USE OF EARLY BIOLOGICAL DETECTION DATA BY DECISION MAKERS TO MINIMIZE THE CONSEQUENCES OF NO-NOTICE INFECTIOUS DISEASE OUTBREAKS

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ABSTRACT

Amy L. Kircher: Use of Early Biological Detection Data by Decision Makers to Minimize the Consequences of No-Notice Infectious Disease Outbreaks

New and reemerging diseases pose significant challenges to the United States. Providing decision makers with data early to help characterize the event may allow for better -informed decisions and the initiation of appropriate responses. There is a limited amount of literature on the factors that lead decision makers to implement the appropriate response. The purpose of this study was to generate knowledge about the use of early biological detection by decision makers. A case study design of two cities was employed to determine if early biological detection capability affected the decisions to implement public health interventions. Multiple methodologies were used to collect and analyze data from primary and secondary sources. A review of previous outbreaks provided insights into disease characteristics and response activities which were used to build realistic disease scenarios for use in key informant interviews. Interviews with decision makers in each of two cities were conducted to understand how early biologic data were used, the availability of data, and to determine decision making processes. Several overarching themes emerged: data types, sources, and confidence is varied among different professional types of decision makers; strong relationships support the notification of an event and assist in effective, rapid response; public relationships and the media are beneficial partners in response with ability to rapidly communicate guidance; authority for decision making is unclear during crisis;

significant events initiated preparedness activities in each city; and the 2009 H1N1 experience tested the US's capability to respond to a public health crisis.

Federal and local stakeholders have a role to play in improving the level of preparedness of cities for a public health emergency. At the federal level, an assessment of federally funded biological detection capabilities and an appropriate realignment of federal support based on actual threat is required to improve the capacity for our cities to rapidly respond. In addition, the federal government has a unique opportunity to identify and fund cities to participate in National Special Security Events and National Level Exercises which improves their preparedness posture as a community. Our nation's cities have the responsibility to understand their information requirements and create an infrastructure that supports appropriate decision making. This study presents a plan to help local governments assess their information requirements and create an information network.

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There is no greater support structure than the one that lives in my house. For this, I am so very thankful. To Jon, my rock, who was a constant source of motivation and picked up the slack with a smile. For Jake who asked all the right questions and reminded me to take a break every now and again. To Gillian, who sat next to me injecting a continuous stream of humor into life. And my sweet baby Rhett, born in the middle of this crazy adventure, you are an amazing reminder of what is truly important. With this, I put “Bob” to bed to go out on a date, toss the football, color a picture, and “play hockey for you”.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

PROLOGUE

San Antonio, TX

Imagine the following scenario occurring on American soil today.

Day 1: October 31st, 4 p.m. - The emergency department at University Hospital is teeming with activity. Exam rooms are full and the staff is busy. Getting patients admitted seems to be taking longer than usual and waiting times are exceeding four hours. It *is* Halloween so Dr. Schroeder chalks this up to the craziness associated with the holiday.

October 31st, 6 p.m. - Sally, a 36 year old woman, arrives by ambulance at the emergency department from a university clinic in the city. Seems like pneumonia. She is complaining of fever, chills, nausea and general malaise. Dr. Schroeder orders a chest x-ray.

October 31st, 8 p.m. - Sally's x-ray shows possible bilateral pleural effusion and she is placed on oxygen. The admitting team diagnosis is community-acquired pneumonia. Sally is finally moved to an inpatient bed at midnight.

Day 2: **November 1st, 9 a.m.** - Dr. Schroeder returns for morning rounds and learns that Sally's high temperature remained constant and she vomited throughout the night. She is also experiencing shortness of breath. Sally's sister reports to Dr. Schroeder that Sally has had no previous medical problems and has not been out of the area for the past 9 months.

November 1st, 12 p.m. - A resident returns to Sally's room to find her extremely short of breath. Sally is sent immediately to the ICU where she becomes hypotensive, codes, and dies. The family agrees to an autopsy.

Day 3: November 2nd, 8:30 a.m. - Dr. Schroeder is troubled by Sally's death. She starts to wonder if the increased level of patients in the emergency department may not be business as usual. A quick review of the current situation reveals that 15 patients were admitted since 4 p.m. on October 31st, 10 patients were awaiting admission: 7 with pneumonia, 2 with chest pain, and 1 trauma patient. Eight emergency department staff members call in sick for their morning shift. Dr. Schroeder's concern is heightened by a breaking story on WOAI that San Antonio hospitals, including the 3 trauma centers, are being overwhelmed by walk-in patients. All city ambulances are currently responding to 911 calls. Local news stations are reporting the unraveling story at the top of each hour.

November 2nd, 12 p.m. - Due to the severity of patients reporting to the hospital with unusual pneumonia-like conditions, the infection control officer calls Metro Health to begin an investigation. Five more patients die. The emergency department is overflowing with patients. The public is demanding information. Businesses start closing their doors. Mayor Gonzalez is working with the trauma centers to develop a press release. A rumor starts circulating about a possible biological terrorist attack on the River Walk. Tourists head for the airports.

In a small apartment in Dallas, a man, code name Crocker, sends a message to his headquarters in the Middle East that “the cake has been baked and now it is time to see them pay.”

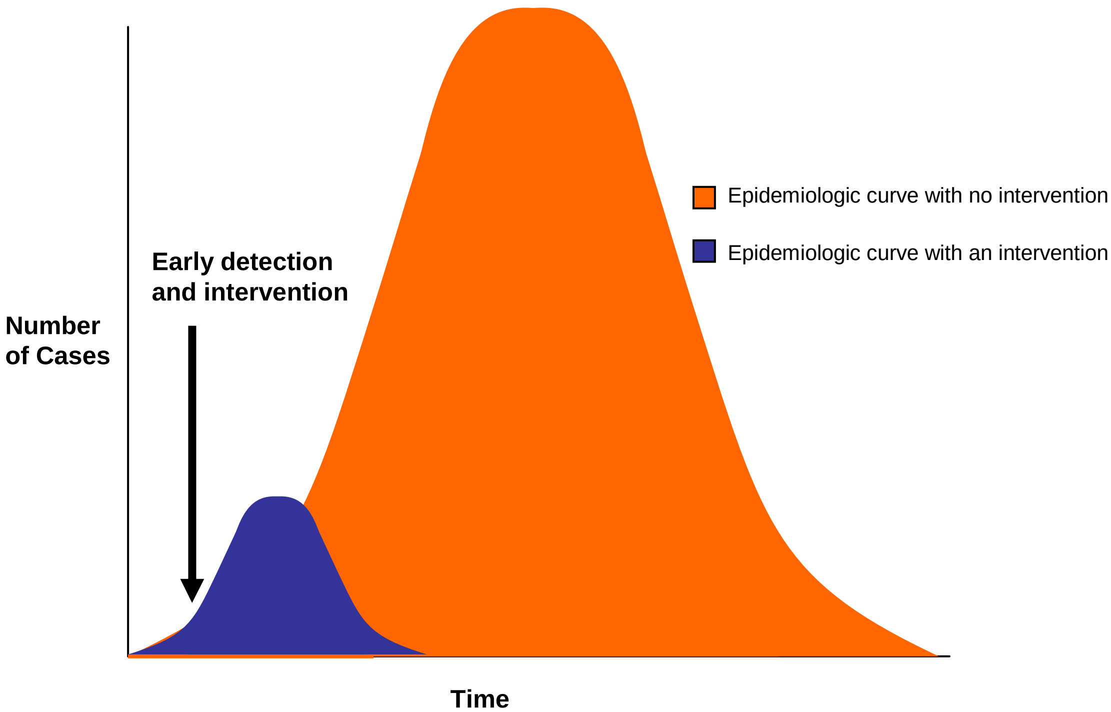
CHAPTER I: INTRODUCTION

Problem Statement

New and reemerging diseases pose significant challenges to the United States. High density population centers, rapid transit systems, importation of food and animals, and bioterrorism are all avenues through which an infectious disease could be introduced. Once an uncontrollable infectious disease enters the public arena, our healthcare system will be tested as never before and it will create second order effects that will put unparalleled pressure on our medical and public infrastructure. Failure to adequately respond to such an event could leave people without critical resources for survival (food, power, and sanitation). [1] Minimizing adverse outcomes, such as loss of life, economic impact, and social disruption, will require early detection and response.

Providing usable data to responders that characterizes the event is key to initiating the appropriate response. The data will serve as a catalyst, or trigger for decision makers to take pre-determined actions or develop new responses as the event unfolds. For example, the absence of 20% of elementary school students due to illness may serve as the trigger for school closure during an infectious disease outbreak. In this case, the decision maker (school superintendent) has data, a trigger (20% absenteeism) to take action (close school) which will avoid further spread of the disease. The ability to intervene at the appropriate time, based on reliable data, will decrease morbidity and mortality along with minimizing second order effects such as closure of key public infrastructures (e.g. power, water). The impact of health is described graphically in Figure 1 where the disease caseload is decreased due to early detection and the early implementation of medical countermeasures or non-pharmaceutical public health interventions (e.g. social distancing).

