RISK-BASED DECISION MAKING DURING PUBLIC HEALTH EMERGENCIES INVOLVING ENVIRONMENTAL CONTAMINATION

by
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Dissertation Abstract

When major contamination emergencies involving chemical, biological, and radiological hazards occur, decisions about actions to protect public health are often needed very quickly. However, there is very little guidance for leaders about how to make these decisions, which may be very consequential. The goal of this research is to learn from disparate disciplines that deal with crisis decision making and risk-based decision making in order to understand the elements that are important for successful decision making in contamination emergencies, and translate those findings into a framework that can help guide risk assessors and decision makers through the process in future contamination emergencies.

This research was conducted in three parts. First, a case study on biological threat characterization was conducted using a modified Delphi approach to gather subject-matter expert opinion on the process of characterizing contaminants and conducting human-health risk assessment prior to an emergency. Second, an integrative literature review was conducted to bring together relevant findings from different types of literature from the fields of risk-based and crisis decision making. Finally, building on the findings of the literature review, semi-structured interviews with subject matter experts were held to discuss the important elements, information needs, and processes that can support a political-level decision maker such as a mayor or governor, who may be in the position of making these difficult decisions.

Findings from the Delphi case study revealed the importance of characterizing potential hazards before an emergency occurs, so that data about a contaminant and information about risk to human health can be used to make more-accurate decisions to protect the public's health. The literature review uncovered a number of key findings regarding cognitive factors affecting decisions, key sources and topics to incorporate into decisions, and decision-making processes and supporting structures that can improve the quality of decision making in a time-pressured and uncertain environment. Interviews with subject matter experts helped to further explore and validate the themes derived from the literature review, which were then condensed into a decision-making framework. This framework is intended to inform future development of guidance for mayors and governors.

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I dedicate this work to future decision makers who will be charged with protecting public health in the midst of chaos and uncertainty.

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Introduction

Public health emergencies involving environmental contamination require a rapid response from leaders and health officials, and risk-based decision making, to help ensure that public health is adequately protected. Yet, in such emergencies evidence about human health risks is often limited, making risk-based decisions difficult. Further compounding this difficulty is the fact that every decision has not only public health implications, but also economic, ethical, social, political, legal and, in many cases, environmental implications that must be considered.[1]

In contamination emergencies, decision makers are often thrust into a chaotic situation involving very high stakes.[2] Many times this happens without preparation or warning; in fact, decision makers are typically not equipped with the training or knowledge to make risk-based decisions. We know that, in these emergencies, decision makers often neglect to consider the multifaceted nature of every decision, sometimes making decisions that are politically motivated and not risk-based, or else making decisions based on science without regard to stakeholders and real world issues.[3]

Large contamination emergencies are not infrequent in the United States: in the last 16 years alone, major examples of public health emergencies involving chemical, biological or radiological contaminants include the anthrax letter attacks in October, 2001;[4] Hurricane Katrina in 2005;[5] the Deep Water Horizon (BP) oil spill in 2010;[6] the West Virginia Elk River chemical spill in 2014;[7] and the 2014 Ebola outbreak in West Africa, which resulted in cases imported to the United States and elsewhere in the world and decontamination efforts aimed at reducing further spread.[8] These incidents have involved a range of contaminants, circumstances, and affected populations. Yet, despite the heterogeneous nature of these events, there are also commonalities that can be considered when planning for future events.

Pre-Event Characterization of Risks

Decision making in contamination emergencies can be improved with access to better risk information.[2] However, data about the risks to human health posed by a contaminant may be limited or absent in an emergency because an agent has never been or has been incompletely characterized.[9,10] With a multitude of potential chemical, biological and radiological threats and scenarios to worry about, it is unrealistic to expect that human health risk data can be collected for all of them. Currently, there are tens of thousands of toxic industrial chemicals (TICs) and materials (TIMs) in use,[11] and potentially scores of biological contaminants, which would require risk assessment to understand the health effects related to contamination – many of which have not been characterized.[12] Radiological materials are better understood due to decades of work on nuclear defense, medicine, and power, but they are still incompletely characterized with regard to human health effects.[13]

Resources to conduct human health risk assessment on each chemical, biological or radiological (CBR) contaminant of concern are severely limited.[14] There is not enough time, political will, or funding at the local, state or federal government levels, or in academia, to characterize every CBR contaminant. Furthermore, industry often has a disincentive to produce and publicize high-quality risk assessment data on the CBR materials they use in business and rely on for economic viability.[15]

Yet, despite the size and difficulty of this challenge, it is not unreasonable to expect governmental and nongovernmental entities to make strategic investments toward improving CBR risk data to reduce uncertainty, and ultimately improve decision making in an emergency. Targeted investment in research to characterize a subset of CBR risks, including research on mechanisms of action (toxicology or pathology), dose-response, and health effects, can improve the odds of effective response when a disaster occurs.

Within the federal government, there are programs dedicated to improving data for CBR human health risk assessment and emergency response. Some federal programs conduct research focused generally on human health risks of contaminants regardless of their origin; namely, the Environmental Protection Agency (EPA). Some–the Department of Homeland Security (DHS) and Department of Defense (DoD)–focus more on intentional use of CBR agents and accidental releases.

Prioritization of federal resources for risk assessment and agent characterization is complicated. It is impossible to predict with certainty which contaminants will be involved in future disasters, and many other political, economic, and bureaucratic factors influence risk assessment priorities and timelines. However, each federal program aimed at reducing uncertainty regarding risks to human health from CBR contaminants has the need to prioritize research due to limited time and resource availability. There are many possible ways to accomplish this prioritization and many possible downstream consequences of every prioritization scheme.

Decision Making in the Midst of a Crisis

In every emergent environmental contamination event that threatens the health of the public, risk assessors must work quickly to understand and address the risks to public health via risk assessment, and then apply the findings of risk assessment to the emergency response through risk management and risk communication. However, even in the best of circumstances, risk assessment results alone often do not provide definitive answers to the complex questions in these emergencies. So, decision makers must be able to balance uncertain and incomplete scientific findings, ethics, and political and social realities in their decision making. In nonemergency periods, conduct of risk assessment in response to environmental contamination can be a deliberate and thorough process. In the setting of an emergency, the response must be rapid and yet still be accurate and appropriately protective of health.

Risk management does not lead to zero risk. So, it is up to leaders and residents of affected communities to take what is known about risk and use that knowledge to undertake risk tradeoff analyses regarding what levels of risk are acceptable and what tradeoffs need to be made in order to achieve acceptable risk.[16] The process of achieving acceptable risk in a community is greatly influenced by the handling of the response by public officials and decision makers.

Ideally, risk-based decisions would be made by risk managers who are familiar with the risk assessment process and have in-depth knowledge about the related scientific data and the circumstances of the contamination. In reality, and particularly in emergencies, risk management is often implemented by high-level political decision makers who are somewhat removed from the risk assessment process.[16] In an emergency, where stakes are high and media attention is intense, decisions in the United States tend to be made by a top public health official or emergency manager, or by a local, state or federal political leader such as a mayor, governor, or the president.

To improve the response to contamination emergencies, two important steps should be taken: 1) make an effort to reduce scientific uncertainty by collecting and improving risk data for contaminants that might be involved in emergencies, and 2) equip leaders with a framework that can guide decision making during such highly stressful and uncertain events. Currently, there is relatively little time or funding allocated to risk assessment for many CBR agents, and no such guidance on risk-based decisions in public health emergencies exists.

Research Goal

The purpose of this research is to gain an understanding of common issues and information needs that arise during contamination emergencies, regardless of the contaminants involved, in order to; 1) inform investments into pre-crisis risk characterization; and 2) build a decision framework that can serve as a guide for leaders as they make decisions during the early phases of response to these emergencies.

Study Aims and Research Questions

The specific aims of this research study included the following:

Specific Aim 1 – Explore approaches to improving risk information and availability of that information in contamination emergencies through pre-crisis characterization efforts

- *Research Question 1.1 - What do experts in biosecurity and biodefense think is important in characterizing biological threat agents?*
- *Research Question 1.2 - How can the findings be implemented so that public health officials are better informed by risk data in future events, and can be*

incorporated into the broader decision-making process along with other ethical, socioeconomic and political considerations?

Specific Aim 2 – Describe the process of making risk-based crisis decisions from the literature and from open source reports about real contamination emergencies.

- *Research Question 2.1 – What decision frameworks from the fields of risk analysis, risk management, risk-based and crises decision making, and other applicable fields have been used?*
- *Research Question 2.2 – How do the identified decision-making frameworks balance science/evidence, uncertainty, and social, political, legal and fiscal realities?*
- *Research Question 2.3 – What decision-making elements were included or excluded from real world events, and how did those elements shape the outcome of those events?*

Specific Aim 3 – Elicit information from experts about approaches to risk-based decision making, and develop a decision-making framework to guide political level leaders.

- *Research Question 3.1 – What is the process of decision making in real world contamination events?*
- *Research Question 3.2 – How are risk assessments carried out during a contamination emergency?*
- *Research Question 3.3 – What are the most important decision elements that should be considered in every contamination emergency that threatens public health?*

- *Research Question 3.4 – What format would decision makers find most useful to deliver guidance on risk-based decision making?*

Background Literature Review

The body of literature pertaining to risk-based decision making in emergency contamination events, including biological, chemical, and radiological events, is very limited. However, there are separate topic areas that do have distinct bodies of literature, which can be taken together to understand the full scope of the problem from the beginning of the emergency, through risk assessment and decision making.

In environmental health policy making, there has been a tendency to separate the science of risk analysis from the inherently political process of risk management and decision making.[17] Reasoning for this separation is understandable in that scientific fact should not be altered by outside factors such as political climate or social dynamics. However, as noted in *Science and Decisions: Advancing Risk Assessment* (known as the "Silver Book"), risk analysis does not exist in a vacuum and is often fraught with uncertainty.[18] It is important that risk assessors understand the other factors that influence decision makers when they incorporate risk information into their risk management decisions.[18] The Silver Book discusses and provides a framework for how risk assessors can make risk assessments maximally useful for decision makers. This framework includes three phases of the risk assessment process: planning and scoping of the risk assessment to ensure that it is answering the right questions; conduct of the assessment based on the plan, including hazard identification, dose-response assessment, exposure assessment, and risk characterization; and confirmation of utility to review whether the assessment has addressed the relevant questions, is scientifically sound, and provides enough information to inform risk management options. The framework also emphasizes pre-risk assessment problem formulation discussions, dialogue with risk assessment stakeholders throughout the process, and discussions with risk managers and communicators when decisions are made.[18]

Once a risk has been assessed, characterized, and translated into risk management options, decision makers use this information to make complex decisions that involve many considerations beyond the risk-based health information.[18] As part of its agency level decision-making process, the EPA has identified factors – in addition to risk assessment and characterization information – that play roles in decision making, including laws and regulatory requirements, economic analyses, sustainability, technical feasibility and impact, political considerations, and public and social considerations.[19] Other experts have detailed some of the sociopolitical considerations in decision making such as risk perception by experts and the general public, political climate and budget constraints, and cultural differences among affected populations.[20] While these factors are all separate from the scientific risk assessment process, they cannot be separated from the decision-making process in almost any context. Risk-based decisions are made in the real world and thus benefit from or are hampered by real-world conditions. Results of the risk assessment process are often not clear-cut, and scientific uncertainties can make decisions very difficult. So, while risk can and should inform decision making, it is rarely the only driving force behind a decision.

Human Health Risk Assessment in Emergencies

The literature base focused on conducting human health risk assessments in emergencies is small. Most of the literature covered in this review does not apply specifically to emergency situations, although a few examples could be found in the realm of radiological emergency risk assessment.

First, the term "emergency risk assessment" has been used in contexts other than scientific human health risk assessment. In particular, the emergency management/first responder community uses emergency risk assessment to mean: 1) a community preparedness planning assessment of the threats, hazards, and risks that a community might face in the future;[21, 22] and 2) a process for first responders to quickly assess the hazards and risks associated with responding to an emergency situation (e.g., structural integrity of a building on fire).[23] In both cases, the "risk assessment" process is high-level, is mainly qualitative and not quantitative, and is often not specifically or explicitly health-focused. This body of literature is not directly applicable to this research and will not be explored further.

There is a wealth of guidance by the EPA, the National Academy of Sciences (NAS), and other environmental agencies and organizations, about conducting routine human health risk analyses during nonemergency periods. These analyses are routinely conducted by the EPA and state agencies for the purpose of setting environmental standards for acceptable contamination levels in air and water, and to remediate hazardous waste sites to make them safe for human habitation. The most helpful guidance for routine risk analysis is *Science and Decisions: Advancing Risk Assessment* (known as the "Silver Book") from the NAS Committee on Improving Risk Analysis Approaches

Used by the US EPA.[18] This guidance builds upon the 1983 NAS "Red Book" titled *Risk Assessment in the Federal Government: Managing the Process*, and reviews and recommends updates to risk analysis approaches in use at the EPA.[17] The Silver Book concludes with a chapter on "Improving the Utility of Risk Assessment," which provides a framework to ensure that "risk assessment is maximally useful for decision making."[18] The framework proposed in this chapter provides an excellent guide for risk assessors and managers addressing all phases of the risk analysis process including problem formulation and scoping prior to the initiation of a risk assessment; planning and conduct of the risk assessment itself; and risk management and communication.

Recommendations by the NAS Committee in the Silver Book have since been taken into consideration by the EPA, which released updated guidance based on this proposed framework. The EPA *Framework for Human Health Risk Assessment to Inform Decision Making*, published in April 2014, puts into EPA practice those NAS recommendations for improving the utility of human health risk assessment. [19]Also in 2014, an article published in *Environmental Health Perspectives* titled "A Framework for the Next Generation of Risk Science," details some updated approaches to risk assessment discussed in the context of the EPA's NexGen project, which builds upon the Silver Book recommendations and is intended to make risk assessments "faster, less expensive, and more scientifically robust."[20]

In addition to the EPA and NAS guidance on conducting risk assessment, there are some hazard-based guides to conducting risk assessment specifically for biological, chemical or radiological materials. For biological agents, in 2012 the EPA issued *Guidelines for Microbial Risk Assessment* focused on food and water,[24] and there is a second edition text on all aspects of *Quantitative Microbial Risk Assessment.*[25] For chemical hazards, there are a number of resources on risk assessment on the EPA website including the Integrated Risk Information System (IRIS).[26] Also, the World Health Organization (WHO) provides a *WHO Human Health Risk Assessment Toolkit* for Chemical Hazards.[27] Finally, the EPA's risk assessment program provides radiological models and tools to calculate risk from radiological materials.[28]

The above publications are all important for establishing the scientific process of risk assessment, but they do not explicitly address how risk assessment should be undertaken during emergencies when time is of the essence and uncertainty is great. In each emergency contamination event, risk-minded public health and environmental health officials should conduct a rapid risk analysis to understand the human health risks and inform leaders about protection decisions. However, the process of conducting and implementing human health risk assessments in an emergency has largely not been captured in the literature with a few exceptions.

Only one article, published in 2012, could be found that discusses the general process of scientific human health risk assessment following a disaster. [29]This publication is focused on the exposure assessment step of risk assessment, and provides some high level recommendations for conducting exposure assessment during different phases of a disaster from "rescue to re-habitation."[29]

More has been written on the process of human health risk assessment in response to radiological and nuclear emergencies because of the world's experience with nuclear power, nuclear weapons, and nuclear and radiological disasters including Chernobyl, Three Mile Island, and Fukushima. One article, published in 2010 in *Health Physics*, discusses a proposed framework for radiation dose assessment for radiological public health emergencies (either accidental or intentional).[30] Other articles model the risks from radiological events including radiological dispersal device (RDD) and improvised nuclear device (IND) detonation and accidental releases.[31] Also, in 2013, the WHO published a health risk assessment of the Fukushima nuclear accident following the 2011 Great East Japan Earthquake and Tsunami.[32]

Generally, there is very little literature specifically focused on conducting emergency risk assessments following chemical accidents or attacks, or on conducting microbial risk assessments for natural, accidental, or intentional contamination events.

Nonemergency Risk Management Literature

The available literature on risk management is largely focused on nonemergency processes. This body of literature is important to understanding risk management, but it does not specifically provide guidance for emergency settings. However, the literature and guidance surrounding risk assessment for nonemergency periods is important to consider in the context of characterizing CBR contaminants to enable better decision making in an emergency. In this area, the Silver Book and EPA human health risk assessment guidance provide the most robust direction on risk management, specifically focused on characterizing risks for risk managers.[18,19]

One article on *Risk management frameworks for human health and environmental risks* provides some useful guiding ethical principles for risk management including: "beneficence and non-maleficence, justice, equity, utility, honesty, acceptability of risk, precaution, autonomy, flexibility, and practicality."[33] Taken together these principles are important points for risk managers and decision makers to consider alongside other factors identified in the literature, including legal and economic analysis, sociological, cultural and political contexts, and risk perception in the affected community.[20,33]

Risk Management in Emergencies

The available literature on risk management in emergencies is limited. Many of the risk management articles or reports in this area are "after-action" reports or articles that review the response to real disasters. In this literature it is common to find information about the general response to the disaster, but limited information about the decision processes that led to the response. So, while this literature is very useful for this research, it needs to be augmented by literature in the areas of risk-based and crisis decision making. The literature on risk management in contamination emergencies is largely focused on chemical releases, oil spills, and radiological/nuclear disasters, with the majority focused on radiological/nuclear disasters.

For major chemical emergencies, one important source of risk management information is *Learning from Disaster: Risk Management after Bhopal*. This text details the risk management process as it played out following the accident at the Union Carbide pesticide factory in Bhopal, India in 1984.[34] There are also articles focused on the response to more recent chemical spill emergencies, including for the Elk River chemical Spill in West Virginia n 2014,[35] and the Metam Sodium spill in the Sacramento River in California in 1991.[36] Each of these articles provides a retrospective critique of the risk management response, and some extract "lessons learned" from these responses. However, they do not provide a framework for decision making and risk management for future emergencies.

For oil spills, there are a number of recent after-action discussions about risk management. The most recent and most relevant to public health is the literature on the BP oil spill in 2010. Articles focused on the BP disaster primarily discuss the mistakes that BP made in managing the risks of system failure prior to the explosion and spill in 2010, and the mistakes the company made in managing the disaster itself.[37,38] The literature on oil spills does not tend to focus on the risks to the public's health; instead it focuses more on risks to the environment and ecosystem, and economic risks to industries and businesses in areas affected by oil spills.

There are a number of after-action reports and articles that discuss risk management following radiological emergencies, particularly following major nuclear power plant accidents. One article in the *Bulletin of the Atomic Scientist* highlights and compares risk management following three nuclear power plant emergencies: Three Mile Island, Chernobyl, and the Fukushima Daiichi Nuclear disasters. [39]There are also a number of after-action reports specifically on the Fukushima disaster, which is the most recent of the nuclear power plant disasters mentioned above. The major report on risk management for Fukushima is *The Fukushima Nuclear Accident and Crisis Management* book, published by the Sasakawa Peace Foundation in 2012.[40] This review assesses the Japan-USA response to Fukushima, including the risk management response, and the decision-making process that occurred.

Historical accidents, attacks, or natural disasters involving biological hazards do not appear to have the same volume of literature that captures the risk assessment and management processes in those events. The exception to this is the after action review of the "Amerithrax" anthrax letter attacks that occurred in October 2001. The US

Government Accountability Office (then the General Accounting Office) (GAO) reviewed the EPA cleanup response to the Anthrax attacks, in 2003.[41] This review mainly focused on the funds and contracts used by the EPA to do the cleanup, but does not specifically analyze the decisions that led to the cleanup itself. In 2005, The National Research Council Committee on Standards and Policies for Decontaminating Public Facilities Affected by Exposure to Harmful Biological Agents published a book on *Reopening Public Facilities After a Biological Attack: A Decision-Making Framework.*[42] This publication examines the question of "how clean is safe" for re-occupying a building with biological contamination. In this analysis, re-occupation decisions are discussed, and this document provides a good decision-making guide specific for biological contamination.[42]

Separately, in response to the threat of bioterrorism, the Department of Homeland Security (DHS) issued guidance for recovery from a bioterrorism incident, which provides planners with "Key Planning Factors" that they should consider in preparation for an event.[43] This guidance is not intended for real-time use by decision makers in the midst of a crisis, but is useful for preparedness planning.

Cognitive Basis of Crisis Decision Making

There is a large body of research dedicated to the biological and psychological factors in human decision making. Much of this literature is outside the scope of this research, including neurobiological studies of decision making that focus mainly on areas of the brain involved in decision making and neurological diseases that affect decision making. However, there is some relevant literature that describes the cognitive factors that influence judgment in stressful decision-making situations.[44,45] One interesting example of this research is the work by Daniel Kahneman, a social psychologist who won the Nobel Prize for economics in 2002. The work by Dr. Kahneman, and his collaborator Amos Tversky, focuses on the psychology underlying human judgment and decision making in times of uncertainty.[46] This literature is relevant because it helps define the factors that influence decision makers in a crisis. Understanding the psychological processes that affect a decision maker will aid in understanding what tools and processes can be put in place to improve decisions made in a crisis.

Risk-Based Decision Making

There is a substantial body of literature that focuses on risk-based decision making, much of which deals with financial risk or clinical risk-based decisions, which are generally outside of the scope of this dissertation research. There is a limited body of reports/studies on corporate or financial decision making following product contamination and recall events.[47]

The body of literature on decisions pertaining to human/population health risk assessment is smaller and mainly focused on decision making in nonemergency periods; for example, for superfund sites and urban hazardous waste remediation.[48,49] No literature was found that specifically focused on risk-based decision making during contamination emergencies.

The literature that focuses on risk-based decisions for nonemergencies includes the Silver Book and the EPA *Framework for Human Health Risk Assessment to Inform Decision Making*, already cited above.[18,19] Another foundational article in this area comes from the first volume of the journal of *Risk Analysis* in an article titled "Risk Analysis: Understanding 'How Safe is Safe Enough.'"[50] This article provides a definition of acceptable risk as "the risk associated with the best available alternatives."[50] The article goes on to discuss the evaluation of risk management alternatives and identifies other "complicating" technical social, political and ethical elements of the decision-making process for achieving acceptable risk.[50]

Crisis Decision Making in Public Health Emergencies

The topic of crisis decision making in public health emergencies does have a small established body of literature. Articles in this topic area focus not on scientific risk information as a basis for decision making, but on general approaches to decision making and on ethical decision making in public health emergencies.

One tool, published by the RAND Corporation in 2009, proposes measures of good crisis decisions in public health emergencies. According to RAND, elements of successful crisis decision making include the following processes: developing a common operating picture (situational awareness); deciding on actions that will mitigate human health effects ("action planning"); and management of the decision-making process (process control).[2]

Publications on ethical frameworks for decision making in public health crises include articles on the topics of pandemic influenza,[51] and on SARS.[52] These articles provide ethical frameworks to consider in future public health emergencies based on what occurred during those natural events.

METHODS

Conceptual Framework

Previous Conceptual Models

There is currently no one conceptual model or framework that encapsulates the topic of this dissertation: Risk-based decision making during public health emergencies involving environmental contamination. However, there are a number of conceptual models that capture parts of this problem and can be used to build a new conceptual framework for this research.

Conceptual frameworks from human health risk assessment, risk management, and risk-based and crisis decision making influenced the creation of this new conceptual model. Each of these pre-existing frameworks addresses a part of the problem identified in this research. The human health risk assessment framework from the Silver Book and the *EPA Framework for Human Health Risk Assessment to Inform Decision Making* provide guidance to make risk assessment information useable by decision makers.[18,19] Risk management literature for emergency responses is also influential, providing information about the various considerations that go into formulating risk management options. Finally, the crisis and risk-based decision-making literature that identifies public health actions following an emergency is important.

New Conceptual Model for Emergency Response to Contamination Events

As was addressed in the background literature review section of this dissertation, there is currently no unified approach to making risk-based decisions in a public health emergency involving environmental contamination (i.e., chemical, biological or radiological contamination via natural, accidental, or intentional means).

The conceptual model presented below attempts to capture the processes and information necessary to risk-based decision making in a contamination emergency that threatens public health. This conceptual model incorporates both pre-crisis risk assessment steps aimed at improving risk data for use in an emergency, as well as the components that contribute to risk-based decision making in the initial stages of a contamination emergency. The decision-making components in this framework include an initial assessment of the situation and identification of advisors to provide information and support for the decision maker; definition of the goals, objectives, and desired outcomes for the response; refinement of the situation assessment, gathering of data and evidence, and quick turn risk analysis; development of risk management options and deliberation of those options, informed by consultation with advisors and consideration of political realities, ethical boundaries, social and economic factors, and legal and fiscal constraints; and the decision that come from this deliberation. Included in this framework is the John Boyd concept of the cyclical process of decision making, which is characterized by observation, orientation, decision, and action (OODA), looping back to observation.[53] Following the decision, but outside the scope of this research, communication and implementation of the risk-based decision is essential. All of these steps must be applied rapidly but with enough fidelity that acceptable risk can be achieved in an affected community (Figure 1).

Aim 1

The purpose of Aim 1 is to conduct an in-depth case study of one program that is aimed at reducing scientific uncertainty and improving availability of risk data in advance of an emergency – the Biological Threat Characterization Program (BTCP) at the Department of Homeland Security (DHS).

Aim 1 Data Collection

A modified Delphi technique was employed to elicit judgments of national security, biosecurity, and biosafety experts, in order to understand their perception of the biological weapons threat and their opinions about biological threat characterization research conducted to address these threats. Experts were invited to participate in this study based on their responsibilities for shaping public policy in life science and national security, their expertise and knowledge in the field, or recommendations of other participants (using a snowball sampling methodology).

The Delphi survey instrument was developed through a series of subject matter expert interviews (a subset of those who participated in the Delphi survey) conducted during an earlier phase of the study. The Delphi survey was designed and administered online through SurveyMonkey®, and included questions with both quantitative and qualitative components. Question formats included percentage likelihood questions (0-100%), rating scale questions using a 1-10 scale (1 being low and 10 being high), binary questions (yes/no), and questions that required participants to choose one answer from a set of possible answers. Each question included a qualitative component where participants were required in round one and asked in round two to explain their answers. This is an important part of the process because, by giving participants in subsequent rounds insight into why other participants selected a given response, it allows respondents to calibrate their own estimates and minimize misperceptions about the nature of the questions and underlying assumptions.[54] The Delphi survey instrument was piloted by three subject matter experts and the project team, and was revised after the pilot to improve understandability of the questions, shorten the survey, and make the questions as useful as possible.

Once the survey instrument was piloted and revised, the survey was fielded to the 62 participants who agreed to take part in the study. Participants' names were removed to protect their identities and participants were assigned identification numbers. For the first round of the survey, Delphi participants were asked to respond to all questions and provide reasoning for each of their responses. Participants were given approximately one month to complete the first round of the Delphi survey. Once the first round was completed, the authors processed the data by producing frequency histograms and summary statistics for each question and sub-question, and providing all data and justifications in a readable, de-identified format for participants to review. This information was sent to participants along with a link to the round two survey instrument, which was unchanged except for some minor clarifying language.

In round two of the survey, participants were asked to review one another's answers, either amend or maintain their answers after reflecting on others' opinions, and respond to the survey again. Data and justifications from round two were again collected, processed, and analyzed.

Finally, the survey results for the two rounds were compared to determine "group stability" or response consistency between rounds. The Delphi process for this study was terminated when, for successive rounds, the mean response did not change more than 1 standard deviation (SD) across all questions, which occurred after two rounds.

Aim 1 Analysis

The final results (round two) of the study were analyzed using STATA statistical package 11.2. Data were first characterized using summary statistics (mean, median, mode, range, SD) and histograms. The data for each question were then analyzed for normality through a visual check of the data via histogram and then using the Shapiro-Wilk test as a statistical test of normality.[55] Many of the questions and sub-questions were non-normally distributed based on these analyses, which signaled the need for nonparametric tests in further analysis.

The Delphi data were analyzed by comparing the distributions of answers by subgroup (e.g., gender, age group, training or affiliation) and by comparing distributions of multiple sub-questions. For comparison of questions by subgroup, the Wilcoxon rank-sum test was used as a nonparametric hypothesis test to compare distributions.[56] The null-hypothesis of equal variance was rejected at the $p<0.05$ level.

Many of the questions in the Delphi survey included sub-questions, where participants rated each from 1-10. The authors analyzed these questions by comparing the distributions of all sub-questions using the Friedman test, a nonparametric test used for one-way repeated measures analysis of variance by ranks. When the null hypothesis of equal variance for the group of sub-questions was rejected at the $p<0.05$ level, post-hoc analyses were conducted comparing pairs of sub-questions using the Wilcoxon signed-rank test, which is a nonparametric test used for repeated variables.[57]

In order to reduce the likelihood of Type I error in comparing sub-questions (incorrectly rejecting the null hypothesis and reporting a significant finding falsely), we accounted for the problem of multiple comparisons, by applying a Bonferroni correction to each instance where multiple comparisons are made. The Bonferroni correction was applied by dividing the significance level of p=0.05 by the number of sub-questions being compared.[58]

Qualitative justifications provided by the participants were instrumental to the Delphi process. Participants were asked to use the qualitative justifications to shape the group's responses in the second round of the study. In addition to their use during the survey process, qualitative answers were used in the final analysis of the Delphi data, to help interpret the statistical findings from the quantitative component of the study. Following the statistical analysis, we reviewed the qualitative responses for each question to find reasoning for the different ratings seen in the data. The most relevant comments are reported to help explain each significant finding.

This research was submitted to the Institutional Review Board (IRB) of the University of Maryland and was granted exempt status (Appendix 1).

Aim 2

The purpose of research Aim 2 is: 1) to identify and analyze the literature with the goal of understanding different decision-making frameworks from the fields of risk analysis, risk management, risk-based and crises decision making, and other applicable fields; and 2) to understand the decision-making process through examination of publicly available information on recent real-world events including after-action reports that discuss decision processes

Aim 2 Data Collection

The integrative literature review format was chosen for this analysis because it is designed specifically for synthesis of literature "in an integrated way such that new frameworks and perspectives on the topic are generated."[59] Because there is currently no body of literature focused specifically on risk-based decision making in public health crises involving contamination, and much of the knowledge on this topic resides outside of traditional academic settings, this integrative method made it possible to analyze pertinent perspectives from multiple fields and types of literature and bring them together in a new framework. The literature review focused on two major categories: crisis decision making and risk-based decision making. These categories were chosen because they represent theoretical and operational viewpoints, as well as both the time-sensitive nature of crisis decisions and need for integration of data and other information to make informed decisions.

To conduct the search, the author chose three databases: *PubMed* to capture public health literature, *Web of Science* (all databases) to cover other scholarly publications on non-public health-related decision and risk assessment science, and *OAIster* to gather relevant grey literature and other open-access materials. The initial search was broadly inclusive to help ensure that no major literature was missed relating to the main topics of crisis and risk-based decision making and contamination emergency decision making. A number of key words and phrases were used to conduct the search. These were applied consistently to each of the three database searches (Table 7).

The initial search, conducted in February 2016, generated a total of 1895 pieces of literature for review. Of that total, 1303 were related to crisis decision making and 592 were related to risk-based decision making; and 522 were from *PubMed*, 897 were from *Web of Science*, and 476 came from *OAIster*. These results were then screened for relevance through review of titles, abstracts, and duplicate checking. A piece of literature was excluded in this first round of review if it was a duplicate, if it had no focus on decision making, if it had no focus on or relevance to public health or emergencies, if its focus was on personal decision making (e.g., personal medical decisions) without relevance to broader population-level decision contexts, or if it was a non-English language publication. This first level of review resulted in the inclusion of a total of 428 pieces of literature, including 265 related to crisis decision making and 163 related to risk-based decision making.

The author then implemented a second round of review to narrow down the time period for article inclusion and also to continue more in-depth review for relevancy. During this stage, literature inclusion was restricted to publication after the year 2000. This date was chosen because it was inclusive of a number of major contamination events in the US and around the world beginning with the anthrax letter attacks in 2001, and ensured that the literature would be relevant to modern decision-making contexts. Theories that are influential in the areas of risk-based and crisis decision making have been built upon over decades and still largely underpin current decision-making approaches. Thus, they should be adequately represented in this review in spite of the temporal restriction.

The second review round was conducted by reading abstracts and the full text of each included piece of literature. Exclusions were made based on the following criteria: publication prior to the year 2000; non-applicability to the short crisis decision-making time period that is the focus of this review; focus on environmental regulation and not on response to contamination events; and a focus on mathematical models and technological tools to aid in decision making that are not developed for use in emergencies. In this second round of review, a total of 370 articles were excluded. Fifty-one were included for final review and analysis, with 24 pieces of literature under the topic of crisis decision making and 27 under risk-based decision making.

Aim 2 Analysis

Once the second review round was completed, the author reread the 51 final articles and highlighted and organized findings using open coding and constant comparative methods of qualitative analysis. These methods were used rather than quantitative coding because they are meant to generate theoretical ideas and hypotheses from disparate types of evidence, and to refine them throughout the review process in order to develop a new theory or framework.[60] As part of this approach, each piece of literature was reviewed for relevant points under the initial categories of crisis and risk-based decision making. Relevant points were highlighted and notes about each piece of literature were recorded in an outline organized by category and theme as they emerged from the review. All reviewed literature was also recorded in a literature concept review matrix, which identifies conceptual frameworks employed, major findings, types of literature, strengths and weaknesses, and concept focus for each reference (Tables 8 and 9).[61] Findings from the final review stage were then summarized by category and topic area and are reflected in the discussion section of this review.

Aim 3

The purpose of this research aim is to obtain knowledge from experts in risk analysis, risk management, public health emergency response, and other related fields about the decision elements that are needed for effective risk-based decision-making in contamination emergencies.

Aim 3 Interview Guide Development

We first developed a semi-structured interview guide, based on findings from an integrative literature review, which identified major themes and decision elements that are important for contamination emergency decision making. Key domains for the interview guide included structures supporting decision making, decision-making process, and key considerations for decisions.

The interview guide was reviewed by multiple risk assessment, emergency management, and public health preparedness and response experts prior to its fielding, and was revised based on expert feedback. The guide was then piloted with an emergency management official with experience in contamination emergency response, and was subsequently revised based on feedback from that pilot interview.

Aim 3 Selection and Recruitment of Participants

Interview subjects were identified first from an integrative literature review, which led to both researchers who are prominent thinkers in the areas of crisis and risk-based decision-making, and practitioners with significant experience with public health emergency and contamination emergency responses. Additional interviewees were identified through snowball sampling via suggestions from other interview participants. In particular, interviewees were sought who had relevant expertise or experience with decision making by political leaders in major contamination emergencies. Potential interviewees were excluded if they had no expertise or experience with decision making in crises, or no knowledge or experience that could be applied to contamination emergencies.

Aim 3 Data Collection

Semi-structured interviews with selected participants were conducted over the phone and via Skype from September 2016-January 2017. Interviews were recorded with permission of participants and were transcribed verbatim to ensure maximal accuracy. Interviews were not-for-attribution. During the interviews, key observations and points were recorded to capture immediate impressions and important points.

Aim 3 Analysis

Themes were derived from the interviews using a combination of inductive and deductive approaches. *A priori* themes were identified first from the previously conducted integrative literature review, and based on the interview guide. Further themes were identified and added as the transcripts were coded (Table 10). Interview transcripts were coded based on identified themes using QSR NVivo for Mac v10.3.2.[62] Peer debriefing with an impartial party who had expertise in the topic was conducted during the data analysis phase to aid in identifying themes, analyzing coded findings, and developing the draft framework.[63]

A Johns Hopkins Bloomberg School of Public Health Institutional Review Board determined this study was not human subjects research and was therefore exempt (Appendix 2).

PAPER 1

Expert Views on Biological Threat Characterization for the U.S. Government: A Delphi Study[1]

[1] The text of this paper was published in *Risk Analysis* in 2017. The version presented here includes an expanded and structured abstract, and expanded introductory section, which were not included in the final published version in *Risk Analysis*. The citation for the publication is: Watson CR, Watson MC, Ackerman G, Gronvall GK. Expert Views on Biological Threat Characterization for the U.S. Government: A Delphi Study. *Risk Anal*. 2017. doi: 10.1111/risa.12787 [Epub ahead of print]. http://onlinelibrary.wiley.com/doi/10.1111/risa.12787/abstract.

