enhance morale by restoring a sense of control over uncertain and menacing conditions.

12) Monitor public responses and update communication efforts to meet people's evolving information needs.

noted below is advisable). FDA should therefore work to engender greater understanding of, and faith in the agency's fundamental ability and commitment to protecting public health and safety.

When unique, unforeseen circumstances arise, the agency can then rely on its established reputation when stewarding a MCM and implementing a EUA or other regulatory measure. An organization seen to be enacting proven core values in a crisis is more likely to enlist public support and to bolster its reputation.[19]

2) Widen and Reinforce Communication Partnerships: Continuously network with intra- and interagency partners as well as external stakeholder groups to comprehend diverse audiences, coordinate communication resources, and build up trust that can be tapped in an emergency.

   FDA cannot be the sole communicator on MCM safety and efficacy to the US populace; it needs others to amplify its messages and to know what diverse audiences require of the agency. Doctors, nurses, pharmacists, state and local health officials, and other frontline professionals interpret MCM risks and benefits for the public, and individuals turn to these and other trusted sources for information. A host of traditional, new, and emerging media platforms transmit critical health information to diverse publics. FDA can bolster current stakeholder ties and create new ones: eg, strengthen the role of the Office for Minority Health in the MCMi to help uncover, understand, and address the MCM communication needs of vulnerable and historically underserved populations; reach further into health professional societies on top of FDA's ongoing participation in national level workshops, meetings, and webinars; and hold informational workshops for journalists to increase media awareness of current practices in regulatory science, including how MCMs are authorized and approved.

3) Anticipate Problems and Rehearse Solutions: Scan in advance for signs of novel communication dilemmas (or evidence of persisting ones), and with agency partners and stakeholders, develop and drill early solutions that can preempt failure and enhance real-time responses.[19]

   Tabletops can focus on specific communication dilemmas, allowing agency personnel and its collaborators to rehearse challenges and solutions (eg, issuing a timely EUA that strikes the right balance between technical accuracy and ease of comprehension; explaining in an emergency why the government may still not authorize the use of foreign products already used in large populations overseas; addressing public concerns in an emergency about using clinical trials that involve placebos). Table 6 provides a rubric for thinking about MCM emergency communication dilemmas; many of these themes can be interwoven into simulations and used to generate collective ideas about comprehensive mitigation strategies.

4) Set a Research Agenda; Work from the Top Down: Study topics that affect the agency's ability to facilitate good outcomes in an emergency (eg, fewer illnesses and lost lives; preserved public trust); develop and test messages; investigate people's information consumption habits.

   Advance research can fortify the agency's ability to communicate on MCMs in a crisis. Recent emergencies suggest that some topics and audiences require prompt, deeper understanding: in particular, the sensitivity among historically underserved populations about unfair distribution of either MCM risks or benefits, and the moral ambiguity that some people attach to randomized controlled trials for investigational products amidst mass tragedy. Other issues and topics also deserve further exploration, when resources allow (eg, polling on FDA as the gatekeeper for MCM safety and efficacy, audience testing of MCM fact sheets, design/testing of info-graphics to make the EUA process more intelligible). In general, to meet the information needs of citizens who come from diverse cultural, social, and demographic backgrounds, the agency should take steps to understand different audience segments and develop messages that address their concerns.[44–45] In conjunction with efforts to "profile" the needs and preferences of intended audiences, the agency can pretest messages and materials as well as media planned for their dissemination, to determine if they resonate with end users.[46]

5) Exceed the Limits of "Printed Statements" Communication: Expand modes of communication to reach a broader, non-technical audience: eg, balance published statements with public remarks, supplement heavy text with graphics, and design the agency website with end users in mind.

   As a regulatory agency, FDA is under pressure to represent its public health activities and decisions in ways that are true to the science and in line with legal mandates. Partiality for highly precise terminology and the written word can lead to unintended opaqueness, when broader public understanding around MCMs is called for. Some steps to enhance the agency's ability to convey messages that are meaningful to a broad audience include: enhancing risk and crisis communication training of individuals serving as the public face of the agency on MCM issues; engaging user experience experts to improve the accessibility and visibility of the FDA website which is the central archive for its key messages and where the agency drives consumers via twitter and other social media; supplementing text-heavy documents with infographics that can help make the agency's regulatory decisions, processes, and complex topics intelligible to a wider array of audiences; and pre-testing communication with end users to check for comprehensibility.