Figure 1.1. Early detection and implementation of a public health intervention decreases the number of overall cases and duration of the event.



To successfully reduce the epidemiologic curve (blue) as shown in the figure above requires: a) early data to show that the event is occurring; and b) an action on a defined trigger, or specified sequence of events. Historically, obtaining early warning data of a biologic event has been difficult based on fragmented surveillance systems and limited coordination among agencies at the local, state, and federal levels. [2] Currently, many national efforts, including a National Biosurveillance Strategy for Biosurveillance, are working toward improving the surveillance network and enhancing the communication of data from these systems. [3] The next hurdle is determining who makes the decisions to implement intervention strategies and what action(s) they will take when they receive early warning data. It is important to recognize that these decisions might be made by decision makers who are not from the public health profession and may not know how to react to the data they have received. [4]

Background

Diseases are not contained by geographic or political borders. Global travel patterns make it possible to easily spread diseases that were previously endemic only in remote parts of the world. Therefore, the world's population is potentially at significant risk of a no-notice infectious disease pandemic. (The term 'no-notice' is used here to mean that an infectious disease outbreak is discovered in a community without prior knowledge that the biological agent was active in the population.)

Historically, infectious disease threats have been naturally introduced through routine contact with an infected person. By this method, the pace at which the disease agent is spread is controlled by frequency and number of contacts. However, events in the latter part of the 20th century have generated the concern of disease introduction through bioterrorism – an artificial introduction of a contagion in great quantities. Either method of introduction of disease poses significant risk to our population, especially if the event happens with limited or no-notice. Unfortunately, there are examples of both methods in recent history.

Through natural introduction, Severe Acute Respiratory Syndrome (SARS), a previously unknown illness, affected 29 countries with 8096 human cases and 774 deaths worldwide. [5] In addition to radically increasing the public health and healthcare workload, this disease created economic problems for countries affected by travel restrictions and prompted drastic changes in human behavior to include wearing masks and avoidance of activities in social settings. [6] Similarly, the 2006 Iowa mumps outbreak dominated the attention of public health officials who were working to stop the outbreak, leaving unattended their traditional responsibilities to support other public health matters. Support activities surrounding the outbreak included the delivery of press conferences, screening, data analysis, and development of recommendations for clinics, schools, travelers, and health care workers. This vaccine preventable disease outbreak produced over four thousand cases in 13 states. [7] Currently, the 2009 H1N1 pandemic influenza strain is a priority of top health officials, prompting deliberate planning for prevention and active response. [8] Although the current strain appears to be similar in severity to seasonal influenza strains, there is concern that mutation could cause a public health emergency. [9] This threat is significant since worst case scenarios, based on the 1918 influenza pandemic, estimate a death toll of 64 million people if an influenza pandemic were to occur today. [10] Providing decision-makers with early access to relevant data on naturally occurring pandemics is critical to the health care community and general public as a whole.

Compared to frequently occurring public health threats such as seasonal influenza or food contamination, bioterrorism has a low probability of occurring but would present dire consequences if successfully delivered. Improved understanding of biotechnology has given terrorists an opportunity to create new kinds of diseases that are more virulent than previous strains. If these genetically engineered agents were to fall into the wrong hands they would create a sizeable concern for our nation. [11, 12] In addition to improved technology, Dr Kenneth Alibek, defected Soviet Union scientist, fears that biological agents created in the former Soviet Union biological warfare program may still exist in unknown locations since the collapse of the Soviet Union. [13] The Commission on the Prevention of Weapons of Mass

Destruction Proliferation and Terrorism reported, in 2008, their belief that a biologic terrorist attack would be conducted by 2013 unless there is a global effort to mitigate the threat. [14]

Unfortunately, the world has already experienced examples in the intentional use of harmful pathogens. In 1984, the Rajneeshee cult intentionally contaminated a salad bar in The Dalles, OR, on Election Day in an attempt to change the political outcome. The cult was able to infect 751 persons covertly, leaving public health professionals investigating what they thought to be a routine food borne outbreak. [15] Secondly, prior to the successful release of Sarin in the Tokyo subway, the Aum Shinrikyo cult conducted several covert biological attacks in Japan. [16] Neither the Rajneeshee nor Shinrikyo biological attacks were initially detected by public health officials. Law enforcement investigators later revealed the intentional terrorist plots when interviewing suspects. Finally, and perhaps most significantly, the 2001 anthrax attack (Amerithrax) in the U.S. perpetuated fear throughout the country even though it only resulted in 22 confirmed cases. [17] This single covert act substantially increased the workload of public health officials requiring them to test all incidents of suspicious white powder. At the same time, it generated billions of dollars in response costs. [18] Seven years after the event, questions still remain about how it was delivered and who was involved. If first responders had access to early detection data, the story might be different today.

Significance of Issue

It is imperative that the U.S. be prepared for a public health crisis. Analysis of this country's capabilities to respond to national disasters are concerning. A 2008 Trust for America's Health (TFAH) report calls America "complacent" regarding preparedness for public health emergencies. TFAH expresses concern that while work has been accomplished since 9/11, significant gaps still exist and will suffer further during economic crisis at the state and federal levels. [19]

Because naturally introduced diseases occur and terrorists are committed to harming our nation, we must not lose our momentum in filling gaps in our preparedness to include developing new detection capabilities, creating informed decision models, and developing plans for response based on infectious disease triggers. [13] Regardless of the amount of data available, leaders in the public and private sectors will take whatever actions are necessary to minimize the consequences. However, by providing decision makers with early data that helps to characterize the event, it will allow them to make better informed decisions.

In 2003, the federal government created the BioWatch program, which is designed to provide early data on possible biologic threats to decision makers. The program deploys an early warning system that captures biological materials in the air to determine if a health hazard exists. This early warning capability is being used in the nation's largest cities where routine air samples are collected and the data analyzed. [20] However, there has been limited effort to determine if the dollars spent equate to better outcomes at the local level.

This study has been designed to determine how information from an early detection system, like the BioWatch program, affects emergency preparedness and response communities' decision making processes. The results inform policy makers and program managers on the applicability of the data for use in decision making.

The knowledge gained from this study provides the preparedness community with information on the decision making process associated with the implementation of public health interventions during no-notice infectious disease outbreaks. A thorough understanding of this process can positively influence policy development and incident planning.

Purpose and Specific Aims

The purpose of this study was to understand how biologic data delivered early affects decision makers' actions to implement public health interventions. The research aims of the study were:

Aim 1: Determine who makes decisions to impact the public's health in a no-notice infectious disease outbreak. Determine what detection capabilities exist to provide information beyond the steady state.

Aim 2: Understand the context of past outbreaks and the decision to implement interventions. Determine the factors that lead to success or failure. Build realistic disease scenarios.

Aim 3: Understand the process by which decision makers choose to implement interventions during a no-notice disease outbreak. Determine what information they need and how their decisions are affected by early biologic detection data.

Aim 4: Determine the effectiveness of the timing for taking action.

Definitions

Decision Makers – persons in leadership positions that are involved in making decisions that impact the public's health in a community. Examples of these decisions include public service closures, movement restrictions, removal of products, or release of antivirals.

Public Health Intervention – an action taken to minimize the amount of human cases and deaths. Examples include movement restriction (isolation/quarantine/volunteer restriction of movement), treatment, vaccination, and risk communication.

Public Health Trigger - an event or specified sequence of events that results in a public health action.

No-Notice Infectious Disease Outbreak - an infectious disease outbreak that is discovered in a community without knowledge that the biological agent was active in the population.

Early Biologic Detection Data - data received from an early warning system that has the capability to detect biologic agents in the environment.

CHAPTER II: REVIEW OF THE LITERATURE

This chapter reviews literature from two areas of specific inquiry related to the outbreak of infectious diseases:

1) Characteristics of infectious disease outbreaks (real and simulated), and

2) Decision making during crisis events.

Characteristics of infectious disease outbreaks (real and simulated)

Real and simulated studies of infectious disease outbreaks were reviewed in order to understand early detection, identification of triggers to take action, and effectiveness of interventions that affect the public's health. Nine of the studies reviewed used an experimental method to study intervention strategies. [21-29] The majority of studies utilized experimental modeling to determine the effects of interventions on the outcome of an infectious disease outbreak. Four studies performed descriptive analysis of previous outbreaks in order to discover beneficial intervention strategies. [30-33] One study produced a retrospective cohort to determine the effectiveness of school closures. [34]

While differences existed in study design and type of infectious disease, major themes emerged. Those themes included: no standard definition of what triggers an intervention, the success of multiple intervention strategies, social distancing, early identification of cases, and the problem of unknown infectious disease variables.

No standard definition of what triggers an intervention.

No consistent triggers that lead to the implementation of public health intervention strategies were identified. The breaking of thresholds, a known set of cases that are expected to occur, was identified as one potential trigger point to implement interventions. [27, 31] Other literature consistently referred to the disease reproduction rate (R_0)[1] as the means for taking some public health intervention action. [21, 22, 24, 28, 30, 36] None of the articles reviewed stated a specific R_0 that was the standard point at which an intervention should be implemented. The goal of any outbreak response is to decrease the $R_0 < 1$. [27]

Success of multiple intervention strategies.

