

Recommendations on How to Manage Anticipated Communication Dilemmas Involving Medical Countermeasures in an Emergency

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Abstract

National investments to facilitate prompt access to safe and effective medical countermeasures (MCMs) (ie, products used to diagnose, prevent, protect from, or treat conditions associated with chemical, biological, radiological, or nuclear threats, or emerging infectious diseases) have little merit if people are not willing to take a recommended MCM during an emergency or inadvertently misuse or miss out on a recommended MCM during an emergency. Informed by the Expert Working Group on MCM Emergency Communication, the Johns Hopkins Center for Health Security developed recommendations for achieving desired public health outcomes through improved MCM communication based on a review of model practices in risk communication, crisis communication, and public warnings; detailed analysis of recent health crises involving MCMs; and development of a scenario depicting future MCM communication dilemmas. The public's topics of concern, emotional requirements, capacity for processing information, and health needs will evolve as an emergency unfolds, from a pre-event period of routine conditions, to a crisis state, to a post-event period of reflection. Thus, MCM communication by public health authorities requires a phased approach that spans from building up a reputation as a trusted steward of MCMs between crises to developing recovery-focused messages about applying newly acquired data about MCM safety, efficacy, and accessibility to improve future situations.

Keywords

medical countermeasures, risk communication, public health emergency, crisis communication, emergency preparedness

The nation must have the nimble, flexible capability to produce and effectively use medical countermeasures (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.

—2016 Public Health Emergency Medical Countermeasures Enterprise Strategy and Implementation Plan¹

The US government has committed substantial resources to facilitate prompt, appropriate access to safe and effective medical countermeasures (MCMs)—drugs, biologics (eg, vaccines), and devices (eg, personal protective equipment) that are used to diagnose, prevent, protect from, or safely treat conditions arising in connection with an emerging infectious disease or a chemical, biological, radiological, or nuclear (CBRN) attack.^{1,2} Nonfederal partners also play critical roles in getting affected individuals and communities the right MCM at the right time during a crisis. For

example, researchers help uncover promising MCM products; pharmaceutical and biotechnology companies develop and manufacture various MCMs; and state, local, tribal, and territorial governments, public health systems, and nongovernmental partners plan jointly for mass distribution and dispensing.³⁻⁷

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These preparations are not useful, however, if people are not willing to take or inadvertently misuse a recommended MCM, or if consequential disparities exist in the level at which people can access knowledge about the risks and benefits of MCMs during an emergency.⁸⁻¹² The technical novelty of certain MCMs, accelerated regulatory approval, or other unfamiliar and/or complex circumstances may heighten people's perceived risk of MCMs, diminish public trust in MCM regulators or recommenders, or seed public aversion, all of which can jeopardize population health in an emergency.¹³⁻¹⁶ An amplified sense of fear and vulnerability during a CBRN event may lead some people to overdose on a prescribed MCM, based on the incorrect assumption that a greater quantity of an MCM is more protective than a small quantity, or lead those not at risk to demand an MCM that is best reserved for others.¹⁷⁻¹⁹

In 2014-2016, the Johns Hopkins Center for Health Security (formerly the UPMC [University of Pittsburgh Medical Center] Center for Health Security) undertook a communication research project to help public health authorities better ensure that the US population can get the full benefit of MCMs during an emergency. The project aim was to catalog MCM emergency communication dilemmas and, based on empirical research and expert judgment, to provide practical and strategic recommendations to public health communicators on how best to achieve desired outcomes.²⁰ To incorporate the best available science and meet end-user needs, the project team convened the Expert Working Group on MCM Emergency Communication Strategies to provide input to the project at all stages, including development and review of the final recommendations issued by the Johns Hopkins Center for Health Security.

An MCM communication dilemma, in the broad sense of a problem or difficult situation, has circumstance(s) that could contribute to the public's inappropriate use of an MCM, whether by dismissing it when it is needed, demanding it when it is not needed, denying it to others, or using other maladaptive behaviors that lead to negative population health outcomes. Public encounters with or perceptions of the MCM, the emergent health threat, the affected populations, and/or the responding authorities could generate MCM communication dilemmas. For example, MCM qualities that induce dread or run counter to everyday sensibilities; health threats that are novel, frightening, or dynamic; or groups that exist at the margins of society with limited access to essential health information and/or who are distrustful of authority figures could all generate MCM communication dilemmas (Table).

This report summarizes project findings on how health emergencies and MCMs can cause public communication dilemmas. The report forecasts how MCM communication dynamics are likely to evolve and recommends steps for public health communications before, during, and after a health emergency. The goal of this report was to help preserve public trust in MCMs for use in emergencies and to ensure their appropriate use.