During the Emergency:

1) Keep Ear to the Ground on Responses to the MCM Campaign: Conduct real-time monitoring of traditional and social media to gauge public confidence in the MCM campaign, including rumors, knowledge gaps, and waxing/waning trust, and then adjust messages and outreach strategies.

   A strong social media presence, in particular, will allow FDA to "listen" and anticipate potential communication issues before they become full-fledged crises (eg, concerns about MCM use or uptake of alternative or fraudulent products). Social media engagement is not a just-in-time endeavor; the relationships that make social media an effective tool in an emergency are built over time. While technology platforms will evolve, FDA should commit in the near term to provide messages to, and monitor information from the public (and providers) via social media. For more on FDA's social media use, see Appendix A.

2) Address Public Priorities around Self-Protection: During an emergency, help 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.

   While FDA has specific regulatory responsibilities in an emergency, the agency nonetheless is part of the larger public health response system that has the paramount goal of reducing illness and saving lives. Past emergencies suggest that even if FDA is not a prime responder, the agency should embrace a supportive role in assuring that members of the public have the information they need for self-protective behavior. This supportive role can involve disseminating science-based messages that provide greater legitimacy to the public information and directives of other agencies regarding a health threat and appropriate protective actions.

3) Put Communication "Best Practices" into Action: Act on evidence-informed advice regarding how to communicate when knowledge is uncertain and rapidly evolving in an emergency,[19] when outrage causes the public's appraisals of risks/benefits to be non-aligned with that of authorities,[47] and when the goal is to adequately inform health decision-making by the public.[48]

   a. Uncertainty: Admit limits to the ability of FDA to determine all aspects of the emergency due to missing, complex, or rapidly evolving information. Share in your audience's distress and describe how FDA will get more answers. When policy positions shift, alert your audience, explain why what you are saying is different from before, and acknowledge any emotive responses to the change.[47]

   b. Outrage: Recognize variables known to provoke public outrage including dreaded hazards and perceived unfairness, moral indifference, and impacts on vulnerable groups. When

b. (contd.) When these elements are present, do not dismiss them as mere misperception; use values-based language with supporting evidence to enhance public understanding and to diminish impassioned critiques of the agency (see Tables 2-3 for examples).[47]

c. Adequacy: Test the adequacy of a communication (eg, on MCM risk/benefit) by checking if it equips a person with information essential to making an effective health decision (ie, it is material), if it reaches a person via their normal information channels and gathering practices (ie, it is accessible), AND if it is readily digestible so that a person can apply it to make a sound choice (ie, it is comprehensible).[48]

4) Show Agility as a Communicator: Communicate knowing the crises are time-sensitive. Strive for minimal time lags in connection with internal FDA clearance procedures for MCM emergency communication to keep up with growing public demands for prompt sharing of information.

Promptly communicating and staying ahead of the issues are critical, because for members of the public, the first source of information often becomes the preferred source.[23] FDA should actively seek out opportunities to communicate with the media and the public in order to ensure key messages are provided frequently and are readily accessible in the memories of target audiences.

After the Emergency:

1) Share "After Action" Results and the Path Forward: Publicly share what FDA and its partners learned from MCM use in the health emergency, including response missteps and successes; communicate how the agency plans to address concerns on the basis of that information.[19]

In the aftermath of an emergency, it will be important to acknowledge any blunders and outline how systematic changes are being implemented to improve MCM stewardship in the future. The inclusion of external stakeholders in preparation of after-action reports regarding the overall MCM campaign can help increase trust and provide viewpoints that are more representative of public concerns. Recommendations resulting from after-action reviews should be quickly implemented.

2) Reassess Overall Communication System Performance: Conduct an "after action" analysis of the agency's performance as an MCM emergency communicator and incorporate improvements.