In seven studies, analyzing retrospective outbreaks and simulations, benefits were identified when implementing various intervention strategies. [21-24, 28, 29, 32] Effective strategies included combinations of at least two interventions. Six studies identified social distancing measures to include isolation/quarantine as a key component to decreasing cases. [21, 22, 24, 28, 29, 32] Vaccination was mentioned as an effective strategy in three different articles when implemented with either prophylaxis or social distancing measures. [23, 24, 29] The World Health Organization offered the only recommendations to combine more than 2 interventions (isolation, quarantine, and antivirals) early in an outbreak. [32]

The study of Norovirus in a shelter during Hurricane Katrina was the only study that did not demonstrate benefits from the multiple intervention strategies. Yee et al. stated that there may have been some success from multiple interventions but it could not be proven

[1] R_0 is the average number of new infections that a typical infectious person will produce during the course of the person's infection in a fully susceptible population in the absence of disease. Alterations in the disease, host, environment, or social networks could change the R_0. [35.Heffernan., J.M., Smith, R. J., and Wahl, L. M., *Perspectives on the Basic Reproductive Ratio.* The Journal of Royal Interface, 2005. **2**(4).

since the simultaneous implementation and rapid population change, in the shelter, made it difficult to measure any positive impact in multiple interventions. [33]

Social distancing.

Decreasing the opportunity for societal mixing or social distancing was the most frequently mentioned intervention strategy. [21, 22, 24, 25, 28-30, 32, 34] Of those studies mentioning social distancing, the majority included a combination of isolation and quarantine as a means of separating those exposed and demonstrating symptoms in order to reduce the overall case load. [21, 22, 25, 28-30, 32] School and/or work closures were identified as a valuable public health intervention by five studies. [21, 22, 24, 32, 34] Only two studies used actual outbreaks to suggest social distancing was an effective strategy. One study took advantage of a real school closure to determine if the amount of infectious disease cases were changed. The analysis indicated that visits decreased during the two weeks of closure compared to the two weeks previous and following. [34] An analysis of cities affected by the 1918-1919 pandemic influenza outbreak found that early compliance with social distancing was the most effective strategy in order to mitigate the disease. [30] The World Health Organization includes isolation, quarantine, and school closures as effective methods to delay spread of disease when implemented early in the outbreak. [32]

Early detection of cases.

Several studies indicated effective interventions, which relied on the early detection of cases and identification of case contacts. [22, 28-32] Without early detection, studies noted outbreaks would likely become too large to carry out contact tracing and implementation of intervention strategies. Strong public health infrastructure and disease surveillance were identified as means of achieving the early identification of outbreaks. Woods et al. noted that delays in interventions for meningococcal epidemics in northern Ghana were associated with higher morbidity and mortality. [31]

The problem of unknown disease variables.

The unpredictability of infectious disease was noted several times specifically as a limitation to effectively responding to an outbreak. [23, 24, 26, 28, 32] Identifiable barriers for dealing with emerging and reemerging disease include unknowns such as: transmission rates, disease infectivity, and effectiveness of prophylaxis and/or treatment options. The other reviewed literature implied that lack of information was problematic but did not define any specific way to bridge the information gap.

Table 2.1. Summary of Public Health Intervention Literature

Year of publication	Author	Intervention	Research Design	Research Setting	Results
2000	Woods, Armstrong, Sackey, Tetteh, Burgri, Perkins, Roenstein	Vaccination	Descriptive	Ghana, West Africa	Initiation of emergency vaccinations is based on the breaking of a set threshold of cases. The most effective strategy is one of routing immunization in which high rates of coverage are achieved and maintained. Surveillance is critical in emergency vaccination programs. Delays in initiation are associated with higher morbidity and mortality.
2002	Halloran, Longini, Nizam, and Yang	Vaccination	Experimental Comparison (Modeling)	General	Found mass vaccination before or immediately after the release was more effective than targeted vaccination if there was no herd immunity. If there is herd immunity then targeted and mass vaccination after the release increased effectiveness. Further research should look at increasing herd immunity.
2003	Lipsitch, Cohen, Cooper, Robins, Ma, James, Gopalakrishna, Chew, Tan, Samore, Fisman, Murray	Isolation and Quarantine	Experimental Comparison (Modeling)	Singapore (SARS)	Both isolation and quarantine intervention strategies will be necessary as they each have limitations. Quarantine is limited by the ability to trace contacts before they are infectious, non-compliance, and the possibility that persons remain asymptomatic after a10 day quarantine. Isolation is limited by the number of facilities, speed of isolating and potential failures of infectious disease control.

2004	Becker, Glass, Li, and Aldis	Isolation, Quarantine, Contact Tracing, Education, and School Closing	Experimental Comparison (Modeling)	Singapore and Hong Kong	Contact tracing and quarantine in combination was the most successful tool in reducing transmission. Implementation of multiple strategies was a consistent finding.
2004	Heymann, Chodick, Reichman, Kokia, and Laufer	School Closure	Retrospective Cohort	Israel	A temporary decrease in respiratory morbidity was identified in outpatient visits during a two week school closing as compared to two weeks prior and two weeks subsequent to closing.
2004	Gupta, Moyer, and Stern	Quarantine, infection control precautions, isolation, and immunizations	Experimental Comparison (Modeling)	Toronto	Quarantine is effective at containing emerging infectious disease and has proven to be cost beneficial as compared to not implementing. In the instance of a new, highly transmissible infectious disease medicine may be of limited use and vaccine/prophylaxis options would be limited until more is understood of the disease.
2005	Ferguson, Cummings, Cauchemez, Frser, Riley, Meeyai, Iamsirithaworn, and Burke	Antiviral prophylaxis, social distancing (school/work closure), quarantine zones	Experimental Comparison (Modeling)	Thailand	Containment of a pandemic strain is possible at the point of origin using a combination of antiviral prophylaxis and social distancing measures. Effectiveness is going to be determined by transmission rate and speed of identification of new cases.
2005	Fowler, Sanders, Bravata, Nouri, Gastwirth, Peterson, Broker, Garber,	Vaccination and Antibiotic Prophylaxis	Experimental Comparison (Modeling)	Metropolitan US cities	Use of vaccine plus antibiotic prophylaxis was the most effective strategy and had lower costs than other strategies for post-attack scenarios. This strategy was less expensive because it prevented more cases of inhalational anthrax and more deaths than the individual strategies.

	and Owens				The combination resulted in a gain of 0.33 life-year and cost saving of $355 per person as compared with vaccination alone.
2005	Pourbohloul, Meyers, Skowronski, Krajden, Patrick, and Brunham	Quarantine, infection control precautions, isolation, and immunizations	Experimental Comparison (Modeling)	General	The use of face masks and general vaccination (not targeted) is only moderately effective. Quarantine and ring vaccination in comparison does more to prevent the spread of respiratory disease.
2006	Germann, Kadau, Longini, and Macken	Antiviral agents, vaccines, and social distancing (school closure and travel restrictions)	Experimental Comparison (Modeling)	US	Travel restrictions after outbreak detection is likely to slow an influenza pandemic without impacting the final number ill. Rapid production and distribution of poorly matched vaccination could slow disease spread and limit number of people ill, especially if children are targeted for vaccinations. For low transmission rates targeted, aggressive antiviral agents may be effective given appropriate contact tracing and distribution. A high transmission rate will need multiple strategies.
2006	Handel, Longini, and Antia	Containment strategies	Experimental Comparison (Modeling)	General	There is a critical threshold of susceptible persons during an outbreak where the rate of transmissibility falls below 1. During multiple outbreaks where resources are limited it is best to obtain the acceptable threshold between susceptible persons and infected persons. This will minimize effects of secondary outbreaks and limited resources.

2006	Markel, Stern, Navarro, Michalsen, Monto, and DiGiovanni	Protective Sequestration (measures taken to protect a defined and still healthy population)	Retrospective Descriptive	US Communities in 1918-19 influenza pandemic	Protective sequestration enacted early with compliance was the most successful measure during the 1918-1919 influenza pandemic in the US. Though limited in data, it was noted other non-pharmaceuticals were not successful. Has most applicability in today's world to specific subcommittees such as college dorms or military installations.
2006	World Health Organization Writing Group	School closings, social distancing, quarantine, isolation, vaccination, and hygiene	Retrospective review of previous pandemics	Global	Interventions vary depending on transmission pattern, pandemic phase, and illness severity and extent. Early on WHO recommends isolation, quarantine, and antivirals. As the pandemic progresses social distancing and school closures may be effective to delay the spread. Hygiene should always be recommended.
2007	Yee, Palacio, Atmar, Shah, Kilborn, Faul, Gavagan, Feigin, Versalovic, Heill, Panlilio, Miller, Spahr, and Glass	Personnel hygiene, Secondary Transmission Prevention (additional facilities, re-hydration, isolation room), Improved environmental controls	Retrospective Descriptive	New Orleans, LA	Norovirus continued from clinic opening until clinic close despite intervention efforts. A small decrease in cases at the end of the clinic's tenure suggested that perhaps the combination of interventions yielded some success. No one strategy was identified as effective perhaps due to the simultaneous start times.