Abstract

Background: This aim provides a specific case study of one federal program aimed at reducing scientific uncertainty and improving the availability of human health risk information, which can be used for decision making in response to contamination emergencies. This case study is focused on the Biological Threat Characterization Program (BTCP) in the US Department of Homeland Security. The BTCP conducts laboratory research to better understand the characteristics of and risks posed by biological agents as weapons. BTC research is conducted to inform planning and preparedness in anticipation of an attack, and to inform emergency response and crisis decision making if and when an event occurs.

Objective: BTC is important for improving risk assessment and resource prioritization for biological defense. However, there are also risks involved in BTC work, including the potential for misuse of the research results or accidental release of a pathogen. Given the benefits and risks of BTC research, and resource limitations for conducting this work, it is important that there be guiding principles for prioritizing BTC research, and safeguards in place to ensure that it is done safely and securely. This analysis looks at what those principles and safeguards should be.

Methods: The research team conducted a modified Delphi study to gather opinions from experts in biosecurity and biodefense about what mechanisms and processes should be in place for U.S. Government BTC research. The Delphi process went through two rounds and included responses from 59 experts. Participants were asked to give their considered opinions about the need for BTC research in the USG; the dangers that might arise from conducting this research; the rules or guidelines that should

be in place to ensure that the work is safe and effective; components of an effective review and prioritization process; rules for when characterization of a pathogen can be considered complete; and recommendations about who in the USG should be responsible for BTC prioritization decisions.

Findings and Discussion: While there were some disagreements and generational differences in participant responses throughout the Delphi process, expert participants generally agreed on the importance of BTC research, that BTC is a necessary function of the USG, and that it should be conducted with a focus on informing preparedness and response decisions, particularly related to medical countermeasures development. The biggest worries about BTC research were that it might increase the potential for insider threat from a laboratory, and that the research could be viewed as a violation of the Biological and Toxin Weapons Convention (BWC).

In response to the need for BTC research and its accompanying risks, experts weighed in on the rules and guidelines that should be in place for the research. First and foremost, experts agreed that BTC work should never violate the BWC. They also agreed that intelligence information used as an impetus for BTC research should be deemed plausible and valid first, and that any research done for threat characterization purposes should inform biodefense decisions and should not be done just for the sake of knowing more about a pathogen. Experts agreed that a review process should be in place for BTC work, which prioritizes scientific review of planned experiments. Finally, experts agreed that the Department of Homeland Security (DHS) should continue to lead in making prioritization decisions for threat characterization research.

Conclusions: This study represents the first time that questions about BTC research have been posed systematically to a group of experts. The findings from this study reinforce the need for BTC research at the federal level as well as a need for continued review and oversight of this research to ensure it is conducted safely and effectively. Findings from this study can also be applied more broadly to other federal programs aimed at information gathering and risk assessment prior to contamination emergencies. It may be useful for tother federal programs, focused on different types of potential contaminants, to ask similar questions about how those programs prioritize their work, are structured, and are executed.

Introduction

A scientific understanding of the threat posed by biological weapons is critical to determine biodefense priorities, set preparedness and response policies, and implement prevention and mitigation measures. The U.S. is committed to upholding the Biological and Toxin Weapons Convention (BWC)[64] and 18 U.S. Code 175,[65] which make it a crime to knowingly possess a biological agent, toxin or delivery system for use as a weapon or if the material is not intended for peaceful purposes. For the purposes of defense, the U.S. government has deemed it necessary to conduct risk assessments and characterize the threat posed by biological weapons use to the U.S. homeland. Yet, the data required to develop risk assessments is largely insufficient; there are large gaps in our knowledge and understanding regarding biological weapons.[66] We often have limited data on the biology of many potential biological threat agents (e.g., their dose-response profile, behavior under different conditions, and environmental persistence), and rather limited understanding of the intentions of adversaries who possess or seek to possess biological weapons. This uncertainty about both the biology of a threat agent as well as its likelihood of use makes effective decision-making about biodefense resource prioritization difficult.

As with other risk assessment problems, in order to best manage bioweapons risks, it is critical (to the extent possible and within the bounds of prudence and reason) to fill knowledge gaps so as to better enable decision making and a more effective response. Risk assessment always involves a characterization component: an assessment of the "nature and presence or absence of risks, along with information about how the risk was assessed, where assumptions and uncertainties still exist, and where policy choices will need to be made."[67] In human health risk assessment, this characterization step includes hazard identification (to understand the potential health problems caused by the hazard/threat), dose-response assessment (to understand how health problems caused by the hazard change at different levels of exposure), and exposure assessment (to understand how people might be exposed to the hazard/threat).[67] The characterization of intentional threats, including bioterrorism and state use of biological weapons, involves an additional component which is not considered in traditional human health risk assessments: the capabilities and intent of a thinking adversary.[68]

Countering biological threats requires long time horizons and sustained investment.[69] For example, medical countermeasures development (particularly vaccines) may take up to a decade from initial R&D through advanced development, regulatory approval, and manufacturing.[70] Thus, early prioritization decisions based on threat characterization and risk assessment can have long-term implications. The prioritization decisions are also consequential: making evidence-based decisions to improve defenses against biological weapons is a potential life-saving endeavor, while poor decision-making or misallocation of resources could ultimately harm national security and public health.

With stakes this high, threat characterization, risk assessment, and decision-making processes should be robust, and periodically re-examined to ensure that biological threats are being well-considered. To that end, this analysis focuses on how the US government conducts Biological Threat Characterization (BTC) – an area of scientific inquiry directed at improving knowledge regarding potential biological threats for the purposes of defending against them.

BTC research for civilian biodefense in the U.S. is primarily the responsibility of the U.S. Department of Homeland Security (DHS), Science and Technology Directorate (S&T), Chemical and Biological Defense Division (CBD). This work is directed under the DHS Biological Threat Characterization Program (BTCP), and is carried out primarily at the National Biodefense Analysis and Countermeasures Center (NBACC), a laboratory located in Frederick, MD.[71]

The BTCP is specifically charged with directing laboratory research to better understand the nation's vulnerability to biological threats. The program generates knowledge and data from laboratory research on specific biological threat agents, which then are meant to inform the government's key risk assessment tool for bioterrorism – the Bioterrorism Risk Assessment (BTRA), run by DHS S&T; and to guide intelligence assessment, preparedness planning, development of medical countermeasures, detectors, decontamination technologies, and other mechanisms to blunt the effect of a biological attack on civilians. The work conducted through the BTCP is often not published or publically available because information produced is inherently dual-use, and may be prone to misuse by adversaries with malicious intent. Moreover, if the research and its results are sufficiently sensitive and might compromise national security, they may be protected by classification. Additionally, the NBACC has implemented biosecurity measures, including a personnel reliability program, which limits the risk of insider threat or outside access to pathogens or classified data.[72] Finally, the laboratory is certified at the highest biosafety levels.[73] BTC research includes scientific analysis of agent characteristics, such as environmental stability, infectivity, and dose response relationship, which then can inform estimates of the consequences that would follow from attack. BTC work also supports validation of intelligence information.

Biological threat characterization, when it was first proposed, was a source of controversy within the biodefense community. In 2005, biodefense experts Drs. Jonathan Tucker, James "Ben" Petro, and Seth Carus exchanged commentaries debating the establishment of NBACC and the resulting potential benefits and risks of establishing such a research facility. In that exchange, Drs. Carus and Petro argued in favor of NBACC and BTC, stating that threat characterization was needed to address "technical gaps that currently exist in intelligence threat assessments."[74] Dr. Tucker opposed NBACC and threat characterization for several reasons. He thought that it would not be useful for its intended purpose, stating that such a research agenda would be "dangerous and counterproductive," and would be a poor basis for countermeasures development. He thought that it would be profoundly destabilizing to international nonproliferation efforts, particularly the norms against biological weapons development established by the Biological and Toxin Weapons Convention (BWC), which bars the development and use of biological weapons. Tucker also worried about criminal misconduct in the generation of this research, i.e. that it would increase the possibility of "leakage" of a novel pathogen or associated information, which could be acquired by a rogue state or terrorist organization.[75] These concerns were countered by Carus and Petro with proposals for how these problems could be ameliorated, including a detailed compliance review process incorporating information from the *Fink Report*, which recommends practices to prevent "destructive application of biotechnology research" while still allowing legitimate research to continue; [76] limitations on size, scope, and types of experiments to be performed; a scientific review process; and detailed documentation of the decision-making process.[77]

Subsequent to this exchange, Congress authorized and funded NBACC and BTCP, and DHS and NBACC have implemented a number of the recommended steps and processes proposed in the exchange between Tucker, Carus, and Petro. Subsequent to this exchange, Congress authorized and funded NBACC and BTCP, and DHS and NBACC have implemented a number of the recommended steps and processes proposed in the exchange between Tucker, Carus, and Petro, that would address Tucker's concerns. DHS has since developed a management directive regarding compliance with the BWC and other international arms control agreements.[78] The Compliance Assurance Program (CAP) at DHS provides a legal review of proposed BTCP projects to examine whether a project is clearly for prophylactic, protective, or other peaceful purposes; whether the types and quantities of biological agents or toxins are consistent with and justified for the intended prophylactic, protective, or other peaceful purpose; and whether the project includes any weapons, equipment, or means of delivery designed to use agents or toxins for hostile purposes or armed conflict. The CAP office also reviews projects for compliance with U.S. regulatory requirements, including Select Agent Rules, human and animal subject rules, and biosafety.[79]

The goal of the current BTC program is to maximize the benefits for biodefense and to minimize the risks of potential harm that could result from research in this area. However, experts still debate the safety and security, dual-use implications, and needed regulation and oversight of the technical work the BTCP undertakes. Given the potentially risky nature of BTC work and the need for prioritization of government resources available for this work, BTCP has a continued need to make careful and wise decisions regarding what threat characterization studies it should support. The principles and criteria that inform these decisions are of great importance, but are generally not well understood or widely publicized.

Pursuing threat characterization studies that do not meet the right criteria would risk negative consequences as envisioned in the earlier debate between Tucker, Petro, and Carus, such as the wasting of limited resources more appropriately applied to other biological threats; misperceptions regarding the legitimate defensive nature of the work; and/or the potential to produce new knowledge that could deliberately or accidentally increase dangers from new biological threats.

This study examines the continued need for BTC research for U.S. biodefense, and the boundaries and oversight mechanisms that might guide this research. The aim of this analysis is to provide findings, based on expert judgment, which inform DHS and other policy efforts regarding how to conduct BTC work in a manner that minimizes the risks and maximizes efficient usage of resources.

Methods

Research Leading to the Delphi Study

The University of Maryland National Consortium on the Study of Terrorism and Response to Terrorism (START) Center of Excellence and the UPMC Center for Health Security performed this research through a contract with the DHS Science and Technology Directorate (S&T), Chemical and Biological Defense Division (CBD). The purpose of the research was to provide the DHS Biological Threat Characterization Program (BTCP) with information to help inform the decisions of program leaders as they consider funding experimental work to characterize biological threats; provide principles, criteria, and decision-making processes for evaluating such possible projects; and recommend how the BTCP might determine appropriate endpoints for threat characterization studies.

Within this research, the project team performed a number of activities. First, we conducted a review of the peer-reviewed and grey literature to gather policy analyses on threat characterization and dual-use research of concern. This literature review was used to provide background information about BTC research, and to gain a better understanding of past and current policy and opinions surrounding this topic. For the review, the project team relied on sources that were neither classified nor for official use only (FOUO), and included web, periodical, and newspaper archive searches, as well as publicly available materials from NBACC and BTCP. Themes from the literature were identified, categorized, and utilized as a basis for development of an interview guide for a series of semi-structured interviews with experts.

The project team conducted 45 telephone and in-person interviews with experts to gather their knowledge and opinions about biological threats, biological threat characterization, the BTC Program specifically, and the process and policy for biological threat characterization for the USG generally. Experts were identified through the literature review, professional contacts, and a snowball sampling methodology of recommendations from other subject matter experts. Interviewees included SMEs in the fields of biological science, biodefense policy, intelligence collection, international relations, and other fields that touch on biological threat characterization.

Interview results were analyzed for themes and were used to build a straw man Framework for Threat Characterization Research for discussion at a working group meeting involving a subset of experts interviewed in the first project phase. This meeting was organized into five discussion sections:

1. National strategic direction for biological threat characterization
2. DHS S&T biological threat characterization
3. Decision-making framework components
4. How a decision-making framework should be implemented
5. Planning for unexpected disclosure of threat characterization information

Following the meeting, the discussion was summarized and the Framework for Threat Characterization was amended to reflect the working group meeting. The results of this process were reported to DHS. Following the working group meeting, the project team used the framework information gleaned from discussion with experts to design a modified Delphi study aimed at producing more fine-grained insights about perceptions of biological threats and the BTC process, the results of which would be made publicly available.

The focus of this paper is on the results of the modified Delphi study and will examine the data points specifically related to biological threat characterization. Results of the Delphi study pertaining to judgments about the biological threat will not be examined here, but have recently been published in *Science Policy Forum*.[80] In that publication, major findings included the observation that experts are not in agreement about the likelihood of a biological attack or about what agents are most likely to be used and by what potential actors. They were in agreement, however, that intelligence information will likely not provide actionable warning before a biological attack occurs. They also agreed that there is a "red line" for types of BTC research that should never be conducted, but were unable to reach consensus about what constitutes the "red line."[80]

Modified Delphi Method

The Delphi method, developed by the RAND Corporation in the 1950s and 60s, is a structured method for gathering, refining and aggregating judgments from groups of experts.[81] Designed to minimize the bias created by "groupthink," the process usually consists of experts completing several rounds of a structured survey, with iterated response and feedback across rounds and statistical aggregation of responses. After each survey round, the results are returned to the group and respondents are asked to review the anonymized answers from other experts and to consider revising their original responses for the next round based on others' judgments.

For this study, a modified Delphi technique was employed to elicit the judgments of U.S. national security, biosecurity, and biosafety experts, in order to understand their perception of the biological weapons threat and their opinions about BTC research conducted to address these threats. Experts were invited to participate in this study based on their responsibilities for shaping public policy in life science and national security, based on their expertise and knowledge in the field, or based on recommendations of other participants (using a snowball sampling methodology). All results were de-identified during this process so that no answer could be attributed to any participant.

The Delphi survey instrument was developed through a series of subject matter expert interviews (a subset of those who participated in the Delphi survey) conducted during an earlier phase of the study. The Delphi survey was designed and administered online through SurveyMonkey®, and included questions with both quantitative and qualitative components. The Delphi survey included 15 questions about the threat of biological weapons use and about biological threat characterization. This analysis addresses only the questions focused on BTC (numbers 7-8, 10, 12-15). Question formats included yes/no questions, probability estimates (0-100%), rating questions (1-10), and multiple-choice (choose one) questions. One question was excluded from this analysis because several participants found its wording confusing.

Each question included a qualitative component where participants explained the reasoning behind their answers; this was required in round one of the Delphi study and requested in round two. This is an important part of the process because it allows respondents to calibrate their own estimates and minimize misperceptions about the nature of the questions and underlying assumptions.[54] The Delphi survey instrument was piloted by three subject matter experts and the project team, and was revised after the pilot to improve understandability of the questions, shorten the survey, and make the questions as useful as possible.

Once the survey instrument was piloted and revised, the survey was fielded to the 62 participants who agreed to take part in the study. Participants' names were removed to protect their identities and participants were assigned ID numbers. For the first round of the survey, Delphi participants were asked to respond to all questions and provide reasoning for each of their responses. Once the first round was completed, the authors processed the data by producing frequency histograms and summary statistics for each question and sub-question, and providing all data and justifications in a readable, de-identified format for participants to review. This information was sent to participants along with the link for them to take the round two survey instrument, which was unchanged except for some minor clarifying language. In round two of the survey, participants were asked to review one another's answers, either amend or maintain their answers after reflecting on others' opinions, and respond to the survey again. Data and justifications from round two were again collected, processed, and analyzed.

Finally, the survey results for the two rounds were compared to determine "group stability" or response consistency between rounds. The Delphi process for this study was terminated when, for successive rounds, the mean response did not change more than one standard deviation (SD) across all questions, which occurred after two rounds.

Statistical Analysis

The final results (round 2) of the study were analyzed using STATA statistical package 11.2. Data were first characterized using summary statistics (mean, median, mode, range, SD) and histograms. The data for each question were then analyzed for normality through a visual check of the data via histogram and then using the Shapiro-Wilk test as a statistical test of normality.[55] Many of the questions and sub-questions were non-normally distributed based on these analyses, which signaled the need for nonparametric tests in further analysis.

The Delphi data were analyzed by comparing the distributions of answers by subgroup (e.g., gender, age group, training or affiliation) and by comparing distributions of multiple sub-questions. For comparison of questions by subgroup, the Wilcoxon rank-sum test was used as a nonparametric hypothesis test to compare distributions.[56] The null-hypothesis of equal variance was rejected at the $p<0.05$ level. Many of the questions in the Delphi survey included sub-questions, where participants rated each sub-question from 1-10. These questions were analyzed by comparing the distributions of all sub-questions using the Friedman test, a nonparametric test used for one-way repeated measures analysis of variance by ranks. When the null hypothesis of equal variance for the group of sub-questions was rejected at the $p<0.05$ level, the project team then conducted post-hoc analyses comparing pairs of sub-questions using the Wilcoxon signed-rank test, which is a nonparametric test used for repeated variables.[57]

In order to reduce the likelihood of Type I error in comparing sub-questions (incorrectly rejecting the null hypothesis and reporting a significant finding falsely), we accounted for the problem of multiple comparisons, by applying a Bonferroni correction to each instance where multiple comparisons are made. The Bonferroni correction was applied by dividing the significance level of $p=0.05$ by the number of sub-questions being compared.[58]

Qualitative Analysis

Qualitative justifications provided by the participants were instrumental to the Delphi process. Participants were asked to use the qualitative justifications to shape the group's responses in the second round of the study. In addition to their use during the survey process, qualitative answers were used in the final analysis of the Delphi data, to help interpret the statistical findings from the quantitative component of the study. Following the statistical analysis, we reviewed the qualitative responses for each question to find reasoning for the different ratings seen in the data. The most relevant comments are reported to help explain each significant finding.

This research was submitted to the Institutional Review Board (IRB) of the University of Maryland and was granted exempt status (Appendix 1).

Results:

Demographic Data

Of the 63 experts originally approached to participate in the study, 62 completed the first round of the Delphi survey, with one person declining to participate due to time limitations. Of the 62 round one participants, 59 completed the second round (of 2 total rounds) for a response rate of 94%. Individuals who dropped from the study following round one, also said that they did not have time to continue to participate (Table 1).

Gender: of the 59 participants in round two of this Delphi study, 41 (69.5%) were male, and 18 (30.5%) were female**.**

Age: Ages of the participants were binned by generation in order to assess potential differences in opinion among a variety of career levels. Participants who were aged approximately 21-33 were captured in the Millennial Generation, participants aged 34-49 were in Generation X, participants aged 50-69 were in the Baby Boomer Generation, and participants who were aged 69-86 were in the Silent Generation.[82] For the purposes of statistical analysis, these generations were also placed into 2 larger bins: earlier generations (aged 50+), and later generations (aged 21-49).

Training: Participants were associated with an area of "primary training," defined as the area they focused on in their graduate training or the primary area of focus for their careers. Of the 59 participants, 2 (3.4%) were trained in political science, 1 (1.7%) in foreign policy/international affairs, 3 (5.1%) in national security, 3 (5.1%) in public health, 7 (11.9%) in medicine, 32 (54.2%) in biological science, 2 (3.4%) in chemistry, 2 (3.4%) in physical science, 2 (3.4%) in veterinary medicine, and 5 (8.5%) in other areas (including economics, history and law).

Training was also binned and analyzed in a number of ways: By biological scientist (33) vs. not a biological scientist (26); by scientist (48) vs. non-scientist (11); and by terrorism expert (6) vs. not a terrorism expert (53).

Affiliation: Participants' professional affiliations (at the time the survey was conducted) were identified as follows: 14 participants (23.7%) worked for nongovernmental organizations (NGOs), 7 (11.9%) worked in academia, 12 (20.3%) worked in the private sector/industry, 23 (39.0%) worked in government for the public sector, and 3 (5.1%) were former government but were retired at the time of the survey. Affiliation was binned and analyzed by current and retired government (26) vs. non-government (33).

The Delphi survey included 15 questions about the threat of biological weapons use and about biological threat characterization. This analysis includes only the questions focused on BTC (numbers 7-8, 10, 12-15). Question formats included dichotomous yes/no questions, probability estimates (0-100%), rating questions (1-10), and multiple choice (choose one) questions. Eight of the 15 total questions posed in the survey dealt with BTC, and 7 of those 8 are addressed in this analysis. One question was excluded because participants found it confusing.

Results by Question and Sub-Question

Question 7: Does the Nation (the United States) need biological threat characterization?

The overwhelming majority, 55 of 59 participants (93.2%) in round two of the Delphi process, responded "Yes" the nation does need programs for biological threat characterization. Of the 4 participants who didn't answer "Yes" in round two of the study, 2 (3.4%) answered "No" and 2 answered "I don't know." Support for BTC was similar in round 1 of the Delphi study, with 53 (85%) of the 62 participants answering "Yes," 3 (4.8%) answering "No," and 6 (9.7%) answering "I don't know." Between rounds one and two, one of the participants who answered "No" changed to "Yes." Of the participants who answered "I don't know" in round one, 2 did not change their answers in the second round, 2 dropped out of the study, and 2 changed their answers to "Yes."

Question 8: We will now turn to the reasons that you would give to explain/justify the need for biological threat characterization programs in the US government.

The survey provided 6 reasons (sub-questions) and participants were asked to score each reason on a scale from 1 (very unimportant) to 10 (very important).

- **Question 8_1:** To enhance our understanding of the biological weapons threat by addressing technical gaps in the information provided by the intelligence community.
- **Question 8_2:** To prioritize funding for medical countermeasures (e.g., a smallpox vaccine vs. an antibiotic).
- **Question 8_3:** To inform the Department of Homeland Security's Bioterrorism Risk Assessment (BTRA) – a probabilistic risk assessment which is required under Homeland Security Presidential Directive 10 that helps the country prioritize biological threats.
- **Question 8_4:** To prepare for biological weapons that are a strategic possibility based upon the current trajectories in scientific research (for example, threat characterization research may be directed in response to a published scientific paper that appears to be dual use research of concern, and which could be exploited by an adversary. In this scenario, there is no intelligence indication that the research is currently being misused).
- **Question 8_5:** To acquire information that could help attribute an attack. For example, what does the nature of the attack suggest about which off-the-shelf equipment was used?
- **Question 8_6:** To provide useful information to help in detection of and response to an attack (e.g., could urban animals like squirrels, rats, or pets, serve as sentinels of an attack on a city; How long does an area need to be avoided after an aerosol attack?)

When the mean scores for the final round of these six sub-questions were compared (Table 2), question 8_2–*to prioritize funding for medical countermeasures*, scored highest with a mean score of 7.44, while question 8_3–*to inform the DHS Bioterrorism Risk Assessment*, scored lowest with a mean score of 5.26.

When participant responses were compared for all six sub-questions, both through a visual appraisal of the data using box plots (Figure 2) and statistical tests comparing the distributions (Friedman test and post-hoc Wilcoxon signed-rank tests), we found that some reasons for the USG to conduct BTC work were rated significantly higher than others at the $p<0.008$ level (Bonferroni correction of $p<0.05/6$).

Sub-questions 8_2–*to prioritize funding for medical countermeasures*, 8_6–*to provide useful information to help in detection of and response to an attack*, and 8_1–*to enhance our understanding of the biological weapons threat by addressing technical gaps in the information provided by the intelligence community*, all scored significantly higher at the $p<0.007$ level, than the other three reasons for supporting BTC research (Table 2). Many participants who rated 8_1, 8_2, and 8_6 higher than the others provided similar justification for this prioritization: namely that biological threat characterization should be focused on informing government efforts to prepare for and respond to an attack in order to better protect the public. Participants felt that these three reasons encompassed that focus, and the other reasons were not as important because they did less to contribute to preparedness and response.

Notably, when responses to question 8_1 were compared (using the Wilcoxon rank-sum test) by age group (later vs. earlier generations), the earlier generations (Baby Boomers and Silent Generation) rated question 8_1 significantly higher ($z=-3.191$, $p=0.0014$) than the later generations (Millennials and Gen X).

Of the three sub-questions that were rated significantly lower, question 8_5 (*to acquire information to help attribute an attack*) was rated highest. Some participants felt strongly that research to improve attribution of a biological attack is among the most important reasons for BTC research:

"Attribution is critical for multiple reasons including increasing the odds of stopping follow-on events."

However, a majority of participants rated attribution lower than the other reasons for conducting BTC research, with justifications including:

"Attribution research is worthwhile but not near the priority of protecting people."

"I see little possible progress in attribution so I would not recommend wasting a lot of money on it."

Sub-question 8_4 (*To prepare for biological weapons that are a strategic possibility based upon the current trajectories in scientific research*) was rated second lowest of the six reasons for BTC work. While some participants felt that BTC research should try to characterize novel threats that may come out of the *"era of genetic engineering,"* more participants rated this reason lower than other reasons. These participants tended to question whether this type of BTC research would be worth the risk:

"Testing out BW that is "a strategic possibility" based on S&T trends, absent some indication of interest by others in misusing them, will tend to waste large amounts of money pursuing a large number of leads, AND it will tend to persuade others (either due to knowledge of what we are doing, or due to our secrecy) that we in fact have an offensive program."

"…the strategically possible space is enormous and will require significant thought about a systematic or prioritized approach to that research. Otherwise, the program could frankly flail about without doing much real useful work."

The reason for BTC research that participants rated the lowest was question 8_3 (*to inform the DHS Bioterrorism Risk Assessment (BTRA)*). Delphi participants who gave a low rating of 5 or less to this question and who commented about this rating either felt that the BTRA could not or should not be improved through additional BTC research, or felt that improvement of the BTRA itself is not an end that justifies BTC work.

> *"…the largest sources of uncertainty in the DHS BTRA are not technical but behavioral: how many terrorist groups want to acquire and use biological weapons? What kind of agents do they find most appealing? What types of targets and effects are they most interested in? None of these questions can be answered in the lab."*

> *"The BTRA, for all its weaknesses, is an important policy product and it should benefit from, though not serve as the justification for, biological threat characterization."*

When the responses to this sub-question were compared by age (later vs. earlier generations), the earlier generations rated question 8_3 significantly higher than the later generations at the $p<0.05$ level, when compared using the nonparametric Wilcoxon rank-sum test ($z=-2.212$, $p=0.0270$).

Question 10: What, in your opinion, are the biggest dangers or shortcomings that might result from a US government program directing laboratory characterization of biological threats?

The survey provided seven possible dangers/shortcomings (sub-questions) and participants were asked to score each danger/shortcoming on a scale from 1 (very unimportant) to 10 (very important).

- **Question 10_1:** It may be destabilizing to international regimes such as the Biological Weapons Convention, as other nations may believe that the US has an offensive biological weapons program.
- **Question 10_2:** It may increase the potential for insider threats, as more people would have access to select agent pathogens and technical skills to manipulate them.
- **Question 10_3:** It may increase the probability of an accidental release of a select agent from a laboratory.
- **Question 10_4:** Laboratory threat characterization work will not provide actionable information for policymakers.
- **Question 10_5:** Money spent on laboratory threat characterization could be used more effectively in other areas of biodefense.
- **Question 10_6:** If the results of the laboratory experiments were unexpectedly released, it could help an adversary.
- **Question 10_7**: If the results of the laboratory experiments were unexpectedly released, it would result in public controversy.

When the mean scores for the final round of these seven sub-questions were compared (Table 3), question 10_2 (*it may increase the potential for insider threats*), scored highest with a mean score of 5.95, while question 10_4 (*threat characterization will not provide actionable information*), scored lowest with a mean score of 3.86. The mean responses for all sub-questions were fairly low – with none above a mean of 6.0.

When participant responses were compared for all seven sub-questions, using box plots (Figure 3) and statistical tests comparing the distributions, we found that rankings for two of the seven sub-questions differed significantly from the others. Scores for question 10_4 (*Laboratory threat characterization work will not provide actionable* *information for policy makers*) were rated significantly lower than all other questions except for 10_5. Question 10_5 (*Money spent on laboratory threat characterization could be used more effectively in other areas of biodefense*) was rated significantly lower than all sub-questions except for 10_4 and 10_7, when compared using the Wilcoxon signed-rank test with a significance level of $p<0.007$ (Bonferroni correction of $p<0.05/7$).

Reasons that were given for the lower rating of these two sub-questions included:

> *"Lab threat characterization results have already provided actionable information for policymakers."*

> *"The lack of actionable info and how we spend biodefense money go hand in hand but the argument could be made that spending money on other biodefense programs is a waste of money."*

> *"The cost of experiments to better prioritize other investments is relatively small, with the threat characterization projects measured in single digit $M and less, but countermeasure projects in 10s and 100s of $M."*

All of the other sub-question distributions were rated similarly and did not differ significantly from one another. A majority of the participants discussed the BWC in long-form answers to this question, and sub-question 10_1 (*It may be destabilizing to international regimes such as the BWC*) was rated second highest in concern with a mean response of 5.814, but the distribution for this sub-question did not differ significantly from the other sub-questions except when compared to questions 10_4 and 10_5.

There were some significant differences in distributions at the $p<0.05$ level when sub-questions were analyzed by age using the nonparametric Wilcoxon rank-sum test. Sub-questions 10_2 - *It may increase the potential for insider threats* ($z=2.203$, $p=0.0276$), 10_3 - *It may increase the probability of an accidental release* ($z=2.603$, p=0.0092), 10_4 – *BTC will not provide actionable information* (z=3.350, p=0.0008), and 10_5 - *money spent on BTC could be used more effectively elsewhere* (z=3.171, p=0.0015) were rated significantly higher at the p<0.05 level (as bigger dangers or shortcomings) by the later generations than by the earlier generations.

Question 12: In your opinion, what rules or guidelines for threat characterization should be in place to ensure that these programs are safe and effective?

The survey provided seven possible rules/guidelines (sub-questions) and participants were asked to score each rule/guideline on a scale from 1 (very unimportant) to 10 (very important).

- **Question 12_1:** The USG should not conduct an experiment if it violates the Biological Weapons Convention (BWC)
- **Question 12_2:** The USG should not conduct an experiment in which a pathogen is changed/mutated/altered unless the change/mutation/alteration has already occurred in nature (for example, antibiotic resistant anthrax has been seen in nature, so it would be acceptable to characterize it for biodefense purposes).
- **Question 12_3:** The USG should not conduct any experiment unless there is some intelligence information about a particular biological threat that supports the need for that experiment.
- **Question 12_4:** The USG should not conduct an experiment based on intelligence information unless the threat is determined to be scientifically plausible.
- **Question 12_5:** The USG should not conduct an experiment unless the result of the experiment has the potential to affect policy, funding, or prioritization of biological threats.
- **Question 12_6:** The USG should not conduct an experiment to assess a threat unless there is something that can be done to combat or respond to that threat (e.g., there is reason to believe that a countermeasure to the threat is scientifically plausible or is likely to be funded).
- **Question 12_7**: The USG should not conduct an experiment unless there is reason to believe that the experiment has been done before (e.g., in published scientific research, in classified studies, previous offensive work, or in a clandestine laboratory that there is intelligence about).

When the mean scores for the final round of these seven sub-questions were compared (Table 4), question 12_1 (*The USG should not conduct an experiment if it violates the BWC*) scored highest with a mean score of 8.29, while question 12_7 (*The USG should not conduct an experiment unless there is a reason to believe that the experiment has been done before*) scored lowest with a mean score of 3.41.

When participant responses were compared for all seven sub-questions, both through a visual appraisal of the data using box plots (Figure 4) and statistical tests comparing the distributions, we found that the distributions of a number of sub-questions differed significantly at the $p<0.007$ level (Bonferroni correction of $p<0.05/7$).

Sub-question 12_1 (*The USG should not conduct an experiment if it violates the BWC*) was rated significantly higher than then next highest ranked sub-question (sub-question 12_4) ($z=3.695$, $p=0.0002$), and significantly higher than all of the other sub-questions. Reasoning by the participants for this high rating included:

> *"Compliance with the BWC is a sine qua non for all threat characterization work."*

> *"Clearly, the United States should not violate the BWC, or applicable US law (which is even more restrictive than the BWC). However, the BWC does not prohibit defensive related research, so it is a relatively low barrier."*

> *"Above all, the USG should not be conducting any experiments that violate or could be perceived as violating the BWC."*

> *"Experiments should always be for defensive purposes and not involve the exploratory optimization of parameters of weaponization."*

For those few participants who did not rate this sub-question highly, reasoning included:

> *"I believe that the necessary research can be done without violating the BWC through the use of the full range of model systems. Should the situation arise*

> *where no alternative was possible and the need were deemed urgent then I would conduct the study openly with international representation and justification. All this is situationally-specific and the BWC conflict problem is somewhat over exaggerated."*

> *"I think we need to weigh our international obligations against our strategic interests which is why I gave this a 5."*

> *"It specifically allows for defensive research, and if that means studying offensive concept is necessary for defense then it's still defensive research."*

Sub-question 12_4 (*The USG should not conduct an experiment based on intelligence information unless the threat is determined to be scientifically plausible*) was rated significantly higher than any of the other sub-questions with the exception of question 12_1 and 12_5 (Table 4). Reasons for this prioritization emphasized a common-sense approach to BTC research:

> *"…intelligence driven decisions without scientific plausibility would create frantic research efforts without strategic guidance and would rarely provide useful information for the intelligence and responder communities to react accordingly."*

> *"Efforts should be made to not perform research that is totally implausible. However, care must be taken not to discard concepts that simply don't match our understanding."*

> *"Threat characterization should be focused on determining the boundaries of the scientifically plausible and should not be driven by intelligence."*

> *"Limiting research to items deemed scientifically plausible seems to be a first basis for any kind of experiment. If we think something is scientifically implausible, it makes no sense to undertake the research."*

Question 12_5 (*The USG should not conduct an experiment unless the result of the experiment has the potential to affect policy, funding, or prioritization of biological threats*) was the next highest rated sub-question, and was rated significantly higher than all other sub-questions (with the exceptions of 12_1 and 12_4), including the next lowest rated sub-question 12_3 ($z=-2.802$, $p=0.0051$). Participants' reasons for rating this highly included:

> *"if there is no rationale to gain information of value to defensive policy or practice, then there is no basis for that kind of effort being funded by the USG."*

> *"Development of good tools and methods rests on basic research, which (a) is rarely targeted at its eventual use, (b) can take years or decades to become "relevant," and (c) contributes to a broad discussion among researchers, practitioners, and users. That said, I think a different standard may apply to threat characterization work because most such work will qualify as Dual Use Research of Concern. In this case, such work should in most cases be plausibly linked (if perhaps not strictly limited) to policy, funding or prioritization decisions."*

> *"Experiments should be done for scientifically valid reasons, and with a clear reason of why the experiment is needed (to inform funding, policy, MCM development decisions.)"*

Question 12_7 (*The USG should not conduct an experiment unless there is reason to believe that the experiment has been done before*) was rated statistically significantly lower than any of the other 12 sub-questions. Reasoning for this low rating included:

> *"Because the main role of threat characterization is to define the boundaries of plausibility, and because techniques and instruments are evolving continuously, it does not make sense to limit studies to cases in which countermeasures already exist or are envisioned or to experiments that have been done before."*

> *"If an experiment has been done before, past research should be used especially if the science is reproducible, high quality, and well-constructed and conducted."*

> *"I do think that there are reasons to conduct experiments that have not be conducted before - that is going to often be the most important work to be done. I am not, however, comfortable doing gain-of-function experiments that have not been done before or do not exist in nature."*

> *"if it's been done before...why re-do it? I know, to validate results...but it would seem to me if it's never been done and it's a plausible threat, you'd want*

resolution."

When question 12 was analyzed by comparing sub-question distributions by gender, two of the seven comparisons had statistically significant findings: by age, one of the seven had significant findings; and by government vs. non-government employment, one of the seven had significant findings at the $p<0.05$ level when compared using the nonparametric Wilcoxon rank-sum tests.