Potential issues to consider are: how well did spokespersons perform and is more training in crisis and risk communication necessary; was the clearance process efficient; did unforeseen topics arise that deserve further audience research to be ready for next time; were there any groups to whom the agency could have reached out harder to get them information or to understand their

3) (contd) information needs better; what were the successes and how can they be repeated?

Casebook Methods

A project team of analysts at the UPMC Center for Health Security conducted 4 in-depth case studies of select public health emergencies involving MCMs, with input from the Expert Working Group (EWG) on MCM Emergency Communication Strategies (Table 1). This expert panel included top scholars in risk and crisis communication; seasoned MCM developers, producers, and regulators; leading practitioners in medicine, public health, and pharmacy science; and decision makers experienced in public health emergency management. Moreover, the EWG had strong interagency representation (eg, CDC, NIH, HHS/ASPR, and former FDA staff). The purpose of the casebook was to characterize recent communication challenges for FDA, with implications for public behavior around MCMs, and based on leading literature and professional judgment concerning risk and crisis communication, to develop suggestions on how to mitigate similar problems in the future. Tables 2-5 summarize the communication dilemmas and recommendations from chapters 2 through 5.

Casebook development entailed a recursive process of research and analysis by the UPMC team, review and feedback from EWG members and agency sponsors, and external review by authorities on risk communication and medical countermeasures.* Initially, the project team identified a preliminary list of potential cases to pursue through a review of LexisNexis, the scholarly literature, and government reports. They later refined the list, based on interviews with the EWG and sponsors to ascertain which issues were priorities. The EWG provided virtual feedback on the final plan to guide casebook research and organization. The 4 selected cases presented a broad range of health threats; MCMs with variable testing, availability, and risk/benefit profiles; social media influences; and trust issues.

Analysts relied primarily upon secondary sources when constructing their case studies, and where noted in individual chapters, also incorporated content from key informant interviews. In general, analysts performed a web-based review of the available scholarly literature using an array of search engines (eg, PubMed, Google Scholar). Using other databases (eg, LexisNexis, Google), they also identified NGO and government reports, news articles, and blogs that provided further details especially in the case of the urgent and rapidly evolving Ebola outbreak. Initiating research in the fall

* External reviewers were Brad Smith, PhD, Policy Director, FasterCures, Milken Institute; Ji Sun Lee, JD, Director, Security and Resilience Program, Survey Research Division, RTI International; Kunal Rambhia, MS, Health Team Lead, Zell Lurie Commercialization Fund, and Doctoral Candidate, University of Michigan; and Rita Obey, former Director of Public Information, Harris County Public Health and Environmental Services, and Co-Chair Risk Communication and Information Sharing Working Group, National Association of County and City Health Officials.

Table 3.

MCM Communication Dilemmas & Mitigation Strategies for FDA

Case #1: Recent West Africa Ebola Epidemic

Dilemma	Finding	Action Items
The FDA stance on the best way to enable access to investigational MCMs (ie, clinical trials versus broad availability) met opposition from diverse quarters including other experts, Congress, and the public.	To communicate most convincingly about clinical trials during emergencies, the FDA can approach this topic as one where technical and normative issues are inextricably linked, values about the public good can be perceived to be in competition (eg, scientifically defensible data versus hope amidst mass tragedy), and the merits of the opposition's arguments are acknowledged.	In advance of any future crisis, commission research that would elicit public views and values about the appropriate use and clinical study of unproven MCMs during emergencies, and on this basis, be prepared to embed any technical clams about the advantages of clinical studies in a larger values-based narrative.
Dilemma	**Finding**	**Action Items**
The FDA legal requirement to protect confidential commercial information triggered accusations of government secrecy and perceptions of privileging agency/ industry relations over human health.	While protecting confidential commercial information (CCI), FDA can work concurrently to strengthen communication channels with non-industry stakeholders (ie, Congress, providers, consumers, the media), offsetting perceptions that the agency is obstructionist.	To mitigate against public outrage, acknowledge people's concern in FDA communication about protecting CCI; engage with industry partners developing emergency MCMs to underscore the public health value of disclosing CCI (eg, clinical trial data) during a crisis; and work with sister agencies bound by less-restrictive confidentiality laws to describe to Congress regulatory challenges around CCI.
Dilemma	**Finding**	**Action Items**
Initial authorization of investigational MCMs for use by Americans and Europeans outside of clinical trials fueled concern over inequities experienced by West Africans affected by the epidemic.	To reverse unfounded perceptions that certain people are given preferential access to investigational MCMs, particularly over historically disadvantaged groups, FDA can acknowledge people's concerns about fairness and relate to them in a way that helps abates frustration.	Train FDA spokespersons to recognize variables known by risk communications to provoke public outrage including perceived unfairness, moral indifference, and impacts on vulnerable groups. When these elements are present, do not dismiss them as mere misperception; use values-based language with supporting evidence to diminish impassioned critiques.