2007	Bootsma and Ferguson	Review of public health measures during the 1918 influenza pandemic	Retrospective modeling	United States	A range of interventions were tried in the US in 1918 in an attempt to minimize the effects of influenza (school and church closing, banning public gatherings, mask wearing, case isolation and hygiene measures). Timing of public health interventions had an impact on the disease waves. Early introductions had moderate effects on mortality. Extending the interventions longer resulted in greater reduction in mortality. Stopping transmission too early left a substantial amount of susceptible persons in the population which allowed transmission to restart (second epidemic).

Decision Making During Crisis Events

Responding to a crisis requires making a multitude of decisions in a constantly changing environment. [37] Exercises at all levels have identified command and decision making as significant weaknesses to crisis response. Lack of clarity on who has responsibility to make decisions, along with the limited time decision makers have contributes to the deficiencies in command and control when faced with a biological threat. [38]

Characteristics of decision making in a crisis.

A crisis is composed of many complex variables which are often obscured in the initial hours of the event. [37, 39] In a study of fire chiefs, over half of the group identified limited information as the main stressor during the initial hours of a crisis. [37] Researchers noted that in a crisis, decisions were made at a higher level in the organization by fewer people, therefore increasing the amount of stress experienced by decision makers. [40, 41] Decision making during a crisis is complicated by the potential loss of qualified professionals and their expert opinions. [42]

Successful crisis decision making.

A majority of the literature reviewed argued that planning for a crisis is beneficial, [38, 39, 41-43], and Harrald and Mazucchi specifically note that the actual success comes from the planning process and not necessarily the plan that is developed. [42] Given the unpredictable nature of a crisis, it is impossible to plan for every contingency therefore plans should be flexible and routinely tested. [39, 41, 43]

Key elements of any contingency plan should include identification of leadership, the information and resources necessary for decision making, and the appropriate dissemination method for the given situation. [38, 41, 43] Matthew and McDonald remarked that in addition to these elements, persons with local credibility must be identified so as to provide communication about the situation and any necessary instructions to the public. [38]

Kaempf et al recognized successful leaders as able to use past experience in order to assist them in making decisions with limited information. [40]

Table 2.2. Summary of Decision Making in a Crisis Literature

Year of publication	Author	Topic	Type of Literature	Results
1987	Stubbart	Crisis Thinking	Review of empirical research	Crisis decision characteristics include uncertainty, complexity, conflicts of interests, and emotional involvement. Crisis decision making puts pressure on people to process information. Effective responses require several steps: do not try to anticipate and plan for every contingency, form a crisis assessment team, become familiar with crisis response techniques, use techniques flexibility.
1993	Harrald and Mazzuchi	Crisis Management	Exercises and experimental modeling	Expert opinion is lost when plans focus on resource listings, procedural doctrine, and organizational responsibilities. Gaming technology, decision analysis, and risk analysis are innovative options for planning. The success of the planning process is the preparation for an event not an actual document. Identify critical success factors (things that must go right to succeed or be perceived as a success and Response Casual Factors (things that could prevent achieving one or more success factors)
1996	Kaempf, Klein, Thordsen, and Wolf	Decision Making	Qualitative interviews	The recognition-primed decision model reflects decision makers relying on past experiences to determine solutions for implementation. The study notes that situation awareness is a concern. Navy commanders used feature-matching and story-building strategies to understand the situation they were faced with. Feature-matching occurred when decision makers recognized the scenario and used previous knowledge to build situational awareness. Story-building is the creation of a story to create a picture of the event. Future research should include development of interventions that can assist decision makers do their job more effectively.

2000	Danielsson and Ohlsson	Decision Making	Qualitative	Emergency management involves a series of independent decisions in a continually changing event, dynamic decision making. Decisions are difficult due to the complexities of the event. Fire chiefs’ responses to most difficult decisions were lack of routine and practice, communicational shortcomings, and feelings of isolation. Over 50% of respondents identified their main stressor as lack of knowledge in the initial phase of the response.
2004	Clark, Harman	Crisis Management	Expert opinion	Good initial decisions can make the crisis manageable. Crisis management will require timely, rational decision making to be successful. To accomplish this, adequate pre-planning must occur. Planning will never cover every contingency. A good plan has the capability to be flexible and make quick decisions. The plan should also be tested routinely. A balance between quick reaction decisions and intensive analysis is necessary to make the best decision. Best plans have the concepts of analysis, plan, measure, and communicate.
2005	DiGiovanni, Bowen, Ginsberg, and Giles	Voluntary Quarantine	Tabletop quarantine exercise	Agreements for collaboration should be developed to build a coordinated command capability. Quarantine measures are initiated by health officers, but they are largely implemented by nonmedical personnel. Identify challenges early even if there is no current resolution.
2006	Matthew and McDonald	Planning; Infectious Disease	Expert opinion	Urban areas are more vulnerable. Local, regional, and national exercises identified Command and Decision-making as 1 of 2 major weaknesses. If events require additional responders it is important to have persons with local credibility to communicate clear answers to questions. Recommended steps to improve urban response include identification of who will be in charge, what intelligence is necessary, what resources will be required, how decisions will be communicated, and how implementation will be monitored.

Discussion

The literature reviewed indicates that public health interventions are successful in mitigating the effects of an infectious disease outbreak. To successfully intervene there needs to be data available early that allows decision makers to implement interventions at the appropriate time.

A significant portion of the literature reviewed used models to determine effective public health intervention strategies. Modeling allows for the rapid adjustment of interventions in a controlled environment so as to determine the most advantageous strategy for disease mitigation. Unfortunately, mathematical modeling does not readily include human behavior factors. Understanding how the population will behave in a given infectious disease situation is critical to controlling the outcome of the situation. Future research should include modeling of human behaviors in order to fully comprehend the response necessary to mitigate the effects of an infectious disease outbreak.

The limited amount of literature on the factors that trigger the decision to implement a public health intervention is worrisome. As described above, there was no uniformity in what serves as trigger for action. Lack of data puts public health professionals, and other leaders expected to make intervention decisions, at a disadvantage without understanding the effects of their decisions to implement an intervention. The paucity of research regarding the factors that affect the decision to implement an intervention put us, as a society, at risk for suboptimal outcomes of a disease outbreak.

The timing for implementing an intervention is crucial to avoid intervention fatigue or to delay strategies to the point where they are useless. Bootsman and Ferguson found, through the review of the 1918 influenza, that timing of interventions affected the outcome of the disease. Interventions too early achieved less success in mitigating mortality, as the early intervention successfully halted the epidemic, but left too many susceptible persons in the population; so that subsequent outbreaks re-emerged in the population at a later date. [36] An intervention implemented too early could also create financial and social hardship. An intervention executed too late will offer limited benefit to the population, perhaps utilizing scarce resources inappropriately. Understanding the correct points at which an intervention should be implemented will relieve human suffering from disease.

Decision making during a crisis is difficult as information is limited. Established decision making processes may not be followed, thus increasing the amount of stress on individuals required to make those decisions. To improve crisis decision making, pre-planning has been identified as a solution. The process of planning and thinking through possible situations is perhaps the most advantageous part of the effort, rather than the plan itself. In order to support the crises the plan must be flexible and routinely tested.

In summary, it is necessary to understand the factors that affect the decision to implement public health interventions, as well as the outcome of interventions based on the timing of the implementation. Knowing this ahead of time and appropriate planning provides San Antonio Mayor Gonzalez action points for response in the opening scenario.

CHAPTER III: METHODS

Study Overview

This study sought to understand how the availability of biological data from an early warning system affects decision makers' actions so as to minimize the effects of no-notice infectious disease outbreaks. The case study approach was used for data collection, organization, and analysis since it permits the comparison of cases with and without early biologic detection systems. [44] This strategy is considered advantageous to study contemporary occurrences with real life context where the investigator has no or little control. [45] Four separate research aims were accomplished to answer the research question.

Research Question:

Does early biological detection data affect decision makers' actions to minimize the consequences of no-notice infectious disease outbreaks?

Study Aims

Aim 1: Determine who makes decisions to impact the public's health in a no-notice infectious disease outbreak. Determine what detection capabilities exist to provide information beyond the steady state.

Aim 2: Understand the context of past outbreaks and the decision to implement interventions. Determine the factors that lead to success or failure. Build realistic disease scenarios.

Aim 3: Understand the process by which decision makers choose to implement interventions during a no-notice disease outbreak. Determine what information they need and how their decisions are affected by early biologic detection data.

Aim 4: Determine the effectiveness of the timing for taking action.