Methods

Stakeholder Input

The 26-person Expert Working Group included risk and crisis communication scholars; MCM developers, producers, and regulators; practitioners in medicine, public health, and pharmacy science; and experienced public health emergency managers (Box 1). Federal interagency representation included the Centers for Disease Control and Prevention, the National Institutes of Health, the US Food and Drug Administration (FDA, former staff member), and the Office of the Assistant Secretary for Preparedness and Response with the US Department of Health and Human Services. The Center for Health Security project team elicited input from the Expert Working Group through in-depth interviews in fall 2014 to collect initial ideas about MCM communication dilemmas and their management; 2 one-day, in-person meetings in Baltimore, Maryland, on June 9, 2015, and October 26, 2015, to consider MCM communication lessons learned from a comprehensive literature review, a study of recent health emergencies, and a prospective scenario forecasting communication challenges on the horizon; and circulation by email for review and revision of the documentation that emerged from the literature review, retrospective study, and prospective scenario.

Literature Review

In preparation for the first working group meeting, the project team conducted an initial literature review (of works published up to December 2014) to identify model practices in risk communication, crisis communication, and public warnings and their application in the context of a public health emergency. The project team performed an online review of the available scholarly literature using PubMed and Google Scholar, and used the Google search engine to identify relevant nongovernmental and governmental reports. The project team used the following search terms: "health emergency," "public health preparedness," "best practices," "model practices," "crisis communication," "risk communication," "emergency communication," and "public warnings"; the project team then selected studies and reports based on their relevance to the project's MCM focus. The Expert Working Group reviewed a summary of the literature review findings at the June 9, 2015, meeting and recommended further resources and themes to consider in relation to the management of MCM communication dilemmas (eg, social disparities in health information access). The project team researched the recommended sources and issues, repeated former keyword searches, and prepared a second summary of findings for review by the Expert Working Group at its October 26, 2015, meeting.

Case Studies

The project team developed detailed case studies for 4 health emergencies involving MCMs: 2014-2015 West Africa

Table. Examples of medical countermeasure (MCM)^a emergency communication dilemmas,^b by category

Category	Examples
Certain MCM aspects make the public uneasy.	
<ul style="list-style-type: none"> ● Attributes of the MCM <ul style="list-style-type: none"> ○ Induce dread. ○ Suggest that an MCM product is unsafe because it is not fully tested. ○ Raise fears because the MCM has been adulterated. ● Unfamiliar technical jargon spurs misunderstanding. ● Regulatory process seems opaque because: <ul style="list-style-type: none"> ○ Regulatory mechanisms under which an MCM is being made available are unfamiliar. ○ Regulatory terms have ambiguous popular meanings. ● Administration of the MCM might contradict everyday norms and personal experiences. 	<ul style="list-style-type: none"> ● Irradiated or genetically modified component ● Developed via the animal rule, in clinical trial, under accelerated regulatory approval, and/or in sped-up surge production ● Adjuvanted or compounded ● Killed vs live vaccine, egg-based vs cell-based production ● Emergency use authorization, investigational new drug ● Approved, authorized ● Use of expired products in the Strategic National Stockpile, unfamiliar use of a familiar drug, or administration by a nontraditional provider
MCM supply and demand are out of sync.	
<ul style="list-style-type: none"> ● A novel and/or highly lethal threat prompts unwarranted demand among low-risk groups. ● High-risk individuals and groups are not aware of the threat and/or the appropriate MCM and, as a result, do not seek out the recommended MCM. ● High-risk groups and infected people 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, potentially eliciting public concern about being left out. ● Too few MCMs exist to meet genuine needs in an emergency. ● Out of misplaced belief or misinformation, or because they are unable to access MCMs, people turn to unsafe, ineffective, or fraudulent alternatives. 	<ul style="list-style-type: none"> ● After the shock of the 9/11 attacks, and as cases of anthrax infection emerged in connection with tainted letters, public demand for ciprofloxacin escalated, affecting decisions about the antibiotic's production and distribution.²¹ ● During the 2009 H1N1 influenza pandemic, pregnant women were more likely than women in general to have concerns about the vaccine and to resist vaccination, despite being more vulnerable to complications from H1N1 infections.²² ● During the 2014-2015 West Africa Ebola epidemic, as investigational vaccines and therapeutics began to show efficacy in animal trials and safety in Phase I clinical trials, public demand arose for the compassionate use of the potentially life-saving MCM in affected communities, a position argued as the most ethical. Some experts countered that using MCMs without knowing whether the products would help, prove useless, or even harm those who took them would be itself unethical.²³ ● During the 2009 H1N1 influenza pandemic, local public health departments and organizations opted to implement national vaccination guidelines in various ways as a result of the limited supply of vaccine, the availability of various formulations, and on-the-ground exigencies. Various applications of the priority group framework, especially when occurring in close geographic proximity, led some people to wonder why one jurisdiction was vaccinating a certain subset of its population and another was not.²⁴ ● In a pandemic influenza, the supply of vaccine—given current technology—will exceed demand, at least during the initial stages of the crisis. It typically takes approximately 6 months from the outset of any outbreak for the first doses to become available, and logistical challenges will likely slow down distribution and affect early availability.²⁵ ● In the United States, after the 2011 Fukushima nuclear accident, some consumers sought out potassium iodide—in some cases, they unknowingly purchased fake potassium iodide—despite messages by health authorities not to purchase, stockpile, or administer the drug. Moreover, when potassium iodide was not available, some people turned to salt and other dietary supplements as potential remedies for perceived risks from radiation exposure.²⁶
Authorities have discordant views on MCMs.	
<ul style="list-style-type: none"> ● Various health officials issue divergent guidance on MCM allocation and administration. 	<ul style="list-style-type: none"> ● During the anthrax attacks, health authorities in Maryland and Virginia followed CDC guidelines about prophylaxis, whereas authorities in Washington, DC, had their own policy. Differences among the jurisdictions fostered confusion in affected groups about which advice to follow, whether that from the jurisdiction in which they worked or the jurisdiction in which they lived.²⁷