Table 4.

MCM Communication Dilemmas & Mitigation Strategies for FDA

Case #2: Fukushima Nuclear Accident of 2011

Dilemma	Finding	Action Items
Despite the vast distance between the US and the Fukushima accident, Americans still had a strong interest in self-protection against the dread-inducing threat of radiation.	Fulfilling its regulatory duties may be the primary role for FDA in certain emergencies, but the agency is still part of the larger public health emergency response system that has a priority interest in appropriate public use of MCMs. Although not legally required, FDA may be expected to communicate the science-based messages that provide greater legitimacy to directives put out by other agencies.	To deter the public from using unnecessary and/or possibly harmful MCMs, coordinate at the interagency level to draft and deliver common warnings, based on evidence regarding content and style (see chapter 3), that will motivate people to take appropriate actions.
Dilemma	**Finding**	**Action Items**
Amidst an information void and inadequate government coordination, people actively sought out a countermeasure (KI) that held no benefits and posed some risks.	To help counter inappropriate MCM-seeking behaviors, as in the case of KI for an unfounded radiological risk, FDA can along with its partners empathize with people's desire for self-protection when faced with a dreaded hazard, specify the impacts of potentially ineffective or unsafe products, and redirect the personal impetus to act in a more positive direction.	During an emergency, help 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. During an acute health crisis, help be responsive to top public information demands. Make public information about the risk and proper protective actions more prominent, for instance, on the FDA website.
Dilemma	**Finding**	**Action Items**
With limited KI access, some people turned to substitutes such as home remedies, fake KI, and other fraudulent products, prompting the need for another critical line of public health messages.	During the US response to Fukushima, FDA played a critical role in educating consumers about how to spot and avoid buying suspicious products, a role that can be further strengthened by making FDA statements on fraudulent products the headline news that people readily access on the web.	Design the FDA website based on user experience principles. Optimize message accessibility through search engine providers and "debunking" websites to ensure that agency messages are high ranking in internet search results and that opposing messages do not go unchallenged. Consider purchasing placement with leading search engines when the public safety issue is immense.

Table 5.