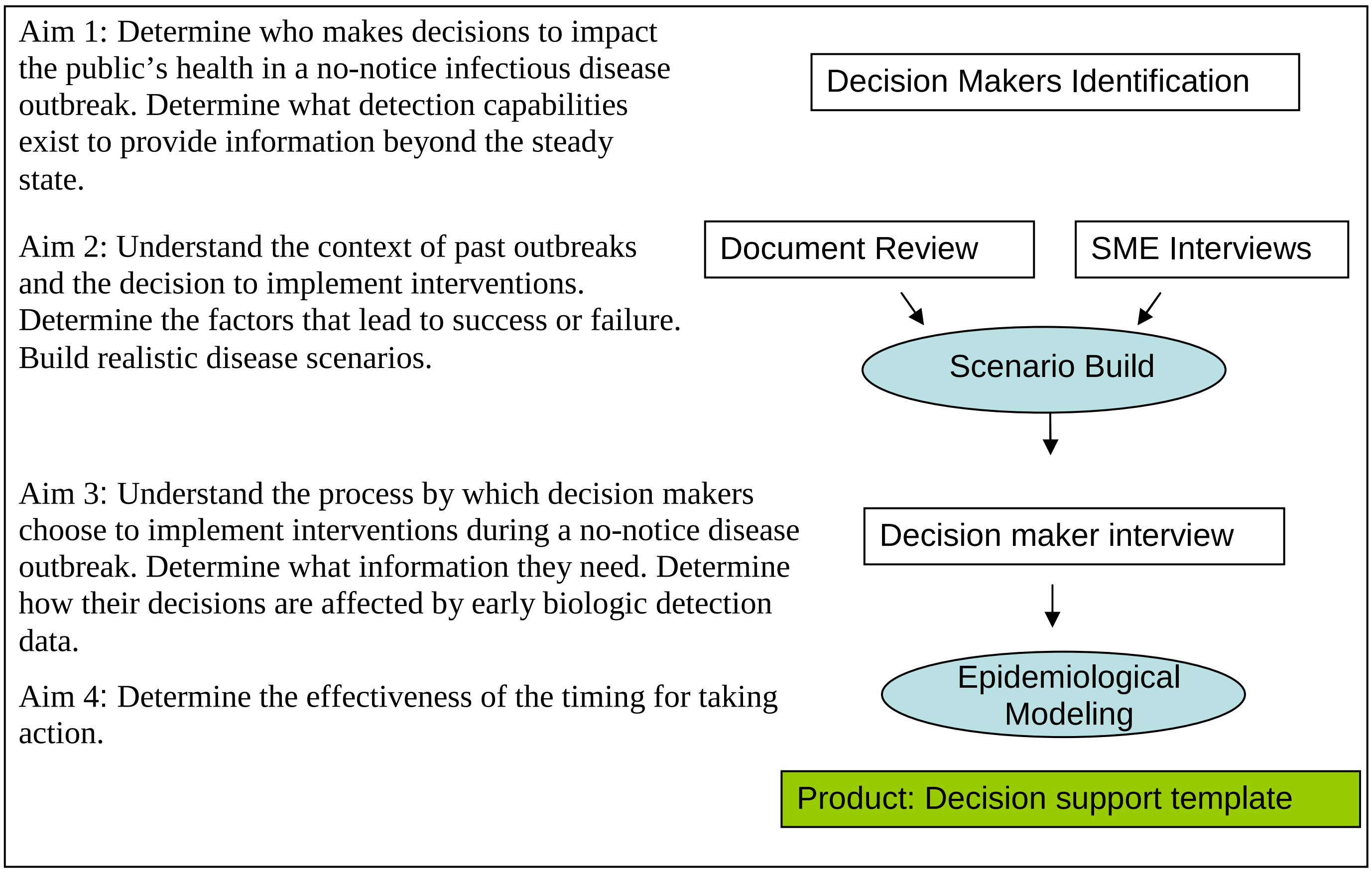
Study Design

Data were collected using multiple methodologies in a systematic, thoughtful approach to fully comprehend who makes decisions and how their decisions may be influenced by early biologic detection data. The methodologies were laid out in the research four aims to be conducted independently with the results of each informing the subsequent aims. In combination, the raw data obtained allowed for comparison of two cases that provided a holistic picture of how the availability of early biologic detection data affects decision making during a no-notice infectious disease outbreak. [44] The sequence of the research aims is diagramed in Figure 2.

The unit of analysis for this case study design was two cities. Individual decision makers in each city provided the data for the overall case study. Both of the cities selected were considered to be prepared to respond to a public health emergency. The determination of prepared was made by committee members and technical advisors that are active in the emergency preparedness community through development, funding, implementation, and evaluation of preparedness activities. This selection approach was utilized instead of using immature public health preparedness measures which are considered flawed by a majority of the emergency preparedness field.

One of the cities selected has an early biologic detection capability that provides quantitative data that a biologic threat is present (hereafter referred to as City A). The second city does not have the early biologic detection system (hereafter referred to as City B). The cities selected have populations between 550,000 and 640,000 individuals with approximately 225,000 households in each city.[46] The median household income in city A is $39,500 and in city B is $46,975. [46] Both cities have experience preparing for potential disasters or responding to actual disasters. Each city experiences extreme weather and as a result has had to accomplish emergency planning and response to protect their citizens from Mother Nature.

Figure 3.1. Research Framework



Data Collection

Data were collected in multiple forms as the study progressed through each of the four study aims.

Aim 1

Contact was made with a senior leader involved in emergency management in each of the two cities to obtain a list of decision makers that would be involved in a no-notice infectious disease outbreak to serve as key informants for Aim 3 of the study. These initial discussions were held with City A's Office of Emergency Management (OEM) Director and City B's Director of Public Health (DPH)/ Homeland Security Coordinator. Both individuals are required, in their position, to be prepared for and respond to a public health emergency

The OEM Director in City A sent out an introductory email to potential informants. The investigator followed this introductory message with an email describing the study and a request to schedule an interview. City B's DPH provided a list of potential informants and their contact information to the investigator. In this instance, the investigator sent the introductory email to describe the study and initiate the scheduling of interviews. In both cities, at least one representative from each of the identified agencies was interviewed with the exception of the fire department in both cities. Several attempts were made to schedule an interview with a member of the fire department; however, due to operational demands and summer leave schedules neither city's fire department was available to participate. During the initial contact with City A's OEM director and City B's DPH, the investigator requested a description of each cities capability to detect a biologic agent. Both provided a verbal response to the question when asked.

Aim 2

A review of previous no-notice infectious disease outbreaks was conducted to understand how decisions were made to implement interventions that affect the public's health. Data were collected through a literature review and interviews with two individuals who had responded to a no-notice infectious disease outbreak in the past. Each source was probed for: a) the characteristics of the disease outbreak; b) what information decision makers had to make a decision; c) why and when did decision makers implement interventions; d) what was the outcome of the outbreak; e) who were the decision makers; and f) what lessons were learned.

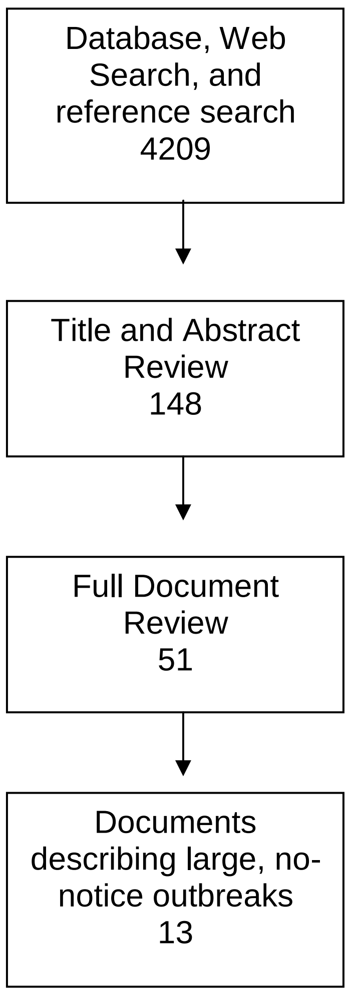
Outbreaks included in the document review were infectious disease transmitted through respiratory droplets, appeared without notice, and involved a response beyond the local community capabilities. These criteria excluded those outbreaks that are seasonal or are endemic to a region of the country. By exception, endemic diseases, such as measles, were included if the outbreak broke endemic thresholds and required support beyond the local community capabilities to respond. The investigator reviewed outbreaks from the United States, Canada, and Western Europe as the ability to identify an outbreak and respond in these countries was similar. Due to budget constraints, only documents in English were reviewed. Search terms used to identify outbreak documents are found in Table 3.1.

Table 3.1. Search terms used to identify documents describing no-notice, infectious disease outbreaks.

Communicable	**AND**	Disease	**AND**	Outbreak	**AND**	Human
Communicable	**AND**	Disease	**AND**	Outbreak	**AND**	Unexpected
Communicable	**AND**	Disease	**AND**	Outbreak	**AND**	Emerging
Communicable	**AND**	Disease	**AND**	Emerging		
Emerging	**AND**	Disease	**AND**	Outbreak		

Documents were identified through three searches for scholarly or authoritative information: 1) University of North Carolina at Chapel Hill Library database searches; 2) internet searches for relevant non-published works; 3) references from reviewed literature obtained in database searches (aka snowball method). The results of the document search are summarized in Figure 3.2. The documents included investigation papers, academic reviews, and government reports.