Statistically significant differences by gender: Question 12_2 (*The USG should not conduct an experiment in which a pathogen is changed/mutated/altered unless the change/mutation/alteration has already occurred in nature*), and question 12_3 (*The USG should not conduct any experiment unless there is some intelligence information about a particular biological threat that supports the need for that experiment*) were both rated significantly higher by women than by men (both sub-questions had the same z score and associated probability ($z=-2.370$, $p=0.0178$)).

Statistical significance by age: Question 12_2 was rated significantly higher by the later generations than by the earlier generations ($z=2.316$, $p=0.0206$). Statistical significance by government expertise: Question 12_1 (*The US should not conduct an experiment if it violates the BWC*) was rated statistically significantly higher by experts in government than by non-government experts ($z=-2.079$, $p=0.0376$).

QUESTION 13: What do you think are the most important components of an effective review process for this kind of threat characterization research, which is often dual-use research of concern and highly sensitive?

The survey provided 13 possible components of an effective review process (sub-questions) and participants were asked to score each review components on a scale from 1 (very unimportant) to 10 (very important).

- **Question 13_1**: Projects are reviewed to ensure compliance with applicable laws and treaties, such as the Biological Weapons Convention (BWC).
- **Question 13_2:** Research protocols are reviewed by technical experts **inside** government for scientific soundness.
- **Question 13_3:** Research protocols are reviewed by technical experts **outside** of government for scientific soundness.
- **Question 13_4:** A technical advisory committee/group helps with the strategic prioritization of work with limited resources.
- **Question 13_5:** A technical advisory committee/group reviews and is able to vouch for the compliance of the work in the event of a data breach.
- **Question 13_6:** Decisions about why and how threats were prioritized are documented for the program.
- **Question 13_7:** Decisions about why an experiment was undertaken are documented (for example, intelligence, strategic possibility, gaps in the BTRA, countermeasures development, maintenance of capabilities).
- **Question 13_8:** The risks in not doing the experiment are identified and documented (e.g., lack of preparedness).
- **Question 13_9:** The potential national security benefits to performing the experiment are identified and documented.
- **Question 13_10:** The consequences of a laboratory accident during the course of performing the project are considered and documented.
- **Question 13_11:** The consequences of a data breach in the course of this project are considered and documented.
- **Question 13_12:** A process is undertaken to determine how technically difficult this experiment is, and what it indicates about a potential adversary.
- **Question 13_13:** Alternatives to an experiment, such as the use of simulants or computer models, are considered and documented.

When the mean scores for the final round of these 13 sub-questions were compared (Table 5), question 13_2 (*Research protocols are reviewed by technical experts inside government for scientific soundness*) scored highest with a mean score of 8.80, while question 13_12 (*A process is undertaken to determine how technically difficult this experiment is, and what it indicates about a potential adversary*) scored lowest with a mean score of 7.76.

When participant responses were compared for all 13 sub-questions, both through a visual appraisal of the data using box plots (Figure 5) and statistical tests comparing the distributions, we found that the distributions of only a few of the sub-questions differed significantly at the at the $p<0.004$ level (Bonferroni correction of $p<0.05/13$). The 13 components of an effective review were rated similarly for this question, and most people felt that many of these components should be considered for BTC programs in the USG, with some caution that they be applied in a smart way that does not hinder the research process.

> *"These are all important components of an effective review system that will minimize risks and ensure that researchers properly balance the benefits and costs of experiments."*

> *"All of these seem reasonable and very important with regard to the scientific validity, use of resources, and maintaining public trust."*

> *"All of these ideas are good practices to determining what should be done. However, if all of these were to be undertaken, this process would be very cumbersome. So, the cost/benefit of each of these steps should be considered."*

While most of the sub-questions (components of an effective review process) were rated similarly, sub-question 13_7 (*Decisions about why an experiment was* *undertaken are documented*) was rated significantly higher at a p<0.004 level than questions 13_4, 13_5, and 13_12. Reasons for rating the component highly included:

> *"Justification, while a pain, is a fact of life for government programs. Given the challenges the BTCP is likely to face, clear consideration and demonstration of the benefits of doing the work (and the risks of NOT doing the work) is critical."*
>
> *"Documentation of what and why things are done is essential."*

Sub-question 13_12 (*A process is undertaken to determine how technically difficult this experiment is, and what it indicates about a potential adversary*) was rated significantly lower at p<0.004 level than questions 13_1, 13_2, 13_7, and 13_10. Only one participant commented specifically about why this was rated lower than the other components:

> *"Not sure we want to do a lot of work to determine how technically difficult a project might be - that could entail doing the project."*

Finally, when questions were compared by subgroups (age, gender, expertise, etc.) using the Wilcoxon rank-sum test, we found that question 13_2 (*Research protocols reviewed by experts inside government for scientific soundness*) was rated significantly higher at the p<0.05 level by experts in government than by non-government experts (z=-2.373, p=0.0176)

Question 14: In your opinion, when is a biological threat "adequately characterized?" In other words, when can you stop doing laboratory research on a biological agent and move on to other important, pressing problems when resources are constrained?

The survey provided seven possible scenarios (sub-questions) and participants were asked to score each scenario on a scale from 1 (very unimportant) to 10 (very important).

- **Question 14_1:** When we have successfully created a medical countermeasure to combat an agent.
- **Question 14_2:** When we know how an agent behaves in the environment, including how long it persists and the risks to public health posed by environmental contamination.
- **Question 14_3:** When we can estimate the dose response relationship in humans for an agent.
- **Question 14_4:** When we understand how an agent could be manipulated to defeat our defenses (e.g., antibiotic resistance).
- **Question 14_5:** When we know the basic characteristics of an agent and can estimate a range of possible consequences.
- **Question 14_6:** Biological agents have already been characterized enough. Any additional work is of diminishing returns for decision-makers.

When the mean scores for the final round of these seven sub-questions were compared (Table 6), question 14_1 (*When we have successfully created a medical countermeasure to combat an agent*) scored highest with a mean score of 6.88, while question 14_6 (*Biological agents have already been characterized enough*) scored lowest with a mean score of 2.73.

When participant responses were compared for all seven sub-questions, both through a visual appraisal of the data using box plots (Figure 6) and statistical tests comparing the distributions, we found that the distributions of one sub-question in particular differed significantly at the at the $p<0.007$ level (Bonferroni correction of $p<0.05/7$).

Sub-question 14_6 (*Biological agents have already been characterized enough*) was rated significantly lower at the $p<0.007$ level than any of the other scenarios/reasoning for when a biological agent has been "characterized enough" through the BTC process. Participant comments that explained this low rating focused on the need for continued characterization due to the ever-changing threat environment.

> *"I am skeptical that we can know enough to stop paying attention to any particular threat. We don't stop paying attention to naturally occurring bugs just because we have an effective treatment."*

> *"Basic characteristics are not enough. As weapons presumably evolve and as scientific knowledge becomes more dispersed and better, threat characterization will always be needed to some extent."*

> *"Characterization of an agent should continue as long as that work generates actionable information that will improve our ability to prevent or defend against use of that agent."*

> *"Infectious agents evolve and host responses evolve. Given the dynamic nature of this interaction, one is probably never "done" with biological threat characterization. The challenge here is how to set priorities."*

> *"It's hard to rank when a biological threat is adequately characterized. Because we are dealing with living and evolving organisms, until we understand the full environmental interactions, we will never fully understand how the organism acts."*

Sub-question 14_3 (*When we can estimate the dose response relationship in humans for an agent*) was rated significantly lower than sub-question 14_1. Few participants provided reasons for this low rating specifically, but reasoning does include the following statement:

> *"much of that [dose-response estimation] can now be addressed/investigated with sophisticated modeling and simulation - that same approach that DTRA is now taking with advanced chemical threat agents - this minimized the number of laboratory experiments that need to be performed and shortens the timeline to understanding the threat."*

Participants also rated question 14_7 (*Characterization of agents should continue indefinitely because there is always more we can know that will help us prepare for and respond to an attack*) statistically significantly lower than the highest rated sub-question (14_1). So, while participants generally disagreed with the statement that "*biological agents have been characterized enough*," some felt that characterization should have some boundaries.

> *"The notion that characterization should continue indefinitely violates the basic economic law of diminishing returns. Yes, you can always learn more and secure more benefit--but the cost per unit of gain will tend to rise sharply after a certain point."*

It should be noted that the range of answers for this sub-question was large, indicating a lack of consensus on this issue. In addition, when sub-question 14_7 was analyzed by subgroups using the Wilcoxon rank-sum test, we found that earlier generations rated question 14_7 significantly higher at the $p<0.05$ level than the later generations ($z=-3.333$, $p=0.0009$).

Participants rated questions 14_1, 14_2, 14_5, and 14_4 higher than the other sub-questions, but the difference in distributions for these answers was not distinguishable or significant at the $p<0.007$ level. Reasoning for this lack of prioritization included a number of comments like the one below:

> *"I don't think you can take any of the first five thresholds in isolation. The first three are the most important - once we have a good countermeasure and know how long the agent persists in the environment and the dose-response relationship, we've got the bulk of what we need to know about the threat agent."*

Question 15: In your opinion, who in the US government should have the primary responsibility for determining priorities for biological threat characterization as a Nation?

The survey provided a choice of one of the following government agencies or offices and space to explain that reasoning: Department of Homeland Security (DHS), Department of Defense (DoD), Department of Health and Human Services (HHS), Executive Office of the President (EOP), The Intelligence Community (IC), The Department of State (State), or Not a government function.

Of the 59 Delphi participants in round two of the study, 21 participants (35.5%) answered that DHS should continue to have primary responsibility for determining BTC priorities for the U.S. Another 16 participants (27.1%) said that the White House (EOP) should have the lead, followed by 12 participants (20.3%) who said that HHS should take the lead, 5 participants (8.5%) who voted for the IC, 3 participants (5.1%) who voted for DoD, and finally 2 participants (3.4%) who feel that BTC should not be a government function at all. There were 0 participants who felt that the Department of State should lead prioritization for biological threat characterization.

When this question was analyzed by subgroups using the Wilcoxon rank-sum test, we found that there was a significant difference at the $p<0.05$ level in how preferred agency responsibility was ranked between earlier and later generations ($z=2.784$, $p=0.0054$). Earlier generations preferred to leave responsibility for BTC priority setting with the Department of Homeland Security, with 16 of 28 (57.1%) of earlier generation participants voting for DHS. In the later generations, only 5 of the 31 participants (16.1%) voted for DHS, while 10 of these participants (32.3%) preferred HHS and 10 others preferred that the EOP take the lead.

Discussion

The Need for Biological Threat Characterization

Findings from this study indicate that the U.S. biosecurity experts who participated in this Delphi exercise believe in the importance of implementing and maintaining a BTC capability in the USG. An overwhelming majority of Delphi participants support BTC work, with only two participants who thought that BTC work was counterproductive. These dissenting participants cited concerns about the appearance of violating the BWC, about the potential for an increased insider threat as more scientists work in this area, about the danger posed by an accidental laboratory release, and about the prioritization of research into bioterrorism threats when naturally occurring outbreaks are higher in likelihood. Other participants also expressed these concerns to varying degrees, but the large majority felt that BTC research performed by the USG was still warranted despite the risks, or perhaps they felt that appropriate policies ameliorated or could ameliorate those risks.

When the large majority of experts who supported BTC research in the Delphi study were asked why it is necessary, they emphasized its application to preparedness and response for biological weapons attacks. Experts showed in their ratings and justifications that they support BTC research that informs prioritization and development of medical countermeasures (MCMs), provides information to aid in detection of and response to an attack, and improves our understanding of information generated by the intelligence community in order to more effectively prevent or interdict an attack.

Experts favored less those reasons that were not directly related to prevention, preparedness, or response – particularly information gathering in order to assess more distant future threats, efforts to attribute future attacks, and data collection for the express purpose of informing the Bioterrorism Risk Assessment (BTRA). Participants were less favorable toward these reasons generally because they were less likely to inform decision-making or contribute to immediate risk reduction.

Importantly, this finding demonstrates that to these experts, the value of BTC is in experimental research that is connected to the USG ability to prepare for and respond to biological threats. Other goals of the program are not perceived to be as valuable or yielding as many benefits.

Interestingly, the earlier generations of experts who participated in the study were significantly more favorable toward BTC work for the purpose of understanding intelligence information and to inform the BTRA, than were the later two generations. This may indicate that the experts in earlier generations (over 50 years of age) are more steeped in, reliant on, and less skeptical of these government efforts than the experts from later generations. This finding may be indicative of a need for DHS and the IC to provide more education to younger stakeholders about the utility of intelligence and risk assessment, and about the threats that are assessed by these efforts.

The Biggest Dangers/Shortcomings that Might Arise from BTC Work

As a group, experts who participated in this study weighted the potential risks of BTC research very similarly, with the highest rated concern being that the research might increase the potential for insider threat, followed by the concern that the research could be destabilizing to international regimes including the BWC. None of the proposed dangers were rated especially highly, with the mean for the top-rated danger only 6 out of

10. This might indicate that experts are not overly concerned with the risks of BTCP work, a finding that might differ considerably if non-experts were to be queried instead.

Different generations did vary in their responses to this question. Later generations of experts rated concerns about an increased probability of an accidental release significantly higher than did earlier generations. This finding may indicate there is a rising worry about biosafety in the current biosecurity/biodefense workforce. DHS should be aware of these concerns and should emphasize the measures being taken to address biosafety at NBACC. In addition, later generations worried significantly more about BTC work not providing useful information to policy makers and about the need to prioritize funding and resources away from BTCP and toward other areas of biodefense. Many of the experts in the later generations are currently in positions of decision making in the government, and perhaps have not seen the utility of BTC research for their own work. It would benefit the BTCP to engage these experts further to see how threat characterization information could be more useful to them.

Rules or Guidelines for Threat Characterization to Ensure that BTC is Safe and Effective

Above all other current or proposed rules or guidelines for BTC work, experts felt most strongly that DHS should steadfastly not violate the BWC. Government experts were most adamant about this and rated compliance with the BWC most highly, possibly due to a more intimate involvement with international diplomatic work. While this finding seems intuitive, it is an important validation of the work DHS has done to build its compliance review process, and it supports continued efforts to maintain a rigorous approach to compliance assurance.

Experts also gave significant weight to the need for the BTCP to conduct experimental work based on intelligence information only if the threat is judged to be scientifically plausible, and to make sure that every BTC experiment has the potential to affect policy or resource prioritization decisions. This is reflective of the earlier group responses that prioritize BTC work to inform prevention, preparedness and response to biological threats.

Despite this preference toward research with a tangible impact and away from experiments to investigate implausible threats, experts did not feel that BTC work should only be limited to research on established or traditional threats. This is an indication that, while experts feel research should be practical, it should not be limited only to the realm of the known.

In regards to BTC work to address possible future threats, experts did not draw a hard red line that would proscribe BTCP from conducting work in which a pathogen is altered in some way that has not previously been seen in nature. Such a rule or guideline was not rated highly by the group as a whole. However, experts did comment that BTC work in this area should proceed with caution to avoid experiments that may result in the creation of novel pathogens, more virulent agents, or agents that can defeat our biodefenses. Notably, both women and later generations of experts rated prohibition of this type of work significantly higher than did men and earlier generations, which may mean that women and younger experts want to see more concrete, empirical information on threat before they are willing to countenance extensive BTC work. This speaks to a continued need to address and allay these concerns.

Important Components of an Effective Review Process

The proposed components of an effective review process for ensuring that BTCP work has maximized utility and minimized risk were all rated highly by experts, with the mean for each component rated above 7.5 out of 10. Delphi participants were most supportive of a technical review process in which experts inside government review experiments for scientific soundness. Government experts felt particularly strongly about the need for this component, likely due to their past experience in this area and the perceived need to review the data in a classified environment, which is most easily done inside government.

In addition, experts felt strongly that documentation of the decision-making process and reasoning for each experiment was significantly important. This kind of documentation was felt to be critical for ensuring the rigor of the work, its defensibility, and continued justification and demonstration of the benefits of BTCP.

Overall, these findings indicate that these review processes should be implemented in support of the threat characterization, but implemented in a reasonable way, which would aid and not hamstring the important scientific work being done in the program.

Recommended Stopping Points for BTC Research

The question of stopping points for threat characterization research – when enough research has been done on a pathogen – is a difficult one. Additional information to reduce uncertainty can almost always be obtained through continued research, but this research comes with diminishing returns and resource tradeoffs. Our Delphi experts did not reach consensus on specific stopping points for BTC research, and while they rated development of a medical countermeasure to combat an agent the highest among proposed stopping points, it was not a statistically significant frontrunner.

The group did agree on one thing: BTCP research should continue and biological threat agents have not been “characterized enough.” However, the group as a whole also did not think that threat characterization for each biological agent should continue indefinitely, and concurred that there should be some stopping points/boundaries on the amount of resources invested. However, government experts were more apt to support indefinite research than were non-government experts.

These findings indicate that stopping points for BTC research will likely need to be addressed on a case-by-case basis; that is, in a methodical way that can be documented and defended.

Responsibility for Determining BTC Priorities for the USG

Determination of BTC priorities for government is an important responsibility, one that should be considered carefully. Currently, this responsibility lies at the program level with BTCP within DHS S&T. However, some experts argue that prioritization decisions might be better made either at a higher level or in a different agency. Because it is such a pivotal decision point, with many downstream implications for biodefense resource prioritization, the project team asked the Delphi group who they think should have the primary responsibility for this; that is, whether it should continue to reside at DHS, be elevated to the White House level, or transferred to another agency in the federal government. Alternate government bodies/agencies proposed to participants included HHS (because of its role in leading the Public Health Emergency Countermeasures Enterprise (PHEMCE) process for the government); DoD (because of its role in leading defense of the country); State (because of its role as the lead for international security and nonproliferation); or the IC (because of their knowledge of the threat from adversaries intending to use biological agents as weapons).

Experts generally felt that DHS should continue to hold the responsibility for BTC research prioritization, with more support for this position from earlier generations of experts than from later generations, who more strongly supported the White House EOP or HHS to take the lead for determining priorities.

This finding is important because, while the group did support DHS to continue in this role, there was not complete agreement. DHS should continue to work with its partners in the White House and the interagency community to communicate about how prioritization decisions are made and to coordinate priority setting with other elements of the USG biodefense enterprise.

Conclusions

This Delphi study is important because it is the first time that questions about BTC research have been posed systematically to a collective of biodefense experts. Most importantly, this research indicates that experts view BTC research as a necessary USG function and that despite the risks inherent in this kind of research it should go forward under the leadership of the Department of Homeland Security. Additionally, we found that the risks of most concern to participants, namely the risk of insider threat and the risk of violating or appearing to violate the BWC, are currently being addressed by DHS in its Biological Threat Characterization Program, which is encouraging. Further communication to biodefense stakeholders about the safeguards already in place at NBACC will be important to reassure those experts who have ongoing concerns.

The results of this study show that experts are in favor of implementing a review process for BTC research that includes the components proposed in the Delphi survey. However, it is also clear that this process should not be overly burdensome and thus hamper the important characterization work that is needed for biodefense. While not all experts agreed on all points related to BTC work, findings often did not differ by type of expertise, training, or gender. Responses did often differ by generation, however, with earlier generations tending to be more comfortable with and confident in existing government processes, and less concerned about the risks of BTC research; and later generations less confident in existing approaches and infrastructure and more concerned about risks of research. This generational divide may speak to the need for further engagement of current and rising government leaders; to understand their concerns, to communicate with them about the benefits and risks of BTC research, and to socialize the steps that are being taken to make sure that this research is safe and effective.

This study did not illuminate any hard and fast rules for BTC research that crosses a "red line" and should not be undertaken, with the exception of the rules that the research should never violate the BWC or involve human subjects research. But, experts did indicate that research with the potential for creating novel pathogens or pathogens with novel mechanisms that could defeat vaccines, drugs, or diagnostics, should be reviewed very carefully prior to the work being done. There should be strong justification for this type of research, and each such experiment should be reviewed and considered individually.

Finally, this research shows that there is no agreement about when biological agent characterization can be stopped. Experts felt that there ought to be some stopping point, but once again it will need to be evaluated on a case-by-case basis. This finding does indicate that research on “traditional” select agent pathogens should be continued along with research on emerging or future threats.

The research team recommends that biological threat characterization research programs in the USG and internationally review these findings with an eye toward evaluating program processes and stakeholder engagement approaches, and refine programs accordingly in order to maximize the benefits, minimize risks, and cultivate support for BTC work.

Findings from this Delphi study can be extrapolated to other security-related threat characterization programs, and similar efforts should be applied more broadly to other federal programs that are working to prioritize research for CBR agents prior to the next contamination emergency.

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PAPER 2

Applying Crisis and Risk-Based Decision Making Frameworks to Public Health Emergencies Involving Contamination: An Integrative Literature Review

Abstract

Objective: Response to major contamination emergencies often requires that decisions about protective actions are made rapidly in order to protect the health of the public. However, under considerable time pressure and uncertainty, decision making that balances risk-based information with other important considerations can be difficult. This review examines the literature for ways that decision making in contamination emergencies can be improved.

Methods: An integrative literature review was conducted in February 2016 using three databases and a set of key words and terms. Fifty-one pieces of literature were included for final review and analysis. Themes were identified using open coding and constant comparative methods of qualitative analysis, and summarized by category and topic area.

Findings and Discussion: Relatively little has been published on the topic of risk-based decision making in contamination emergencies. As a result, this review analyzed separate bodies of literature on risk-based decision making in non-emergency periods, crisis decision making, and real world events to identify properties of successful decision making in those contexts. Key themes identified from the literature include cognitive factors in decision making, decision process and structure, risk assessment, addressing uncertainty, formulating and weighing options, and decision support tools.

Conclusions: Findings from this review show that multiple relevant frameworks exist that could be beneficial to future decision makers responding to contamination emergencies. Future research should focus on tools that can enable leaders faced with

contamination emergencies to make protective decisions that are timely, transparent, based on evidence and sensitive to other important considerations.

Introduction

Emergencies involving an accidental or intentional release of a contaminant, be it chemical, biological, or radiological, can significantly impact public health. Contamination events occur with relative frequency around the world, with some of these events affecting public health over the long term, and some rising to the level of emergency where urgent action is required to mitigate acute impacts on the health of those affected. In these acute contamination emergencies, early analysis and decision making will have a large impact on how the event unfolds. In fact, research suggests that decisions such as evacuation or sheltering, made during the earliest phases of a response, can have a significant impact on outcomes. This impact could be positive or negative depending upon the quality and timeliness of those decisions [83]

Often in major contamination emergencies such as large chemical spills, decision making is pushed up to the political level because of the serious and public nature of the event. In these emergencies, therefore, decisions are often made not by risk assessors or scientists who analyze available data, but by political leaders such as mayors, or governors, who may have had little experience in scientific analysis or response to emergencies, but will need to make decisions rapidly nontheless.[1]

Emergency response to contamination emergencies may require decisions to be made within the first hours of recognition of an event. Ideally, this response will be well informed, risk-based, and will provide maximal protection to the population at risk. However, with significant pressure to take action, comes a high degree of uncertainty and stress, making optimized decisions very difficult.[84] Compounding this difficulty is the complex nature of these emergencies, which often requires consideration not only of scientific evidence about risk to public health, but also political, social, economic, legal, ethical and other considerations that inevitably influence the decisions and outcomes. It is important for decision makers in these crises to address the complexity and uncertainty of the situation by considering these inputs as well as public values and risk perception.[84]

Ideally, it would be best to gather data to inform risk assessment and create and exercise plans prior to an emergency.[85,86] Crisis management does not come naturally, and so it may be important for governors or other leaders at the state or local level to gain training in crisis management and to also train their staffs.[83,87] Yet, in reality, most decision makers at the political level are not formally trained in crisis response or risk assessment and management, and contamination events are unexpected and difficult to plan for and are characterized by deep uncertainty. Therefore, political leaders are usually thrown into a decision-making role without warning or time to prepare when a crisis occurs. As such, the US Institute of Medicine (now the National Academy of Medicine) Forum on Medical and Public Health Preparedness for Catastrophic Events has called for the US to "prepare governors to be ready to take extraordinary, unprecedented action" for public health emergencies.[83(p187)]

Response to contamination emergencies will require decision makers to make both risk-based and rapid crisis decisions that mitigate the consequences of a contamination event. Training in emergency management is available, and can be conducted with decision makers prior to an emergency. But these trainings are mainly focused on structure; for example the incident command structure (ICS), and are rarely focused on the actual process of decision making itself.[88] Moreover, while training in risk assessment is available for public health officials and scientists for non-emergency events, risk-based decision making is not taught to decision makers directly, and is rarely focused on the emergency context. As a result, there is currently no established body of literature or guidance that addresses the process of risk-based decision making during the initial response to contamination emergencies.

Within the literature, the area that is least well understood or reported is the actual process of decision making. Most of the literature and after-action analyses from real emergencies or exercises are focused on the outcomes of decision making, but not on the process itself, which leaves a large knowledge gap about how decisions are actually made during contamination emergencies.[88] The purpose of this integrative literature review is to bring together literature from the fields of crisis decision making and risk-based decision making, to synthesize knowledge into a cohesive framework that will inform risk-based decision making in major public health crises involving chemical, biological, or radiological contaminants.

Methods

The integrative literature review format was chosen for this analysis because it is designed specifically for synthesis of literature "in an integrated way such that new frameworks and perspectives on the topic are generated."[59] Because there is currently no body of literature focused specifically on risk-based decision making in public health crises involving contamination, and much of the knowledge on this topic resides outside of traditional academic settings, this integrative method made it possible to analyze pertinent perspectives from multiple fields and types of literature and bring them together in a new framework. The literature review focused on two major categories: crisis decision making and risk-based decision making. These categories were chosen because they represent theoretical and operational viewpoints, as well as both the time-sensitive nature of crisis decisions and need for integration of data and other information to make informed decisions.

To conduct the search, the author chose three databases: *PubMed* to capture public health literature, *Web of Science* (all databases) to cover other scholarly publications on non-public health-related decision and risk assessment science, and *OAIster* to gather relevant grey literature and other open-access materials. The initial search was broadly inclusive to help ensure that no major literature was missed relating to the main topics of crisis and risk-based decision making and contamination emergency decision making. A number of key words and phrases were used to conduct the search. These were applied consistently to each of the three database searches (Table 7).

The initial search, conducted in February 2016, generated a total of 1895 pieces of literature for review. Of that total, 1303 were related to crisis decision making and 592 were related to risk-based decision making; and 522 were from *PubMed*, 897 were from *Web of Science*, and 476 came from *OAIster*. These results were then screened for relevance through review of titles, abstracts, and duplicate checking. A piece of literature was excluded in this first round of review if it was a duplicate, if it had no focus on decision making, if it had no focus on or relevance to public health or emergencies, if its focus was on personal decision making (e.g., personal medical decisions) without relevance to broader population-level decision contexts, or if it was a non-English language publication. This first level of review resulted in the inclusion of a total of 428 pieces of literature, including 265 related to crisis decision making and 163 related to risk-based decision making.

The author then implemented a second round of review to narrow down the time period for article inclusion and also to continue more in-depth review for relevancy. During this stage, literature inclusion was restricted to publication after the year 2000. This date was chosen because it was inclusive of a number of major contamination events in the US and around the world beginning with the anthrax letter attacks in 2001, and ensured that the literature would be relevant to modern decision-making contexts. Theories that are influential in the areas of risk-based and crisis decision making have been built upon over decades and still largely underpin current decision-making approaches. Thus, they should be adequately represented in this review in spite of the temporal restriction.

The second review round was conducted by reading abstracts and the full text of each included piece of literature. Exclusions were made based on the following criteria: publication prior to the year 2000; non-applicability to the short crisis decision-making time period that is the focus of this review; focus on environmental regulation and not on response to contamination events; and a focus on mathematical models and technological tools to aid in decision making that are not developed for use in emergencies. In this second round of review, a total of 370 articles were excluded. Fifty-one were included for final review and analysis, with 24 pieces of literature under the topic of crisis decision making and 27 under risk-based decision making.

Once the second review round was completed, the author re-read the 51 final articles and highlighted and organized findings using open coding and constant comparative methods of qualitative analysis. These methods were used rather than quantitative coding because they are meant to generate theoretical ideas and hypotheses from disparate types of evidence, and refine them throughout the review process in order to develop a new theory or framework.[60] As part of this approach, each piece of literature was reviewed for relevant points under the initial categories of crisis and risk-based decision making. Relevant points were highlighted and notes about each piece of literature were recorded in an outline organized by category and theme as they emerged from the review. All reviewed literature was also recorded in a literature concept review matrix, which identifies conceptual frameworks employed, major findings, types of literature, strengths and weaknesses, and concept focus for each reference (Table 8 and 9).[61] Findings from the final review stage were then summarized by category and topic area and are reflected in the discussion section of this review.

Discussion

Crisis Decision Making

Literature in this section of the review is focused on how decisions are made during a crisis period, where "a primary distinction between a 'problem' and a 'crisis' is the pressure of time involved."[88(p.4)] Crisis decision making has been studied in a number of contexts including political, environmental, financial, and public health crises. Because contamination emergencies that impact public health require rapid decisions with uncertain or limited information,[89,90] this literature review method captured a body of literature applicable to crises that require action and decisions within hours to days, and applicable to population-level contexts. Literature on crisis decision making is organized into three categories: cognitive factors affecting crisis decisions; decision process; and leadership and structure for crisis decision making.

Cognitive Factors Affecting Decisions in a Crisis

A large focus of the crisis decision making literature is on the cognitive processes that influence how a person makes decisions in a crisis. Research in this area primarily discusses two types of decision making: 1) intuitive and 2) rational or analytical decision making. Nobel Prize-winning social psychologist Daniel Kahneman describes these processes as System 1 (intuitive) and System 2 (analytical) or the dual process model.[46]

Broadly, intuitive or system 1 decision making involves quick recognition of a situation and near-immediate decision making about courses of action. Richard Gasaway, a veteran of fire-EMS service, describes intuition as "a pre-conscious (or subconscious) process of logical reasoning that has manifested its effects in conscious, systemic form." He notes that, "The subconscious intuitive mind can think logically and make decisions without registering any processes in the conscious mind, and with superior speed." [91]Paul Slovic, et al. recognize this intuitive process as "Affect," and describe it as a "faint whisper of emotion," or the "specific quality of goodness or badness" that is associated either consciously or unconsciously with a stimulus.[92] Reliance on these feelings for decision making is termed the "affect heuristic" and it is a quicker and easier way to make decisions, particularly in a crisis. Slovic suggests that affect might be used as an "orienting mechanism" to help decision makers think quickly about a problem when time is short.[92]

There are examples where intuitive decision making in crises is very important and reliable. Gasaway and others have studied fire-fighting decision making and have concluded that fire ground commanders rely mostly on intuition to make decisions, particularly when in extremely time-compressed and stressful situations. In these situations, commanders have time only for intuition or “gut feelings” because decisions must be made in minutes or even seconds. Often, when the commander is very experienced, these decisions tend to be relatively sound.[91] Gassaway notes that a majority of the research on crisis decision making favors a rational decision process and trends toward checklists, automation, and decision-support tools. However, at least in the fire emergency decision context, he emphasizes the importance of accounting for and using intuition.[91] Both Gasaway and Slovic recognize that intuitive decision making is not appropriate for every context, and it should not be relied upon completely especially by inexperienced decision-makers, but it is an important and unavoidable human component of decisions, and should be acknowledged, accounted for and used to the extent appropriate depending on the context.[91,92]

Kahneman, Kayman, and others are more skeptical of reliance on intuition, and stress it can be relied upon only if it has been developed through repetitive action and lengthy experience.[46,93] They find that decision makers are often over confident about their intuitive decisions. They find that in order for a decision maker’s intuition to be reliable, the environment needs to be relatively familiar with regularities and without too much complexity and the decision maker needs to be very experienced in order to have enough basis for their intuition. A number of studies have shown that computer simulations often outperform the intuition of decision makers who are not truly experts, who often choose correctly less than 50% of the time.[46,94] Greater experience can enhance accuracy based on intuition when situational cues are consistent with what has been seen before. However, even for experts, if cues deviate from past experience, it can undercut the value of intuition.[95]

Kayman and others advocate for a more rational approach to decision making because they find that intuitive processes are subject to error due to a number of "cognitive, moral, and emotional 'traps' and biases," which can have a negative effect on judgment.[46,94(p.167)] These cognitive traps and biases include altered perspectives, where framing, compelling stories, and recent events can cause decision makers to frame a situation only one way and not consider different possible situations or solutions; optimistic bias, where excessive optimism and overconfidence can result in inaction by a decision maker; appeal to authority, where decision makers look up to higher levels of authority or expertise and delay decision making waiting for someone else to provide guidance; escalating commitment, where decision-makers throw "good money after bad" and neglect to consider new approaches; anchoring, where a pre-identified solution prevents consideration of a full range of options; and loss aversion, which can cause decision makers to delay decisions.[93,96]

Kayman finds that moral considerations, guided by personal moral development can also unconsciously affect decision making and should be considered and discussed. [94] Furthermore, risk-seeking attitudes at the individual and institutional levels can also influence intuitive decision making.[95] Even when decision makers are expert and can rely on intuition to a greater extent for decision making, their expertise can also cause them to be subject to status quo bias, where new alternatives are not considered because past approaches are relied upon.[95]

In addition, information pathologies can delay and influence decision making. In particular, information bias, or continually demanding more information, can delay response. [93] This is particularly true in a crisis when decisions need to be made very quickly with limited, even negligible information. What you see is all there is (WYSIATI), or considering only the information immediately available can result in decisions made on bad information, and failure to communicate important or contradictory information among a team; for a decision maker this can result in poor decisions based on incomplete information.[46,93,94] Cognitive overload/strain can also affect decisions when the large amount of information, which is complex and dynamic in a crisis, overwhelms a decision maker.[97]

According to Higgins and Freedman, inappropriate approaches to crisis decision making include a "lack of a systematic decision-making process, the application of intuitive decision making to non-intuitive problems and the application of cognitive decision-making techniques that are ill-suited to the situation."[93] Critical thinking is very important in crisis decision making. This involves asking difficult questions, gathering and evaluating data and information, and testing the logic of proposed decisions.[93]

In a crisis like a contamination emergency, where time is a factor but not so urgent that critical thinking is impossible, pushing decision making to be more deliberate and conscious may improve the quality and reliability of decisions. Decision makers who first rely on System 1 (rapid automatic and intuitive judgments) to reach an initial decision, and then interrogate that decision using System 2 (slow, conscious, and controlled) are shown by Kahneman and Kayman to be more successful than either alone. [46,94] Both lines of thinking come together in the literature to show that intuitive and analytical approaches are not at odds. The two systems operate in tandem and the analytical approach depends on the intuitive analysis for input.[46,98] Slovic concludes that good risk management will capitalize on the advantages of both intuitive and rational processes and mitigate the limitations of both systems.[98]

Decision Processes and Approaches

A second major focus of the crisis decision-making literature is on decision-making processes, including the types and timing of decisions that need to be made, how decision making can be organized, and approaches to ensuring that crisis decisions are as good as they can be despite significant time pressure. All of the processes evaluated in this review have been developed through, or applied extensively to real world crisis decision making.

Early in a contamination emergency, the first decisions that are often needed are protective action recommendations (PARs), or decisions to help limit exposure and reduce further harm to the affected population.[99] PARs are often implemented in the face of significant uncertainty, but if PARs are delayed there may be significant consequences from not protecting the public early enough.[96] Lindel emphasizes that "minimizing the chance of unnecessary exposures requires taking action as early as possible, but this increases the likelihood of unnecessary protective action."[96] There are many factors that must be considered in making initial PARs, including the type, amount, and geographic distribution of the hazard; population dynamics of who is most and least at risk; and feasibility of implementing protective actions.[96]

According to Lindell, who discusses PARs in the context of radiological contamination emergencies, "irreducible uncertainties in the chains of events for the release and population response create the potential for two types of decision errors."[96] These errors are false positive response, where protective action decisions are made but are not needed or appropriate; and false negative response, where protective actions are not implemented, but are needed. Protective action decisions can have significant consequences that either significantly reduce or increase the risk to public health. The potentially negative impact of early protective action decisions was demonstrated in one federal bioterrorism exercise in 2001, when decision-makers made the PAR to have residents shelter in place for an extended period of time to avoid exposure, but gave no thought to the secondary effects of depriving people of food or medical care. In that exercise, the chosen protective action would actually have done more harm than good.[100]

There are a number of decision models and theories that emphasize a deliberative evaluation of protective action options to reduce or eliminate the cognitive biases, traps, and heuristics identified in the section above. These models include the recognition-primed decision model, the disruption management model, the observe, orient, decide, act (OODA) loop model coupled with the sense-making framework, the medical decision model, and core processes in public health emergency response. All of these process models have in common a loop of information gathering, deliberation of the situation at hand, and development and verification of possible response options, but they differ somewhat in their approach and degree of information gathering and deliberation.