MCM Communication Dilemmas & Mitigation Strategies for FDA

Case #3: H1N1 Influenza Pandemic of 2009-2010

Dilemma	Finding	Action Items
Perceptions of the H1N1 vaccines as "risky," "rushed" through production, and/or "untested" motivated some people to shun vaccination.	FDA can strengthen its ongoing communication efforts to demonstrate the ways in which the agency ensures the safety of vaccines in the US, pre- and post-licensure.	Enhance public resources on FDA's role in assuring safety over the lifecycle of a vaccine: eg, continue using the FDA Basics Webinar series to represent the agency's commitment to, and procedures for assuring vaccine safety; link to CDC materials, benefiting from the trust people hold in this agency; and supplement "text heavy" FDA communications with more readily consumable graphic representations.
Dilemma	**Finding**	**Action Items**
Unmet public expectations about when and how a newly manufactured vaccine would become available during the pandemic had an adverse impact on its uptake.	FDA can work with partners to help demystify the vaccine production process that is, to most people, a black box operation, and better align public expectations with the actual timetable for when the product can realistically be available in an emergency.	In cases where MCMs are developed during an emergency, provide either generic details on the manufacturing process (within the confines of CCI) or work with manufacturers to develop and share MCM production details, as these are relevant to the public. If delays are possible, then be prepared to explain why production may be slower than anticipated and share in your audience's distress at the wait.
Dilemma	**Finding**	**Action Items**
In the absence of trustworthy and culturally appropriate information, certain groups were less likely to seek out vaccination against the H1N1 virus.	FDA can help mitigate against differential rates of morbidity and mortality in future health emergencies by helping assure 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 lifesaving MCMs.	Strengthen the Office of Minority Health's (OMH) role in the Medical Countermeasures Initiative (MCMi) to uncover, understand, and meet the communication needs of a diverse US populace, in particular, historically underserved communities.
Dilemma	**Finding**	**Action Items**
Difficult-to-access and hard-to-understand information undermined efforts to make antivirals available to the public.	To avoid inadequate emergency MCM communication (eg, antivirals authorized for emergency use), FDA and its partners can aim to use information channels on which people normally rely, provide information that users see as relevant to key decisions about their health (and/or that of their patients or dependents), and deliver information that is readily consumed and integrated into a person's decision making.	Assess any FDA communication about new MCMs or new uses of MCMs in terms of the 3 standards of accessibility, materiality, and comprehensibility. For instance, survey intended audiences about their routine information gathering behaviors, and test written materials for salience and understandability with end-users before these are disseminated.

Table 6.

MCM Communication Dilemmas & Mitigation Strategies for FDA

Case #4: Anthrax Letter Attacks of 2001

Dilemma	Finding	Action Items
An evolving health crisis with a high degree of uncertainty generated acute demands for timely information, including that regarding MCMs, which leaders were not prepared to meet.	During periods of uncertainty, FDA can preserve the agency's credibility and remain responsive to information demands by the public, media, and health practitioners, by adopting crisis communication strategies and language.	Admit limits to the ability to determine all aspects of the emergency due to missing, complex, or rapidly evolving information. Share in your audience's distress and describe how FDA will get more answers. When policy positions shift, alert your audience, explain why what you are saying is different from before, and acknowledge any emotive responses to the change.
Dilemma	**Finding**	**Action Items**
Contradictory messages and inadequate coordination of risk communication across multiple governmental jurisdictions and the private sector impeded response efforts and generated public mistrust.	Between crises, FDA can extend the reach and impact of its emergency MCM communication by strengthening relationships with other agencies and stakeholders, maintaining familiarity with its partners' priorities and capabilities, and creating a cooperative environment that allows for ready exchange of information.	Re-commit to PHEMCE coordination and collaboration, including that needed to get "credible, understandable, and actionable information" to responders and the public before and during health crises.[49] Maintain FDA's frequent contact with public health NGOs and state/local health officials to support their MCM preparedness and response capabilities, and ensure coordinated communications.
Dilemma	**Finding**	**Action Items**
Inconsistent public health interventions coupled with historic disparities nurtured perceptions that health authorities delivered substandard care to, and even experimented on certain populations.	Sensitive to the historical conflicts between public health and minority communities, FDA can take steps prior to, and during an emergency to address any public anxiety around discrimination and human experimentation in the context of MCM clinical trials.	Seek OMH's strategic help in framing and conveying communications, namely those involving clinical trials and investigational products, to reassure affected groups that equal consideration is given to all. Enlist PHEMCE partners in developing, testing, and delivering MCM messages that are culturally appropriate, respond to community concerns, and help reestablish trust within historically underserved communities.

Table 7.

Forseeable MCM Emergency Communication Dilemmas: A Typology

Uncomfortable MCM Qualities

- MCM attributes induce dread (eg, GMO or irradiated component), suggest product is not fully tested (eg, in clinical trial, "sped up surge production," accelerated approval, animal rule), or raise fears of adulteration (eg, adjuvanted, compounded).
- Unfamiliar technical jargon spurs misunderstanding and hesitation (eg, killed versus live vaccine, egg versus cell-based production).
- Regulatory mechanisms under which a MCM is being made available are unfamiliar (eg, EUA, IND); regulatory terms may have divergent popular meanings (eg, "approved," "authorized").
- Administration of the MCM may contradict everyday norms and personal experiences (eg, "expired" SNS stock, unfamiliar use of familiar drug, administration by non-traditional provider).