Figure 3.2. Summary of Document Search



The second method of data collection for Aim 2 was interviews with two individuals who are Subject Matter Experts (SMEs) in public health and each had an experience responding to a major, no-notice infectious disease outbreak in their city. The outbreaks affecting their cities, with populations greater than 5 million, were the result of novel diseases that had not previously been seen in the global population. Both outbreaks occurred after the terrorist attacks of 9/11 and the Amerithrax events in the U.S. This was important to note as public health activities and resources changed after 2001 with both increased funding and a cultural change to create an all-hazard approach to responding to disasters. Neither outbreak resulted from terrorist introduction, although it was considered in both instances before the disease was fully understood. Both SMEs were asked to respond to a series of questions based on their experience responding to a no-notice infectious disease outbreak (Appendix A)

Aim 3

Informant interviews were conducted to understand the process by which decision makers choose to implement interventions during a no-notice outbreak with early biologic detection data. In total, 17 informant interviews were conducted from the list of decision makers generated in Aim 1. Nine interviews were conducted in City A with eight conducted in City B. Informants were categorized as public health practitioners, public/environmental health administrators, emergency medical services, police, education, and emergency managers.

All interviews were conducted in person or by phone if the informant was not available to speak in person. The investigator traveled to locations identified by the informants that were most convenient for them. In most circumstances, the interview was conducted in the informant's office space. However, there were several occasions where the informant identified a location that met the needs of their schedule. This included a hospital emergency room and the reception desk of the health department, among other unusual locations. Several members paused the interview to answer their colleagues H1N1 response questions. It was incredibly apparent that the informants were busy with the current situation of preventing and responding to H1N1 in their city. Each interview session consisted of two parts; scenario-driven questions to identify response activities followed by guided questioning that focused on the capabilities and process of making decisions in a no-notice infectious disease outbreak.

Scenario- Driven Questions: Two scenarios were delivered to all key informants. The first scenario introduced an outbreak through confirmed data from a biological detection system in City A and through lab results in City B. The second scenario provided informants with information on increased clinical cases presenting in the community without any confirming data to indicate the disease or an outbreak was occurring.

The scenarios were delivered in a day-by-day format. At the end of each day the informant was asked, “Would you implement an intervention that affects the public’s health today?” If the respondent answered “yes” they were asked, “What prompted your decision to take action?” If the respondent answered no to the initial question they were asked, “What additional information would you like to have?” Each scenario continued with 5 days of information, repeating the implementation and information questions at the end of each day.

General Interview Guide Questions: The second phase of the informant interviews was conducted using an interview guide and probes to collect data (Appendix B). All informants were asked all of the questions in the interview guide.

Each informant was asked for their permission to be audio recorded. The interviews were digitally recorded and detailed investigator notes were taken for each session. The length of the interviews ranged between 42 and 80 minutes. During two interviews, the informant brought an employee with them to the interview. In the first instance, the informant had only been in the position for 6 months and wanted to assure that historical information could be provided if necessary. In the second instance, the informant wanted her program manager for the BioWatch program in the room to provide details if required. An inquiry to the UNC - Chapel Hill IRB was sent to request guidance on revising the approved IRB with the change in process to interview informants. The UNC – Chapel Hill IRB responded that no revision was required since all signed a consent form. Both interviews, with two persons, were treated as one interview since the informant provided response with the additional person only clarifying or amplifying the data given.

Aim 4

Based on an understanding that there is an optimal time for intervention during a no-notice infectious disease outbreak, this aim attempted to determine how the choices made by decision makers compare to the optimal outcomes from scientific modeling. The epidemiologic model used, a hybrid between deterministic models and stochastic models, was built based on requirements to provide decision makers a rapid analysis of an infectious disease event and course of action that could be taken to mitigate adverse outcomes. It was run based on the disease parameters (e.g. reproductively rate) from each scenario to obtain the optimal timing of the interventions for each scenario.

Data Analysis

Aim1

No analysis required.

Aim 2

The data obtained, from both sources, were collected and organized into the parameters identified in Table 3.3. The information was reviewed and analyzed to identify themes.

Table 3.3. Definitions of the Parameters Used to Review No-Notice, Infectious Disease Outbreak Documents.

Epidemiologic Characteristics	Characteristics that define the outbreak from a clinical or public health perspective to include disease characteristics, physical presentation of disease, populations affected, timeline of disease. These characteristics are important to review as many diseases initially present similarly and it is difficult to differentiate between public health emergency (natural or terrorist introduced) from a routine endemic disease.
Political Environment	Agendas and priorities of those involved in the policy process.
Social Environment	Demographic characteristics of the population, opinions of consumers, taxpayers, voters, audiences, and the mass media.
Economic Environment	State of economy and resources available in the region affected including the economic impact of the response.
Organization Environment	The intra- and inter-organizational relationships and hierarchies of those organizations involved in the response.
Information Available	Types of data available to decision makers to determine size and scope of outbreak. Understanding available data allows for evaluation of what assisted or hindered response.
Strategic Actions	Interventions implemented to mitigate disease and stop the outbreak.
Success/ Failure	Achievement of results that furthered or lessoned the ability to stop the outbreak.
Decision Maker	Agency, group, or persons who made decisions to implement strategic actions.
Lessons Identified	Lessons that were identified in the documents describing what enabled success or lead to failure of response to the outbreak.

Using analysis from Aim 2, the two no-notice, infectious disease scenarios developed were realistic, therefore minimizing artificiality that may cause informants to focus on the plausibility rather than respond to the questions being asked. Each scenario was built in a manner that affects the entire community and requires involvement of decision makers from different professional backgrounds.

The scenarios were reviewed by five public health professionals that have experience in responding to public health outbreaks. The reviewers included three MD/MPHs, a PhD epidemiologist, and a laboratorian. The reviewers were provided the scenarios in person or via email. Each was asked to review the scenario for plausibility, timeline of events, and appropriateness of how information was delivered. Reviewers' comments clarified the process for how information would be released in an event, the appropriate escalation of cases and fatalities, and the realism of the scenario based on their experience.

Aim 3

Following the interviews, the digital recordings were transcribed verbatim and verified against the audio recording and investigator notes. The investigator began an analysis of interview data by reviewing notes and transcribed interviews to identify broad categories for a coding manual. The interview transcripts were then loaded into CDC EZ-Text software for coding and organization of the data. [47] This software program assisted in managing a significant amount of transcript data from key informant interviews. CDC EZ text allowed for a data entry design that was tailored to the semi-structured qualitative interviews. Once data entry had been accomplished, the investigator used the software to apply codes to interview responses and analyze the data (Appendix C). The data were read several times to ensure all data were formally coded.[44] Emergent codes were used to supplement the coding manual throughout the analysis.

Pattern-matching logic was used to compare predicted patterns with the patterns identified through data analysis. [45] Using this analytical technique, the investigator was able to explore whether the informants from each city yielded similar results to others in their city and whether the informants from the two cities yielded different results from each other. In addition, pattern matching logic investigated whether informants from similar professional fields respond similarly. This content analysis competency looks for descriptive patterns in qualitative data. [44]

Aim 4

Epidemiologic model output was analyzed for each of the two scenarios. The investigator, program manager for the model, and select committee members reviewed the output to validate it against what was expected.

IRB and Confidentiality Issues

This research proposal was submitted to the UNC – Chapel Hill IRB and approval was granted without exception (IRB Study # 09-0583). All informants provided written or verbal consent (Appendix D) at the time of their interview. Each participated voluntarily, understanding that their responses were provided anonymously. Informants were assigned alpha-numeric identifiers. Only the identifiers were used during the collection and analysis of data. Participant identifiers were stored separately from identifiable data in a password protected file. Once the data were analyzed and the study completed, all digital recordings and identification of persons were destroyed.

CHAPTER IV: RESULTS

This chapter presents the results of this study according to the 4 research aims.

Aim 1

Determine who makes decisions to impact the public's health in a no-notice infectious disease outbreak. Determine what detection capabilities exist to provide information beyond the steady state.

From the initial list of decision makers provided by City A and City B, seventeen informants were interviewed during Aim 3 of this study. Table 4.1 indentifies the positions and agencies of the key informants that were interviewed. It should be noted that more than half of the informants self-reported having multiple positions/titles.

Table 4.1. Key Informants Interviewed Job Titles and Agencies

City A	**City B**
Director of Environmental Health, City Department of Environmental Health	Director of Public Health, County Public Health Department Homeland Security Coordinator, County Homeland Security Department
Director of Preparedness, City Public Health Department Director of Informatics, City Public Health Department	Epidemiology Specialist, County Public Health Department Preparedness Coordinator, County Public Health Department
Medical Director for Paramedic and Fire, City Health and Hospital Authority Associate Director of Emergency Medicine, Health Care System	EMS Medical Director, Health Care System Emergency Department Faculty, Health Care System
EMS Chief of Operations, City Health and Hospital Authority	EMS Director of Medical Services, County EMS Agency
Manager of Public Health Preparedness, City Public Health Department	Director for Communicable Disease, County Public Health Department
Deputy Police Chief, City Police Department	Director of the Tactical Support Division, City Police Department
Director of the Office of Emergency Management, City Office of Emergency Management and Homeland Security	University Director of Business Continuity of Operations, State University Emergency Management Coordinator, State University
Section Chief in the Office of Emergency Management, City Office of Emergency Management and Homeland Security	Director of Safety, County School System
Public Health Administrator, City Public Health Department	

During the initial conversation with City A's OEM director and City B's DPH, the investigator asked for a description of the capabilities their city had to detect a no-notice infectious disease in their community. This request was made to increase the investigator's familiarity with the city capabilities prior to the key informant interviews. City A's OEM Director identified three sources for information which included a personal notification (i.e. phone call) from the Department of Public Health, the BioWatch system, and information provided by the state intelligence agency. City B's

DPH identified a health surveillance system, an airborne detection system at post offices, information provided by the law enforcement and intelligence community, and lab data from the local, state funded BSL-3 lab as their capabilities to identify a no-notice infectious disease outbreak. Additional information on how decision makers receive data was obtained during the key informant interviews conducted in support of Aim 3.