The recognition-primed decision model accounts for both intuitive and rational decision making and breaks decision making into two fundamental components: evaluation of the current situation and evaluation of a course of action. In recognition-primed decision making, Dunn describes three possible scenarios: 1) a simple match where a decision maker recognizes a situation as "typical of others dealt with in the past," and matches that situation to a relevant action; 2) diagnosis, where a decision maker is "unable to recognize a situation as typical," and so enters into a "data-acquisition loop" where new information is acquired and applied to the situation; and 3) evaluation, where the situation is not ambiguous, but there is uncertainty with regards to the best course of action.[101] In the first scenario, intuition is a primary guide to decision making, while in the other two scenarios, analytical processes are used to understand the situation and to evaluate options for action. Dunn, et al., find that successful acquisition and application of data in complex crises, where both the situation and courses of action are very uncertain, is highly reliant on effective communication between a decision maker and a decision-making team.[101]

As with scenario two in recognition-primed decision making, the disruption management model focuses on a loop of information gathering, assessment of impact, formation of options, and actions, then back to information gathering.[102] This model calls for crisis management teams to seek information inputs from thoughtful people, but only to the extent that time allows, because in a crisis, careful consideration of evidence and options must be balanced with timeliness. Information overload can occur when a decision maker or team demands more and more evidence, seeking perfect information.[2,102] According to McAlister, "a timely, carefully-planned decision is far more likely to be fit for purpose and to withstand scrutiny at a later date" than an intuition-driven process.[102] However, McAlister also suggests that decision makers need to remain focused on the fact that the "need to act quickly is more important than the search for flawless information."[102]

Possibly the best-known and most widely applied model for crisis decision making is the OODA loop model, which also focuses on a cyclical process looping back to observation.[93] OODA was developed by US Air Force Colonel John Boyd to help fighter pilots make rapid and accurate decisions in dog fights with enemy planes. This model, in combination with the Cynefin Sensemaking Framework, described by Higgins and Freedman in their research on improving crisis decision making, provides a situationally-nuanced way for leaders to approach decision making in a crisis.[93]

The OODA loop provides the process for investigating, analyzing, and deciding in a crisis, and the Sensemaking framework applies this loop to different crises of varying complexity. Sensemaking is aimed at reducing ambiguity in the decision-making process by encouraging decision makers to first have a collective understanding of the situation, which will then translate to evaluating options for action.[90] As with the recognition-primed decision model, the Sensemaking Framework defines different levels of event complexity: simple (ordered), complicated (ordered), complex (un-ordered), and chaos (un-ordered). Ordered situations might include small to medium-sized contamination events with a known contaminant and a largely homogeneous population, for example.

According to Higgins, complicated situations are those that can be explained by cause and effect and can be understood through collection and analysis of data and expert knowledge, mostly involving “known unknowns.” The approach to complicated situations is to follow the OODA loop of sensing, analyzing, and responding. Decision making in radiological events can potentially be categorized in this level of complexity because the characteristics of radiological contaminants and their effects on human health are well understood, and acceptable levels of exposure have already been pre-determined.[83(p.78)]

In contrast, complex situations cannot be fully understood because they involve complex adaptive systems and "unknown unknowns." An example of a complex situation might include a chemical spill in which the chemical has not been studied, and human health effects are unknown. In complex situations, a decision maker enters the OODA loop at the act phase by trying something and seeing what happens in order to better understand and stabilize the situation. According to Higgins and Freedman, intuitive decisions are dangerous in complex situations because these situations are not linear or well-understood, and so in these situations intuition should be reviewed and amended through careful thought. Finally, the Sensemaking Framework defines chaotic situations as beyond comprehension that have never been experienced before, with "unknowable unknowns." In chaos, decision makers also enter the OODA loop at the act phase, and proceed through the loop many times, rapidly, with the goal of stabilizing the situation and eventually understanding it. Chaotic situations may involve compound exposures to multiple types of contaminants or novel contaminants that have never before been dealt with. An example of chaos is the contamination events resulting from the terrorist attacks on September 11, 2001 in New York City.[93] Most of the time, contamination events will fit into the complicated or complex levels, but they may also fit into chaotic.[93] Higgins and Freedman find that in complicated, complex, or chaotic situations that call for analytic (system 2) decision making, the more solutions that are carefully examined, the more likely that a good/best solution will emerge, but they are also careful to emphasize that "a good decision 'in time' is much better than a 'perfect decision' made and executed too late."[93]

Kayman and Logar apply the OODA loop model in creation of a Framework for Training Public Health Practitioners in Crisis Decision Making. The Kayman and Logar framework is aimed at promoting System 2 (analytical) thinking, taking advantage of System 1 (intuition), and avoiding some of the pitfalls of heuristics, biases, and traps, which were discussed in the previous section of this review. This framework presents a deliberative decision model that is primarily rational, but also accepts and incorporates intuitive and less-rational cognitive and emotional inputs, recognizing and accounting for the role they play in decision making. Kayman and Logar's framework provides a stepwise approach to decision and action in public health crises (but not specifically in contamination events), advising decision makers to quickly identify up to three alternatives or choices for action using intuition, or a combination of intuition and deliberation (depending on the urgency to act). In both urgent and nonurgent decision contexts, they emphasize that decision makers need to consider and weigh ethical, legal, political, and logistical concerns along with scientific data as part of their choice, asking themselves how each alternative does under legal, political, ethical, and logistical scrutiny. They also specifically recommend acknowledging and dealing with emotions directly instead of repressing them. The authors note that people handle stress in different ways, and even experienced leaders can have decisions be derailed by emotional reaction.[94] Kayman and Logar suggest that failure to consider any of the above categories can have serious consequences for the success of the response, and they propose that their framework can help decision makers to consider them. [94] Finally, Kayman and Logar emphasize that documenting how decisions are made as the response unfolds can help improve awareness and clarity of thought during a response, and justification afterwards if decisions are questioned.[94]

Rebera et. al. also discuss the importance of considering legal, political, logistical, socioeconomic and especially ethical concerns, in crisis decision making. The authors suggest that a crisis decision-making approach should provide a “workable heuristic for comparing competing courses of action,” and should include rational justification of any decisions.[103] With regard specifically to ethical considerations, they acknowledge that in a crisis, traditional approaches to weighing ethical principles and values are likely too complex and time consuming, and so they propose a simplified approach for use in a crisis. They first discuss a consequentialist approach, comparing consequences of courses of action and choosing the one that saves the most lives.[103] However, Rebera reminds us that saving lives is very rarely the only relevant value in a crisis. So, in order to incorporate other values, a modified consequentialist approach may be used. In this modified approach, courses of action that elevate lifesaving would first be identified, and then other core values or “side constraints” are interrogated as a secondary consideration. If a course of action violates any of the critical side constraints, that course of action can be discarded.[103]

Like the OODA loop model/Sensemaking Framework and recognition-primed decision model, the Medical Decision Model in Urgent Settings highlights a cyclical decision process. In this process, much like Sensemaking in complex or chaotic situations, a decision maker starts by acting with an initial intervention, then proceeds to gather additional data and consult with others, and loops back to further intervention based on more-complex data, ultimately to identify a definitive management course.[104] Medical decision making is primarily focused on individual patient care and is largely not applicable to population-level decisions. However, the process itself is similar. As part of this process, as with population-level decision making, Koerner et al. emphasize that having a decision maker and subject matter experts co-located helps with situational awareness including both informal and formal exchanges of information and opinions.

The core processes in public health emergency decision making, as described by Parker, et al. in a RAND Corporation report on measuring effective decision making, are also part of a continuous loop from establishing situational awareness, action planning to mitigate health effects, initial execution, and back to situational awareness.[2] In gaining situational awareness, the authors emphasize the importance of acknowledging unknowns and developing "strategies for reducing uncertainty."[2] As with the OODA loop, the Sensemaking Framework, and the Medical Decision Model, this public health emergency process focuses on consideration of multiple alternative options (if time allows). In addition, Parker et al. suggest that alternatives should be explicitly considered in the context of their potential consequences, pros, and cons.[2]

Leadership Roles and Decision-Making Structure

In large public health crises, including significant contamination events, it is often an elected official (mayor, governor, or department head) who has the responsibility for final response decisions. Political leadership is therefore important in the management of large-scale crisis, but these leaders are seldom risk or scientific experts and often require the participation of experts in the decision-making process.[100] Inglesby, et al. note that whoever is ultimately responsible in an emergency, has to have the "legal and moral authority" to make the necessary decisions, especially when the impacts of protective actions are potentially large (as they can be with travel restrictions and evacuation or shelter-in-place requirements/recommendations).[100(p.66)]

There are a few variations on the possible organization and structure of crisis decision making: a decision maker decides for him/herself what course of action is best without consulting others in the process–an expedient and potentially effective approach in an extremely time-sensitive situation; a decision maker gathers information and advice from other sources to inform his/her decision; or a decision-maker delegates or spreads out decision-making authority among multiple parties. The literature in this area focuses mainly on the latter two options, acknowledging that diversity of inputs and perspectives is a priority especially for non-expert decision makers in extremely time-pressured situations.

The Incident Command System (ICS) is one structure that is often used to aid in emergency response. It provides a hierarchical structure that identifies a single commander and defines each actor's role in the response.[105] Its primary strength is that ICS provides a top-down approach in which the commander can control the situation, communication flows systematically down to responders, responders' roles are known and can be executed according to a pre-set plan and the incident commander is the one who makes decisions.[106] Under ICS, the commander needs to understand leadership, but is not necessarily a subject matter expert, and commanders must rely on subordinate individuals to provide the best information to inform decision making.[101,105] However, while important decisions can involve a team, the decision authority in ICS ultimately lies with the commander.[97,102] Higgins and Freedman find that defining decision-making roles clearly at the start of the crisis, as is done under ICS, may be critical to avoiding information overload and making effective decisions. Having a crisis management team provide options, but ensuring that the decision maker has the ultimate authority and responsibility for deciding on a course of action may be particularly important.[102] Yet, while ICS has established standard roles for response to a crisis, it provides little guidance on how decisions should actually be made by the commander in a crisis.[2] According to Van Santen et al., netcentric (command and control) conditions do not often exist in a crisis decision-making context. Instead, decisions are often made in a bureaucratic political context where there is not one clear decision maker and many different agencies/stakeholders have priorities and opinions.[107]

Other approaches to top-down decision making have also been researched and applied in emergencies. The RAND Corporation, in their report on measuring decision making in public health emergencies, highlights the need for process controls or deliberative management of the flow of information and resources. This includes managing who is needed as part of the decision-making process, understanding authorities and legal restrictions, maintaining focus on timeliness and making decisions, and ensuring that multiple perspectives are considered.[2] Rosqvist suggests that the decision maker should provide the initial scoping and problem definition of the situation, determine decision rules (acceptable risk), and be ultimately responsible for making the decision once options have been evaluated, while advisors, normative and subject matter experts, and stakeholders all have a role in conducting risk assessment, formulating risk management options and providing feedback into and about the process.[108]

Many experts agree that in complex public health crises, there is no one single person who has all of the technical expertise and real-time data about the situation, sufficient to make a decision without additional input or advice. As with ICS, other top-down approaches to response involve gathering teams in support of a decision-making process.[94,96] Research shows that "cognitive diversity" or diversity of thought improves decision making, often because it helps mitigate errors and biases.[93,109] The more diverse the viewpoints are, the better those contributions will be, and the more likely that risks and advantages of solutions will be identified.[93] Different viewpoints to be incorporated in the process are scientific, operational, reputational, psychological and legal perspectives, among others.[88] In addition, Mirandilla emphasizes that a public relations expert should be included not only in the decision-implementation phase, but also in the decision-making process itself in order to incorporate public views and values that will enable a successful response.[90] Importantly though, having too many people in the decision-making process can tip the balance toward chaos and confusion, resulting in decision-making delays as happened in the Three Mile Island nuclear response.[96] Inglesby et al. recommend that the decision support team should be fairly limited in size, as large groups of people without specific knowledge to contribute to the decision-making process can lead to "inefficiency, indecisiveness, and significant delays in action."[100(P.66)] In summary, the literature on group-informed decision making in a crisis generally recommends a small, but diverse decision-advisory group.

Another approach to crisis decision making is a distributive decision model, where multiple people are responsible for making decisions, not one single individual. In a contamination event this might mean that within a team responding to the emergency, each team member performs a specialized function and makes decisions about that function, resulting in decision making being distributed across team members.[101] Particularly in a bureaucratic/politicized environment, this type of decision making may be required. In these environments, a top-down decision-making approach may be inadequate, because decision makers from multiple agencies or organizations have decision-making authority. Instead Van Santen suggests that team effectiveness will be better if team members have a shared mental model of the response, shared goals, in order to better negotiate the elements of the response.[107] Creating a shared mental model can take different forms including haggling, cost-benefit analysis, competition (game playing), partnership and problem-solving/collaboration to solve a problem. [107]Dunn suggests that the success of distributive decision making requires a high level of interaction, without which it will fail.[101] "Optimal performance for distributive decision making requires both good taskwork and good teamwork."[101(p.720)]

Risk-Based Decision Making

Literature in this section of the review is focused on how risk assessment information and scientific evidence can be incorporated into the decision-making process during a contamination emergency. Most of the literature on risk-based/informed decision making does not focus on emergencies, so the purpose of this section of the literature review is to extract applicable lessons from past contamination emergencies, and from non-emergency decision contexts, and apply them to crisis decisions. Literature on risk-based/informed decision making is organized in this review into five sections: defining the role of risk-based decision making, risk assessment process, acknowledging and addressing uncertainty, formulating and weighing options, and modeling and decision support tools.

Defining the Role of Risk-Based Decision Making

Pollard et al. states that in "risk-informed decisions, we seek to understand the significance of a risk, decide whether it requires management and what that might cost, and then implement the decision effectively, so reducing risk to an acceptable residual level; recognizing that zero risk is not achievable."[109] In contamination emergencies that threaten the health of the public, potentially more so than with other emergencies, it is important to consider risk-based information in decision making, because without scientific data on the contaminant, its effects on human health, the type and levels of exposure, and other context-specific factors, decisions-makers cannot effectively determine protective courses of action. However, as noted in the crisis decision-making literature, there are many factors that have to be considered in making a decision, science being only one of them. The role of scientific data and how it should best be utilized can be debated.

Rosella et al. propose that there are three different potential ideologies with respect to the role of evidence/data in decision making: evidence-based ideology, which puts scientific evidence as central to any decision without reinterpretation by policy-makers; policy-based ideology, which says that evidence should inform and not dictate policy; and pragmatist ideology, which says that science should be a primary, but not the only, consideration for decision makers.[110] Rosella et al. come to the conclusion that the pragmatist ideology is probably the most appropriate, but that policy-makers should strive to be transparent in their decision-making processes in order to reassure the public and other stakeholders that evidence has been carefully considered alongside other considerations.[110]

Risk-Based Decision Process

The process of risk assessment and risk-based decision making has been studied extensively in a variety of contexts, including financial industry, environmental and occupational health, and the nuclear power industry. As a result, the literature reflects work that has been done to help standardize and systematize this process. However, within the risk-based decision-making literature, there are still very few studies or reports focused on public health emergencies involving contamination. Literature on the nuclear industry and its preparation for potential radiological emergencies has the most relevance to this review because it deals with both contamination and emergency response.[84,111,112] However, this literature is also difficult to extrapolate to other emergency situations because, unlike for other hazards, the nuclear industry has developed substantial plans, models, and decision support tools that are available to guide decisions in an emergency. It is unlikely that in a non-nuclear radiological emergency or other types of contamination events that the same level of resources will be in place to help decision makers. Despite the lack of an exact contextual match, this review analyzes the literature on risk-based decision making to extract elements that should be considered in a contamination emergency.

The risk-based decision literature generally focuses on a decision process beginning with a clear definition of the problem, then proceeding to defining options through a number of quantitative and qualitative approaches, evaluating options, and making and implementing a decision, followed by performance monitoring, and modified actions as needed.[113] Mengersen and Wittle, in their article on "Improving Accuracy and Intelligibility of Decisions", emphasize that "data-based risk assessment is underpinned by three critical interacting components: the data used to inform the decisions, the statistical methods employed to analyze these data, and the inferences and consequent decision making that ensue on the basis of these analyses."[114(p.S15)] The 2009 National Academy of Sciences, *Science and Decisions* report, which is focused on human health risk assessment for (non-emergency) environmental hazards, lists three phases of risk-based decision making: scoping the problem, planning and risk assessment, and risk management.[18,115]

The first phase in risk-based decision making of problem formulation and scoping, includes identifying the problem, identifying preliminary options for dealing with the problem, and identifying the needed technical assessment approach to evaluate risk management options.[18] Pollard et al. suggest that this step should also seek to define what questions can actually be answered by scientific/risk information and which ones cannot.[109] Problem formulation should identify what the risk is and to whom, and identify the level of residual risk that the decision maker can accept.[109] A clear definition of the problem is critical. This definition should include both life-saving and health-protection goals, but also other goals such as economic stability, ethical goals, public acceptance, etc. The more specific a decision maker can be about the goals that need to be met, the better risk-informed decisions can be.[111]

In defining the problem and setting goals for the response, the literature shows that it is important to incorporate an understanding of an affected community's perception of the risk and of acceptable levels of risk. Without this understanding or involvement of community representatives in the process, the problem definition, risk perception, and goals of the response may differ between the decision maker and the public.[116] When this happens, it is difficult to implement risk-based decisions that require the cooperation of the community.[117] In many situations, risk management fails because the risk-based decisions are unsatisfactory to the community affected by the decision. The Red River flood of 1997 in Manitoba is one example where risk perception differed among the decision maker and the affected population. In this emergency, the decision makers had a higher perception of the risk of flooding, and prioritized life-saving through evacuation as the primary protective action, while the affected community perceived a higher risk to property than to life and thus prioritized protecting their properties. When the government forced evacuation, the public was less than happy or helpful, which complicated the response, and may have resulted in lost lives.[117] In another example, Younger et al. recount risk-based decision making during a river contamination response in the UK, and report that despite clear evidence that the water was safe to use, the public perceived use of the water as risky because of the unusual color, and would not use it until further remediation was conducted.[118] According to Amandola et al., this problem can be ameliorated by incorporating public views and values throughout the risk-based decision process, including early in the process before risk assessment is conducted.[116]

Another early step in risk-based decision making is to identify how risks will be assessed. In an emergency contamination event, because of the time-pressure involved, there will likely be little time to create a comprehensive statistical model, and deterministic calculations may be all that can be accomplished before initial risk-informed management decisions are needed.[84,108,115,119] Deterministic calculations are simple, and can be done quickly, but can also be overly simplistic and may lead to either under- or overestimation of risk.[113] More-complex risk analyses, such as a fully quantitative probabilistic approach, might be more rigorous, but would require much more time and available data to conduct – time and data that will likely be unavailable in a crisis. It will be important to – decide quickly on an approach and acknowledge its strengths and limitations before proceeding, making sure it meets the needs of the decision maker in the situation at hand.

Regardless of the complexity of the analysis, there are a number of standard steps identified in the *Science and Decisions* report that decision makers should consider and which require corresponding data or judgment: hazard identification, dose-response assessment, exposure assessment, and risk characterization.[18] Scientific evidence for each of these steps will be of varying quality and availability in a crisis, and decision makers may need to evaluate multiple competing theories or lines of evidence.[109] Pollard et al. in their article on *Better Environmental Decision Making*, advocate for ranking evidence on a numerical or qualitative scale to evaluate the strength of the evidence for risk assessment.[109] In the event where evidence is severely lacking or decisions are needed before evidence can be fully evaluated, it may also be necessary to rely more on qualitative information and expert judgment than on hard data. Tony Rosqvist, in his dissertation *On the Use of Expert Judgment in the Qualification of Risk Assessment*, posits that expert judgment is needed in every phase of risk assessment and can be systematically applied.[108] For the hazard identification step Rosqvist notes the importance of generating multiple scenarios for consideration, and suggests that can be accomplished through a group process and generation of a risk matrix.[108] To ensure that the right hazards have been identified, additional stakeholder review could be incorporated if time permits.[108] Rosqvist also advises that expert judgment can be elicited from multiple people to help with estimating various parameters (e.g., for dose-response and exposure assessments) for the risk assessment. If estimates differ among experts, discussion should focus on the possible reasons for the differences and attempt to achieve consensus on values to be used.[108] In characterizing the risk, in the lead-up to decision making, Rosqvist recommends incorporating an evaluation of stakeholder perspectives and needs, and even seeking stakeholder input if time permits, since stakeholders may provide unique socioeconomic, political, and other perspectives that might otherwise be missing.[108] Finally, Rosqvist recommends independent peer review from people without vested interest in the risk assessment for completeness, credibility, transparency, and fairness, and to ensure that the decision maker's initial framing criteria and acceptable risk definitions are met.[108]

Acknowledging and Addressing Uncertainty

One recurring theme in the literature on risk-based decision making is the need to acknowledge and adjust for uncertainty, both in assessing risk and generating options for action. Uncertainty exists in many stages of a risk-based decision process. It may stem from inherent gaps in knowledge about a contaminant and lack of information about the event itself (e.g., how many people were exposed, when, for how long?) (epistemic uncertainty), or simple randomness of the event and changes in trajectory (aleatory variability).[44] Depending on the situation, some of this uncertainty can be reduced through additional data collection and some, like natural variability, cannot.[120] Amendola suggests that, in addition to epistemic and aleatory uncertainty, "operational uncertainty" or "human factors" in different stages of risk-based decision making – including the definition of the problem, measurement approaches, choice of risk assessment methods, and biases – also introduce uncertainty into the process. Like other types of uncertainty, operational uncertainty cannot be completely eliminated, but it can potentially be reduced through including multiple perspectives in the discussions about risk.[116] Johansen et al. have also identified "ambiguity" as a potential source or type of uncertainty in risk-informed decision making. Ambiguity is "the existence of multiple interpretations concerning the basis, content, and implications of risk information."[121] Ambiguity may also exist in many of the steps and stages of risk-informed decision making, but can be reduced through discussions aimed at identifying potential sources and types of ambiguity in the process and coming to consensus on definitions, assumptions, and risk-based conclusions.[121]

There are a number of approaches to representing and quantifying uncertainty from qualitative to fully quantitative, depending on the time and resources available. But, regardless of the method, Su and Tung stress the importance of having an explicit approach to identifying and evaluating uncertainty.[120] Both Mengerson and Whittle, and Dubois and Guyonnet, recommend recording where uncertainty in risk assessment values exists and making that an explicit consideration when weighing and comparing options for risk management.[114,122] Even when sufficient time or resources are not available to conduct a quantitative risk assessment incorporating measures of uncertainty, it is still important to ask questions like "What do I know and not know?" and "How might risk change in different populations, geographic areas, and over time?"[122]

Formulating and Weighing Options

Once risk assessment has been accomplished and risks and uncertainties are identified, decision makers will need to formulate and evaluate risk management options or protective action recommendations. Introducing some method of weighing options against one another can help counter and minimize unhelpful biases and heuristics and enable incorporation of relevant information to make a better decision.[84,123,124] Su and Tung emphasize that when decision makers are evaluating different uncertain courses of action, it is important that the projected outcomes of those courses of action correlate with the initial problem scoping and definition of acceptable risk by the decision maker.[120] The literature shows that analysis of different alternatives can be optimized if each option is evaluated for how it meets the original objectives.[113] If a risk management option does not meet original objectives, it may not be a viable option and should be considered carefully. [120] Su and Tung specifically point out that in evaluating risk management options, the consequences that are expected to follow a decision need to be explicitly identified and discussed in order to anticipate different scenarios and optimize decisions.[120] As part of that consequence evaluation, Dombroski and Fischbeck stress that public behaviors and reactions to decisions should be seriously considered. If risk management options do not take realities of population density, transit behaviors, etc., into account they may result in increased and not decreased risk.[125]

One structured approach to comparing risk management options, based on the initially identified goals of risk-based decision making in the emergency situation, is Multiple Criteria Decision Analysis (MCDA). MCDA allows decision makers to weigh the positive and negative impacts of each potential decision alternative. It also provides a way to document the decision-making process should there be questions about it in the future.[84] MCDA is typically conducted using statistical analysis and computer modeling, which may be impossible during a crisis, but the principles of listing options/scenarios, weighting decision criteria, and comparing among multiple options can still be applied in a simplified way during a crisis.[111,112,126,127] Part of the MCDA approach is to create a value tree listing the key considerations (e.g., lifesaving, economic, ethical, political) and goals of the response and then displaying how many values are met by each decision option to allow for comparison between options. Such a tree can be constructed and modified quickly in an emergency, and provides decision makers with a systematic way to compare options.[84,111] Another similar approach to option comparison is the application of Operational Risk Management (ORM), which is used in the US military. Under ORM, a decision maker identifies threats and vulnerabilities and then conducts a "criticality assessment" to understand whether a risk management option or course of action (COA) meets the threshold of acceptable risk as defined by a commander.[128] Overall, evaluation and comparison of different risk management options is encouraged in the literature, whether through a simple mental comparison by a decision maker, using checklists, systematic pairwise comparison, decision trees, or more-complex and time-consuming methods.[122,129]

Regardless of how a decision maker determines risk or what response alternatives are identified, the literature shows that it is important to take public risk perception into account when making decisions for risk management. Slovic and Weber's research on risk perception in extreme events shows that public risk perception will differ depending on the familiarity and "dread factor" associated with the hazard. If a hazard is more unknown and dreaded, the public will expect a stronger response to mitigate the risk. If the risk management measures chosen do not match public risk perception, there is a danger that the population will not follow recommended actions.[98] The *Science and Decisions* framework specifies that stakeholder involvement is essential in each phase,[18] and Hamalainan et al. re-emphasize the importance of taking values and risk perception of the public into account when developing risk management options.[84] This tenet is also promoted by Ken Sexton, who proposes three main benefits to involving the public/stakeholders in all phases of risk-based decision making: 1) it promotes stakeholder buy in and acceptance of management options; 2) helps incorporate stakeholder/public knowledge of the situation; and 3) promotes the social value of environmental democracy that treats stakeholders as equal partners in decision making.[130]

Modeling and Decision Support Tools

Much of the literature incorporated in this review was primarily focused on development and use of mathematical models and decision-support tools for risk analysis. A number of mathematical modeling approaches, when applied appropriately – mainly in non-emergency contexts – have been shown to improve decision making, through integration and analysis of large amounts of data and statistical analysis to guide decision making.[89] However, access to modeling tools may not be available or applicable to an emergency where a state or local leader will need to make rapid decisions. [83]The nuclear industry probably has the most extensively developed models for prediction, response, and decision-support in an emergency contamination event.[112,131] Even so, many of these models are intended for use more as planning than response tools and they often presuppose the availability of large amounts of data on contaminants, the amount and concentration released, and levels of human exposure, among other assumptions. In the early hours of any type of contamination emergency, it is unlikely that these data will be available to the extent where models could be confidently run, and meet the unique challenges of an emergency response.[112] It has also been shown that the complexity of some of these models and decision-support tools creates overconfidence in decision makers, which may lead to false assumptions and poor decisions in early emergency phases. These tools may not fully convey the imprecision of the data, or communicate the uncertainty of the situation.[91,112] This is not to say that there will never be tools that can be helpful in emergency contamination events. However, for the purposes of this review, it was determined that prioritization of decision speed will likely preclude use of complex computational models and decision support tools, at least in the early crisis period.

Conclusions

This review of the crisis and risk-based decision-making literature serves to bring together two separate perspectives on response and decision making: crisis decision literature, which is largely focused on making decisions quickly; and risk-based decision literature, which prioritizes incorporating evidence and rigor into decision making. Through this review it is clear that a body of work focused specifically on contamination emergencies, which require both timely and evidence-informed decisions, is largely absent. However, findings from this review can be extracted to inform future research in this area.

Findings from the crisis decision literature show that initial intuition, followed by rational interrogation of an emergency situation, is a promising two-step approach to improving the quality of decisions; that analysis of the situation can help mitigate typical cognitive biases and traps; that having a primary decision maker supported by a small-yet-diverse group of advisors can improve decision making while avoiding chaos; that many types of information, including scientific, ethical, legal, social, economic, and logistical inputs should be considered; and that decision making works best in a cycle that involves data collection and analysis, decision, action, and further data collection and refinement.

Findings from the risk-based decision literature show that scientific data are not and cannot be the only drivers of decision making; that a process of problem formulation, risk analysis, and risk management can be applied, even when time is short; that it is important to clearly define the problem at hand, acceptable risk, and goals of the response at the outset of the decision process; that a risk assessment approach should be carefully chosen to match situation needs; that uncertainty should be acknowledged and accounted for in both the risk assessment and options analysis phases; that a systematic approach to comparing options for action should be used, even if it is simple and quick; and that public risk perception and levels of acceptable risk should be expressly considered throughout the decision-making process.

With these findings in mind, it would be beneficial to future decision makers responding to contamination emergencies to have a framework that incorporates the important and influential factors from the crisis and risk-based decision-making fields. Currently, leaders in the position to make life and death decisions in response to contamination emergencies have little guidance or decision support to inform their process. Future research should focus on providing tools that can enable leaders to make rapid, yet maximally protective, decisions in contamination emergencies. These findings show that multiple relevant frameworks exist, which could be beneficial to future decision makers responding to contamination emergencies. Future research should focus on tools that can enable leaders faced with contamination emergencies to make protective decisions that are timely, transparent, based on evidence, and sensitive to social norms and values.

PAPER 3

Crisis Decision Making in Major Contamination Emergencies: Developing Guidance for Mayors and Governors

Abstract

Objective: Guidance for mayors and governors on decision making during the acute crisis period of a contamination emergency is not currently available. Without such guidance, political leaders responsible for decision making in large contamination emergencies may not make decisions that are optimized to protect public health, while also being, feasible, ethical, and politically possible. This research is aimed at defining the key elements that should be included in decision-making guidance, and proposing a framework that can be used to inform creation of such guidance.

Methods: Semi-structured interviews with subject matter experts in risk and crisis decision making, and practitioners, were conducted from September 2016–January 2017. Interviews were not for attribution, but were recorded, transcribed, and analyzed for common themes and key elements to include in a decision-making framework.

Findings and Discussion: Interviewees discussed common elements of decision making in a public health crisis due to contamination events, including the structures and processes that support decision making, key considerations that should be incorporated into protective action decisions, and the importance of good communication practices.

Conclusions: The framework proposed in this research, informed by the literature and subject matter expert input, is intended as a first step on a path to developing guidance that can be provided to decision makers and used in future emergencies to improve crisis decision-making.

Introduction

Acute environmental contamination events involving chemical, biological or radiological materials occur frequently in the U.S. and around the world. While there is no comprehensive accounting of the overall numbers and types of these events globally, it is clear that small events such as occupational chemical spills or exposures to petroleum products happen nearly every day and are handled routinely by first responders, environmental health officials, and public health officials. According to the U.S. Department of Transportation, hazardous materials incidents during material transport numbered over 10,000 in 2016 alone.[132] A majority of these events involve low levels of contamination or limited human exposure and are managed quickly and not publicized widely. While they can be complex and are sometimes characterized by uncertainty, these relatively circumscribed contamination events can generally be managed through existing response structures and resources available to guide responders at the scene.

Yet, there are some contamination emergencies that go beyond the authority or capability of first responders and local emergency managers to adequately assess, contain, and remediate because of the potential for serious and/or widespread public health impacts. When these emergencies happen, decisions about protective action are often needed very quickly (within hours or a few days) to prevent acute harm as well as to reduce long-term impacts on people who are exposed. In such major contamination emergencies, decisions are made more complicated by amplified social, ethical, and political repercussions. Many times, these responses rise to the executive level of a jurisdiction, where a mayor or governor becomes involved and takes the lead as decision maker.

While the exact triggering mechanisms of senior political involvement in crisis response are not clear-cut, history shows that in major emergencies responsibility for protective action decisions moves to the political level. Examples include the 2014 MCHM chemical spill in West Virginia;[133] radiological releases from the Three Mile Island nuclear generating station in Pennsylvania in 1979 [134] and the Fukushima Daiichi nuclear power facility in Japan in 2011;[135] and the 2014 decontamination response to a case of Ebola in New York City, and the resulting New Jersey quarantine of an Ebola nurse returning from West Africa;[136] in addition to other large or high profile chemical, radiological and biological contamination emergencies. In these major emergencies, mayors and governors have the responsibility to protect the health of their constituents. In these emergencies, too, the response is publicized much more widely, resulting in greater interest and scrutiny by the public, activist organizations (especially environmental groups), and politicians. As a result, a political leader will be "on the hook" if response is unsuccessful. Therefore, it follows that if they have responsibility and accountability for the outcome of a response, they are more likely to assert their authority as decision maker.

Some might argue that there is an abundance of resources to support response to contamination emergencies. For example, the widely-implemented incident command system (ICS), along with National Incident Management System (NIMS) training modules and tools, provides a well-defined, scalable, and flexible scaffold on which to organize response to these incidents. But, what is not addressed by ICS, NIMS, or other similar resources is how to approach the actual decision-making process during these events. NIMS focuses on facilitating "command, operations, planning, logistics, intelligence and investigations, and finance and administration,"[137] but not decision making.

The absence of decision-making guidance for contamination emergencies is generally reflective of the absence of research in this area. Separate bodies of literature exist on crisis decision making, and on human health risk assessment and risk-based decision making in non-emergency periods, but there has been little focus on where the two meet: crisis decision making specifically in contamination emergencies. One exception to this is the literature on emergency response to nuclear accidents like Three Mile Island. These accidents galvanized a major focus on building decision support and modeling tools to enable rapid characterization of a radiological hazard and support tradeoff analysis between options for action.[134] Yet, lessons from these events have not been broadly applied to development of decision-making guidance outside of the very specific context of the nuclear power industry.

There are a number of other disparate areas of study and topics in the literature that together can be applied to crisis decision making in major contamination emergencies. Literature on decision science that focuses on the cognitive factors affecting decision making is one key area that can inform this work. Daniel Kahneman, in his work with Amos Tversky, described the intuitive and analytical systems that comprise human judgment, defining the fundamental ways that we as people make decisions and the biases and heuristics that govern our reasoning.[46] Other scholars like Paul Slovic have contributed significantly to this work, applying it to crisis decision making and suggesting ways to both harness our natural intuitive processes, and also mitigate the impacts of bias and heuristics.[92] Findings from this research suggest that harnessing intuition, followed by analysis of that intuition, along with input from a diverse set of viewpoints can limit error in decision making and counter biases and heuristics, making judgment more accurate.

John Boyd's work in developing the OODA loop model (Observation, Orientation, Decision, Action, looping back to Observation),[53] and similar frameworks, such as the Medical Management Model described by Koerner et al. in the context of radiological emergencies,[104] provide the theoretical structure for a process of decision making that can be applied to contamination emergencies. Moving through the phases described in these models, even briefly, can enable clearer thinking and consideration of the situation and available options.

In the area of risk assessment, the *Science and Decisions* report from the National Academy of Sciences outlines the key phases of risk assessment including scoping the problem, planning and risk assessment, and risk management, as well as the specific steps in carrying out human health risk assessment and approaches to acknowledging and addressing uncertainty.[18] This framework can be incorporated in an abbreviated way into contamination emergency response, to improve the fidelity of the risk information guiding decisions.

Finally, the risk-based decision literature focuses largely on developing options for action based on risk information. While much of this literature is intended for non-emergency periods, the fundamental concepts of defining goals and objectives, developing action options, and comparing between options to find the one that enables the most desirable outcome, can be incorporated into emergency contamination decision guidance.[84,111] This process also serves to enable more careful deliberation to mitigate decision errors.