(continued)

Table. (continued)

Category	Examples
<ul style="list-style-type: none"> Health professional guidance competes with advice from other trusted sources (eg, media, political, religious, community). 	<ul style="list-style-type: none"> Among low-income African Americans in Los Angeles County, California, longstanding distrust in the US government stemming from the Tuskegee experiment led local faith-based leaders to urge congregants not to accept the H1N1 pandemic influenza vaccine, local disc jockeys to advise their African American audiences against vaccination, and community members to forward chain emails and to like Facebook posts with anti-vaccination messages.²⁸
<ul style="list-style-type: none"> Information on benefits and risks change as MCMs are used and clinical information is reviewed, which alters their recommended use. 	<ul style="list-style-type: none"> During the anthrax attacks, CDC switched from recommending costly ciprofloxacin to inexpensive doxycycline as an equally efficacious, prophylactic antibiotic for inhalational anthrax. Some observers perceived the shift as an instance of health care inequity because postal workers received doxycycline, whereas Capitol Hill employees received ciprofloxacin.²⁷
<ul style="list-style-type: none"> Opinions differ on using randomized controlled trials to test efficacy of MCMs in an emergency. 	<ul style="list-style-type: none"> During the 2014-2015 West Africa Ebola epidemic, compassionate-use advocates saw broad distribution of investigational vaccines and therapeutics as the best way to provide the most benefit to the most people in an outbreak with a high case fatality rate. They argued that clinical trials were unnecessary because historical data from Ebola outbreaks could serve as a control group and that giving someone a placebo in the Ebola context would be unethical. In contrast, others asserted that a trial design without a placebo control group would be invalid and unethical, random allocation would more fairly distribute a scarce resource that could also cause more harm than benefit, and a randomized controlled trial was the most robust study design for testing efficacy.²⁰
<ul style="list-style-type: none"> Public health authorities overseas promote or prohibit an MCM in contrast to US policy and practice. 	<ul style="list-style-type: none"> As a result of manufacturing problems, a predicted shortfall occurred in mid-2017 of the yellow fever vaccine currently approved by the FDA (YF-VAX) at a time when the mosquito-borne disease posed an increased threat. In response to the shortage, the FDA allowed the manufacturer to import into the United States another yellow fever vaccine licensed in 70 other countries, as an expanded access investigational new drug.²⁹
Certain groups have unmet or poorly considered needs.	
<ul style="list-style-type: none"> Previous grievances with biomedicine or public health erode trust in MCM recommendations. 	<ul style="list-style-type: none"> Some African American postal workers potentially exposed to anthrax during the 2001 letter attacks were hesitant to be vaccinated and expressed fears of being experimented upon given the lack of a public health consensus about the value of the anthrax vaccine against the historic background of the Tuskegee experiment.⁹
<ul style="list-style-type: none"> Individuals do not access critical MCM information because major health institutions remain unschooled in how language, culture, and citizenship status can create barriers. 	<ul style="list-style-type: none"> During the 2009 H1N1 influenza pandemic, some migrant and seasonal farmworkers—whether documented or undocumented—hesitated to travel to clinics for information, vaccination, and/or treatment, fearing deportation with federal Immigration and Customs Enforcement officials present in local communities.³⁰
<ul style="list-style-type: none"> Guidance for pregnant women, children, and other at-risk groups must be issued despite limited data on safety, efficacy, and dosing. 	<ul style="list-style-type: none"> Constituting 25% of the US population, children have age-specific characteristics (eg, increased skin permeability, faster metabolism, higher respiratory rate, greater surface area-to-mass ratio) that increase their vulnerability to the effects of chemical, biological, radiologic, and nuclear threats.³¹ Despite children being more often severely affected in disasters, many vaccines and pharmaceuticals approved for use by adults as MCMs do not currently have pediatric formulations (eg, liquid vs pill form), dosing information, or safety information.³²

Abbreviations: CDC, Centers for Disease Control and Prevention; FDA, US Food and Drug Administration.