Aim 2

Understand the context of past outbreaks and the decision to implement interventions. Determine the factors that lead to success or failure. Build realistic disease scenarios.

The search for no-notice infectious disease outbreaks that required support beyond local capabilities resulted in 13 outbreaks (See table 4.2). Once the outbreak was identified, several documents provided details for the analysis of characteristics and factors that may have affected the response (Appendix E). In addition to the document review, interviews were conducted with two Subject Matter Experts (SMEs) in public health who had been in a leadership role during a response to a significant outbreak in their city. These two individuals provided a wealth of insight on challenges they encountered and the activities that were successful to stop the outbreak in their city. The SMEs are from different countries but resided in similar sized cities during their outbreak.

Table 4.2. No-notice infectious disease outbreaks reviewed to understand context of previous events

Disease	Location	Year
Measles	New Jersey, United States	1985
Meningitis	Minnesota, United States	1995
Measles	Dublin, Ireland	2000
Measles	Netherlands	1999
Meningitis	Edmonton, Canada	1999
Pertussis	Wisconsin, United States	2003
Monkeypox	United States	2003
SARS	Toronto, Canada	2003
Mumps	United Kingdom	2005
Mumps	Midwest, United States	2006
Measles	Switzerland	2006
Adenovirus	Texas, US	2007
Influenza A H1N1	United States	2009

Emergent Themes (Aim 2).

Data collected from both the document review and the SME interviews was examined and emergent themes were identified.

New, emerging, reemerging, and vaccine preventable disease will always be a challenge to preventing large scale outbreaks.

It is logical to assume that an emerging infectious disease, not seen elsewhere on the globe, would create a challenge for responders. This was true of the first appearance of SARS and the current Influenza A H1N1 (H1N1) outbreaks. The public health and medical communities were faced with many unknowns and no obvious way forward to test, treat, or prevent disease during the initial days of each outbreak. [8, 48-50]

Although they are known, reemerging diseases are another potentially catastrophic category of disease. Reemerging diseases are those that have existed for some time in history but are presenting themselves in a different location or genetic form. [51] The U.S. monkeypox event is a prime example of reemerging disease, which generated the first cases seen in this country. [52] Other reemerging outbreaks identified were those that had genetically different disease, such as the Edmonton meningitis and Lackland Air Force Base (AFB) adenovirus 14 outbreaks.[53, 54] The mutation of these diseases created incidents that required support beyond the local capacity. [53, 54]

Finally, vaccine preventable diseases remain as an opportunity to cause large scale disasters in global populations. Seven of the outbreaks reviewed were initiated by vaccine preventable diseases. [55-62] Two of these seven outbreaks were not attributed to low vaccination rates. [57, 61, 63] The 2005 mumps outbreak in the U.K. primarily affected adolescents and young adults due to limited amount of vaccine. This population was older than the target window to vaccinate and they were too young to have prior exposure when mumps was a common childhood disease. [57] The 2006 mumps outbreak in the U.S. primarily affected college populations where three quarters of the cases had two doses of vaccine. With a high vaccination rate, researchers determined that the outbreak had been the result of waning immunity or less than 100% effectiveness of vaccine. [64] Of the outbreaks instigated by low vaccination rates, two were the result of religious or fundamental opposition to vaccines. [56, 62] These communities have seen outbreaks every 5-7 years and will continue to see disease every several years. [65, 66]

This finding emphasizes that public health and medical professionals must remain vigilant to deal with the continual reality that emerging, reemerging, and vaccine preventable diseases will affect our populations. A new wrinkle realized in the identification of common disease, such as measles or mumps, is the lack of disease recognition by young clinicians who have not seen it before. This dilemma, where common disease has been successfully eliminated by vaccination, will result in misdiagnosis and delayed recognition of outbreaks. [58, 59, 64, 67]

A global community equals global transmission.

Travel patterns have significantly altered disease transmission. Six outbreaks specifically cited that cases were imported or exported from their community to another state, province, or country. [8, 48-50, 53, 58, 62, 64, 68, 69] There is little or no oversight to keep sick individuals off airplanes. Even if there was, it would be impossible to identify asymptomatic individuals that utilize air travel and transmit disease unknowingly every day. [64] Through contact tracing, the U.S. mumps outbreak was traceable back to the U.K. mumps outbreak the year prior. Public health officials traced the contacts of infected individuals that had been on commercial flights to find additional cases. In total, 33 commercial flights were affected and 11 additional cases were found. [58]

Media is a factor to the benefit and detriment of a response.

Of the documents reviewed, 10 outbreaks specifically cited a public messaging campaign as one of their strategic actions to inform and provide guidance to the public. [8, 48, 49, 55, 56, 59, 61, 70-75] Toronto officials cited the success of the voluntary self-quarantine was largely due to the media campaign describing its importance. [72] Senior U.S. government officials were quick to use the media as a venue to update and educate the American public during the spring H1N1 was identified. [8] President Obama used his weekly address to provide reassurance to the public that his administration would be clear on the H1N1 events and activities. [75]

The media has a job to inform their audience and they accomplish it with or without comment from leaders, responders, or subject matter experts. In Toronto, the media did both by providing updates given by senior officials but also broadcast individuals with opposing opinions which left the public confused. [72] Confusion was also prompted by the media during the Minnesota meningitis outbreak when inaccurate information was broadcast. One example was the mistaken announcement of school closures that frustrated parents. To make matters worse, the outbreak occurred during the annual news “sweeps” month. Satellite trucks were set up in city parking lots to provide live news coverage on the events and response. [73] The media’s characterization of an outbreak shapes the public perception. During SARS, the media chose words that produced anxiety in the public such as “new plague” and “deadly”. [50]

It has also been realized that the media is no longer described as the 6 and 10 o’clock broadcast news but rather a 24 hour television production which now includes web coverage and immediate messaging services such as Facebook ™ and Twitter™. Those responding to mumps on an Iowa college campus learned quickly that the most effective messaging to college students was not the traditional news broadcast. [71] The U.S. government has also caught on that media messaging through these services is beneficial to informing the public. Email feeds and Twitter™ updates are being offered by the CDC to keep the public informed with the latest information on H1N1. [76]

The public is fearful of infectious disease.

The unknown characteristics of SARS and H1N1 created significant panic in the population. Each disease was initially described as severe with a high case fatality rate affecting otherwise healthy individuals. [8, 50] These fears are magnified by the perception that anyone, anywhere, could be infected and subsequently die. [72] Initially, both of these emerging diseases were compared to the 1918 influenza pandemic which led people to fear large portions of the global population succumbing to disease. [50, 72, 77]

Death from infectious disease in previously healthy individuals, especially young children and adolescents, also leads to panic in a community. Public anxiety was reported by parents during both the Minnesota and Edmonton meningitis outbreaks where unexpected teenage deaths occurred. [73, 78, 79] The appearance that the disease could not be controlled, and there was no way to tell who the next victim would be, led to fear in the Minnesota community. Parents claimed officials were playing “Russian roulette” with the lives of their children when discussing potential intervention strategies. [73, 78] In Edmonton, the public demanded expansion of the vaccine campaign from 15-19 year olds to include all children over 2 years of age.

Human behavior is hard to predict.

It is difficult to predict human behavior in normal situations but determining what individuals will do when they are faced with an infectious disease in their community may be impossible. During the New Jersey measles outbreak, the recommended age to vaccinate children was lowered to 12 months and then to 6 months to protect infants.

Even with this change, parents did not bring their children to vaccination clinics to receive free immunizations. [55] In the Edmonton meningitis outbreak, adolescents and young adults were adversely affected. [54, 79] Even with the knowledge that they were at high risk, the 18 -24 year old age cohort did not get vaccinated, leaving the public health professionals frustrated. [70]

In Toronto, the SARS concern altered citizens' behavior. A lot of the behavior changes were good common sense: practice good hygiene, stay home if you are sick, or wear a mask. However, other behaviors have been considered extreme. [50] As an example, individuals started to boycott anything related to the Chinese culture; including shops, restaurants, or areas of the city with a high Chinese population. Since the disease was initially transmitted from China, people feared exposure if they were in the proximity of anything related to the country. [50, 72] During the second wave, healthcare workers were significantly impacted by the disease. Once the media began covering the high infection rate in medical professionals, they became the lepers in the community. [72, 80, 81]

One SME interviewed stated that even with significant public messaging advising the community to stay home, unless they had serious medical concerns, overcrowding of emergency rooms continued. [49] The public perception was that the disease was in their city and they would need treatment immediately if they had any signs or symptoms, real or perceived. [49]

Behaviors during the Lackland AFB experience were different than those observed during the other outbreaks. Individuals did not report illness or seek medical care. The culture of recruits in Basic Military Training (BMT) is that you are tough enough to make it 6.5 weeks to graduation. Injury and illness was considered a delay to graduation goals, so most recruits would rather suffer through pain to get to the end. This behavior led to underreporting of disease and likely increased transmission to other BMTs. [82]

Population characteristics matter.