In summary, guidance for mayors and governors on decision making for contamination events is not currently available, and does not have a directly applicable basis in the literature. However, there are findings from the literature that can be tied together to inform development of guidance for mayors and governors faced with uncertain decisions in these emergency circumstances.

Guidance developed by Kayman and Logar, which provides considerations for public health officials responding to health emergencies more broadly, is an important place from which to start.[94] Their framework provides a theoretical basis and begins to outline the concrete steps that a public health official should take to make decisions in an emergency. While not perfectly applicable to contamination events, this framework can be adapted and expanded to include contamination emergency-specific elements, account for the risk assessment and data needs of these emergencies, be applied directly to mayors and governors, and be made to be user friendly in a crisis environment.

Given the above elements of the crisis and risk assessment literature, and the guidance developed by Kayman and Logar,[94] we sought to build on this existing body of knowledge by obtaining additional information and opinions from experts regarding the key considerations, processes, and structures that are needed to support decision making in contamination emergencies. This study presents findings from and analysis of interviews conducted with experts both in the theory of decision and risk assessment science, as well as practitioners who have been involved in responses to major contamination emergencies. Themes from these interviews are summarized in the Findings section of this paper and are then distilled into a proposed preliminary framework, which can inform future development of guidance aimed at mayors and governors for use in response to major contamination emergencies.

Methods

Interview Guide Development

We first developed a semi-structured interview guide, based on findings from an integrative literature review, which identified major themes and decision elements that are important for contamination emergency decision making. Key domains for the interview guide included structures supporting decision making, decision-making process, and key considerations for decisions.

The interview guide was reviewed by multiple risk assessment, emergency management, and public health preparedness and response experts prior to its fielding, and was revised based on expert feedback. The guide was then piloted with an emergency management official with experience in contamination emergency response, and was subsequently revised based on feedback from that pilot interview.

Selection and Recruitment of Interview Participants

Interview subjects were identified first from an integrative literature review, which led to both researchers who are prominent thinkers in the areas of crisis and risk-based decision making, and practitioners with significant experience with public health emergency and contamination emergency responses. Additional interviewees were identified through snowball sampling via suggestions from other interview participants.

In particular, interviewees were sought who had relevant expertise or experience with decision making by political leaders in major contamination emergencies. Potential interviewees were excluded if they had no expertise or experience with decision making in crises, or no knowledge or experience that could be applied to contamination emergencies.

Data Collection and Analysis

Semi-structured interviews with selected participants were conducted over the phone and via Skype from September 2016–January 2017. Interviews were recorded with permission of participants and were transcribed verbatim to ensure maximal accuracy. Interviews were not for attribution. During the interviews, key observations and points were recorded to capture immediate impressions and important points.

Themes were derived from the interviews using a combination of inductive and deductive approaches. *A priori* themes were identified first from the previously conducted integrative literature review, and based on the interview guide. Further themes were identified and added as the transcripts were coded (Table 10). Interview transcripts were coded based on identified themes using QSR NVivo for Mac v10.3.2. [62] Peer debriefing with an impartial party who had expertise in the topic was conducted during the data analysis phase to aid in identifying themes, analyzing coded findings, and developing the draft framework.[63]

A Johns Hopkins Bloomberg School of Public Health Institutional Review Board determined this study was not human subjects research and was therefore exempt (Appendix 2).

Findings

Of the 32 individuals contacted for this study, 20 responded, and 16 were interviewed, with one exclusion and three individuals unable to schedule an interview during the study timeline – resulting in a response rate of 50%. Interviews were conducted with researchers (n=5), practitioners (n=5), and individuals who classified themselves as both researchers and practitioners (n=6). Affiliations represented included academic institutions (n=4), national laboratories (n=2), federal government (n=5), and state/local government (n=5). Expertise and focus of interviewees included toxicology (n=2), decision science (n=3), environmental health (n=2), emergency management (n=2), and public health preparedness and response (n=7) (Tables 11 and 12).

Interviewees answered questions about decision-making structure, key considerations in decision making, and the decision making process during contamination emergencies to inform development of a framework that can guide decision making in future emergencies. Interviews focused on the key considerations that are important for political-level decision makers in a contamination event that is highly uncertain and time pressured.

Structure Supporting Decision Making

Organizational Structure for Response

All 16 interviewees discussed the organizational structure needed to support the decision maker in a contamination emergency, most noting that having a reliable structure is important to supporting quality decisions. The Incident Command System

(ICS) was the structure mentioned most often during these discussions. Merits of ICS mentioned by interviewees included that it is an established and well-exercised hierarchical approach to response; provides clear protocols and roles for the response team; establishes a chain of command with an incident commander in charge; and is flexible enough to scale for many types and sizes of emergencies.

> *"I grew up with ICS in the fire service obviously, so we have always used that structure, which is, you know there is very clear cut language and documentation on how you set that up, and we do that every time."* – Interviewee #16

Some interviewees felt that ICS was sufficient to support decision making in and of itself, while other interviewees felt that ICS was important but not sufficient to guide the decision-making process during a major contamination emergency. Interviewees with this view expressed that a highly uncertain and rapidly unfolding contamination emergency requires a greater degree of expert/advisory input directly to the decision maker very early in the unfolding response.

> *"I think there has to be some kind of way that it's easy for incident commanders to be able to solicit and get good feedback…In truth, from the local perspective there's just this massive confusion of different voices that are coming at them in the moment, and there's a tendency (an understandable one) to feel like 'oh my God, I'm in charge, what am I going to do?' and just kind of wing it in the best way that they can."* - Interviewee #14

Decision Responsibility

In the interviews, 11 of the 16 participants discussed the issue of responsibility for making early protective action decisions in a contamination emergency that rises to the political level. Many interviewees discussed group decision making as an important approach, particularly because *"most elected officials don't come to the position with that* *kind of [decision making] experience,"* and *"when you get to the decision maker at the political level…that decision maker doesn't necessarily have the technical knowledge to make sound technical decisions."* – Interviewee #5

Yet, as the interviews unfolded, even the participants who suggested group decision making tended to clarify their position in favor of a single decision maker supported by a group of trusted and knowledgeable advisors. All interviewees who discussed the topic of decision responsibility expressed the desire to have *"those with expert knowledge drive the decisions* (Interviewee #12),*"* and many suggested that a small group of individuals with expertise should advise the mayor or governor (or other decision maker), but noted that ultimately it comes down to a single individual to make protective action decisions and be responsible for them.

> *"I think societally we have evolved in working together and trying to make decisions together. But, ultimately it still comes down to who is the responsible person who is going to make the call? And, sometimes that's the most difficult thing."* – Interviewee #4

> *"There needs to be a recognition that there is a pecking order, that there is a hierarchy, and that ultimately somebody is in charge."* – Interviewee #2

Overall, participants suggested that, particularly early in the decision making cycle, a small group of advisors, gathered quickly, is needed to support a political leader in making quality decisions.

> *"I think you've just got to find good folks to inform your decision. You have to have reached out to enough folks to have the buy in and create others that will support your decision publicly. So, you're not standing alone in it."* – Interviewee #7

Then, the decision maker is responsible for *"listening to a large number of people and getting as much as you can. But, ultimately having to make a call* (Interviewee #3)*"*

Advisors to the Decision Maker

There was a general consensus among interviewees that a group of advisors should be quickly formed to aid in decision making – 15 of 16 interviewees discussed the composition of this advisory body.

Interviewees discussed both the need to have trusted advisors who are familiar and close to the decision maker, as well as the need to have outside subject matter experts and advisors with differing viewpoints who may not be familiar or have not yet built trust with the decision maker. Most interviewees who discussed this point felt that both familiarity and expertise are important as attributes of an advisor. A number of interviewees suggested that decision makers first look to their existing trusted advisors, whom they rely on regularly to provide input, but then also look to outside experts who can fill knowledge gaps.

> *"I would pretty quickly turn to my agency expertise in terms of epidemiology office, environmental health office. Then I would also turn to partner expertise."* – Interviewee #7

> *"So, you've got your pools of experts doing their work internally, as well as talking to other pools of experts that have a slightly different focus."* – Interviewee #6

> *"[K]nowing your team is so critically important…not just the obvious things that people in emergency response might focus on, but know who your team are."* – Interviewee #13

Interviewees noted the variety of experts that should be included in this early advisory body. First and foremost, there was a general feeling that decision makers needed, maybe more in contamination emergencies than in other public health emergencies, subject matter expert input to the decision process. One interviewee was emphatic about this point, saying, *"…[decision makers] are pretty much guaranteed to make the wrong decision unless you have an expert panel* (Interviewee #11).*"*

Many interviewees explicitly addressed the federal role in advising decision makers in contamination emergencies. One interviewee noted that *"Federal expertise was always really welcomed and appreciated,"* and in the real world events discussed during the interviews, the Centers for Disease Control and Prevention's (CDC) Agency for Toxic Substances and Disease Registry (ATSDR) Emergency Response Teams was cited as a significant asset particularly in the early decision making and response phases of an emergency. ATSDR and other federal partners were discussed as providing trusted scientific and risk assessment expertise that could be counted upon by decision makers and should be utilized to the extent possible during early protective action decision making.

In addition to scientific expertise, interviewees noted that other advisory roles are also key to the response.

> *"I think what's important is, you have to understand the political aspects of things and who you're dealing with, but you also need the science, you need the law and who has regulatory authority in order to formulate a response, and then you also need the boots on the ground capacity to get out there and do things. It seems to be universal, whether it's Ebola waste in Manhattan or Texas, or whether it's Flint, or Gold King Mine, or a pesticide spill."* – Interviewee #4

One specific advisory role mentioned by a number of interviewees was that of a public advocate or representative, which is needed both for the purpose of gaining situational awareness and for engaging with the public to ensure a successful response to protective action decisions. Most interviewees felt that it would be *"hard to bring the public in in the midst of a crisis situation* (Interviewee #2)*"* but that, decision makers *"need the community to buy into what [they] are saying, and if they don't do that, things can be much more complicated then they have to be. So, making sure that [they] have community engagement* (Interviewee #3)*"* is important.

One point that was made in a number of interviews was that the decision maker needs to be aware of the incentives and motivations of the people included as advisors in the initial decision-making process. Interviewees mentioned, when discussing a number of different contamination emergencies, that often the company or entity responsible for (or the cause of) a contamination event has the most data about the contaminant itself, and is therefore relied upon in early decision making to supply data and risk assessment information. Interviewees cautioned that this expertise could come with competing incentives to protect a company's interests above that of the health of the public, and should thus be taken and used with caution and awareness of potential conflicts of interest.

Overall, interviewees felt that *"it's all about the right combination of people, with an understanding of the components that go into these decisions* (Interviewee #4)*,"* as well as the quality and perspectives of those advisors.

> *"The most important thing is to have qualified people at every level responding and understanding."* – Interviewee #4

> *"The unique characteristics that I've seen first for good advisors is they also have a breadth of knowledge and a breadth of experience."* – Interviewee #6

Key Considerations in Decision Making

Related to the composition of the advisory body for decision makers are the key considerations or types of information that should be incorporated into early protective action decision making. Interviewees recognized a number of factors that will need to be considered.

> *"[T]here are a lot of different aspects of that decision making that need to be taken into account. Whether it's jurisdiction or whether it's the question of the risk management options that are available, the kinds of issues that decision makers have to have or have to make, are going to be including that science, but not necessarily driven by it."* – Interviewee #15

Cognitive Factors in Decision Making

Both practitioners and policy makers who interviewed for this study, but particularly experts in decision science, emphasized the importance of cognitive factors in time-pressured crisis decision making. Interviewees discussed a number of cognitive biases and heuristics in human decision making that could affect the quality of decisions in an emergency situation and ways to combat them.

Interviewees characterized the decision environment in a contamination emergency as chaotic, saying that as a decision maker, *"you're stressed, you're amped up a little bit, a little scared, you are kind of in the dark, you don't understand the whole incident yet* (Interviewee #16)*."*

One expert noted that, *"in none of the emergency response literature do people talk about feelings* (Interviewee #13)*."* However, *"most of the time we as decision makers are reacting to risk through our gut feelings* (Interviewee #10)*,"* especially in such uncertain situations. However, without extensive prior experience to inform those feelings, they might be inaccurate.

Interviewees felt that *"really any of the classic cognitive biases that exist might limit the effectiveness of a decision maker's role* (Interviewee #2)*."* But they also suggested that, *"in the moment of instant decision making…there's probably only a handful that [decision makers] need to be fully conscious of and concerned [about]* (Interviewee #12)*,"* including confirmation bias, relationship bias, the escalating commitment heuristic, and the prominence effect:

> *"I think confirmation bias is a big issue…I think if a decision maker gets very comfortable seeking out say one expert's opinion, any flaws that are in that particular expert, or maybe even a small subgroup of experts around that decision maker, it's going to trickle down."* – Interviewee #2

> *"Relationship bias. I tend to listen to and believe people that I know well, and tend not to listen to and dismiss information from people given to me that I don't know well."* – Interviewee #12

> *Escalating commitment: "You'll always be in the mode of assessment and never to the point of a triggered decision, because 'I just need a little bit more information, a little bit more information,' and then you get to the point where you have this…'analysis paralysis'."* – Interviewee #12

> *Prominence effect: "there's often a bias toward actions that will be more politically defensible." Those actions may violate basic values such as life-saving, but decision makers "may not even be aware of how much they're being influenced by the defensibility of the decision, as opposed to the intrinsic values at stake."* – Interviewee #10

Interviewees suggested, the best way *"to overcome a bias is to realize 'I potentially have this bias'* (Interviewee #12)*,"* then take actions to interrogate intuition and feelings in order to counter potential biases and unhelpful heuristics. Broadly, interviewees suggested that having a process in place that incorporates a variety of opinions and viewpoints and enables careful analysis of the situation and options for action could help mitigate these cognitive factors that may derail decision making. The extent to which this is possible will depend on the nature of the emergency, but can still be implemented to some degree even in time-pressured situations.

Time Pressure and Need to Act

Interviewees discussed a number of acute contamination emergencies in which there was "*considerable time pressure through the whole situation* (Interviewee #1)*."* As a result, interviewees noted that one of the first considerations by decision makers should be to get a rapid understanding of the urgency to act, *"to assess how long can I put off making this decision so that I can gather more information in the meantime? What's the critical time when it has to be made* (Interviewee #5)*?"*

One part of that consideration should be for a decision maker to ask him/herself, *"do I have time to consult with other experts to find out [more]* (Interviewee #10)*?"* If there is time–and interviewees suggested that in many large-scale contamination events there is at least some time to gather more information–then, consultation still needs to *"happen relatively fluidly and relatively informally,"* without too much delay waiting *"to form the committee of sages in order to get to some of these early decisions* (Interviewee #6)*."*

Interviewees cautioned that waiting for perfect information or perfect council can lead to "analysis paralysis" where decision makers seek better and better information and are unable to make a decision. One interviewee noted that *"whatever data that policy makers are getting is outdated, almost invariably. Until you get to the incident stabilization, where things are not changing, generally the information is outdated* (Interviewee #8)*."* Two interviewees noted explicitly that delaying a decision in search of more information and fidelity constitutes "*a decision in and of itself, and that decision will have consequences* (Interviewee #6)*."*

Interviewees generally agreed that information will never be perfect in an emergency response and that a decision maker needs to make an explicit judgment about what level of information completeness they are willing to act upon. Interviewees suggested that might be at 30% of desired information (in very time-pressured situations with high levels of risk), up to 80% of information desired (in emergencies with lower acute risks and thus less time pressure to act), but that it will never be 100%.

Scientific Data and Risk Assessment Findings

Interviewees all agreed that data on the contaminant and risk assessment information were critical to decision making in a contamination emergency. Interviewees noted that gathering information about the hazard and the extent and level of contamination (hazard identification and exposure assessment) are some of the first steps a leader should take. *"First is the science - gathering whatever information we can that we have available, but recognizing that's often not sufficient nor perfect, but doing everything we can to canvas what do we know* (Interviewee #7)*."* This is followed by an assessment of what those data mean for public health, understanding the dose response relationship in humans and characterizing the health risks.

> *"One of the first and foremost factors needs to be obviously the risk involved. How much risk are we talking about? Who's potentially exposed? Really getting a very quick assessment…just a realistic assessment of how much risk there is, and are we talking about life or death, or are we talking about injuries as opposed to mortality? And also of course, the extent of that."* – Interviewee #2

> *"You'll need best estimates of expected harm, and associated uncertainty. That's the key focus that I would say is required in order to make meaningful triage decisions."* – Interviewee #11

Interviewees discussed the need to gather as much data as possible, while still balancing the need to act quickly. *"I think you have to act fast, but you have to gather as much information as you can to be able to do that…but you don't want to act too hastily that you miss something big* (Interviewee #1)*."* In addition, multiple interviewees stressed that while acute health effects may be the primary drivers of decision making, long term health effects caused by low levels of exposure should also be considered and weighed.

> *"You have to consider the range of [health effects] whether they're acute or chronic…The more chronic effects are not going to be as prominent in your concern at the initial stages, but they might be at later stages."* – Interviewee #3

Uncertainty

Seven of the 16 interviewees addressed the need to consider uncertainty explicitly in any decisions that are made during a contamination emergency. Uncertainty will be present in many aspects of the decision-making process, including in the data about the contaminant and levels of exposure, in the data about human health effects, in the demographic data about who's impacted and to what level, in the information about how the public responds, etc.

Interviewees stressed that acknowledging and addressing these uncertainties is critical for a successful response, but they also noted that it is not an easy thing to do.

> *"I will tell you that in public health this has been a particular challenge because, normally in our day to day operations…we don't [put out any guidance] until we are really certain, until we've conducted studies or have access to other people's studies where their data have been gathered and analyzed, [and] the results show a degree of statistical certainty above the 0.05 confidence level. Now you get into an emergent situation and you're telling people to stand that paradigm on its head and make decisions based on incomplete information. It's really hard for folks, because we're telling them to do something that goes against the grain that we have engrained in them."* – Interviewee #5

> *"It really takes a special person to be able to execute with so much unknown and oftentimes with so much potential consequence that can result from the unknown parts of that decision process."* – Interviewee #12

Decision makers will need to *"do the best [they] can with what [they] have* (Interviewee #9), and be clear about *"what we do know…what we can know and…what we cannot know,* (Interviewee #6)" and then work to reduce uncertainty where possible in the time allowed.

Information about the Affected Population

Knowledge of the demographics, needs, population dynamics, attitudes, and trust of the people affected by a contamination emergency is critical to the success of protective actions.

> *"I think once [risk] is kind of understood, or at least a little bit of knowledge is built up around that, then you have to start looking at the actual affected population. You've got to start paying attention to the factors involved in that*

> *particular population of people that might be acutely affected by this."* – Interviewee #2

It is important for a decision maker to consider how the public might implement any decisions. One factor to consider is *"simply understanding where the affected population is…and how that might end up impacting their compliance with a particular decision or a particular order."* Once a protective action order is given, *"how is the public going to process it and how are they going to execute it?"* For example, *"If you want people to evacuate, but you are dealing with a population that can't necessarily evacuate that easily, then you've got to be able to provide those services or an alternative that will be successful* (Interviewee #2).*"* This might differ among communities in an affected population.

Interviewees also discussed public risk perception and levels of acceptable risk, which will also differ among communities. In particular, communities that have existing experience with disasters or have felt the impact of "environmental abuses" in the past may have different perceptions of the risk than other communities when an emergency occurs. Populations with lower trust in government may also respond differently to protective action recommendations. These factors, if not considered early in decision making, can result in a failure to protect significant parts of the population at risk.

Relatedly, interviewees discussed the need to consider vulnerable populations at the very beginning of a decision making process. Multiple interviewees noted that decision makers have often failed to take vulnerable populations into consideration in the early response to contamination emergencies.

> *"We have to make sure that they consider sensitive populations. Time and time again, you find that people don't consider things like pregnant women or nursing mothers."* – Interviewee #3

> *"What about our access and functional needs group? I think about all of those folks and that's how I try to make my decisions."* – Interviewee #16

One interviewee suggested that public health services, social services, and mental health issues need to be better integrated into the decision-making process, *"build[ing] that in as early in the process as possible* (Interviewee #14)*."*

Ethics and Values

Some interviewees raised the issue of ethical considerations in decision making during a contamination emergency. One interviewee noted that *"there's ethics in virtually every aspect of [response],"* but that "*we need people more trained in ethics*" involved in decision making (Interviewee #4).

While some interviewees felt that there was not time to consult ethicists or fully consider ethical principles in a time-pressured emergency context, two interviewees noted that this consideration could be made quickly, but explicitly, as part of a decision-maker's initial process.

> *"We sat down, and before we made any decisions, just outlined collectively what our ethical principles were. What were the core principles that we wanted to hold true to as much as we could?"* – Interviewee #7

> *"[I]f I think about the people we are trying to take care of, what's best for them, not what's best for me or my team, then generally that's the right decision. It makes decision making, as complex as it can be…a lot easier. It gives you some sense of stability going into the thing."* – Interviewee #16

Legal and Regulatory Environment

Two of the 16 interviewees mentioned legal and regulatory considerations as important in an emergency response. One interviewee noted that decisions oftentimes are ultimately shaped and limited by these considerations and are thus very important to discuss in decision making.

> *"There's so many things to balance out, and usually we have to be guided by what does the law say?"* – Interviewee #4

"Regulatory and administrative barriers" were also mentioned as potentially limiting and burdensome in a response. One interviewee suggested that a decision maker could facilitate a response greatly by removing or reducing these barriers as appropriate to enable easier implementation of protective action decisions.

Politics

A number of interviewees stated that politics is often a component of decision making, with one interviewee stating that political considerations *"come into play every time"* during an emergency response as a *"huge component* (Interviewee #6)*"* of the decision-making process. Some interviewees felt that politics was inherently bad for decision making, and should be avoided, but others felt that politics are unavoidable and are simply a consideration that should be addressed explicitly in the decision making process.

> *"There are going to be political dimensions to any problem…Those are just sort of natural forces in some ways. And I think with the right kind of front work, those can be mitigated."* – Interviewee #14

Optimistically, multiple interviewees, who had been part of the decision-making process in contamination emergencies, felt that in an emergency political considerations do not usually drive decisions and that political decision makers usually have the public's interest at heart.

> *"Well, I have to tell you, and it's been amazing in my career and my experience, how in a true emergency, there's very little politics in the early decision making. It's not about politics. In fact, I think most political appointees and politicians understand that appropriate management of the emergency is really important to the levers in political power. So, it's usually not an issue in an emergency situation."* – Interviewee #4

Decision Making Process

With the structure supporting decision making in place and key factors to be considered articulated, interviewees discussed the decision-making process itself, which included discussion of different approaches to formulating decision options, the types of decisions that are needed, and ways to improve the success and acceptance of decisions.

Types of Decisions Needed

Interviewees discussed a variety of decisions that are necessary in the early hours of a major contamination emergency. Specific decisions will be highly dependent on the situation, but interviewees discussed decisions about

- the makeup of an advisory body;
- the amount of information needed before protective actions can be determined;
- the amount of time you have to choose protective actions;
- the methods and rigor of a quick turn risk assessment;
- the number of options for protective action that should be considered;

- the protective action(s) that best protect public health, uphold core values, and meet identified objectives;
- approaches to implementing chosen protective actions; and
- approaches to communicating decisions to the public.

Interviewees focused much of their discussion on how to obtain situational awareness and make initial determinations about risk and what that meant for response.

> *"Our big focus initially was, if water samples were going to be taken and tested, at what levels was the water safe, that kind of thing. That was the big focus, and we consulted with CDC, ATSDR on that. So, that's how it all began. It was kind of crazy and hectic that very first few days there. And, it didn't get a whole lot better."* – Interviewee #9

> *"We had to make an assumption that there was some degree of toxicity that we needed to be concerned about, we just didn't know to what level, and then we had to start thinking about what that meant."* – Interviewee #16

> *"[T]ypically without first getting monitoring information and things like that, there's a general discussion about what might we expect to be out there. I think that was one of the first questions that would always come up. In the absence of information that would say exactly what people were exposed to, what do we think?"* Interviewee #15

Approaches to Decision Making

Interviewees discussed three phases of the decision-making process, once an emergency has been recognized and a decision maker engages advisors and gathers information to inform decisions: 1) setting goals and values for the response; 2) identifying decision alternatives; and 3) anticipating outcomes and comparing options to come to a decision.

Some interviewees stressed that a decision maker should first conduct their own assessment of the situation, the values that are important to preserve, and the goals and objectives of the response itself.

> *"I do think that [setting goals for a response] could be effective. The one caveat is that time of course is of the essence."* – Interviewee #2

> *"I think it's a combination of what your objectives are, and what principles you want to stay true to. I think both are important."* – Interviewee #7

> *"I think there is both a science and an art to this. And in the science I think you have to approach the incident and think broadly about what are the issues that are at play here?"* – Interviewee #5

Once the decision maker defines goals, objectives, and values for him/herself, then a group discussion among key advisors about those definitions is helpful to refine and correct any problems.

> *"I would say in a perfect world you would walk in there with a defined goal, but that you would expect that the group might, in a group discussion, that goal might be reframed."* – Interviewee #5

Once these strategic decisions are made, interviewees suggested that decision makers could propose a limited number of potential options for action to reduce public health risk, based on the available information – options initially generated by the decision maker, but then evaluated, adjusted, and expanded upon by advisors.

> *"Getting all the important actors/important players at the table and just walking through the different options, sharing information, and making sure that everybody is on the same page and that everybody understands the risk that's involved, the uncertainties that are involved, and the best pathways going forward."* – Interviewee #2

Decision makers often *"have an incomplete set of action alternatives."* So, a decision maker and advisory group need to ask themselves, *"do I have the full set of action alternatives, is there anything I'm missing* (Interviewee #10)*?"* Once those action options are identified, interviewees suggested that decision makers *"identify a series of choices, and then come up with a kind of weighting system that leads [them] to decide which of the available choices comes out on top* (Interviewee #5)*."*

One approach is to lay all of the options out together *"in a deliberate but quasi-academic fashion* (Interviewee #6)*,"* and then think about *"the objectives that are met, or are not met by different actions* (Interviewee #10)*."*

> *"Basically, the problem is you can't have it all. You can address one need, but you may be then weaker on another important objective. So, how do you make that trade off? Those are not easy judgments."* – Interviewee #10

A number of interviewees suggested that *"playing options out* (Interviewee 2)*"* and predicting the possible outcomes, to see how *"each of these actions meet or fail to meet objectives* (Interviewee #10)*"* is an important step to identifying potential pitfalls and make favorable tradeoffs.

> *"[P]utting aside your certain biases that you might have, and just thinking through 'how is the public going to respond if we tell them to evacuate? Where are they? Is it daytime? Are they at work? At home?' Let's play this through and put ourselves in their shoes, and think about how they would respond to this message, knowing what you know about the affected population, and playing that out before you necessarily issue that order."* – Interviewee #2

Documenting Decision Making

Many of the people interviewed for this study discussed the problem of outside criticism, "Monday morning quarterbacking," and hindsight, which can derail a political-level decision maker who is trying to anticipate and mitigate criticism that will come later (i.e., the prominence effect discussed earlier).

> *"The people that criticized us the hardest weren't here that evening, and they didn't understand the fact that we had little information and little time to make decisions."* –Interviewee #16

Interviewees discussed how to mitigate the impact of hindsight and the prominence effect on a decision-maker's process. One option discussed was the possibility of documenting the actual decision-making process as it occurs, capturing the uncertainty of the situation, and the process and reasoning behind decisions.

> *"I think you have to at least have some justification for [decisions] because they're going to get challenged, and you've got to communicate them. You've got to be able to tell people why…we know that these kinds of decisions will be criticized harshly in hindsight. And, we've studied hindsight and we know that hindsight is a real phenomenon. The problems that seem apparent after we know how the outcome turned out were not necessarily apparent in advance. But, hindsight is real in the sense that it will appear that we should have known that it would go bad in this way. When in fact it was very uncertain. Again that suggests that for political protection, the deliberations should be documented, the state of uncertainty in advance should be documented in some way to try to protect against the fact that 'you should have known.' When in fact you couldn't have known."* – Interviewee #10

A number of interviewees discussed the fact that they already produce after-action reports in the days and weeks following an emergency response and perhaps that was enough, and that documenting decisions in the midst of an emergency would be too difficult. But, other interviewees, particularly decision scientists, disagreed and advocated for setting up a process that focuses specifically on the information available and how decisions were made in the midst of the crisis.

> *"[T]he question is how do you set up structures within the decision process that will try to reduce that kind of post-event criticism in order to free up the decision maker to make what is not just the most defensible decision, but actually the best decision given the values at stake? How do you do that? Maybe part of that is to have multiple people involved and have a record of the careful deliberations that were made at the time."* – Interviewee #10

Communication

Communication is a fundamental component of the decision-making process in response to contamination emergencies. Many interviewees discussed communication, and particularly the need to communicate with the public throughout crisis response. While this study focuses on decision making and not risk communication with the public – a topic that has been a major focus of other research and operational planning in the public health preparedness and response field – interviewees emphasized repeatedly and in almost every interview, that public risk communication is essential for the success of a response.

> *"I'll tell you, good communication and good communication skills can make or break a response. And, it either engages partners and the public or you get discord and distrust."* – Interviewee #7

One interviewee noted that *"most of what people think is panic is not panic, it's anger at information being withheld* (Interviewee #8)*,"* highlighting the need for risk communicators to be honest and forthcoming with the public. As protective action decisions are made, these decisions must be communicated to the public a way that *"helps people process the information, have a role in making their own decisions, and making (what you hope is) the right decision* (Interviewee #7)*."*

In addition, interviewees discussed the need to communicate uncertainty to the affected population with *"messages that say, 'here's what we know, here's what our plan is and what we're doing now, here's what we recommend you do, here's what we are doing to continue learning about this, and don't be surprised if we change recommendations coming forward* (Interviewee #7).*'"*

Some interviewees also discussed the internal process of communication for response, including, and especially between, decision makers and their advisors. Interviewees emphasized the need for advisors *"to communicate rapidly to help inform decisions* (Interviewee #4)*,"* and to enable a decision maker to assimilate the best information available. Multiple interviewees noted that integrating information from many sources can be difficult in a crisis, and can become overwhelming to a decision maker if communication is not structured and information triaged and gated.

Communication structures will need to enable important information to reach the decision maker, while limiting other information not relevant to the decisions at hand. Interviewees cautioned against having too many layers between a decision maker and people with the knowledge and information to inform decisions, and instead having experts with knowledge of and access to information in the group advising the decision maker directly. Within this group, interviewees noted, communication and information flow can be governed through good meeting management.

Discussion: Proposed Framework

Decision making is often a neglected aspect of the contamination emergency response research, analysis, and guidance development process. In contrast to operational aspects of emergency response, which are generally well defined and organized, relatively little attention has been given to how decisions are actually made – the process of collecting and vetting information, developing decision options, and choosing the best response option(s) to protect public health – and how they can be made better.

This is particularly true for mayors and governors in large contamination emergencies. Decision making at that level and for this type of emergency will always be multifaceted and complex. Review of the literature and discussion with interviewees for this study show that decision-making guidance does not currently exist to help political leaders make these complex decisions in very time-pressured and uncertain situations.

The findings presented above, from interviews with subject matter experts and practitioners steeped in the details of decision making and response to contamination emergencies, highlight important structures, processes, and key considerations to incorporate in any future guidance developed for political level decision makers.

These findings informed the development of an initial framework that can serve as the basis for future research and development of guidance for mayors and governors in this context. This research is aimed at helping leaders to arrive at the best possible decisions for public health, given uncertainty and multiple competing influences (Figure 7).

This proposed framework is informed by the literature, particularly the work of Kayman and Logar,[94] Kahneman,[46] Slovic,[92] and John Boyd,[53] and shaped by the interviews conducted in this study. The framework is intended to provide a structure for decision makers that will make them aware of key decision steps, help them to evaluate the evidence, and weigh decisions. It is also aimed at helping decision makers incorporate a broader range of information and options, which will mitigate bias and enable more accurate analysis and ultimately better decisions. Finally, the steps identified through this analysis can be used to increase preparedness before a crisis occurs. Information gathered for the framework could prompt pre-identification of a core decision advisory body, or inform development of training courses for mayors and governors on crisis and risk-based decision making, for example.

Conclusions

Major contamination emergencies present unique challenges to decision makers charged with response. These decision makers, who are often political leaders, are insufficiently equipped and supported to make decisions that optimally reduce health impacts resulting from these events.

The framework proposed here is intended as a first step on a path to developing guidance that can be provided to decision makers and used in future emergencies to improve crisis decision making. This is only an initial step, and further work will be needed to develop this proposed framework, create a usable decision guide, and pilot and revise that guide with decision makers.

DISCUSSION AND POLICY IMPLICATIONS

Summary

When major contamination emergencies involving chemical, biological, and radiological hazards occur, decisions about actions to protect public health are often needed very quickly. However, there is very little guidance for leaders about how to make these decisions, which may be very consequential. The goal of this research is to learn from disparate disciplines that deal with crisis decision making and risk-based decision making in order to understand the elements that are important for successful decision making in contamination emergencies, and translate those findings into a framework that can help guide risk assessors and decision makers through the process in future contamination emergencies.

This research was conducted in three parts. First, a case study on biological threat characterization was conducted using a modified Delphi approach to gather subject-matter expert opinion on the process of characterizing contaminants and conducting human-health risk assessment prior to an emergency. Second, an integrative literature review was conducted to bring together relevant findings from different types of literature from the fields of risk-based and crisis decision making. Finally, building on the findings of the literature review, semi-structured interviews with subject matter experts were held to discuss the important elements, information needs, and processes that can support a political-level decision maker such as a mayor or governor, who may be in the position of making these difficult decisions.

Findings from the Aim 1 Delphi case study revealed the importance of characterizing potential hazards before an emergency occurs, so that data about a contaminant and information about risk to human health can be used to make more-accurate decisions to protect the public's health. This Delphi study is important because it is the first time that questions about Biological Threat Characterization (BTC) research have been posed systematically to a collective of biodefense experts. Most importantly, this research indicates that experts view BTC research as a necessary USG function and that despite the risks inherent in this kind of research it should go forward under the leadership of the Department of Homeland Security. Findings from this Delphi study can be extrapolated to other security-related threat characterization programs, and similar efforts should be applied more broadly to other federal programs that are working to prioritize research for CBR agents prior to the next contamination emergency

The Aim 2 literature review uncovered a number of key findings from the risk-based and crisis decision literature, and from reports of past contamination events, which can improve the quality of decision making in a contamination emergency. Findings from the crisis decision literature show that initial intuition, followed by rational interrogation of an emergency situation is a promising approach to improving the quality of decisions; that analysis of the situation can help mitigate typical cognitive biases and traps; that having a primary decision-maker supported by a small-yet-diverse group of advisors can improve decision making while avoiding chaos; that many types of information, including scientific, ethical, legal, social, economic, and logistical inputs should be considered; and that decision making works best in a cycle that involves data collection and analysis, decision, action, and further data collection and refinement. Findings from the risk-based decision literature show that scientific data are not and cannot be the only driver of decision making; that a process of problem formulation, risk analysis, and risk management can be applied, even when time is short; that it is important to clearly define the problem at hand, acceptable risk, and goals of the response at the outset of the decision process; that a risk assessment approach should be carefully chosen to match situation needs; that uncertainty should be acknowledged and accounted for in both the risk assessment and options analysis phases; that a systematic approach to comparing options for action should be used, even if it is simple and quick; and that public risk perception and levels of acceptable risk should be expressly considered throughout the decision-making process.

Interviews with subject matter experts in Aim 3 helped to further explore and validate the themes above, derived from the literature review, which were then condensed into a decision-making framework. Findings from interviews with subject matter experts and practitioners steeped in the details of decision making and response to contamination emergencies, highlight the important structures, processes, and key considerations to incorporate in any future guidance developed for political level decision makers. These findings informed the development of an initial framework that can serve as the basis for future research and development of guidance for mayors and governors in this context. This framework is intended to inform future development of guidance for mayors and governors (Figure 7).