Unequal Supply and Demand

- A novel and/or highly lethal threat prompts unwarranted demand among low-risk groups.
- Unaware high-risk individuals and groups do not seek out beneficial MCMs.
- High-risk groups and infected persons facing a highly-lethal disease strongly desire access to unproven MCMs that are very early in development.
- A system of designated priority groups determines access to scarce MCMs.
- Too few MCMs exist to meet genuine needs in an emergency.
- Empty-handed or out of misplaced belief or misinformation, people turn to unsafe, ineffective, or fraudulent alternatives.

Discordant Authoritative Voices

- Different health officials issue divergent guidance on MCM allocation and administration.
- Health professional guidance competes with advice from other trusted sources (eg, media, political, religious, community).
- Information on benefits/risks may change as MCMs are used and clinical information is reviewed, which could alter their recommended use.
- Opinions differ on using randomized controlled trials to test efficacy of MCMs in an emergency
- Authorities are split on the MCM risk/benefit balance.
- Public health authorities overseas promote or prohibit a MCM contrary to US practice.

Under-Represented Groups Poorly Served by Status Quo

- Prior grievances with biomedicine or public health erode trust in MCM recommendations.
- Individuals do not access critical MCM information because major health institutions remain unschooled in how language, culture, and citizenship status can throw up barriers.
- MCM guidance for pregnant women, children, and other at-risk groups must be issued despite limited data on safety, efficacy and dosing.

of 2014, the project team submitted draft cases for review by the EWG, the sponsor, and 4 external referees a year later. FDA offered written and verbal feedback on October 22, 2015. EWG members proposed revisions via individual written comments and group discussion at a meeting on October 26, 2015 at the Center's Baltimore offices. External reviewers provided in-depth written comments during the fall of 2015.

After discussing a revision plan with the sponsor, the project team conducted an additional round of data gathering, including follow-up FDA interviews, and they completed a second draft of the casebook in March 2016. In April 2016, 4 EWG members, with expertise in risk and crisis communication reviewed the case chapters, and the project team incorporated their suggestions to produce the penultimate draft. The sponsor performed a final review in May 2016, to which the project team responded with further refinements, producing the final draft represented here. Any errors and omissions that remain in the casebook are those of the project team.

The case studies manifest certain limitations: they do not constitute a comprehensive assessment of every public message or communication activity undertaken by FDA during the incidents examined; the project team was limited to publicly available information and did not have access to internal FDA communication information; and, the use of older examples like anthrax predate the establishment of FDA's MCMi and the PHEMCE, two important initiatives that evolved to help address some of the challenges and "lessons learned" noted in specific cases.

The individual case studies that follow provide a brief overview of the emergency, depictions of significant communication issues for FDA and its partners, and an outline of implications including specific actions for the FDA to manage similar or analogous challenges better in the future. Though they span a period of 15 years, the highlighted dilemmas and mitigation strategies have direct relevance to today's practice. That is, they reflect persistent and significant concerns, involve high-stakes lessons whose continued application by FDA is critical, and/or illustrate foundational "best practices" that individuals new to MCM emergency communication should adopt.

Appendix A.
FDA's MCM Mission and Collaborators:
Setting the Context for MCM Emergency Communication

The FDA's overarching objective in relation to MCMs is to "facilitate the development of and access to safe, effective, and quality MCMs" to manage the health impacts of CBRN emergencies and emerging infectious disease threats.[2] The organizational structure underpinning this objective is the Medical Countermeasures Initiative (MCMi), coordinated by the Office of Counterterrorism and Emerging Threats (OCET), within the FDA Office of the Chief Scientist, in partnership with other FDA offices and centers, including the Office of Regulatory Affairs (ORA) and the agency's 3 medical product centers – Center for Biologics Evaluation and Research (CBER), Center for Drug Evaluation and Research (CDER), and Center for Devices and Radiological Health (CDRH).[3] The MCMi was launched in 2010 to capitalize upon the FDA's existing MCM programs, and by applying additional resources, to expand and strengthen the agency's MCM efforts even further, addressing many of the issues identified during the anthrax and H1N1 responses.[3]