^aDrugs, biologics (eg, vaccines), and devices (eg, personal protective equipment) used to diagnose, prevent, protect from, or safely treat conditions arising in connection with a natural disease emergency or a chemical, biological, radiological, or nuclear attack.

^bComplex circumstances in which effective communication may help counteract the public misunderstanding, misusing, or missing out on a recommended MCM during a public health emergency.

Box I. Expert Working Group on Medical Countermeasure Emergency Communication Strategies
(affiliations as of April 2018)

- Rear Admiral Kenneth W. Bernard, MD, US Public Health Service (Ret), Senior Advisor for National Security and Health, National Security and Health Consulting; former Special Advisor, White House National Security Council
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- Kevin M. Fain, JD, MPH, Senior Advisor for Policy and Research, ClinicalTrials.gov Program, National Library of Medicine, National Institutes of Health
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- Michael G. Kurilla, MD, PhD, Clinical Innovation Director, National Center for Advancing Translational Science, Division of Clinical Innovation; former Director, Office of BioDefense, Research Resources, and Translational Research; Associate Director of BioDefense Product Development, Division of Microbiology and Infectious Diseases, National Institute of Allergy and Infectious Diseases, National Institutes of Health
- Heidi J. Larson, PhD, Director, The Vaccine Confidence Project; Professor of Anthropology, Risk and Decision Science, Department of Infectious Disease Epidemiology, London School of Hygiene and Tropical Medicine
- Captain Deborah Levy, PhD, MPH, US Public Health Service (Ret), Chair and Professor, Department of Epidemiology, University of Nebraska Medical Center
- Meredith Li-Vollmer, PhD, MA, Risk Communication Specialist, Public Health–Seattle & King County; Clinical Assistant Professor, University of Washington School of Public Health and Community Medicine
- Linda M. MacIntyre, PhD, RN, Chief Nurse, American Red Cross
- Gretchen Michael, JD, Director of Communications, Office of the Assistant Secretary for Preparedness and Response, US Department of Health and Human Services
- Seth Mnookin, Professor of Science Writing and Director of the Graduate Program in Science Writing, MIT
- Colonel Ann Norwood, MD, US Army (Ret), former Senior Associate, UPMC Center for Health Security
- Cynthia Pellegrini, Senior Vice President, Public Policy and Government Affairs, March of Dimes
- Greg Pratt, RPh, BSPHarm, Pharmacist, Sparrow Health System; former Emergency Preparedness Coordinator, Michigan Pharmacists Association
- Sandra Crouse Quinn, PhD, Professor and Chair, Department of Family Science, and Senior Associate Director, Maryland Center for Health Equity, School of Public Health, University of Maryland
- Richard Reed, MSW, Head, Corporate Emergency Management and Continuity, Saudi Aramco; former Senior Vice President, Disaster Cycle Services, American Red Cross
- Mitch Rothholz, RPh, MBA, Chief of Staff, American Pharmacists Association
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Ebola outbreak, 2011 Fukushima nuclear accident, 2009-2010 H1N1 influenza pandemic, and 2001 anthrax letter attacks. Each case study, whose complete findings are included in the final project report,²⁰ included an overview of the emergency and timeline of events, a depiction of important MCM communication issues for health authorities, and an outline of implications, including actions to take to

better manage similar or analogous challenges in the future. Case study development entailed a recursive process of research and analysis by the project team, review and feedback from the Expert Working Group and FDA project sponsors, and external review by 4 people (2 industry authorities on MCMs, 1 risk communication scholar, and 1 public health practitioner with risk communication expertise). In gathering

data for the case studies, the project team relied on secondary sources (ie, scholarly literature, nongovernmental and governmental reports, news accounts) and key informant interviews.