Strengths and Limitations

This research has a number of strengths and offers unique findings not reflected elsewhere in the literature. Aim 1 represents the first time that experts in the biosecurity field have been formally surveyed to understand priorities for research to characterize intentional biological threat agents and the risks they pose to public health if used as weapons. This case study was conducted using a modified Delphi method, which is a rigorous survey methodology that gathers expert opinion and provides opportunity for consensus building, while avoiding group-think. Preliminary results from this study were published in *Science,* [80] and the manuscript included here was published in *Risk Analysis.* [138] Findings from this study aim, while focused on this specific case study, also reinforce the larger need to gather data and conduct risk assessment for other types of hazardous materials prior to an emergency.

Aim 2 of this research provides a theoretical and practical basis for future work to improve risk-based decision making in contamination emergencies. Prior to this review, there was no body of literature that specifically addressed decision making in this context. Through the use of a rigorous integrative literature review method of applicable peer reviewed and grey literature, and reports from actual contamination events were brought together from a variety of fields of study. The results of this review can inform development of new conceptual frameworks addressing this problem.

Aim 3 of this research builds upon the unique findings of Aim 2; further exploring the elements of successful decision making in contamination emergencies through interviews with experts. Strengths of this aim are that interviews incorporated expertise both from the research and practitioner community to gain validation by both theorists and individuals who have been involved in emergency response and decision making. The findings from this Aim, along with the findings from Aim 2 informed development of a framework for decision making in contamination emergencies, which is the first such framework to be proposed. Through further research this framework can be developed into guidance, which can be further validated, and eventually disseminated to decision makers for use in crises.

Limitations of Aim 1 of this analysis include those that are inherent in the Delphi process. Although groupthink is minimized through the Delphi approach, there is still the problem of expert bias at an individual level. Experts brought their own knowledge and experiences to the study, but participants were also asked to answer every question regardless of topic, and not all participants had expertise to bring to bear on all questions. In cases where a participant did not feel knowledgeable enough to answer the question with high fidelity, they were required to make their best educated guess. This may affect some of the results and contribute to the wide distributions found in responses. Another limitation is the different possible interpretations of question meanings by different participants. In fact, one question was removed from the survey after round two because of problems with interpretation and understanding among participants. In theory, both the issue of varied knowledge and varied interpretation should have been mitigated somewhat through the second survey round, when participants were asked to read others' responses and alter their responses accordingly if they felt compelled to do so.

Another potential limitation to this research was the approach used to recruit expert participation. The snowball sampling methodology is limited in that participants are not recruited in a random and unbiased way. However, because of the topic, it was necessary that participants have very specific expertise in biological science, biodefense, and national security. So, a snowball sampling approach was used in order to gather experts in this limited field at the nexus of biology and security. An effort was made to gather experts from a wide range of disciplines, with a range of years of experience, and representing demographic diversity, so that a variety of perspectives would be included in the study. Finally, Delphi studies generally have problems with attrition, which can be severe in some instances. In this study, the authors were able to limit attrition to three participants in the second round. Because the study was terminated after two rounds, further attrition was avoided. For this study, attrition was minimal with limited effects on the final results of the study.

In addition to these specific limitations, Aim 1 is only one case study example addressing how information should be collected to inform preparedness efforts for and decision making in one type of contamination emergency – a bioterrorism event. Other efforts are needed to characterize and conduct human health risk assessments for other categories of contaminants. These efforts are spread throughout government and the private sector and will be difficult to standardize.

Aim 2 has several limitations. Although a systematic search of the literature was conducted, because of the diversity subjects included in this analysis there may be sources and topics that were not available within the chosen databases, and which may have then not appeared in the returned results. Moreover, this methodology necessitates some subjective judgment about whether a piece of literature meets inclusion or exclusion criteria, which may have resulted in articles/pieces of literature that were excluded when they should have been included in the review. Another potential limitation is the temporal cutoff for the literature included. This cutoff was necessary due to the large volume of literature from many sources. However, there may be research or accounts of disasters that could have added substantively to the analysis had they been included and it should have been applied initially rather than in a second round of review. Finally, the inclusion of non-peer reviewed literature, while adding important dimensions to the analysis not found in traditional sources, must also be considered carefully because of the lack of peer review.

The research for Aim 3 was conducted with the goal of informing the development of a novel framework, and involved a variety of types of interview participants, who had different perspectives on the topic. While these different perspectives enriched the research, the study could have also benefitted from repeated exposure to similar points of view to verify or corroborate findings. A second limitation was that the practitioners interviewed for this study, while they may have been exposed to or involved in political-level decision making in contamination emergencies, were primarily in the decision advisory role as opposed to being the person responsible for making the decisions. Future research would benefit from discussion and piloting with mayors, governors or other decision makers to ensure the applicability of the tools developed. As discussed above, the framework developed from this research is preliminary and should undergo further development, scrutiny and testing before it can be applied or disseminated to decision makers (Figure 7).

Policy Implications

The recommendations below represent major, overarching themes derived from this research. Additional and more detailed policy implications and recommendations are presented in the three manuscripts of this dissertation.

Acting Prior to a Contamination Emergency to Improve Decision Making

This research highlights the need to plan, prepare, and gather information prior to a contamination emergency in order to enable better crisis decision making. Each research Aim reinforced that anything that can be done in the non-emergency period to improve situational awareness and reduce uncertainty in an emergency should be done. This can be accomplished in a number of ways:

Recommendation 1.1: Federal agencies, including the Environmental Protection Agency, the Department of Energy, the Department of Homeland Security, and the Department of Health and Human Services (in particular the Centers for Disease Control and Prevention) should prioritize characterization of chemical, biological, and radiological contaminants, conduct of human health risk assessment during the pre-emergency period, and make that information widely and easily available to stakeholders who will need it to inform decision making in an emergency.

The absence of basic information for CBR hazards, including information on dose-response and potential adverse health outcomes (both acute and chronic), as well as more comprehensive human health risk assessment data, makes decisions in a crisis much more difficult and subject to errors, which could have serious implications for public health. There are programs in place at the federal level to gather data and conduct human health risk assessments for these contaminants, including the DHS CBRN terrorism risk assessment program, the EPA Integrated Risk Information System (IRIS), and the EPA Radiation Protection Division's radiological risk assessments. However, these and other similar programs are largely under resourced, leaving thousands of potential hazardous materials uncharacterized and with little or no human health risk data. While federal dollars are certainly limited, having human health risk assessment data on more potential contaminants can help prevent or mitigate the impacts of a major contamination emergency and avoid much greater expenditures in the response and recovery period of such an event. These programs should dedicate a portion of their focus and budget to characterize those contaminants that could have a high impact on public health if they were involved in a major contamination event. Finally, risk assessment results and other data should be made available, easily accessible, and known to public health officials and other experts at the state and local levels who will be in a position to advise a decision maker during a contamination emergency.

Recommendation 1.2: Federal agencies with technical reach back capabilities and expertise in risk assessment, public health emergency response, toxicology, and environmental contamination response should continue to ensure that state and local governments, public health agencies, and emergency management agencies are aware of and can easily access their knowledge and technical support in a crisis.

This research demonstrates that having access to expertise in risk assessment, toxicology, and other related technical areas is critical to making quality decisions in a contamination emergency. Often the specific expertise needed is not available at the state or local level, but instead resides within the federal government. For example, the Agency for Toxic Substances and Disease Registry (ATSDR) at the CDC has emergency response teams of scientists with expertise in chemicals and toxicology, who are available to assist during contamination emergencies. Similarly, the EPA and the Assistant Secretary for Preparedness and Response (ASPR) at HHS have scientists who can provide rapid guidance and assistance when needed by state and local decision makers. These resources are called upon in some, but not all emergencies of this type, and it is not always clear to state and local decision makers which of these agencies to call when an emergency happens. The federal agencies, including, but not limited to those mentioned above, should coordinate more extensively and provide clear guidance to mayors, governors, public health officials, and first responders about who they should call within the federal government and how they can best access experts when they are needed.

Recommendation 1.3: Mayors, governors, and public health officials should be trained in crisis decision making.

Crisis decision making is not typically a focus of either public health or emergency management training, and it is even rarer for public officials like mayors or governors to have any exposure to or training in this area. Yet, findings from this research show that there are standard steps individuals can take to reduce biases, obtain and interpret information, enumerate options, and make tradeoff decisions. Moreover, research shows that repeated experience with crisis decision making improves an individual's ability to make quality decisions. This training could be valuable in a number of emergency situations, including contamination emergencies. Leaders would benefit from training developed for this purpose.

Recommendation 1.4: Mayors and governors should identify a team of advisors, who represent the important perspectives outlined in this research, and can be called upon to aid in decision making during a crisis.

As discussed in Aims 2 and 3 of this research, it is important for decision makers to have a team of advisors who can be assembled quickly and can provide guidance to a decision maker during a contamination emergency crisis period. Advisors should represent a variety of perspectives and expertise, including scientific, risk assessment, and technical expertise; political, ethical, legal, and operational expertise; and a community perspective. Some of this expertise can be provided from outside sources as discussed above, but they should all be willing and able to participate in discussions about goals for the response, analysis of available evidence and non-scientific considerations, development of protective action options, and weighing options to find the best possible solution. Having diversity of expertise and input to decisions will be critical to optimized decisions, and having a group that can be called upon quickly in the immediate crisis before more formal systems and command structures are fully operational, will enable the rapid decision making needed in the early hours of a major contamination emergency. Pre-designating advisors, or at least identifying where advice can be found in an emergency, will help to speed up the process, and bolster the confidence of a decision maker in the advice they receive.

Improving Crisis Decision Making during Contamination Emergencies

In addition to the recommendations above, which include efforts to gather information and prepare in advance of an emergency, the recommendations below focus on development of resources that can be used during a crisis to improve decisions and reduce harm to public health.

Recommendation 2.1: Guidance for mayors and governors should be developed to enable rapid decision making with increased fidelity, which can reduce morbidity and mortality following major contamination events.

The decision-making framework proposed in this research is just a first step in creating guidance that decision makers, particularly mayors and governors, can use to improve the quality of their decisions during the very time-pressured and uncertain crisis period of major contamination events. This framework will need to be translated into more detailed, but operationally useful stepwise guidance, piloted with decision makers to ensure that it is helpful, and revised to reflect findings from pilot testing.

Ultimately, if guidance is produced, it will also need to be made available to mayors and governors, so that they can review it in advance of an emergency and have it on hand to use when a crisis occurs. Finally, this guidance could be even more relevant and useful if it is exercised in emergency drills with political leaders. Potential routes of dissemination for this guidance could be through federal preparedness grant programs to states and localities or through the National Governors Association or the US Conference of Mayors.

Recommendation 2.2: Other decision support tools should be developed, which can be used during the crisis period of a contamination emergency.

Many models have been developed to aid and optimize decision making for non-emergent decisions about environmental contamination, for very specific contamination emergencies like nuclear power plant accidents, or in other contexts like for doctors and nurses the healthcare setting. However, tools that are specific to decision making about environmental contamination, including plume models and multi-attribute utility models, are often too complicated or not flexible enough to conform to different kinds of events, or require more data than will be available in the first hours of a contamination emergency.

Little investment has been made in simple models or tools for this specific context. Tools are needed, which may not be highly detailed, but can help decision makers and their expert advisors to analyze available scientific data, conduct quick turn risk analysis, develop protective action options, and quickly and simply compare options and understand how well they meet the objectives of the response. Simple automated tools that enable even rudimentary systematic analysis of the situation could aid decision makers in avoiding unhelpful biases and heuristics, and provide structure to help in identifying and comparing options for action. These tools, if developed or adapted from other contexts, could be incorporated into existing infrastructure at an Emergency Operations Center (EOC), for example, and could be applied to different levels of contamination incidents, from smaller hazmat events to major contamination emergencies with severe or broad public health impacts.

Future Research Direction

Further research is needed to produce more detailed and user-friendly guidance, and to validate, test, and disseminate guidance to be used in a crisis response. The findings from Aim 1 can be used to develop research priorities both for other biological threat characterization programs in the US government and around the world, and to inform characterization and human health risk assessment research for other types of contaminants. With additional work in this area, there will be more data and risk assessment information available, which can be used to inform decisions during a contamination emergency.

Findings from Aims 2 and 3, and the resulting decision-making framework can be further developed into stepwise guidance for decision makers to use during contamination emergencies. This guidance will need to be developed and piloted by decision makers to ensure that it is usable and useful in a crisis setting. The piloted guidance tool will then need to be revised and disseminated in a useful format to mayors, governors, and other leaders. Support for this next phase of research may be available from multiple sources including the CDC, DHS, or national organizations including the National Governors Association.

CONCLUSIONS

Given historic trends, major contamination emergencies involving chemical, radiological, or biological contaminants, will likely continue to occur in the U.S. and internationally at somewhat regular intervals. While there is currently little guidance for leaders in the position to make initial protective action decisions in such emergencies, this research identifies examples of important actions that should be taken prior to these events, and considerations that should be incorporated into guidance to aid decision making during the early crisis period of contamination emergencies. Findings from this research suggest that there are steps that can be taken both before and during a crisis to improve the quality of protective action decisions in contamination emergencies.

In advance of a crisis, findings indicate that gathering data on potential contaminants and conducting human health risk assessment for both acute and chronic exposures, can provide critical information that enables risk-based decisions when a crisis does occur. The more that is known about a contaminant, the better predictions will be about public health impacts, which can then inform options for preventing or reducing exposure through protective actions. In addition, training and identification of resources and expertise prior to an emergency can help to improve decisions and outcomes of a contamination emergency when it does occur.

When major contamination emergencies occur, rapid and decisive action is often needed to protect the public from exposure to and harm from contaminants. In those emergencies, decisions made in the first hours or days of the crisis are critical to protecting public health. This research provides a framework for risk-based decision making during the early crisis period of a contamination emergency, and elucidates key actions and processes, underpinned by theory and operational experiences, to aid decision makers. The proposed framework can be used as the basis from which to develop guidance and decision-support tools for leaders, including mayors and governors, who may be in a position to make these crisis decisions. Support for decision makers is necessary to improve the quality of their decisions – which need to be made quickly and under great uncertainty – and make them optimally protective.

APPENDICES

Table 1 – Delphi Participant Demographic Information

Tables

Category	Sub Category	Answer	Number of participants (% participants)
Gender		Male	41 (69.5%)
		Female	18 (30.5%)
Age	Later Generations	Millennial Generation (ages 21-33)	5 (8.5%)
		Generation X (ages 34-49)	26 (44.1%)
	Earlier Generations	Baby Boomer Generation (ages 50-69)	26 (44.1%)
		Silent Generation (ages 69-86)	2 (3.4%)
Primary Focus of Graduate Training or Career Focus	Scientists	Biological Science	32 (54.2%)
		Chemistry	2 (3.4%)
		Physical Science	2 (3.4%)
		Veterinary Medicine	2 (3.4%)
		Public Health	3 (5.1%)
		Medicine	7 (11.9%)
	Non-Scientists	Political Science	2 (3.4%)
		Foreign Policy/International Affairs	1 (1.7%)
		National Security	3 (5.1%)
		Other (e.g., economics, history, law)	5 (8.5%)
Affiliation	Non-Government	Nongovernmental Organization	14 (23.7%)
		Academia	7 (11.9%)
		Private Sector/Industry	12 (20.3%)
	Current and Retired Government	Government	23 (39.0%)
		Former Government (Retired)	3 (5.1%)

Table 2 – Question 8: Sub-Questions Ranked by Decreasing Mean

Question 8: Reasons to explain/justify the need for biological threat characterization programs in the US Government		
Rank (by mean)	**Mean score**	**Sub Question:** For the 6 sub questions, rank order preference by decreasing mean
1	7.4	Question 8_2: To prioritize funding for medical countermeasures
2	7.4	Question 8_6: To provide useful information to help in detection of and response to an attack.
3	7.2	Question 8_1: To enhance our understanding of the biological weapons threat by addressing technical gaps in the information provided by the intelligence community
4	6.1	Question 8_5: To acquire information that could help attribute an attack.
5	5.8	Question 8_4: To prepare for biological weapons that are a strategic possibility based upon the current trajectories in scientific research
6	5.3	Question 8_3: To inform the Department of Homeland Security's Bioterrorism Risk Assessment (BTRA)

Table 3 – Question 10: Sub-Questions Ranked by Decreasing Mean

Question 10: What, in your opinion, are the biggest dangers or shortcomings that might result from a US government program directing laboratory characterization of biological threats?		
Rank (by mean)	**Mean**	**Sub Question:** For the 7 sub questions, rank order preference by decreasing mean
1	6.0	Question 10_2: It may increase the potential for insider threats, as more people would have access to select agent pathogens and technical skills to manipulate them.
2	5.8	Question 10_1: It may be destabilizing to international regimes such as the Biological Weapons Convention, as other nations may believe that the US has an offensive biological weapons program.
3	5.6	Question 10_6: If the results of the laboratory experiments were unexpectedly released, it could help an adversary.
4, 5	5.5	Question 10_3: It may increase the probability of an accidental release of a select agent from a laboratory.
4, 5	5.5	Question 10_7: If the results of the laboratory experiments were unexpectedly released, it would result in public controversy.
6	4.1	Question 10_5: Money spent on laboratory threat characterization could be used more effectively in other areas of biodefense
7	3.9	Question 10_4: Laboratory threat characterization work will not provide actionable information for policymakers.

Table 4 – Question 12: Sub-Questions Ranked by Decreasing Mean

Question 12: In your opinion, what rules of guidelines for threat characterization should be in place to ensure that these programs are safe and effective?		
Rank (by mean)	**Mean**	**Sub Question:** For the 7 sub questions, rank order preference by decreasing mean
1	8.3	Question 12_1: The USG should not conduct an experiment if it violates the Biological Weapons Convention (BWC).
2	6.6	Question 12_4: The USG should not conduct an experiment based on intelligence information unless the threat is determined to be scientifically plausible.
3	5.9	Question 12_5: The USG should not conduct an experiment unless the result of the experiment has the potential to affect policy, funding, or prioritization of biological threats.
4	4.5	Question 12_3: The USG should not conduct any experiment unless there is some intelligence information about a particular biological threat that supports the need for that experiment.
5	4.4	Question 12_2: The USG should not conduct an experiment in which a pathogen is changed/mutated/altered unless the change/mutation/alteration has already occurred in nature (for example, antibiotic resistant anthrax has been seen in nature, so it would be acceptable to characterize it for biodefense purposes.
6	4.3	Question 12_6: The USG should not conduct an experiment to assess a threat unless there is something that can be done to combat or respond to the threat (e.g., there is reason to believe that a countermeasure to the threat is scientifically plausible or is likely to be funded).
7	3.4	Question 12_7: The USG should not conduct an experiment unless there is reason to believe that the experiment has been done before (e.g., in published scientific research, in classified studies, previous offensive work, or in a clandestine laboratory that there is intelligence about).

Table 5 – Question 13: Sub-Questions Ranked by Decreasing Mean

Question 13: What do you think are the most important components of an effective review process for this kind of threat characterization research, which is often dual-use research of concern and highly sensitive?		
Rank (by Mean)	**Mean**	**Sub Question:** For the 13 sub questions, rank order preference by decreasing mean
1	8.8	Question 13_2: Research protocols are reviewed by technical experts inside government for scientific soundness.
2	8.7	Question 13_7: Decisions about why an experiment was undertaken are documented (for example, intelligence, strategic possibility, gaps in the BTRA, countermeasures development, maintenance of capabilities).
3	8.7	Question 13_8: The risks in not doing the experiment are identified and documented (e.g., lack of preparedness).
4	8.6	Question 13_1: Projects are reviewed to ensure compliance with applicable laws and treaties, such as the Biological Weapons Convention (BWC).
5, 6	8.5	Question 13_6: Decisions about why and how threats were prioritized are documented for the program.
5, 6	8.5	Question 13_9: The potential national security benefits to performing the experiment are identified and documented.
7	8.5	Question 13_10: The consequences of a laboratory accident during the course of performing the project are considered and documented.
8	8.4	Question 13_3: Research protocols are reviewed by technical experts outside of government for scientific soundness.
9	8.2	Question 13_13: Alternatives to an experiment, such as the use of simulants or computer models, are considered and documented.
10	8.1	Question 13_4: A technical advisory committee/group helps with the strategic prioritization of work with limited resources.
11	8.0	Question 13_11: The consequences of a data breach in the course of this project are considered and documented.
12	7.8	Question 13_5: A technical advisory committee/group reviews and is able to vouch for the compliance of the work in the event of a data breach.
13	7.8	Question 13_12: A process is undertaken to determine how technically difficult this experiment is, and what it indicates about a potential adversary.

Table 6 – Question 14: Sub-Questions Ranked by Decreasing Mean

Question 14: In your opinion, when is a biological threat "adequately characterized?" In other words, when can you stop doing laboratory research on a biological agent and move on to other important, pressing problems when resources are constrained?		
Rank (by Mean)	**Mean**	**Sub Question:** For the 7 sub questions, rank order preference by decreasing mean
1	6.9	Question 14_1: When we have successfully created a medical countermeasure to combat an agent.
2	6.7	Question 14_2: When we know how an agent behaves in the environment, including how long it persists and the risks to public health posed by environmental contamination.
3	6.2	Question 14_5: When we know the basic characteristics of an agent and can estimate a range of possible consequences.
4	6.1	Question 14_4: When we understand how an agent could be manipulated to defeat our defenses (e.g., antibiotic resistance)
5	5.7	Question 14_3: When we can estimate the dose response relationship in humans for an agent.
6	5.1	Question 14_7: Characterization of agents should continue indefinitely because there is always more we can know that will help us prepare for and respond to an attack.
7	2.7	Question 14_6: Biological agents have already been characterized enough. Any additional work is of diminishing returns for decision-makers.

Table 7 – Key Words/Phrases Used for the Literature Search

Crisis Decision Making	crisis decision making
	emergency decision making
	decision making AND biological AND emergency
	decision making AND radiological AND emergency
	decision making AND chemical AND emergency
	emergency AND environmental contamination
	contamination AND emergency response
Risk-Based Decision Making	risk based decision making
	risk informed decision making
	public health emergency AND decision
	evidence based decision making AND public health and emergency

Table 8 – Crisis Decision-Making Concept Matrix

First Author	Title	Type	Conceptual Framework(s) Used	Major Finding(s)	Strengths/ Weaknesses in this Reference	Concept Focus		
						Leadership /Structure	Decision Processes	Cognitive Factors
Stanley SAR	Operational Art and the Incident Command System: Public Health's Bridge in Bioterrorism Preparedness and Response	Government Report	Incident Command	Public health officials should use Incident Command System (ICS) for response to public health emergencies	Focused on ICS, but not much on how to make decisions	X		
Harwood CA	Generic Protocol for Decisions Regarding Packages Possibly Containing a Chemical, Biological, or Radiological (CBRN) Agent	Government Report	Incident Command	In assessing a possible hazmat situation the incident commander should first take immediate action to limit further exposures	Mostly not applicable except for the immediate actions to prevent further exposure		X	
Burkle FM	Population-based Triage Management in Response to Surge-capacity Requirements during a Large-scale Bioevent Disaster	Journal Article	Emergency Operations Center approach and SEIRV methodology for population categories	In response to a large bio-event, leadership will be critical and can be supported by a well-organized EOC. In addition, separating the population in to different categories of exposure is helpful in prioritizing resources	The article talks briefly about leadership, but mostly in leading to a triage approach to managing the clinical needs of the population	X	X	

Coleman NC	Public Health and Medical Preparedness for a Nuclear Detonation: The Nuclear Incident Management Enterprise	Journal Article	No specific framework	For radiological incidents, HHS has developed a robust set of resources that can be used by decision makers to gain situational awareness and to inform crisis decision making.	The article talks about the availability of resources, but not directly about decision-making requirements.		X	
Dunn JC	Dynamics of Communication in Emergency Management	Journal Article	Recognition-Primed Decision model, naturalistic decision making, distributive decision making, and communication management	Communication among decision makers as part of a team distributive decision-making approach, is important. Communication among the team has both benefits and costs during a crisis. This research found that periodic exchange strategy is most effective, because it does not require constant communication, which can be a drain on resources. It also can be moderated to adapt to the pace of a response with shorter periods of non-communication as needed.	This study provides important information about how to optimize communication among a decision making group	X	X	X
Ergu D	Estimating the missing values for the incomplete decision matrix and consistency optimization in emergency management	Journal Article	Geometric mean induced bias matrix (GMIBM)	This is a mathematical approach to imputing missing information for a decision matrix in order to support decision making	The authors acknowledge that this has yet to be applied to a real-time crisis event. It can also only be used when pairwise comparisons of decisions are being used to collect expert judgments		X	

Davis M	Nationwide Response Issues After an Improvised Nuclear Device Attack	Book	No specific framework	There are a number of important tools to support decision making in a radiological or nuclear emergency.	This is a good analysis of radiological response, but it does not focus on the decision making process in the crisis period to a great extent	X	X	
Higgins G	Improving decision making in crisis	Journal Article	Dual process model John Boyd OODA Loop. David Snowden Cynefin Sense-making Framework	Decision makers are subject to decision-derailers in a crisis. There are things that can be done to avoid/correct for these, including incorporating cognitive diversity, keeping options open, thinking critically, obtaining more information, not delaying too long for perfect information, and following OODA loop in conjunction with Cynefin framework to characterize uncertainty.	Very key for identifying areas where decision making can fail and mitigating those tendencies. It highlights the problem of needing more information but not delaying too long, but does not offer a robust solution.	X	X	X
Inglesby T	Observations from the Top Off Exercise	Journal Article	No specific framework	Political leadership is critical in the crisis decision-making process. Having too many people weigh in on decisions causes confusion and delays.	This is a good description of a large-scale exercise. It discussions some of the challenges to decision making, but does not provide much detail about the process	X	X	

Kayman H	A Framework for Training Public Health Practitioners in Crisis Decision-Making	Journal Article	Dual process model	The dual process model of system 1 vs. system 2 thinking is very useful approach to crisis decision making. Leaders who use system 2 with a group to discuss and make decisions will help avoid some of the biases and heuristics that can derail decisions.	Provides a preliminary framework from which to approach decision making for public health emergencies. It is lacking detail in some areas and does not incorporate risk based decision making. It is also aimed more toward public health officers than political level decision makers	X	X	X
Koerner J	The Medical Decision Model and Decision Maker Tools for Management of Radiological and Nuclear Incidents	Journal Article	Medical decision model	Having a decision maker and subject matter experts co-located helps with situational awareness, informal and formal exchanges of information and opinions. The model highlights the need for initial intervention, further data gathering, consultation and further intervention based on more complex data to come to a definitive management course.	This analysis applies the medical decision model to a radiological/nuclear response. It fits well with the other conceptual frameworks and demonstrates the possible application to other emergencies	X	X	
Lindell MK	An overview of protective action decision-making for a nuclear power plant emergency	Journal Article	Not formal, but focused on implementing timely and effective protective action recommendations	Protective action recommendations must be made in a timely way in order to protect the public, but they also need to be sufficiently targeted to avoid unnecessary secondary consequences. Improvements can be made by segmenting the population and drills to practice and socialize protective actions	Very good points on protective action recommendations but not many insights on how to avoid errors in either waiting too long to decide or deciding too quickly	X	X	

McAlister J	The disruption management model	Journal Article	Disruption management model	Thoughtful and timely action are important. Command and control is necessary. Group input to decisions allows for identification of a larger range of solutions and improves decisions.	Duplicative to the OODA model, but not as detailed as the Higgins manuscript.	X	X	X
Mirandilla KA	Decision making in the crisis cycle: The need for research and better understanding	Conference Paper	Refers to Weick's Sensemaking framework	Crisis decision-making processes are not well understood or well described in the literature.	Preliminary study, which points out some good questions to ask to interviewees.	X	X	X
Mirandilla KA	Public relations in a crisis decision-making kaleidoscope	Conference Paper	Refers to Weick's Sensemaking framework	It is important to consider the makeup of the key decision making body that will advise and iterate with the decision maker in a crisis. One person who should be integrated into this group and into decision making is a public relations exert. This expert is often integral to implementation of decisions, but not often involved in decision making	This is a good recommendation about one participant in the decision making group	X	X	
Parker AM	Measuring Crisis Decision Making for Public Health Emergencies	White Paper	Core processes of public health emergency decision making	The core processes in public health emergency decision making are proposed in a continuous loop from establishing situational awareness, action planning for sets of actions to mitigate health effects, and initial execution. Throughout this period, there is also process control of the flows of information and resources.	This is one of the few resources that brings together crisis decision making and public health emergencies. This document provides an approach to measuring emergency decision making in public health emergencies, but not specific guidance for decision makers.	X	X	

Rebera AP	On the Spot Ethical Decision-Making in CBRN (Chemical, Biological, Radiological or Nuclear Event) Response	Journal Article	Modified Consequentialist approach to ethical decision making	Traditional approaches to weighing ethical principles and values are likely too complex and time consuming. Thus, a consequentialist approach, comparing consequences of courses of action and choosing the one that saves the most lives, and that doesn't violate other core values or rights, is promising.	This manuscript puts ethical decision making into an emergency contamination event context and combines it with the dual process model. The consequentialist approach is reasonable in a crisis.		X	X
Sniezek JA	Training for Crisis Decisio-Making: Psychological Issues and Computer-Based Solutions	Journal Article	No specific framework	With severe time pressure and high degree of uncertainty, crisis decision making can be difficult. Crises vary a great deal, so trying to learn from real events is difficult. Structured training programs in crisis decision making is therefore beneficial.	This article points to the importance of training in crisis decision-making before a crisis. However, it does not go into the actual process of decision making.	X	X	
Van Santen W	Crisis Decision Making Through a Shared Integrative Negotiation Mental Model	Conference Paper	Integrative Negotiation Mental Model for Decision Making	Netcentric (command and control) conditions do not often exist in a crisis decision-making context. Instead, decisions are often made in a bureaucratic political context where there is not one clear decision-maker and many different agencies have priorities and opinions. For this reason a negotiation approach where team members share a mental model of the response is needed.	Creation of a shared mental model through the proposed approaches is useful and fits well with some of the other conceptual frameworks of decision making.	X	X	X

Wilson RS	Managing Wildfire Events: Risk-Based Decision Making Among a Group of Federal Fire Managers	Journal Article	No specific framework	This article, focused on decision-making by firefighters discusses the major heuristics and biases that drive decision making in a fire emergency. In particular, the loss aversion, discounting and status quo heuristics and bias were observed.	This article discusses potential heuristics and biases, but does provide detail on how to avoid them.			X
Slovic P	Affect, Risk, and Decision Making	Journal Article	Dual process model/Affect Heuristic	Affective responses to risk occur automatically and quickly as part of "risk as feelings." The affect heuristic is a mental shortcut that associates positive or negative emotion with risk perception. The authors talk about affect as an important component of risk-based decision-making that cannot be eliminated, but can be incorporated, if not relied upon in decision-making	The authors discuss affect in the context of individual risk-based decision-making. They offer preliminary suggestions about how to frame decisions to work with the affect heuristic. However, the larger public health decision context is not discussed specifically.			X
Slovic P	Perception of Risk Posed by Extreme Events	Conference Paper	Dual process model/Affect Heuristic	Both the intuitive and rational models to decision making are important to consider. Good decision making will harness the positive aspects of both and minimize the negatives. The authors also discuss the need to consider public perception of risk in risk-based decision-making in response to events. If there is a disconnect between public risk perception and risk management response, the recommended actions may be ignored	This analysis provides important information about the cognitive processes in risk perception and risk assessment. It does not provide specific information to guide decision makers, but provides the theoretical underpinning for risk-based response			X

Kahneman D	Thinking Fast and Slow	Book	Two System Thinking/Dual Process Model	In this book, Kahneman discusses many different aspects of thinking and decision making. He focuses on System 1 vs. System 2 thinking/intuitive vs. rational systems. He outlines the cognitive processes and the major biases and heuristics that contribute to thinking and decision-making	While this book does not specifically focus on decision-making in the context of contamination emergencies, it does pinpoint the major cognitive processes, biases, and heuristics that affect decision-making			X
Gasaway RB	Making Intuitive Decisions Under Stress: Understanding Fireground Incident Command Decision-Making	Journal Article	Intuitive decision-making	For fire ground commanders, intuitive decision-making, influenced by years of experience with similar situations, is the most valuable and practical approach to decisions. Because decisions often need to be made in seconds or minutes in a fire situation, the incident commander does not have the time for a rational decision-process, and if they tried to impose it, it would likely delay decisions and result in poor outcomes	This is valuable insight into the role of intuition in decision-making. However, this applies mainly to very experienced, well trained leaders who have been exposed to these situations many times in the past. In a contamination event, with an inexpert decision-maker, intuition may not be as accurate or reliable.	X	X	X

Table 9 – Risk-Based Decision-Making Concept Matrix

First Author	Title	Type	Conceptual Framework(s) Used	Major Finding(s)	Strengths/ Weaknesses in this Reference	Concept Focus		
						Risk Assessment Process	Weighing Uncertainty	Choosing Among Alternatives
Sorenson JH	Planning for protective action decision making: evacuate or shelter-in-place	Journal Article	Protective action planning	Protective action decisions are often needed as the first phase of a public health crisis. For chemicals, these decisions are often whether to shelter in place or evacuate. These decisions are complex and can sometimes be aided by tools like checklists or decision trees.	This article focuses specifically on chemical releases where shelter in place and evacuation are the only options for early protective actions. There may be other options in other situations. However, the discussion of this early phase of decision making is important.	X		X
Burke TA	Science and Decisions: Advancing Risk Assessment	National Academies Report	Risk-based decision-making framework	This NRC report provides an important foundation for risk-based decision-making. It includes 3 phases: formulating and scoping the problem, planning and risk assessing, and risk management. It also emphasizes the need for stakeholder involvement in each phase.	This is foundational framework for human health risk assessment. While it applies to emergencies, it is not specific to emergencies, and so may need to be simplified in crisis situations.	X	X	X

Pollard SJT	Better environmental decision making - Recent progress and future trends	Journal Article	Democratic science decision framework	Good risk-informed decision-making involves not only empirical data and scientific analysis, but also a democratic process among the decision-team. It also requires that decision makers weigh options using some mechanism like a value tree, and that they follow up on their risk management decisions and evaluate residual risk.	This article builds on the Silver Book's approach to good risk assessment practice, and also discusses possible approaches to evaluating risk management decisions	X		X
Su, Hsin-Ting	Comparisons of Risk-based Decision Rules for the Application of Water Resources Planning and Management	Journal Article	Minimax Expected Opportunity Loss (EOL)	In any decision-making process, there is a chance of making the wrong choice. Traditional quantitative risk assessment can facilitate discussion among the decision team, quantify uncertainty, and facilitate development of alternative risk management choices. In addition, expected opportunity loss analysis can also help understand how much better one alternative is than another, and how feasible it is to implement in reality	The EOL approach is a very quantitative method, which requires knowledge of probability distributions and quantification of outcomes. This is difficult in the immediacy of an emergency, and is probably not feasible to implement in a crisis. However, the principles of this type of analysis are important to consider.	X	X	X
Alipour M	Applying the virtual structure of a risk-informed decision making framework for operating small	Dissertation	Multiple Criteria Decision Analysis	This dissertation evaluates how rapid risk-risk informed decision making can be applied to management of hydropower facilities in emergency/high flow events. The author discusses creation of a risk-informed decision framework	This dissertation focuses on building a MCDA model. The authors recognize that in a true emergency it may be unrealistic to build a model like the one discussed here because of limited time and	X		X

	hydropower reservoirs during high inflow events, case study Cheakamus River system			using MCDA. Multiple criteria are analyzed and options are optimized by matching options back to original goals of the response	information. Yet, the principles of multiple criteria analysis and decision optimization can be applied to risk-based decision-making in a public health crisis.			
Mengersen K	Improving accuracy and intelligibility of decisions	Journal Article	Baysian analysis	This analysis emphasizes the need for greater acknowledgement and consideration of uncertainty in risk-based decision-making.	This article focuses on Baysian analysis as a statistical method for conducting risk assessment and considering uncertainty. While this is a robust approach, this article does not focus on emergency risk-based decision making. It is unlikely that a Baysian analysis could be conducted in a crisis. However, the principle of uncertainty acknowledgement is still important.	X	X	
Dubois D	Risk-informed decision-making in the presence of epistemic uncertainty	Journal Article	Confidence Index	This analysis emphasizes the need to acknowledge and account for both aleatory uncertainty and epistemic uncertainty in decision making. If there is some uncertainty in the value being assessed, then that uncertainty should be considered when comparing possible choices in a pairwise comparison.	This article does not focus specifically on decision-making in a crisis. It presupposes time and resources available to model and consider risk and uncertainty in a detailed and mathematical way. However, the principles of considering both uncertainty in knowledge of a crisis event	X	X	X

					and variability in things like population vulnerability and changing contamination levels over time are important in order to make better decisions in the immediacy of a crisis			
Faherty DM	Risk-Based Decision-Making and the Use of Operational Risk Management (ORM) in Developing a Course of Action (COA) for the Joint Task Force (JTF)	Government Report	Operational Risk Management	This analysis discusses the application of a largely qualitative method for systematizing risk-based decision making in military combat situations. The Operational Risk Management approach provides a framework for a decision maker to consider the likelihood and consequences of a course of action, and vulnerabilities in the system, and to compare coursed of action to a commander's acceptable level of risk and to other courses of action	This approach is better suited than other more quantitative approaches to the tight timeframe and limited data available in a crisis. This description of the application of operational risk management is mostly applicable to a military combat situation and not a civilian contamination emergency, but the approach can be modified to fit other scenarios fairly easily.	X		X