The FDA engages in an array of activities to help advance the development and availability of MCMs. These activities stretch across the entire MCM life cycle and include:

- Expanding the scientific knowledge base to support regulatory decision-making. Through intra- and extramural research support and strategic partnerships with US government agencies, academia, and industry, FDA works to continuously improve the scientific and technical means for assessing MCM safety, efficacy, quality, and performance.[2]
- Conducting efficient and effective regulatory review. Tasks in this vein include clarifying for sponsors, applicants, and the federal agencies supporting product development the requirements for approving or making available investigational MCMs, as well as reviewing and approving MCM marketing applications that meet standards for safety, efficacy and quality.[2]
- Helping ensure an adequate supply of MCMs, as exemplified by granting expiry dating extensions for MCMs after testing them for stability and quality and by inspecting MCM production facilities to ensure the use of current good manufacturing practices and to proactively resolve issues that could lead to potential product shortages.[2]
- Facilitating a swift and effective emergency response. Illustrative tasks include expediting the regulatory review of data for critical products in the development pipeline; when

Appendix A, contd.

- (contd.) necessary, enabling access to potentially available MCMs that are not approved by the FDA through an appropriate mechanism such as an Emergency Use Authorization (EUA); and monitoring the MCM supply chain to identify and forecast product shortages and potential promotion of fraudulent products.[2]
- Providing technical support, with regard to the regulatory matters within FDA's authority, to key MCM partners including the state, tribal, local, and territorial (STLT) stakeholders charged with stockpiling, distributing, and dispensing or administering MCMs during and in anticipation of a health emergency.[4]

Along with the larger MCM community, the FDA participates in the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). Led by the US Department of Health and Human Services (HHS) Assistant Secretary for Preparedness and Response (ASPR) in the interest of national health security, the PHEMCE is the body that coordinates the MCM-related efforts within HHS (ie, FDA, Centers for Disease Control and Prevention [CDC], and National Institutes of Health [NIH]) and in cooperation with interagency partners at the Departments of Veteran Affairs (VA), Defense (DoD), Homeland Security (DHS), and Agriculture (USDA).[1] The PHEMCE also engages non-Federal partners including STLT governments, public health systems, academia, private industry, and the larger US population.[1]

Complex divisions of labor exist among the PHEMCE federal partners, with each agency at times playing either a leading or supporting role, depending upon the mission component as well as agency authority and jurisdiction.[5] A sampling of HHS agencies and their leading roles in relation to MCMs for the civilian population follow below, to help put FDA's contributions (and its communication role) in context; readers are encouraged to consult more comprehensive accounts1 for further clarification and detail:

- ASPR is responsible for developing the strategic framework to prioritize PHEMCE resources and investments, based on the DHS-led threat and risk assessment, and other inputs such as medical consequence and public health response assessments.[5] Via the Biomedical Advanced Research and Development Authority (BARDA), ASPR leads in supporting the advanced development and scale up of MCM manufacturing capacity and in the procurement of certain MCMs for the Strategic National Stockpile (SNS).[5]

Appendix A, contd.

- CDC leads the procurement and maintenance of the commercially available MCMs amassed for the SNS.[5] In collaboration with ASPR, CDC also coordinates the development of federal response plans, policy, guidance, and communication; develops strategies for the allocation and clinical use of MCMs; and coordinates interactions with STLT and private entities "to provide timely and effective deployment, distribution, dispensing, and administration" of MCMs in an emergency.[5]
- NIH carries out and supports basic research on health threats; the knowledge generated then informs the development of medical products as well as strategies for prevention, diagnosis, and treatment.[5] NIH plays an important support role in evaluating MCM safety and performance, such as through clinical trials management.[5]
- FDA's role is to ensure MCMs are safe and effective, including – in conjunction with the CDC – monitoring the safety and performance of deployed MCMs during and after a public health emergency.[5]

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