Prospective Scenario

The project team developed a fictional scenario, “The SPARS Pandemic: 2025-2028,” to enable the Expert Working Group to consider MCM communication dilemmas plausibly on the horizon.³³ The project team developed this scenario using the inductive and deductive approaches delineated by Ogilvy and Schwartz.³⁴ The team began with the focal issue—what is the future of emergency communication about MCMs during the next 10 years?—and then considered the key economic, environmental, political, social, and technological factors they felt were likely to emerge in that time frame. The team, which included subject matter experts in epidemiology, public health preparedness, risk communication, and the biological and social sciences, then decided which factors seemed inevitable given present conditions and which were the most likely to affect the direction of the scenario. With these influential trends in mind, the team created a matrix of 4 possible futures and ultimately selected a world composed of socially isolated and highly fragmented communities with widespread access to information technology—dubbed “the echo-chamber”—in which to develop storylines for the fictional scenario.

Findings

The project team engaged the Expert Working Group in the review, deliberation, and revision of project documents, including the literature search, case studies, and prospective scenario. The project team first identified objectives of an optimal MCM campaign that public communication supports and then examined the features of MCMs and health emergencies that generate communication dilemmas. Characteristics of a successful MCM campaign include the following outcomes and conditions:

- Citizens are able to make smart, informed decisions about MCM uptake.
- Uptake results in a public health outcome of maximized benefit and minimized harm, including psychological effects.
- Individuals and groups most in need of MCMs have ready access to the product(s), and health authorities allocate scarce, potentially life-saving MCMs in ways that preserve public lives and public trust.
- The public has the information needed to discern and refuse false product claims and fraudulent products.
- Unproven MCMs undergo scientifically rigorous testing so that health authorities have interpretable data on product safety and efficacy.

Factors That Make Emergency Communication for MCMs More Complex

Potentially impeding the aforementioned aims are the atypical attributes of the drugs, vaccines, and medical devices being developed to manage public health emergencies that can elevate the public’s discomfort and/or hesitancy. MCMs as a class are often novel, rare, and limited in supply. Insufficient MCMs exist for preventive and therapeutic purposes to match the number and diversity of high-priority threats. Although the nation’s MCM inventory includes large quantities of some well-established products (eg, name-brand antibiotics), many CBRN countermeasures are recent innovations (eg, novel diagnostic platforms) that are still under development and/or not scaled for mass production. Some MCMs may be among the first being developed for a threat, potentially through innovative recombinant and molecular techniques.^{35,36}

MCMs target health threats that are extraordinary and could trigger a maladaptive public response. MCMs are intended to protect against high-priority threats that could affect US national security.² These 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 widespread fear (eg, anthrax, nerve agents, radiological agents, smallpox, and viral hemorrhagic fevers).

MCMs used in an emergency may have limited previous clinical experience in humans. Many 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. MCMs may have been approved by the FDA based on efficacy studies in animals, may be unapproved but authorized for use during a crisis, or may not have been previously used in certain populations (eg, pediatric populations). During the public health response, informed clinical decisions require near-real-time monitoring and assessment of MCM performance (eg, enhanced adverse event tracking, reporting, analysis, and communication).²

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; enabling postal carriers to supply households with antibiotics in the event of an anthrax attack; making available streamlined emergency use instructions).³⁷ In the case of an unapproved, investigational product or the unapproved use of an approved product, the FDA has certain mechanisms to facilitate emergency access (eg, Investigational New Drug or Investigational Device Exemption process, Emergency Use Authorization).²

Finally, liability immunity can exist for an MCM-related claim of loss. The US Secretary of Health and Human

Services can issue a Public Readiness and Emergency Preparedness Act declaration to confer liability protection (absent willful misconduct) in relation to the manufacture, testing, development, distribution, administration, and use of MCMs for an actual or potential emergency threat. Claimants may have recourse through the Countermeasures Injury Compensation Program.³⁷

MCM Communication Dynamics During the Life Cycle of an Emergency

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

Before an emergency, advance discussion about MCMs is difficult. Health threats are abstract and hold little personal relevance, given other more immediate concerns. People commonly believe that they are, as a rule, safe and that a disaster happens only to other people.³⁸ A person may be unaware of the risks and benefits of an MCM; if he or she is aware of an MCM, but no imminent threat exists, then the risks may be more salient than the benefits. Communication that enables individuals to personalize a risk, envision how certain actions protect against that risk, and have a degree of self-efficacy in performing such actions may motivate people to take protective measures in advance of an emergency (eg, learn more about an MCM or an agency's role in stewarding MCMs).^{39,40} Ongoing, repetitive, and mutually reinforcing messages from diverse sources are necessary to break through everyday background noise and to prompt a desired public behavior.⁴¹

Engaging in a preparedness behavior (eg, learning about local plans for MCM dissemination) is the result of many steps: thinking about surprise events in advance, seeking out more information, conferring with others, deciding to do something, and then taking action. A continuous stream of reinforcing messages can help people complete this sequence.⁴¹ Once preparedness messages are received, people typically confer with others, in person or via social media, to assess the importance and relevance of what they have heard. Moreover, people are more likely to engage in a preparedness behavior when they see others around them doing the same.⁴¹ People learn as they interact with the world, developing mental maps along the way that serve as heuristic devices (or shortcuts) for organizing information.^{39,42,43} The operating assumptions that individuals hold about health threats and MCMs in advance will shape how they subsequently react during an emergency.