Rosqvist T	On the use of expert judgment in the qualification of risk assessment	Dissertation	No specific framework	This analysis addresses how expert judgment can be best considered and utilized during risk assessment and risk-based decision-making. The author identifies where expert judgment applies in each step of the risk assessment process.	This is a useful analysis in that it acknowledges the role of expert judgment and provides applications in all phases of risk assessment. Because decision-making in a crisis will likely be more qualitative and based on judgment than in routine situations where risk can be more quantitatively assessed, this is very applicable.	X	X	X
Amendola A	Recent paradigms for risk-informed decision-making	Journal Article	Participatory procedure in risk assessment	This article identifies "human factors" as an additional source of uncertainty in risk assessment, one which is not often considered. This "operational uncertainty" can be somewhat ameliorated through inclusion of multiple perspectives throughout the risk-based decision process, including a participatory approach that involves the community and considers contextual factors during the process.	This article highlights another important source of uncertainty, which should be reduced as much as possible and accounted for in decision making. However, in the context of a crisis, the ability for a decision maker to make the process participatory may be limited due to time constraints.	X	X	X

Bogen KT	Risk Analysis for Environmental Health Triage	Journal Article	No specific framework	This article discusses the need for decision-makers to take better account of sources of uncertainty in risk assessment, particularly for large chemical environmental exposures. The authors emphasize that current Acute Exposure Guideline Levels (AEGL) for chemicals incorporate uncertainty factors, which make judging true uncertainty in an emergency response difficult. The authors argue for in some cases providing AEGLs without uncertainty factors so that uncertainty can be accounted for more scientifically in the risk assessment process in other ways.	This article is good in that it focuses specifically on emergencies and large-scale exposure events. However, the authors presuppose access to large amounts of reliable data and modeling tools and the time to conduct analysis. In the context of this research it is likely that information and resources will be limited and accounting for uncertainty will be done more crudely.	X	X	X
Bogen KT	Probabilistic Exposure Analysis for Chemical Risk Characterization	Journal Article	No specific framework	This article echoes the author's previous article on environmental health triage, but emphasizes that role that probabilistic risk analysis can play in assessing exposures, quantifying uncertainty, and enabling tradeoff decisions in an emergency.	This is a useful perspective on probabilistic exposure analysis in chemical risk characterization, but it likely will not be useful in the initial response to a contamination emergency due to the lack of data and time.	X	X	X

Borysiewicz M	An application of the value tree analysis methodology within the integrated risk informed decision making for the nuclear facilities	Journal Article	Integrated Risk Informed Decision Making using Value Tree Analysis methods	The authors identify value tree analysis as a way to facilitate decision tradeoff analysis, and to incorporate consideration of multiple and diverse sets of factors (e.g. health protection, economic, ethical, political considerations) and help ensure that decisions meet the original goals of the decision-maker with regards to the response.	This is a useful tool and can be scaled up or down in complexity based on the time and resources available.	X		X
Dombroski MJ	An Integrated Physical Dispersion and Behavioral Response Model for Risk Assessment of Radiological Dispersion Device (RDD) Events	Journal Article	Behavioral Response Model	This article focuses on the need to model public behavioral responses in contamination emergencies, specifically radiological dispersal device (RDD) attacks	The complexities of the proposed modeling approach are more suited to planning and scenario generation than to emergency response. However, the idea that public reactions and behaviors need to be considered in assessing risks and deciding on risk management options in an emergency is important.	X		X
Ersdal G	Risk informed decision-making and its ethical basis	Journal Article	Utilitarian and deontological ethical theories	The authors evaluate risk management approaches to determine how they address applicable ethical theories. They determine that there is no specific method based solely on ethical principles. However, they emphasize the need for consideration of ethics in risk-based decision making.	This is useful to show that ethical principles are built into many risk-based decision approaches. It does not provide specific guidance of how ethics should be incorporated, into crisis decision-making. But, the principle that it should be considered is important.	X		

Hamalainen RP	Multiattribute risk analysis in nuclear emergency management	Journal Article	Multiple Criteria Decision Analysis	This article discusses the use of multiple criteria decision analysis (MCDA) in a nuclear emergency situation. The authors highlight the use of a value tree to identify all attributes for consideration during the risk analysis; the use of a neutral facilitator in the decision process; and the use of tradeoff analysis when deciding upon alternative actions.	This is a good example of application of MCDA in an emergency setting when there may not be time or data enough to conduct extensive modeling of risk or decision alternatives. The authors propose a general value tree that can be modified for other scenarios. The authors do not explicitly address uncertainty other than through the general MCDA process	X		X
Hamilton MA	Risk-Based Decision Making for Reoccupation of Contaminated Areas Following a Wide-Area Release	Journal Article	Decision Tree	The authors use a decision tree to show and quantify the desirability of different options under different risk levels. The authors show that different response options can be quantified, but they also discuss the need to understand community views and values when choosing a response option and to communicate choices effectively in order to make the option viable.	This is a good illustration of risk-informed decision-making. It is not intended to be used as a tool in a response, but can inform deliberation in planning for a future response. A decision tree, used to visualize (and possibly quantify) different response options is useful for an emergency situation, as is taking community views and values into account to ensure that residual risk is acceptable and accepted once a decision has been made.			X

Haque CE	Risk Assessment, Emergency Preparedness and Response to Hazards: The Case of the 1997 Red River Valley Flood, Canada	Journal Article	No specific framework	This article examines the response to the Red River Valley flood in Manitoba, Canada in 1997. Findings include that the community should be more engaged in the decision-making process when choosing risk management options; that risk perception may differ between the community and emergency response decision-makers; and that acceptable risk may also differ. If decision makers do not account for these differences, response will be less effective	This article only discusses the decision-making process briefly, and does not go into detail about how decisions were made			X
Sabbaghian RJ	Application of risk-based multiple criteria decision analysis for selection of the best agricultural scenario for effective watershed management	Journal Article	Multiple Criteria Decision Analysis	MCDA can be applied to different degrees, including both simple additive weighting of decision criteria, which accounts for importance of criteria; ordered weighted average, which accounts for weight given to criteria, but not importance; and induced ordered weighted average, which accounts for both.	This process is too complicated for an emergency, little data are available and decisions need to be made quickly. But, the process of quickly comparing scenarios based on simple weights may be possible.			X

Jederberg WW	Issues with the Integration of Technical Information in Planning for and Responding to Nontraditional Disasters	Journal Article	No specific framework	The authors emphasize that risk information should be collected and integrated into an ICS-based decision process before a chemical release occurs. One source of information for chemical incidents is MSDS's. However, they are limited. So, more effort needs to be made to gather data and plan for incidents before they occur.	This article discusses the collection of data and planning under an all hazards system, but does not specifically address what can be done when an emergency occurs and the needed data are not fully available.	X		
Johansen IL	Ambiguity in risk assessment	Journal Article	Ambiguity in risk assessment	The authors identify "ambiguity" as an under-attended to part of the risk-informed decision-making process. They define ambiguity and possible sources of it in this process, and identify a step-wise method for a decision-maker to address it. The authors emphasize the need for incorporating discussion of sources of ambiguity into the discussions that occur between decision makers and stakeholders during a response.	The article has some important points about ambiguity that have not been addressed thoroughly elsewhere. However, this article focuses on risk assessment more broadly and not just in an emergency. The process outlined here may be too time consuming for a crisis. However, in a simplified way it could be applicable.	X	X	
MacGillivray BH	What can water utilities do to improve risk management within their business functions?	Journal Article	Risk-based decision-making maturity framework	The authors outline the risk-based decision-making steps and propose a categorization process for identifying the maturity of decision-making process	The article is very specific to water utilities and doesn't apply specifically to emergency situations	X	X	X

Poston JW	How do we combine science and regulations for decision making following a terrorist incident involving radioactive materials?	Journal Article	No specific framework	The authors discuss how in radiation emergencies such as radiological terrorism, traditional risk assessment approaches that look at stochastic effects, and conservative thresholds may need to be disregarded in order to protect against more acute effects.	This is a good point about modifying risk-based decision-making to fit the timelines of an emergency response.	X		
Rosella LC	Pandemic H1N1 in Canada and the use of evidence in developing public health policies - A policy analysis	Journal Article	Ideologies of Evidence	The authors conducted a study of the decision making processes during the H1N1 pandemic in Canada in 2009. They discuss the different ideologies regarding evidence-based decision-making, and note that a pragmatic ideology that supports prioritizing evidence in decision making, but also incorporating other socioeconomic, ethical, and political considerations among others. The authors emphasize the need for greater transparency and communication of decision-making processes which can be less transparent when not entirely evidence-based.	This article highlights different viewpoints regarding how to approach decision making in an evidence-poor environment. The study itself focuses more on longer-term decision-making, but offers some good recommendations about process that can be applied in a contamination emergency.	X		

Sexton K	Evolution of public participation in the assessment and management of environmental health risks: a brief history of developments in the United States	Journal Article	No specific framework	This article details the evolution of the risk assessment and risk management paradigms to include the public/stakeholders as integral part of each phase of the decision making process. The author identifies the benefits of including stakeholders throughout the process, including that it will improve buy-in from the community, it will tap into unique local knowledge, and it will promote a sense of environmental democracy where stakeholders are viewed as equal partners.	This analysis emphasizes the importance of public/stakeholder participation in risk-based decision-making, but does not address time pressures in this process, particularly as related to an emergency.	X		X
Younger Paul L	The contribution of science to risk-based decision-making: lessons from the development of full-scale treatment measures for acidic mine waters at Wheal Jane, UK	Journal Article	BATNEEC approach: Best Available Technology Not Entailing Excessive Costs	The authors describe the decision making process for remediation of river contamination and mitigation of acidic mine waters at a tin mine in the UK. The authors relay the experience to show that while there was extensive science and data supporting specific mitigation measures, decision-making was highly influenced by public perception of the color of the water, and response measures were chosen that were unsupported or not fully supported by data.	This illustrates the importance of other factors in the decision-making process and that decision making cannot be entirely scientifically driven. The bulk of this article focuses on long-term environmental remediation, which is not specifically applicable to this analysis, but observations about the decision making process are useful	X		X

Haywood SM	Estimating and visualizing imprecision in radiological emergency response assessments	Dissertation	Decision support for radiological emergencies	This thesis details the need for and one possible approach to modeling risk in the early phases of a radiological emergency (specifically a radiological release from a nuclear facility). The author acknowledges that in early emergency response, complicated models will not be useful and that there will be minimal data with which to make decisions. She highlights the importance of understanding and communicating uncertainty to decision makers and providing a simple tool to support risk assessment	This thesis is very specific to radiological emergencies stemming from nuclear facilities, and the tool would not apply to other situations. However, the author's general approach to simplifying risk calculation, communicating uncertainty, and recommending options for response is helpful.	X	X	X

Table 10 – Thematic Codes

Coding Themes	Interviews (n)	Total References (n)
Decision Making Processes	16	141
Approaches to Decision Making	12	67
Cognitive Mechanisms	8	28
Risk Assessment Process	8	25
Types of Decisions Needed	7	14
Documenting decision process	5	6
Decision Making Structures	16	100
Types of People to Include	15	48
Decision Responsibility	11	27
Organizational Structure	11	25
Types of Considerations	16	96
Scientific Data and Risk Information	9	27
Timing	9	14
Demographic Data	6	14
Uncertainty	7	12
Public Behavior and Risk Perception	5	9
Political Issues	4	9
Ethical Principles	4	4
Legal and Regulatory Considerations	2	2
Feasibility	2	2
Communication	12	41

Table 11 – Interview Recruitment and Response Rate

Interviewee Response Categories	**Interviewees (n)**
Total Contacted	**32**
No Response	12
Excluded	1
Included	19
Total Recruited	19
Willing, but Unable to Schedule	3
Total Interviewed	**16**
Response Rate	**50%**

Table 12 – Interviewee Categories

Interviewee Type	Affiliation or Perspective	Focus	Category Combination (n)
Practitioner	State/Local Government	Public Health Preparedness and Response	4
Researcher	Academia	Decision Science	3
Researcher and Practitioner	Federal Government	Environmental Health	2
Researcher	National Laboratory	Toxicology	1
Researcher and Practitioner	Federal Government	Toxicology	1
Researcher and Practitioner	Federal Government	Public Health Preparedness and Response	1
Practitioner	Federal Government	Public Health Preparedness and Response	1
Researcher and Practitioner	State/Local Government	Public Health Preparedness and Response	1
Researcher	National Laboratory	Emergency Management	1
Researcher and Practitioner	Academia	Emergency Management	1

Table 13 – Summary of Policy Recommendations

Acting Prior to a Contamination Emergency to Improve Decision Making	
Recommendation 1.1	Federal agencies, including the Environmental Protection Agency, the Department of Energy, the Department of Homeland Security, and the Department of Health and Human Services (in particular the Centers for Disease Control and Prevention) should prioritize characterization of chemical, biological, and radiological contaminants, and conduct of human health risk assessment during the pre-emergency period, and make that information widely and easily available to stakeholders who will need it to inform decision making in an emergency.
Recommendation 1.2	Federal agencies with technical reach back capabilities and expertise in risk assessment, public health emergency response, toxicology, and environmental contamination response should continue to ensure that state and local governments, public health agencies, and emergency management agencies are aware of and can easily access their knowledge and technical support in a crisis.
Recommendation 1.3	Mayors, governors, and public health officials should be trained in crisis decision making.
Recommendation 1.4	Mayors and governors should identify a team of advisors, who represent the important perspectives outlined in this research, and can be called upon to aid in decision making during a crisis.
Improving Crisis Decision Making during Contamination Emergencies	
Recommendation 2.1	Guidance for mayors and governors should be developed to enable rapid decision making with increased fidelity, which can reduce morbidity and mortality following major contamination events.
Recommendation 2.2	Other decision support tools should be developed, which can be used during the crisis period of a contamination emergency.

Figures

Figure 1 – Conceptual Framework

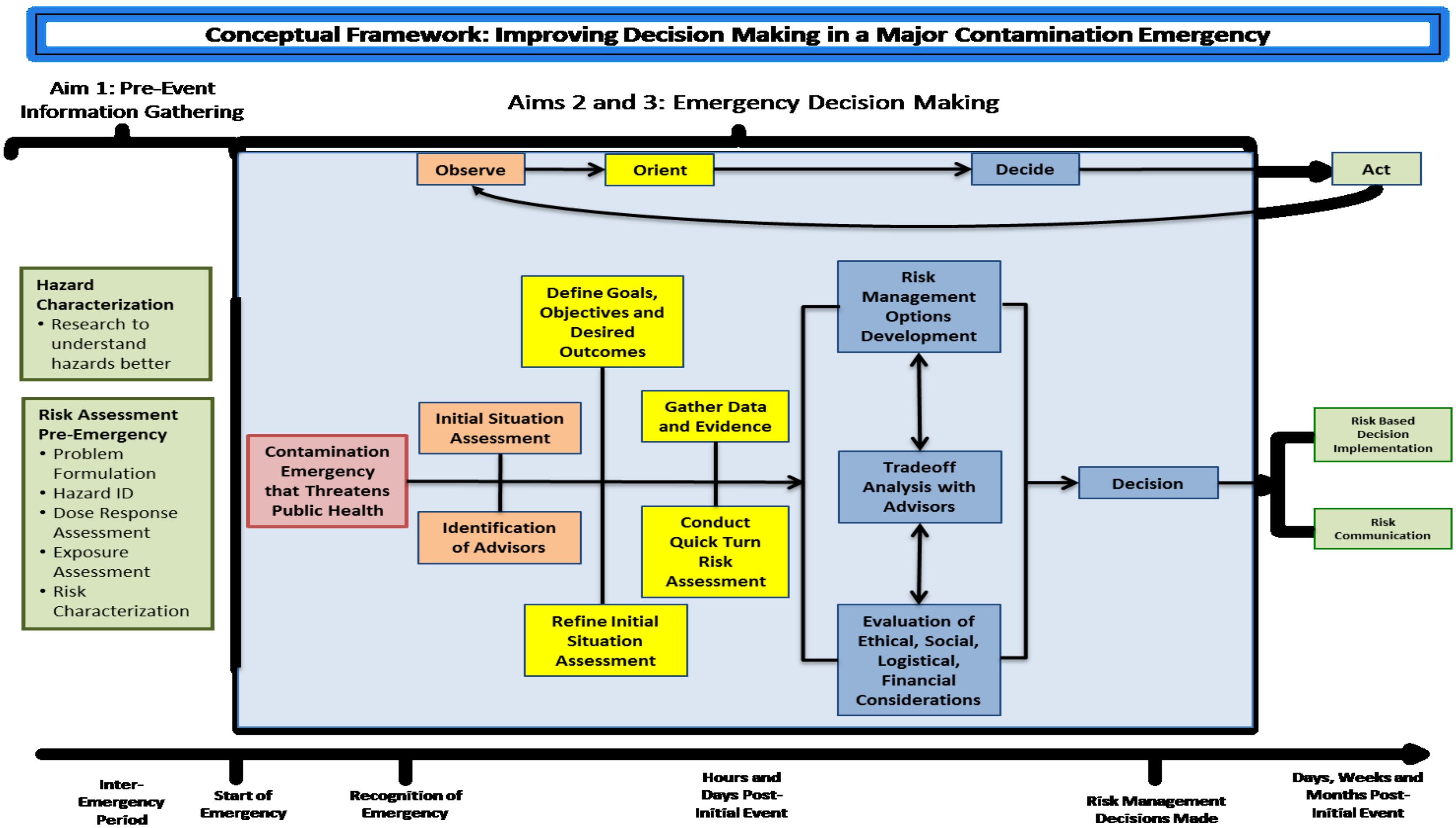

Figure 2 – Question 8: Sub-question Box Plots

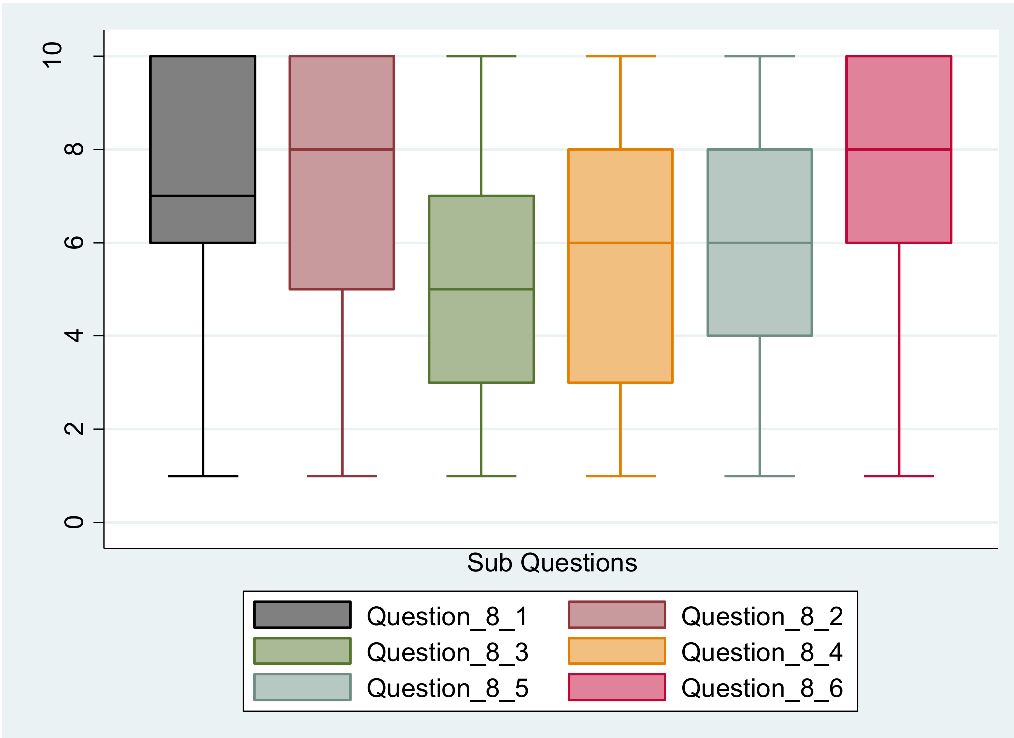

Figure 3 – Question 10: Sub-question Box Plots

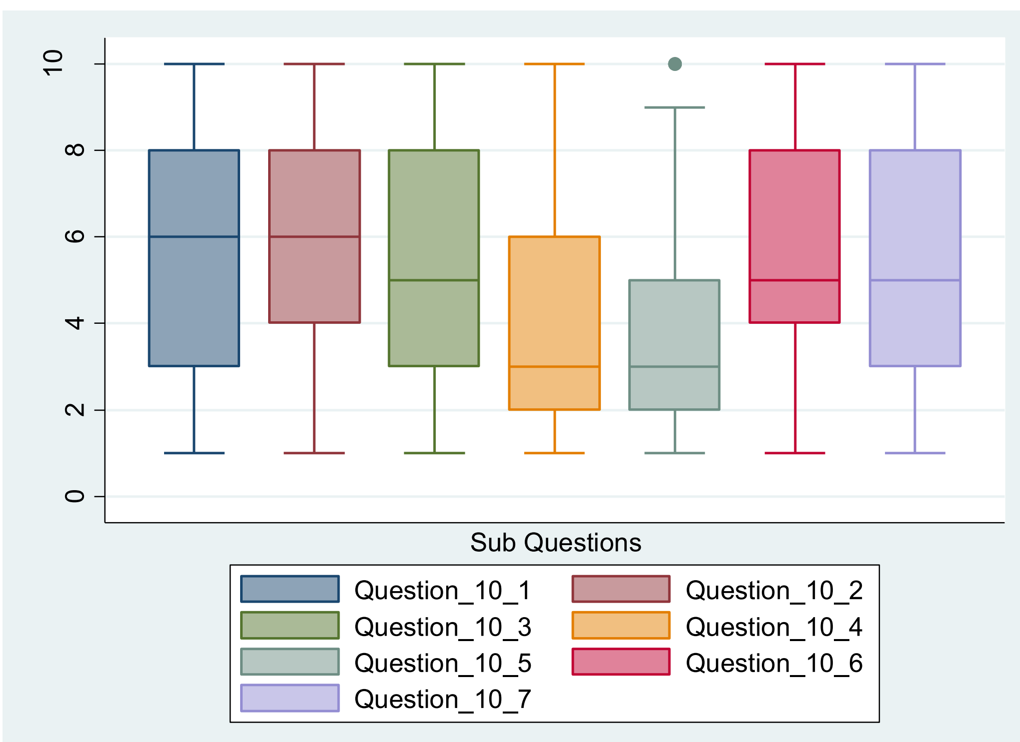

Figure 4 – Question 12: Sub-question Box Plots

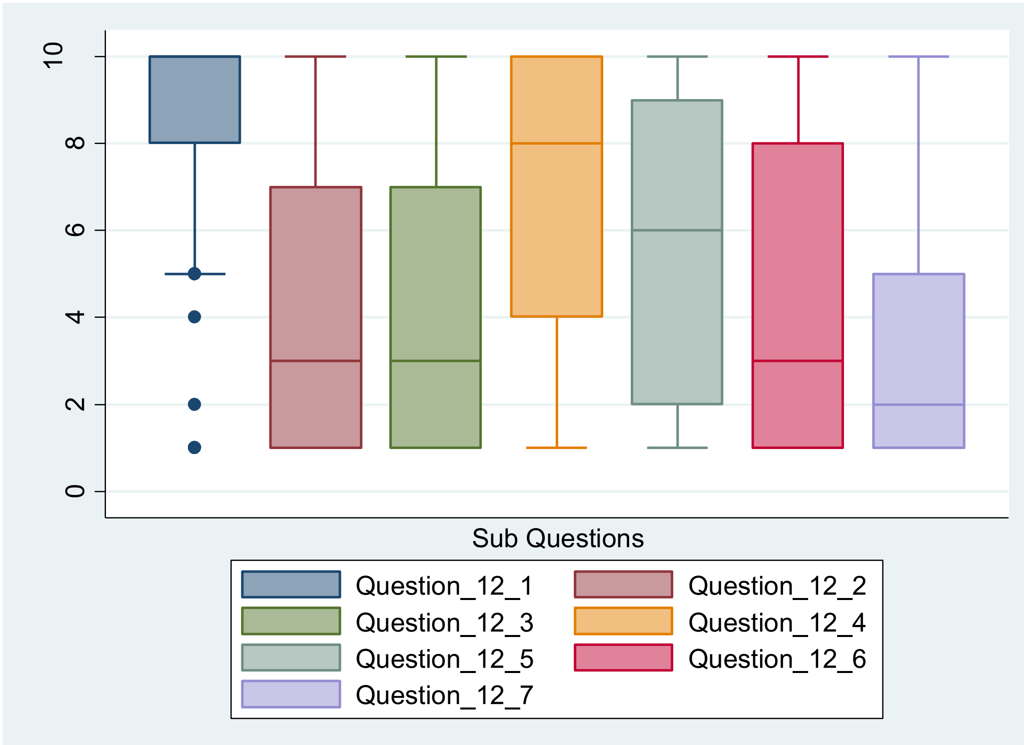

Figure 5 – Question 13: Sub-question Box Plots

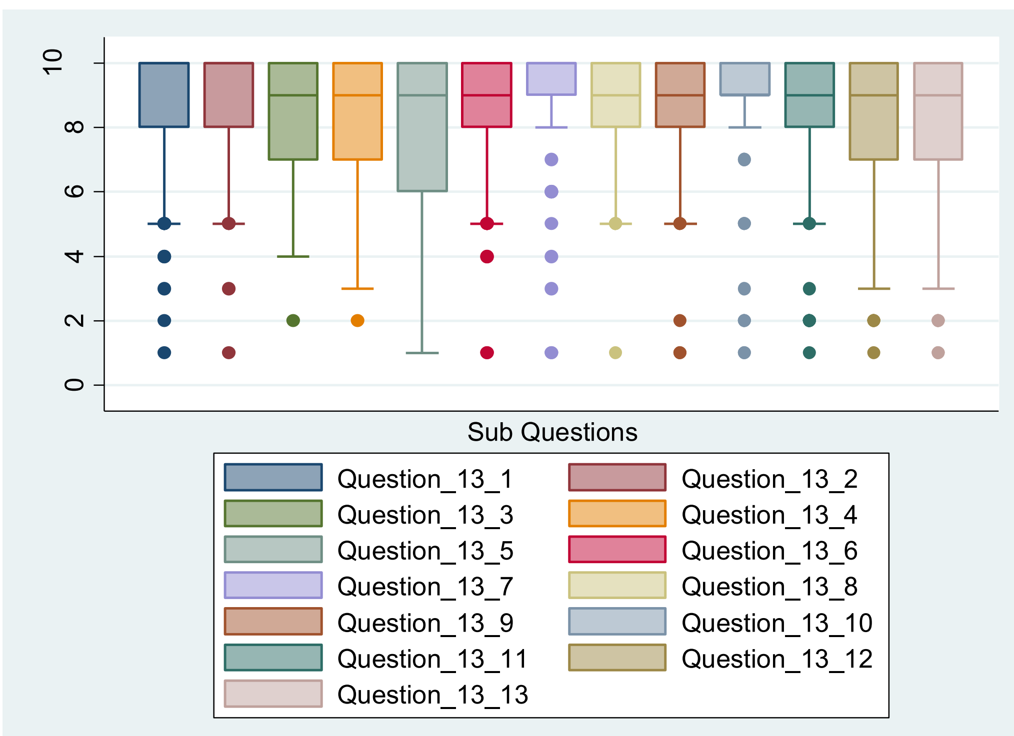

Figure 6 – Question 14: Sub-question Box Plots

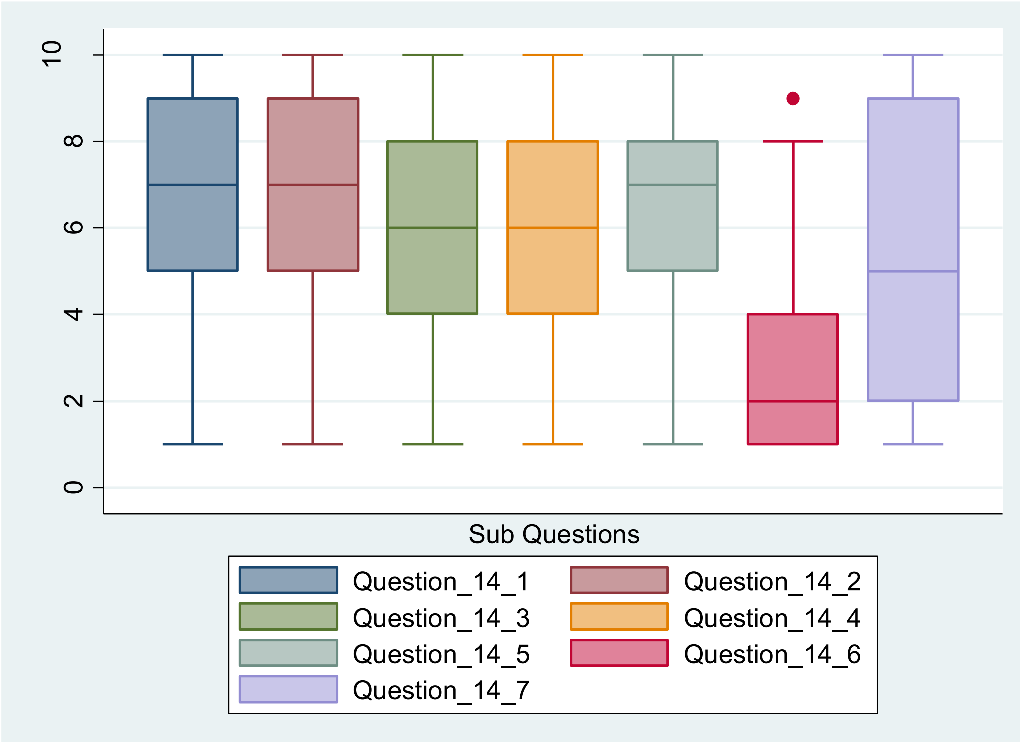

Figure 7 – Initial Framework for Mayors and Governors: Decision Making in a Contamination Emergency

Observe

Context: The time spent in each step will depend upon the urgency of the crisis, with more rapid cycling through the steps given greater urgency.

Step 1: Initial Assessment of the Situation - Make an initial determination about how quickly action is needed to ensure that the public is protected.

- Is action needed immediately? If so, proceed rapidly through the steps.
- Can action be delayed? If so for how long? Proceed through the steps and delve more deeply into analysis.

Step 2: Identify Advisors - The purpose of an advisory group is to broaden the decision maker's view of the situation, provide greater access to more evidence to support decision making, and provide feedback that will improve the quality of decisions and reduce the impact of cognitive biases and heuristics inherent in human judgment.

- Include a combination of individuals that are trusted advisors, and outside experts to fill gaps in knowledge.
- An advisory body should represent a diversity of viewpoints and expertise including:
  - Scientific and risk assessment expertise
  - Ethics
  - Logistical and financial realities
  - Political realities
  - Social and demographic makeup of the affected population
  - Community perspectives
- The advisory body should be tasked to gather data and information in their respective areas of expertise and present that information in a concise way for consideration in decision making
- Identify someone to document the decision making process as it occurs

Orient

Step 3: Refine Assessment and Identify Goals and Objectives – When time pressure is great, relying first on intuition and then conducting a rapid analysis of that intuition and of available information can help orient the decision making process. The more time available, the more in depth the analysis can be.

- Using intuition and the limited data available, develop an initial view of the situation
  - Broadly, what is the problem? How big is it? Who is affected? How urgent is the situation?
  - Ask advisors to react to that initial view and provide information to shape your understanding
- Set goals for your response to the emergency.
  - What would you like the outcome to be?

    - What values are the most important to guide decisions?
- Discuss goals with advisors and make sure that all response elements are working toward achieving the same agreed upon goals, values, and outcomes.

Orient

Step 4: Conduct a Risk Assessment: In order to understand the problem more fully, an assessment of the public health risks is needed. The rigor of this assessment varies with the level of urgency.

- With expert input, decide on an approach to assessing the risks to public health.
    - How will the contaminant be identified, dose-response and exposures be assessed, and risk characterized?
    - Is there time to do sampling or is a rough assessment all that is possible?
- Explicitly address uncertainty. Discuss with experts how uncertain risk estimates are, and who is most at risk in the population.

Step 5: Evaluate Scientific Evidence – With advisors, evaluate the risk assessment results and other information. If there is great urgency to act, quickly move to development of options for action (Step 6)

- Who is at risk and in what ways?
    - How certain are the results? Identify and make explicit uncertain assumptions.
    - Discuss the risks to vulnerable populations. Are they greater than those for non-vulnerable populations? Who is vulnerable?
- Decide on levels of acceptable risk
    - Assess the community's threshold for acceptable risk by consulting with a community advocate or representative.
    - Make a determination about what levels of contamination are acceptable and unacceptable.

Decide

Step 6: Develop Options for Action – Based on the initial assessment of the situation, risk assessment results, and consultation with advisors, propose options for action to mitigate the risks to public health. If great urgency exists, limit the number of options and move to deliberation.

- Propose options for action based on initial assessment of the situation and risk assessment results
- Discuss proposed options with the advisory group.
    - Are there other options to add?

Step 7: Vet Options and Analyze Tradeoffs – Given the options proposed in step 6 evaluate them to determine the best option.

Decide

- If time is very short, conduct a rapid comparison between options to evaluate:
  - How an option helps meet the originally defined goals, values, and preferred outcomes for the response
  - Whether options uphold identified ethical principles, are logistically, legally and financially feasible; will be accepted by the community, and will be politically viable
  - Compare set of options to decide which is the best approach.
- If there is additional time for deliberation, consider adding
  - A more formal comparison of options for action using pairwise comparison
  - Greater analysis of second order impacts of a decision – play out how the decision will work when implemented to identify any pitfalls
  - Greater analysis of key considerations, including ethical, legal, financial, social, political, and logistical feasibility of each option
    - Does the option violate any key ethical principles that were defined as important? If so, is that acceptable or unacceptable?
    - Does the option violate any laws or regulations? If so, can and should the option still be considered?
    - Is the option financially feasible? If funds are not available now, can they be made available?
    - How will the community respond to the option? Will it reduce risks to acceptable levels for the community? What barriers may make community members unable or unwilling to comply with a protective action?
    - Are there political issues that will make this option impossible to implement?

Step 8: Decide – Based on the options and tradeoff analysis, decide which option should be implemented.

Act

Step 9: Implement Decision: Following this decision, work within incident command and with communications experts to implement your chosen option(s).

Step 10: Re-Assess and Re-Evaluate – The decision process is a loop. As more information becomes available, decisions will need to be re-evaluated and revised.