Before an emergency, community partners (eg, community- and faith-based organizations, health professionals, private industry, schools and universities, social service providers, volunteer groups) can enhance the reach and reception of official MCM communication. By collaborating with diverse partners, health authorities can better

understand audiences, tailor messages accordingly, and enlist additional spokespeople who are respected in their own communities.⁴¹ The routine, non-crisis timeframe allows public health entities to be more proactive (eg, developing careful messages about threats, MCMs, regulatory processes, and dissemination plans as part of a longer-term awareness-raising campaign).^{44,45}

During an emergency, the conditions for MCM communication shift as risk perception and public interest escalate. A health threat is present and potentially dangerous. However, individuals' perceptions of personal risk may not match what health professionals believe to be their actual risk based on the current science, whether higher or lower, and perceived risk may vary from one subpopulation to another.^{46,47} MCM risk and benefit information is more salient (ie, personally relevant and important), and public demand and the need for facts become more acute. When a threat is present, people are hungry for information; they rarely if ever get too much information.⁴⁸ 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 get more details before protective actions are started.⁴⁹

For people to implement the protective behavior desired by officials (eg, using MCMs), 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 that others are taking heed, deciding to take action, and acting on that decision.⁴⁸⁻⁵¹ Also affecting this process is whether the protective action is feasible.^{52,53} People who are worried and distressed because of a perceived threat have a reduced capacity to process information effectively and efficiently and to engage in complex decision making.^{39,42,50} Protective action messages should meet style and content criteria proven to prompt a desired public response.^{48,49}

Five kinds of information help to motivate public compliance with official protective actions in an emergency: (1) what (ie, the actions the public should take), (2) when (ie, by what time the action should be executed), (3) where and who (ie, which people should or should not take the action as described in everyday terms [eg, "individuals present in a 10-block radius of the Sears Building," "children from newborn infants to 5 years of age"]), (4) why (ie, the threat and how the protective action will reduce its impact), and (5) whose advice (ie, the person or entities providing the information).^{41,54} People respond well to messages that are free of jargon and use wording that is precise and non-ambiguous, accurate, and consistent.⁵⁴

At the outset of a crisis, an information deficit typically exists; circumstances are unfolding, facts are few, media interest is piqued, the scope of the problem is uncertain, communication channels may be disrupted, and only partial perspectives are possible. 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 officially clearing information before sharing it publicly.⁵⁵ The delay can lead to an information vacuum that is potentially filled by unreliable sources and inaccurate information. Information on MCM benefits and 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 about benefits and risks will require forthright explanation.

Exigencies during the emergency may require MCM-related message development on the fly, a focus on short-term problems, and quick delivery of information.^{44,45} Government-issued details on MCM risks and benefits and on recommended protective actions will not be the only information available to the public on those topics. Monitoring the sea of information in which the public is immersed can help reveal if conflicting information is inhibiting the desired response and, thus, inform necessary corrective actions.⁴¹

After the crisis period, 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. 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.⁵⁵ Themes of having or not having had access to an MCM and/or whether or not the MCM helped may figure prominently in their experiences and personal narratives of the health emergency.

During the recovery phase, people are in a state of reflection, trying to make sense of what happened and why. They rely on images, narratives, and frames of reference around them to help explain what was seen, heard, and felt, and to provide a meaningful framework for processes of coping, grieving, and rebounding.^{56,57} Post-crisis, themes of causality, responsibility, accountability, and the adequacy or inadequacy of the emergency response can dominate.^{44,55,56,58} In a world of instantaneous news and information saturation, the finger pointing that typically follows epidemics and disasters occurs with increasing speed and reach.^{58,59}

After a health emergency, stories held in common that give people's experiences of mass tragedy shared meaning and purpose help facilitate recovery after the event.⁶⁰⁻⁶² Publicly disseminated narratives that emphasize capability, adaptability, optimism, collective learning, and a focus on the future can help ease people's distress and restore their sense of well-being.^{44,60} In the aftermath of an extreme event, a window of opportunity opens for communicating messages that are otherwise ignored (eg, explanations of FDA processes to ensure MCM safety and efficacy before and during an emergency).^{63,64}

Project Recommendations

Based on the aforementioned evidence and expert judgment, the Johns Hopkins Center for Health Security developed

practical and strategic recommendations to public health communicators on how best to achieve desired outcomes; the Expert Working Group and 4 external experts in MCM and risk communication reviewed the guidance. Underresourced and heavily burdened public health agencies are often forced to communicate in an emergency from a reactive position. As a result, the Johns Hopkins Center for Health Security encourages health authorities and agencies to implement as many pre-crisis, preparatory steps as possible so that they can be nimble and influential in a crisis. Moreover, critical self-reflection and organizational retooling after a crisis will pre-position public health agencies for success in future emergencies. When communicating about MCMs, health authorities should implement the following priority actions while cognizant of broadly recommended best practice guidance^{44,65-68} (Box 2).

To stand as a credible source on MCM safety, efficacy, and accessibility during an emergency, public health agencies should strengthen their reputations between crises.

Advanced communication materials cannot anticipate every threat, MCM scenario, or public concern; as such, health authorities should engender greater understanding of, and faith in, their agencies' and the government's ability and commitment to protect public health and safety. When unique, unforeseen circumstances arise, public health agencies can then rely on established reputations when acting in relation to an MCM. Evidence suggests that an organization seen to be displaying proven core values (eg, public safety, equitable access, transparent decision making) during a crisis is more likely to enlist public support and to bolster its reputation.⁴⁴ That is, between crises, a public health agency can develop social capital as a respected authority from which it can then draw in an emergency. A public health agency should periodically assess credibility as a trusted MCM steward (eg, FDA as a gatekeeper for MCM safety and efficacy, CDC as a source of trusted recommendations for use of MCMs) and work to strengthen public standing on these matters between crises.

Before a crisis, public health agencies should network with intra- and interagency partners and external stakeholders to comprehend diverse audiences, coordinate communication resources, and build social capital.

Health authorities are not the sole communicators on MCM safety, efficacy, and accessibility; they need others to amplify messages and to know what diverse audiences require. Physicians, nurses, pharmacists, and other frontline professionals interpret MCM risks and benefits for the public, and people turn to these and other trusted sources for information. Traditional, new, and emerging media platforms transmit critical health information to diverse populations. Public health agencies can bolster current stakeholder ties and create new ones (eg, enlist offices of minority health in helping to uncover, understand, and address the MCM communication needs of vulnerable and historically underserved populations; reach further into health professional societies; and hold informational workshops for journalists

Box 2. Best practices for public health authorities to communicate risk in an emergency,^{44,65-68} endorsed by the Expert Working Group on Medical Countermeasures Emergency Communication Strategies, 2014-2016

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 stakeholders 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 and 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 information 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 and graphics to clarify messages, and use 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 detailed 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 and 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.

on how MCMs are approved, authorized, recommended, disseminated, and monitored).

Public health agencies should scan in advance for potential or persisting communication dilemmas, and develop and drill solutions that can preempt failure and enhance real-time responses with partners and stakeholders.⁴⁴

Tabletop exercises can focus on communication dilemmas, allowing public health agency personnel and their collaborators to rehearse challenges and solutions (eg, issuing a timely Emergency Use Authorization that strikes a 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; explaining how access to a scarce MCM is based on need and not political pull, financial means, or favorable social status). Simulations can use themes to generate collective ideas about mitigation (Table).

Before a crisis, public health agencies should research topics that affect their ability to facilitate good MCM outcomes in an emergency, develop and test messages, and investigate people's information consumption habits.

Advance research can fortify a public health agency's ability to communicate on MCMs in a crisis. Recent emergencies suggest that some topics and audiences require prompt, deep understanding: in particular, the sensitivity among historically underserved populations about unfair distribution of MCM risks or benefits and the moral ambiguity that some people attach to randomized controlled trials for investigational products amid mass tragedy (Table). By researching in advance public views and values about the appropriate use and clinical study of unproven MCMs during emergencies, public health agencies will be better prepared during the next crisis to embed any technical claims about the advantages of clinical studies in a larger, values-based narrative.

To meet the information needs of citizens who come from diverse cultural, social, and demographic backgrounds,

public health agencies should take steps to understand various audience segments and develop messages that address their concerns.^{9,69,70} In conjunction with efforts to better understand the needs and preferences of intended audiences, public health agencies can pretest messages, materials, and media to determine if they resonate with end users.⁷¹

During an emergency, public health agencies should deliver a clear, unambiguous signal to the public about the desired protective behavior in the context of a specific threat and MCM, if any.

When facing a direct personal threat or when witnessing a threat's impact on others, the public desires meaningful, accurate, and timely information about self-protection. To reduce illness and save lives, public health responders should coordinate at the interagency level to deliver MCM information in a way that supports an appropriate response. When the public seeks out MCMs unnecessarily, including the purchase of potentially ineffective or unsafe alternatives, public health agencies should empathize with the public's desire for self-protection and channel the impetus to act in a more positive direction (eg, direct people to additional sources of information about the threat and appropriate measures of self-protection).