Supplemental Materials

Appendix 1 – Aim 1 Institutional Notice of Determination

UNIVERSITY OF MARYLAND
INSTITUTIONAL REVIEW BOARD

1204 Marie Mount Hall
College Park, MD 20742-5125
TEL 301.405.4212
FAX 301.314.1475
irb@umd.edu
www.umresearch.umd.edu/IRB

DATE:	November 25, 2013
TO:	Gary Ackerman
FROM:	University of Maryland College Park (UMCP) IRB
PROJECT TITLE:	[542751-1] Consensus Framework for Informing Decision-making in the Biological Threat Characterization Program
SUBMISSION TYPE:	New Project
ACTION:	DETERMINATION OF NOT HUMAN SUBJECT RESEARCH
DECISION DATE:	November 25, 2013

Thank you for your submission of New Project materials for this project. The University of Maryland College Park (UMCP) IRB has determined this project does not meet the definition of human subject research under the purview of the IRB according to federal regulations.

We will retain a copy of this correspondence within our records.

If you have any questions, please contact the IRB Office at 301-405-4212 or irb@umd.edu. Please include your project title and reference number in all correspondence with this committee.

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within University of Maryland College Park (UMCP) IRB's records.

- 1 -   Generated on IRBNet

START National Consortium for the Study of Terrorism and Responses to Terrorism

A CENTER OF EXCELLENCE OF THE U.S. DEPARTMENT OF HOMELAND SECURITY BASED AT THE UNIVERSITY OF MARYLAND

Institutional Review Board
Johns Hopkins University
1620 McElderry St., Reed Hall - B130
Baltimore, MD 21205-1911

September 30, 2015

To Whom It May Concern,

I am writing to confirm that Crystal R. Boddie acted as an investigator on a project funded by the Department of Homeland Security, entitled "Consensus Framework for Informing Decision-making in the Biological Threat Characterization Program". I worked with Ms. Boddie continually over the entire period of the project and can verify her active participation and inclusion in the project budget.

Please find attached a copy of the University of Maryland IRB Approval for the project.

Sincerely,

Gary Ackerman, Ph.D.
Director, Unconventional Weapons and Technology Division
National Consortium for the Study of Terrorism and Responses to Terrorism (START)
E-mail: gackerman@start.umd.edu
Tel: 301-405-6656

Appendix 2 – Aim 3 Institutional Notice of Determination

JOHNS HOPKINS
BLOOMBERG SCHOOL
of PUBLIC HEALTH

Institutional Review Board Office

615 N. Wolfe Street / Room E1100
Baltimore, Maryland 21205-2179
Phone: 410-955-3193
Toll Free: 1-888-262-3242
Fax: 410-502-0584
Email: jhsph.irboffice@jhu.edu
Website: www.jhsph.edu/irb

FWA #00000287

NOT HUMAN SUBJECTS RESEARCH

DETERMINATION NOTICE

STUDENT PROJECTS

Date: August 26, 2016

To: Crystal Boddie

Re: **DrPH Dissertation Student Project Title:** "Developing a Framework to Guide Leaders in Making Risk-Informed Decisions during Public Health Crises"

The JHSPH IRB reviewed the IRB Office Determination Request Form for Primary (New) Data Collection (received 8/22/2016) on **August 26, 2016**. We have determined that the proposed activity described in your request form will involve key informant interviews with persons knowledgeable about decision-making processes that are applicable to contamination emergencies. Respondents will respond in their professional capacity and no personal or private information will be collected. Thus, the proposed activity does not qualify as human subjects research as defined by DHHS regulations 45 CFR 46.102, and does not require IRB oversight.

We anticipate that you will follow ethical practices in your interactions with individuals in the community during the course of your project. You are responsible for notifying the JHSPH IRB of any future changes that might involve human subjects and require IRB review.

If you have any questions regarding this determination, please contact the JHSPH IRB Office at (410) 955-3193 or via email at jhsph.irboffice@jhu.edu.

/teb

cc Mary Fox, PhD
Faculty Advisor / Assistant Professor
Department of Health Policy & Management
Johns Hopkins University Bloomberg School of Public Health

JHSPH IRB NHSR Determination Notice_Student Projects
V5, 18Sept2014

Appendix 3 – Template Interview Recruitment Email

October ___, 2016

Dear ____,

My name is Crystal Boddie and I am a Doctorate of Public Health (DrPH) candidate at the Johns Hopkins Bloomberg School of Public Health. I am conducting a research project as part of my dissertation entitled *Risk-Based Decision Making during Public Health Emergencies Involving Environmental Contamination.*

I am contacting you because of your research in the field of public health crisis decision-making, and to ask if you would be willing to be interviewed for this project. The purpose of the project is to understand how leaders make decisions during the early hours of public health emergencies involving environmental contamination, when protective action decisions are needed to mitigate the impact on the health of the public.

This research will involve a series of interviews with individuals who have either been involved in response to a contamination emergency, or who have conducted research on decision making in crises. The goal of this interview process will be to gather insights to inform a draft decision guide or checklist that leaders might use to help guide their decision making process in future emergencies.

Your participation in this interview is completely voluntary. The interview will last approximately one hour, and with your permission it will be audio recorded. The interview will be scheduled at a time that is convenient for you. You may skip any questions or stop the interview at any time. Quotes will not be attributed to you or your organization in the written results. Rather, quotes will be attributed to your type of experience related to this topic (e.g., decision maker, scientist, researcher, responder, etc.).

If you are willing to participate or have questions about this project, please contact me by email at cboddie@jhu.edu or by phone at [redacted]. I will then follow up with additional information about the interview questions and logistical information. I have attached my CV for your information as well. Thank you for your time and any insight you provide for my project. I look forward to hearing from you.

Sincerely,
Crystal Boddie, MPH
DrPH Candidate
Johns Hopkins Bloomberg School of Public Health
[redacted]
cboddie@jhu.edu

Appendix 4 – Recruitment Flyer

Risk-Based Decision Making during Public Health Emergencies Involving Environmental Contamination

Semi-Structured Interviews with Practitioners and Decision Makers

Overview

As a doctoral candidate at the Johns Hopkins Bloomberg School of Public Health, I am currently recruiting interview participants for my dissertation research project focused on assessing the early decision making process in response to public health emergencies involving environmental contamination (e.g., chemical spills, radiological accidents, or biological attack/accidental release). The project is particularly focused on large events that are serious enough that they rise to the political level, where a mayor or governor may be the ultimate decision-maker.

When a contamination emergency occurs and protective action decisions are needed quickly (likely within hours) to protect public health, decision makers are not always equipped to make evidence-based decisions that also incorporate other ethical, political, social, logistical, and economic considerations. While structures for response like the Incident Command System (ICS) exist and are extremely important, there is very little in the way of guidance for leaders on the actual decision-making process – how to weigh the evidence and make good protective decisions under extreme time pressure and considerable uncertainty.

Approach and Purpose

This research will involve a series of interviews with individuals who have either been involved in response to a contamination emergency, or who have conducted research on decision making in crises. The goal of this interview process will be to gather insights to inform a draft decision guide or checklist that leaders might use to help guide their decision making process in future emergencies.

Logistics

Participation in this research study is entirely voluntary. Interviews will last 45 minutes to 1 hour, and with permission, will be audio recorded for note-taking purposes. Interviews will be scheduled at a time that is convenient for you. The study is not-for-attribution, and any information or quotes used in the final report will not be attributable to any interviewee.

If you are interested in the study and are and willing to participate, or have any questions, please contact me, Crystal Boddie (cboddie@jhu.edu, [redacted]). You may also contact Dr. Mary Fox, who is overseeing the research at (mfox9@jhu.edu) if you have any questions or concerns.

Appendix 5 – Interview Guide for Researchers

Risk-Based Decision Making during Public Health Emergencies Involving Environmental Contamination

Semi-Structured Interview Protocol for Researchers

Introduction

This interview is part of a broader exploratory study of the early protective action decision making process for response to public health emergencies involving environmental contamination (e.g., chemical spills, radiological accidents, a biological attack), particularly focused on events that are serious enough that they rise to the political level where a mayor or governor may be the ultimate decision-maker. The interview portion of this project aims to understand perspectives of key stakeholders regarding how initial protective action decisions are made in the early hours and days of such an emergency response. The ultimate goal of this interview process will be to inform a draft decision guide or checklist that decision-makers might use to help guide protective action decisions in future emergencies.

You have been identified as someone who has conducted research on crisis or risk-based decision making or has thought extensively about response to public health emergencies.

This interview is designed to last less than an hour. You may stop the interview at any time. I will be taking notes and referring to this guide to ensure that I cover the points outlined here. I will also be recording the interview for note-taking purposes only. Nothing you say in the interview will be attributed to you directly. When this project is completed, I would be happy to provide you with the final abstract and/or a full copy or the report.

Do you have any questions or concerns before we begin?

INTERVIEW QUESTIONS

1. Do you conduct research on decision-making, or are you a leader or public health practitioner who has been in a decision-making role during a contamination emergency or public health crisis?

2. If you are a researcher focused on decision science or public health emergency response, what would you say are the most important elements for a decision-maker to consider during a public health crisis?
   - How should a decision-maker balance intuition and analytical processes?
   - What are the most important cognitive biases and heuristics that apply to crisis decision-making?
     - What are they?
     - How can they be avoided/mitigated?

- What do you feel are the most successful structures to aid in crisis decision-making?
    - Is having one person responsible for decision-making in a time-pressured situation most appropriate?
    - Should a decision maker receive support from experts and advisors but ultimately make the decision him/herself?
        - What types of people should be involved in providing support?
    - Is group decision-making likely to succeed in a crisis?
        - Who/what type of people should be involved?
- How can decision makers balance time pressure and need to act with deliberation and careful consideration of evidence?
- What evidence is most important to consider? Please discuss how you think different types of evidence should be considered (examples below).
    - Intuition
    - Scientific evidence about risk to human health
    - Ethical principles
    - Socioeconomic, geographic, and demographic information
    - Political sensitivities
    - Financial information
    - Logistical feasibility of implementing a decision
    - Legal/regulatory authority
- How can decision-makers move ahead with decisions in an environment of great uncertainty, where data is largely lacking?
- What decision-making processes do you think are most successful in a time-pressured crisis situation (examples below)?
    - Intuition-driven decisions
    - Intuition, then interrogated and analyzed
    - A formal analytical process comparing options?
    - Other?
- How should stakeholders be involved in a decision-making process? How should the public specifically be engaged/involved?
- What advice do you have for future decision-makers in contamination emergencies?
- Would a framework or short guidance document that laid out points to consider in decision-making help leaders to make decisions?
- If so, what would you want to see in a decision framework?

3. Is there anyone else I should speak with who has thought a lot about crisis decision-making or risk-based decision-making in an emergency?

4. Do you have any final questions for me before we conclude the interview?

5. Would it be alright if I contact you again if I have any follow-up questions or need clarification on something we've discussed today?

Thank you very much for your time today.

Appendix 6 – Interview Guide for Practitioners

Risk-Based Decision Making during Public Health Emergencies Involving Environmental Contamination

Semi-Structured Interview Protocol for Practitioners and Decision Makers

Introduction

This interview is part of a broader exploratory study of the early protective action decision making process for response to public health emergencies involving environmental contamination (e.g., chemical spills, radiological accidents, a biological attack), particularly focused on events that are serious enough that they rise to the political level where a mayor or governor may be the ultimate decision-maker. The interview portion of this project aims to understand perspectives of key stakeholders regarding how initial protective action decisions are made in the early hours and days of such an emergency response. The ultimate goal of this interview process will be to inform a draft decision guide or checklist that decision-makers might use to help guide protective action decisions in future emergencies.

You have been identified as someone who was responsible for or was a key stakeholder significantly involved in decision-making during such a public health emergency.

This interview is designed to last less than an hour. You may stop the interview at any time. I will be taking notes and referring to this guide to ensure that I cover the points outlined here. I will also be recording the interview for note-taking purposes only. Nothing you say in the interview will be attributed to you directly. When this project is completed, I would be happy to provide you with the final abstract and/or a full copy or the report.

Do you have any questions or concerns before we begin?

INTERVIEW QUESTIONS

1. Do you conduct research on decision-making, or are you a leader or public health practitioner who has been in a decision-making role during a contamination emergency or public health crisis?

2. If you have been responsible for decision-making, what contamination event(s) were you involved in (Limit to most impactful or most recent events if involved in multiple events)?
    - What was your title/role during those events?
    - What were your overall impressions of the protective action decision-making process?
    - What did you find most challenging as a decision maker?
    - What, if anything, facilitated your decision making process?

- How would you describe the decision-making structure you used?
    - Did you make the decisions alone with relatively little input from others?
    - Supporting information from experts and advisors, but you were ultimately responsible for the decision
        - How many people and what type of people did you rely upon?
    - Group decision-making, where a group of people deliberated and decided together on a course of action
        - Who/what type of people were involved? Did they all contribute equally?
    - Someone else made the decision, but you communicated it?
- What type of early decisions did you have to make?
    - How much time pressure did you feel in making an initial protective action decision?
- What information did you rely upon/incorporate into your decisions? Please discuss how you considered different types of evidence and information (examples below).
    - Intuition
    - Scientific evidence about risk to human health
    - Ethical principles
    - Socioeconomic, geographic, and demographic information
    - Political sensitivities
    - Financial information
    - Logistical feasibility of implementing a decision
    - Legal/regulatory authority
- Did you incorporate scientific data about risk into your decisions?
    - What types of data did you have?
    - Did you wish you had more data to inform your decisions? What data?
    - Did a lack of data delay your decisions, and if so for how long?
- What process did you use to make initial decisions?
    - Did you conduct a formal risk assessment?
        - If so, what methods did you use?
    - Did you go with your initial intuition?
    - Did you weigh options against one another? How did you weigh them/what factors did you consider?
- Did you involve other stakeholders in your decision process?
    - Did they include the public?

- What were the outcomes of your decision-making process (e.g., what decisions did you make and how were they received by the public and implemented)?
    - What were the positive outcomes?
    - What were the negative outcomes?
    - Would you have approached your decision-process differently if you could go back?
- What advice do you have for future decision-makers in a similar situation?
- Would a framework or short guidance document that laid out points to consider in decision-making have helped you to make decisions?
- If so, what would you want from a decision framework if you were the decision maker?

3. Is there anyone else I should speak with who has been in similar decision-making role during public health emergencies involving contamination?

4. Do you have any final questions for me before we conclude the interview?

5. Would it be alright if I contact you again if I have any follow-up questions or need clarification on something we've discussed today?

Thank you very much for your time today.

Appendix 7 – Email Informed Consent Script

Investigator Name: Crystal Boddie, MPH, DrPH Candidate
Institution: Johns Hopkins Bloomberg School of Public Health
Study Title: *Risk-Based Decision Making during Public Health Emergencies Involving Environmental Contamination*

Dear Interviewee,

I am a doctoral candidate at the Johns Hopkins Bloomberg School of Public Health, and I would like to invite you to take part in a research project with the purpose of understanding the key elements of risk-based decision making in public health emergencies involving chemical, biological, or radiological contaminants. You have been selected to participate based on your expertise, knowledge, or experience in this area. You will be asked questions related to your professional experiences and opinions about the decision making or risk analysis processes.

This interview will last approximately 45 minutes to 1 hour. With your permission, I will audio record this interview so that it can be transcribed and referred to later when I analyze the interview results.

There are no foreseeable costs or risks to you from participating in this project, but you will be asked to provide your time and expertise. There is no direct benefit to you and you will not receive payment. However, your contributions to this work could help lead to development of a decision framework that will assist leaders in making decisions during future contamination emergencies.

The results of this project will be shared with you upon completion and publication. Participants will be kept anonymous and your responses will not be identifiable in any way. Interview notes will be kept confidential and will be held in a password protected electronic file. Your participation is voluntary and you can change your mind at any time or decline to answer any question.

This work is being conducted by me, Crystal Boddie at the Johns Hopkins Bloomberg School of Public Health. I can be reached by phone at [redacted] or by email at cboddie@jhu.edu. You may also contact my academic advisor, Dr. Mary Fox (mfox9@jhu.edu) if you have any questions or complaints about this project. If you have any questions about your rights as a research participant, or if you think you have not been treated fairly, you may contact the Johns Hopkins School of Public Health Institutional Review Board (IRB) at 410-955-3193, or 1-888-262-3242, or JHSPH.irboffice@jhu.edu.

Do you have any questions? Is it ok to proceed with the interview, and are you ok with me recording the interview?

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	2014	Certificate in Risk Sciences and Public Policy	
MPH	2009	Johns Hopkins Bloomberg School of Public Health	Baltimore, MD
BA	2004	Molecular, Cellular, Developmental Biology (MCDB), University of Colorado	Boulder, CO

PROFESSIONAL EXPERIENCE

January 2017 – Present	**Senior Associate and Visiting Faculty** Johns Hopkins Bloomberg School of Public Health, Center for Health Security

Principal Responsibilities:

- Conduct, manage, lead, and disseminate findings from research projects to aimed at understanding, preventing, preparing for and responding to large-scale health events, including emerging infectious disease epidemics, contamination emergencies, disasters, and CBRN terrorism
- Research topic areas include crisis decision making, global health security, risk assessment and management, mosquito borne and emerging infectious diseases, and biosecurity
- Associate Editor, *Health Security* Journal – provide editorial review and guide articles through the peer-review and editorial process

September 2013 – January 2017 **Senior Associate**
UPMC Center for Health Security

Principal Responsibilities:

- Principal Investigator leading research projects, grants, and contracts in crisis decision making, global health security, risk assessment and management, mosquito borne and emerging infectious diseases, and biosecurity
- Associate Editor, *Health Security* Journal – provide editorial review and guide articles through the peer-review and editorial process
- Director of the Emerging Leaders in Biosecurity Initiative Fellowship program

September 2012– September 2013 **Program Manager (on loan through IPA program from UPMC)**
Integrated Terrorism Risk Assessment (ITRA) Program,
Chemical and Biological Defense Division (CBD),
Department of Homeland Security – Washington, DC

Principal Responsibilities:

- Program Manager and Contracting Officer's Representative (COR) for the Integrated Terrorism Risk Assessment Program. Budgeting and financial management for a $2.0 million program budget
- Updated the ITRA according to Homeland Security Presidential Directive (HSPD)-18 requirements and stakeholder input

February 2010 **Science Advisor**
U.S. Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism

Principal Responsibilities:

- Contracted to research and produce a policy assessment of federal progress and remaining gaps in preparedness for a remediation of a large bioterrorism attack
- Supported the WMD Commission's assessment of the current state of the US biosecurity enterprise

August 2010 – September 2013 **Associate**
UPMC Center for Health Security

August 2007 – July 2010 **Senior Analyst and Analyst Team Supervisor**
UPMC Center for Health Security

September 2004 – July 2007 **Analyst**
UPMC Center for Health Security

PROFESSIONAL ACTIVITIES

Program or Project Development

- Developed expertise through dissertation research and professional work on crisis and risk-based decision-making in public health emergencies, particularly those involving environmental contamination
- Director for the ELBI fellowship program, with over 100 fellows and alumni, workshops and meetings in the US and internationally, and other biosecurity networking events
- Expert working to improve federal approaches to risk assessment for CBRN agents. PI for multiple projects on risk assessment and biosecurity strategy for the Department of Homeland Security, and was first author on an article in *Science* resulting from DHS work
- Research to support biological weapons non-proliferation and the Biological and Toxin Weapons Convention (BWC) - its implementation and continuation for future generations
- National expert on the funding and organization of biodefense and health security programs in the U.S. Federal Government. Author of annual report series in *Health Security*
- Led an update of the DHS CBRN Integrated Terrorism Risk Assessment (ITRA) according to Homeland Security Presidential Directive (HSPD)–18 requirements
- Project manager and researcher assessing the progress of the Department of Health and Human Services (HHS) Federal Hospital Preparedness Program (HPP), and defining future US healthcare preparedness goals and metrics.
- Conducted research concerning, and authored a number of papers on, the threat of dengue re-emergence in the United States.
- Collaborated with the University of Iowa on researching and running and infectious disease prediction market focused on Dengue emergence in the Americas

Participation on Advisory Boards and Working Groups

- Member of the Private Sector Economic Resiliency and Restoration Working Group. Contributed to a recovery framework for Denver, CO as part of the DHS Wide Area Recovery and Resiliency Program
- Working Group on Community Engagement in Health Emergency Planning – 2007

EDITORIAL ACTIVITIES

- Associate Editor, *Health Security* Journal: provide editorial review and guide articles through the peer-review and editorial process

- Review Applications and Paper Competition submissions for Emerging Leader in Biosecurity Initiative (ELBI) applicants and Fellows
- Reviewer, article in *PLoSOne* on Acceptance of genetic modification. January 2017.
- Special Feature Editor: Remediation. *Biosecurity and Bioterrorism*. 2011;9(3)

HONORS AND AWARDS

2016 **Recipient of the Victor P. Raymond Memorial Fund**: This Endowment award, in the amount of $8,000, was provided in support of dissertation research focused on making change in public health at the national level.

PUBLICATIONS

Journal Articles

38. **Watson C**, Watson M, Ackerman G, Gronvall G. Expert Views on Biological Threat Characterization for the U.S. Government: A Delphi Study. *Risk Analysis.* 2017; *In Press.*

37. **Watson C**. Risk Assessment and Health Security. *Health Security.* 2017;15(1) *In Press.*

36. **Watson C**, Watson MC. Funding and Organization of US Federal Health Security Programs. *Health Security.* 2017;15(1) *In Press.*

35. **Watson (Boddie) C**. Healthcare preparedness and the medical consequences of bioterrorism. Postgraduate Institute for Medicine (PIM), Continuing Medical Education Course. 2016. https://www.cmeuniversity.com/searchResult.aspx?t=2&f=topic&s=9218.

34. Sell TK, **Boddie C**, McGinty EE, Pollack K, Smith KC, Burke TA, Rutkow L. News Media Messages about Ebola and Their Implications for Risk Perception in the United States. *Emerging Infectious Diseases*. 2017;23(1). https://wwwnc.cdc.gov/eid/article/23/1/16-0589_article.

33. Sell TK, **Boddie C**, McGinty EE, Pollack K, Smith KC, Burke TA, Rutkow L. News Media Coverage of U.S. Ebola Policies: Implications for Communication During Future Infectious Disease Threats. *Preventive Medicine*. 21 September 2016, http://dx.doi.org/10.1016/j.ypmed.2016.09.016.

32. **Boddie C**, Watson M, Sell TK. Federal Funding for Health Security in FY2017. *Health Security*. 2016;14(5): 284-304

31. Adalja A, Sell TK, McGinty M, **Boddie C**. Genetically Modified (GM) Mosquito Use to Reduce Mosquito-Transmitted Disease in the US: A Community Opinion Survey. *PLOS Currents Outbreaks*. 2016; Edition 1. http://currents.plos.org/outbreaks/article/genetically-modified-mosquito-use-to-reduce-mosquito-transmitted-disease-in-the-us-opinion-survey/.

30. **Boddie C**, Watson M, Ackerman G, Gronvall G. Assessing the Bioweapons Threat. *Science*. 2015;349(6250):792-793.

29. **Boddie C**, Sell TK, Watson M. Federal Funding for Health Security in FY2016. *Health Security*. 2015;13(3):186-206.

28. **Boddie C**, Federal Funding in Support of Ebola Medical Countermeasures R&D. *Health Security*. 2015;13(1):3-8.

27. Selck FW, Adalja, AA, **Boddie C**. An Estimate of the Global Health Care and Lost Productivity Costs of Dengue. *Vector Borne Zoonotic Dis*. 2014 Nov;14(11):824-6

26. Gronvall G, **Boddie C**, Knutsson R, and Colby M. One Health Security: An Important Component of the Global Health Security Agenda. *Biosecurity and Bioterrorism*. 2014;12(5): 221-224.

25. **Boddie C**, Sell TK, Watson M. Federal Funding for Health Security in FY2015. *Biosecurity and Bioterrorism.* 2014;12(4):162-177.

24. Watson M, Selck F, Rambhia K, Morhard R, **Franco C**, Toner E. Medical Reserve Corps Volunteers in Disasters: A Survey of their Roles, Experiences, and Challenges. *Biosecurity and Bioterrorism.* 2014;12(2):85-93.

23. Morhard R and **Franco C**. PAHPA: Its Contributions and New Potential to Increase Public Health Preparedness. *Biosecurity and Bioterrorism*. 2013;11(2):145-152.

22. Sell TK and **Franco C**. Funding for Nuclear Consequence Management-Related Programs: FY2012-FY2013. *Biosecurity and Bioterrorism*. 2012;10(4).

21. **Franco C**, Sell TK. Federal Agency Biodefense Funding, FY2012-FY2013. *Biosecurity and Bioterrorism*. 2012;10(2).

20. Bouri N, Sell TK, **Franco C**, Adalja AA, Henderson DA, Hynes NA. Return of Epidemic Dengue to the United States: Implications for the Public Health Practitioner. *Public Health Reports* 2012 May-June;127(3):259-266. http://www.publichealthreports.org/issueopen.cfm?articleID=2840.

19. Adalja AA, Sell TK, Bouri N, **Franco C**. Lessons learned during dengue outbreaks in the United States, 2001-2011. *Emerg Infect Dis*. 2012;18(4). http://dx.doi.org/10.3201/eid1804.110968.

18. Sell TK, **Franco C**, Ho ATY, Polgreen PM. Using a prediction market to forecast dengue fever activity in the U.S. [abstract]. *Emerg Health Threats J.* 2011; 4:s148.

17. **Franco C**, Sell TK. Federal Agency Biodefense Funding, FY2011-FY2012. *Biosecurity and Bioterrorism*. 2011;9(2).

16. **Franco C**, Hansen MB. The State of Biopreparedness: Lessons from Leaders, Proposals for Progress. *Biosecurity and Bioterrorism*. 2010;8(4);379-384.

15. **Franco C**, Hynes N, Bouri N, Henderson DA. The Dengue Threat to the United States. *Biosecurity and Bioterrorism*. 2010;8(3)

14. **Franco C**, Bouri N. Environmental Decontamination Following a Large-Scale Bioterrorism Attack: Federal Progress and Remaining Gaps. *Biosecurity and Bioterrorism*. 2010;8(2):107-117.

13. **Franco C**, Sell TK. Federal Agency Biodefense Funding, FY20010-FY2011. *Biosecurity and Bioterrorism*. 2010;8(2).

12. **Franco, C**. Billions for Biodefense: Federal Agency Biodefense Funding, FY2009-FY2010. *Biosecurity and Bioterrorism.* 2009;7(3):291-309.

11. Courtney B, Toner E, Waldhorn R, **Franco C**, Rambhia K, Norwood A, Intlesby TV, O'Toole T. Healthcare Coalitions: The New Foundation for National Healthcare Preparedness and Response for Catastrophic Health Emergencies. *Biosecurity and Bioterrorism*. 2009;7(2):153-163.

10. Nuzzo J, Mair M, **Franco C**. Preserving Gains from Public Health Emergency Preparedness Cooperative Agreements. *Biosecurity and Bioterrorism.* 2009;7(1):35-36.

9. **Franco, C**. Billions for Biodefense: Federal Agency Biodefense Funding, FY2008-FY2009. *Biosecurity and Bioterrorism.* 2008;6(2):131-146.

8. **Franco C**, Toner E, Waldhorn R, Inglesby TV, O'Toole T. The National Disaster Medical System: Past, Present, and Suggestions for the Future. *Biosecurity and Bioterrorism*. 2007; 5(4):319-326

7. **Franco C**, Deitch S. Billions for Biodefense: Federal Agency Biodefense Funding, FY2007-FY2008. *Biosecurity and Bioterrorism.* 2007;5(2):117-133.

6. Maldin B, Lam C, **Franco C**, Press D, Waldhorn R, Toner E, O'Toole T, Inglesby T. Regional Approaches to Hospital Preparedness. *Biosecurity and Bioterrorism*. 2007;5(1):43-53.

5. Schoch-Spana M, **Franco C**, Nuzzo J, Usenza C, on behalf of the Working Group on Community Engagement in Health Emergency Planning. Community Engagement: Leadership Tool for Catastrophic Health Events. *Biosecurity and Bioterrorism.* 2007;5(1):8-25.

4. **Franco C**, E Toner, R Waldhorn, B Maldin, T O'Toole, TV Inglesby. Systemic Collapse: Medical Care in the Aftermath of Hurricane Katrina. *Biosecurity and Bioterrorism*. 2006; 4(2):135-146.

3. Lien O, Maldin B, **Franco C**, Gronvall GK. Getting Medicine to Millions: New Strategies for Mass Distribution. *Biosecurity ad Bioterrorism*. 2006;4(2):176-182.

2. Lam C, **Franco C**, Schuler A. Billions for Biodefense: Federal Agency Biodefense Funding, FY2006-FY2007. *Biosecurity and Bioterrorism.* 2006;4(2):113-127.

1. Smith BT, Inglesby T, Brimmer E, Borio L, **Franco C**, Gronvall GK, Kramer B, Maldin B, Nuzzo J, Schuler A, Stern S, Henderson DA, Larsen RJ, Hamilton DS, O'Toole T. Navigating the Storm: Report and Recommendations from the Atlantic Storm Exercise. *Biosecurity and Bioterrorism*. 2005;3(3):256-267.

Articles, Editorials and Other Publications Not Peer Reviewed

8. **Franco C**. Four Ways to Reduce the Time and Cost of Anthrax Cleanup. Crossroads in Biosecurity. Center for Biosecurity of UPMC, September 2011.
7. Toner E, Waldhorn R, **Franco C**, Courtney B, Rambhia K, et al. *The Next Challenge in Healthcare Preparedness: Catastrophic Health Events.* Prepared by the Center for Biosecurity of UPMC for the U.S. Department of Health and Human Services. 2010.
6. Toner E, Waldhorn R, **Franco C**, Courtney B, Rambhia K, et al. *Hospitals Rising to the Challenge: The First Five Years of the U.S. Hospital Preparedness Program and Priorities Going Forward.* Prepared by the Center for Biosecurity of UPMC for the U.S. Department of Health and Human Services. 2009.
5. Schoch-Spana M, Courtney B, **Franco C**, Norwood A, Nuzzo J. Community Resilience Roundtable on the Implementation of Homeland Security Presidential Directive 21 (HSPD-21). *Biosecurity and Bioterrorism.* 2008;6(3):269-278.
4. Mair M, **Franco C**. HSPD-21: National Strategy for Public Health and Medical Preparedness [Commentary]. October 23, 2007.
3. Maldin-Morgenthau B, Toner E, Waldhorn R, Nuzzo J, **Franco** C, Press D, O'Toole T, Inglesby T. Roundtable: Promoting Partnerships for Regional Healthcare Preparedness and Response [Meeting Report]. *Biosecurity and Bioterrorism*. 2007;5(2):168-173.
2. Schoch-Spana M, Chamberlain A, **Franco C**, Gross J, Lam C, Mulcahy A, Nuzzo J, Toner E, Usenza C. Disease, Disaster, and Democracy: The Public's Stake in Health Emergency Planning [Meeting Report]. *Biosecurity and Bioterrorism.* 2006;4(3):313-319.
1. Toner E, Waldhorn R, Maldin B, Borio L, Nuzzo J, Lam C, **Franco C**, Henderson DA, Inglesby T, O'Toole T. Hospital Preparedness for Pandemic Influenza [Meeting Report]. *Biosecurity and Bioterrorism*. 2006;4(2):207-217.

PRACTICE ACTIVITIES

- Wrote and published two memos to the Trump Administration on "Funding and Organization of US Federal Health Security Programs" and "Risk Assessment and Health Security," Published in *Health Security* Issue 1 of 2017
- Advocated for the Global Health Security Agenda (GHSA) to members of Senate Committees with jurisdiction over Global Health Security, December 16, 2016
- Member of the 2016 Global Health Security Agenda (GHSA) Joint External Evaluation (JEE) of Taiwan's compliance with the International Health Regulations (IHR)
- Statement and presentation at the Meeting of the States Parties to the Biological and Toxin Weapons Convention, Geneva, Switzerland – December 16, 2015

- Developed innovative approach to understanding emerging infectious disease burden and cost through creation of a publicly available, and rigorously developed, Infectious Disease Cost Calculator (IDCC). www.idcostcalc.org
- NGO Lead for the Global Health Security Agenda (GHSA) meeting of Next Generation Leaders in Global Health Security – September 2014
- Provided first time ever CBRN risk-based input to the US Centers for Disease Control and Prevention (CDC) Strategic National Stockpile (SNS) decision process
- Produced an ITRA-based assessment of the CBRNE risks to the DHS mail stream and the DHS Consolidated Remote Delivery Site (CRDS)
- Organized and led a Congressional Seminar Series on biological and nuclear security in coordination with the Senate Caucus on WMD Terrorism.
- Panel member for a session on Healthcare Coalitions at the Integrated Medical, Public Health, Preparedness and Response Training Summit – June 2010
- Helped prepare briefings for presidential candidates on biosecurity for the 2008 presidential election.
- Contributed to the Atlantic Storm project–a transatlantic bioterrorism tabletop exercise that highlighted a series of international biosecurity challenges concerning serious international epidemics. Assisted in developing the scenario, script, and building briefing materials for controllers and participants of the exercise.
- Contributed to Atlantic Storm–Wye River, a bioterrorism tabletop exercise adapted from Atlantic Storm for the members of the House Homeland Security Committee.

CURRICULUM VITAE

PART II

Crystal R. (Boddie) Watson, MPH

TEACHING

February 21, 2017 — **Guest Lecturer, Health Security Preparedness, Spring 2017**
George Mason University School of Policy, Government, and International Affairs. Instructor: Jennifer Nuzzo, DrPH

January 2014–November 2016 — **Teaching Assistant, Risk Certificate Courses**
Johns Hopkins Bloomberg School of Public Health, Health Policy and Management. Instructor: Tom Burke, PhD and Mary Fox, PhD

- Prepared lecture materials and course activities for Risk Policy and Risk Methods courses
- Graded assignments and led laboratory sessions for the students
- Co-led live talks with the instructor, Dr. Mary Fox

September 2014–December 2016 — **Teaching Assistant, Current Issues in Public Health (CIPH)**
Johns Hopkins Bloomberg School of Public Health, Masters in Public Health Program. Instructor: Edyth Schoenrich, MD, MPH

- Prepared lecture materials and course activities for CIPH course each term
- Identified and invited guest lecturers to join the course
- Graded assignments and interacted with students
- Led live talks with Dr. Edyth Schoenrich and guest lecturers in a radio-interview style

March 2016 — **Guest Lecturer, Risk Policy Course**
Johns Hopkins Bloomberg School of Public Health, Health Policy and Management. Instructor: Mary Fox, PhD

- Lectured live to the class on CBRN Risk assessment
- Recorded the lecture for future online/distance education courses

PRESENTATIONS

- Presentation on *National Risk Assessment and Public Health Preparedness* to the National Symposium for the Prohibition of Biological Weapons, Doha, Qatar – March 31, 2016
- *Expert Views on Biological Threat Characterization for the US Government: A Delphi Study*, poster presentation as the Johns Hopkins Bloomberg School of Public Health 2016 Delta Omega Poster Competition
- Panelist on *Comparing Resilience to Natural Hazards and CBRNE Hazards*, at the Annual Natural Hazards Conference in Colorado – June 2014
- Moderator for International Risk Assessment Meeting in Stockholm, Sweden – December 2013
- Panelist at the AniBio Threat Results Dissemination Conference in Brussels, Belgium – September 2013
- Presentation at the International Meeting on Emerging Infectious Diseases (IMED) on *Using Electronic Health Markets to Predict the Spread of Dengue* – February 2011
- Poster presentation on *Using a Prediction Market to Forecast Dengue Fever Activity*. International Society for Disease Surveillance Conference, Salt Lake City, UT –
  December 1–2, 2010
- Panel member for a session on *Pandemic and What it Means for the Hazards and Disasters Community* at the Annual University of Colorado Hazards Workshop – July 2006

ADDITIONAL INFORMATION

The main focus of my work is to conduct research that improves our understanding of how response to large-scale public health emergencies can better mitigate the impacts and enable resilience in the face of disaster. Within that main focus area, I work on understanding and building public health and healthcare systems to improve preparedness; characterizing threats, hazards, and public health risks before an event occurs; understanding how to make better decisions in a crisis; and improving implementation of protective actions and communication and engagement with the public in an emergency response.

Keywords: Public Health Preparedness, Human Health Risk Assessment, Crisis and Risk-Informed Decision-Making, Bioterrorism, Biodefense, Emerging Infectious Diseases, Risk Communication