Public health agencies can test the adequacy of a communication on MCM risks and benefits by determining whether it gives people the information needed to make an effective health decision, whether it reaches people via their normal information channels and consumption habits, and whether a person can apply it to make a sound choice.⁷² It is just as important to communicate to people who are not at risk and do not need MCMs as it is to communicate to those who are at risk because any unwarranted demand can contribute to scarcity conditions, potentially jeopardizing the well-being of those most in need.

During the crisis, public health agencies should monitor traditional and social media in real time to gauge public confidence in the MCM campaign, including rumors, knowledge gaps, and waxing or waning trust, and adjust outreach and messaging accordingly.

A strong social media presence can allow health authorities to listen to concerns and anticipate potential communication issues before they become full-fledged crises (eg, concerns about MCM use or uptake of alternative or fraudulent products). The relationships that make social media an effective tool (eg, members of the public who follow an official Facebook page or who retweet official messages) in an emergency are built over time. Although technology platforms will evolve, public health agencies should commit to provide messages to and monitor information from the public and providers via social media and adapt as new venues emerge.

Public health agencies should act on evidence-based communication advice when knowledge of the crisis is rapidly evolving and when the public's appraisals of MCM risks, benefits, and accessibility do not align with those of health authorities.

In conditions of uncertainty, it is important to admit limits to the public health system's ability to determine all aspects of the emergency because of missing, complex, or rapidly evolving information. Health authorities should share in the audience's distress and describe how they will get more answers. When MCM policy positions shift, health authorities should alert the audience, explain why the new information being provided differs from previous information, and acknowledge any emotive responses to the change.^{44,73} Health authorities should also recognize variables known to provoke public outrage, including dreaded hazards and perceived unfairness, moral indifference, and effects on vulnerable groups.⁷³ When these elements are present, do not dismiss them as mere misperception; rather, use language that speaks to community values (eg, fairness and compassion) and use supporting evidence to enhance public understanding of MCM risks and benefits and to foster public confidence that the public health agency is responding to community concerns.

Health authorities should communicate knowing the crises are time sensitive, and they should strive for minimal time lags in connection with internal clearance procedures for MCM communication.

Promptly communicating and staying ahead of the issues are critical, because for the public, the first source of information often becomes the preferred source.⁵⁵ Public health authorities should actively seek out opportunities to communicate with the media and the public to ensure that key messages are provided frequently and are readily accessible in the memories of target audiences.

After the emergency, health authorities should publicly share what they have learned from emergency MCM use, including response successes and missteps, and how organizations intend to evolve.⁴⁴

In the aftermath of an emergency, it is important to acknowledge blunders and outline how systematic changes are being implemented to improve MCM stewardship. Including external stakeholders in preparation of after-action reports about the MCM campaign can help to increase trust and provide viewpoints that reflect public concerns. Recommendations from after-action reviews should be quickly implemented.

Health authorities should develop crisis resolution and recovery messages in the early phases of the emergency to address anticipated issues, especially high-intensity dilemmas, such as MCM scarcity and adverse effects.

Like response, recovery requires deliberate planning to ensure the best outcomes for a community. Recovery narratives that confer meaning about the experience of mass tragedy and that are forward looking can help lessen people's distress.⁶⁰⁻⁶² For example, messages about plans to apply any newly acquired data about MCM safety, efficacy, and accessibility to improve future situations will be important for helping to renew a sense of well-being.

Public health agencies should conduct an after-action analysis of their performance as MCM emergency communicators and then incorporate needed improvements.

Potential questions to consider are: (1) How well did spokespeople perform? (2) Is more training in crisis and risk communication necessary? (3) Was the clearance process efficient? (4) Did unforeseen topics arise that deserve further audience research? (5) Could the agency have reached out more effectively to certain groups? and (6) What were the successes and how can they be repeated?

Public Health Practice Implications

MCM communication dilemmas represent complex circumstances that could inhibit the public's appropriate use of an MCM, whether that means disregarding it when it is needed, demanding it when it is not needed, denying it to others, or other behaviors leading to negative population health outcomes, diminished psychological resilience, and reduced confidence in government, science, and public health. Critical reflection on recent emergencies involving MCMs and on best practices from the risk communication, crisis communication, and public warnings literature provides health authorities with an opportunity to improve MCM communication in ways that can enable the US population to derive the full benefit of MCMs in future events. The Johns Hopkins Center for Health Security encourages public health authorities to implement pre-crisis, preparatory steps on potential MCM communication dilemmas so that they can be nimble and influential in a crisis. Critical self-reflection and organizational retooling afterward will also pre-position public health agencies for future success.

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