Characteristics of the population may put individuals at higher risk of being infected by disease. Several outbreaks attributed efficient transmission of disease to populations being in close proximity to each other or living in close quarters. [57, 58, 61, 64, 66, 73, 83, 84] The UK mumps, US mumps and the Lackland AFB adenovirus outbreaks all noted the dorm-like environments of campus and barracks living likely contributed to the amount and transmission of disease. [57, 64, 82] In Wisconsin, the close proximity and sharing of equipment among teenagers in a high school gym contributed to the rapid transmission among students. [61]

During the four measles outbreaks reviewed, unvaccinated populations were identified as the cause for the size of the outbreak. [55, 56, 59, 62, 66, 85] In Switzerland, the distribution of unvaccinated individuals throughout the country allowed the outbreak to gradually continue for 15 months. [74] Parental forgetfulness, concerns about side effects, high undocumented alien populations, and religious or fundamental opposition were identified as reasons for low vaccination rates. [55, 59, 86, 87] The Netherlands boasted a high vaccination rate of 95%, yet the country experienced a measles outbreak resulting in 3292 cases and 3 deaths. [65, 66] Of the cases identified, 83% were not vaccinated, claiming religious or fundamental objections. [66] Individuals that were vaccinated and residing in exceedingly unvaccinated communities were among those infected. In comparison, there was a low occurrence of cases where vaccination rates were high. This finding points to the effectiveness of herd immunity in a community. [66]

Policy matters to prevent an outbreak and in response to an outbreak.

In the outbreaks reviewed, lack of requirements for vaccinations left populations susceptible to disease. [58, 66] When the 2006 mumps outbreak occurred in the United States, only 25 states required a two-dose Measles, Mumps, and Rubella (MMR) vaccination for admission to college. Of the 11 states affected, only 3 were among the 25 states that required the two-dose MMR. Considering 43% of global countries do not vaccinate against mumps, there will remain a large concern for imported mumps disease in the United States. [58] Measles vaccination is not a requirement for school admission in the Netherlands. While the country has an overall high vaccination rate, this lack of policy has contributed to the measles outbreaks that occur every several years. [56]

In response to several of the outbreaks reviewed, policy changes were required to mount an effective response. These changes had to occur rapidly in order to alter the course of disease transmission and provide medical countermeasures. During the Minnesota meningitis response there was a need to rapidly dispense medication to the population. [73] According to state law, only pharmacists could dispense medication. With a shortage of pharmacists to assist in response, an exception to policy was requested and approved, to allow public health professionals to support pharmacists for dispensing medication. [73] The Monkeypox outbreak serves as a second example of the need for rapid policy changes. States, the CDC, and the FDA implemented policy to ban the movement of infected animals to mitigate further disease transmission from the animal to human populations. [52, 88] In addition to animal movement bans, CDC provided updated recommendations for the medical countermeasures (i.e. smallpox vaccine) to persons with high risk of exposure to infected animals or persons. [52]

Vaccine policy and recommendations were identified as strategic actions by all outbreaks involving a vaccine preventable disease. Actions included the lowering of recommended age for vaccination, updates to school admission requirements, and advocacy of licensure for booster pertussis vaccines. [55-61, 66, 86, 89, 90]

Outbreak response is expensive, however, lack of funds has not been a significant barrier.

Infectious disease outbreaks come as an unanticipated cost to a community. The cost per case of pertussis during the 2003 outbreak was $1989. [60] The cost estimate focused on the public health, case finding, and prevention costs. It did not take into account the cost of personal protective equipment or disruptive administrative costs in the school or the community. The hospital in the county where the outbreak occurred estimated a non-reimbursable cost of at least $78,000 to respond to the outbreak. [60] Like the pertussis event, a handful of outbreaks noted the cost of response included more than the medical and public health expenditure. [50, 61, 70, 72] Nowhere was this more apparent than the 2003 SARS outbreak in Toronto. [72] The uncertainty of an emerging disease, and risks associated with being affected, led to indirect costs primarily felt by the tourism industry. [50] The World Health Organization’s travel restriction served as a confirmation to outsiders that Toronto should be avoided, which led to the rapid decline of leisure and business travel to the city. [48, 50, 72] The economic cost of SARS has been estimated between 30 and 100 billion dollars globally. This averages out to be 3 to 10 million dollars per case. [50]

Although the cost of an outbreak may be high, there was no documentation of significant barriers to funding a response in the outbreaks reviewed. Public health emergencies were declared to release money for responses to SARS, H1N1, and the MN meningitis outbreak.[8, 72, 73] These emergency authorizations provided money during the response or reimbursed agencies after the event was over. In other outbreaks, efforts to mitigate the disease burden involved the distribution of free services, such as vaccinations, to the public.[54, 70, 73, 91, 92] Even in the current economic crisis in the U.S., Congress authorized $7.65 billion dollars to prepare for and respond to the H1N1.[93] This money provided federal dollars for surveillance, antivirals, medical supplies, and vaccines. At the state and local level, the money was allocated to train staff, buy equipment, improve communications, and plan for a hospital surge.[93]

People and relationships are critical to a response.

Traditionally, public health agencies are staffed to support daily operations which are resourced for a normal threshold of disease. This staffing model becomes a limitation during public health emergencies. Several of the outbreaks reviewed cited that the amount of personnel necessary to respond was significant.[7, 48, 49, 60, 61, 72, 73] During outbreak response in MN, staff members were pulled from their traditional position to assist in outbreak response, working extended hours for multiple days. The overall response effort, along with the criticality of rapidly implementing interventions, wore on staff members.[73] The WI pertussis report revealed that the staff members were involved in lengthy, daily operations for more than 2 months to get the outbreak under control.[60, 61]

It was cited during the Toronto SARS and MN meningitis outbreaks that public health professionals were working 18-20 hours a day to respond to the rapidly escalating situation in each of their cities. [72, 73] This presented a challenge to effectively communicate situation updates and guidance to staff members who were actively responding. One public health senior official indicated that one of her failures was not communicating to her staff. She learned later that the staff was offended because they got information from the media before they heard it from their leadership. [48]

Outbreak documents cited that relationships were critical to their response. [48, 49, 52, 59, 70, 73, 94] Both SMEs interviewed credited relationships with agencies outside of public health as important to successfully countering the outbreak. They named connections with the Office of Emergency Management, the police, and elected leaders as important affiliations that had been built over the years. [48, 49] Edmonton mentioned the importance of including sub-populations such as the First Nation representatives and the Inuit Health Branch as important to create a sense of inclusion and trust among potentially high risk populations. [70] During two reemerging disease outbreaks, resources came readily from the state and federal levels to support the community due to established relationships among professionals. [52, 82]

An assessment of the immunization campaign in Edmonton noted a vital factor for their success was the organizational clarity of roles and responsibilities among responders. The unambiguous line of authority and a general knowledge of agency duties made collaboration and decision making appear effortless. [70]

The lack of established relationships and clear lines of authority frustrated parts of the Toronto response during SARS. City officials had several masters and were often searching for authoritative guidance. One aggravation, in particular, was the multiple requests for data and updates. These activities added to the demands that already taxed public health. [48, 72]

Strategic actions.

The most reported strategic action taken during the outbreaks was public media campaigns. Nine outbreaks reported the use of media to inform the public and provide guidance. [8, 48, 49, 55, 56, 59, 61, 70-75] SARS and the H1N1 outbreaks had the most frequent and most senior officials involved in their messaging. [8, 72, 75] During the first week of the H1N1 outbreak, the White House hosted a press briefing with the Assistant to the President on Homeland Security and Counterterrorism, the Secretary for the Department of Homeland Security, and the acting director of the CDC, which illustrated that the administration pledged to provide clear communication and guidance to the public. [8] This was reinforced during the second week of the outbreak when President Obama addressed Americans, reaffirming his commitment to be clear and honest. [8, 75]

Vaccination campaigns were identified in the majority of outbreaks reviewed as an action to prevent infection and increase the herd immunity of the population. [52, 55-59, 70, 73, 95] In Minnesota, this effort was significant as the meningococcal vaccine was ultimately given to 30,000 individuals in the community of 55,000. The initial push to vaccinate occurred in the school system where 1000 teenagers were vaccinated in 35 minutes. This was followed by a community vaccination campaign where 55% of the community was vaccinated in 4 days. The Herculean effort identified several lessons, including that agencies outside of the public health and medical communities need to be involved to support taskings like traffic management. [73] Currently, the federal H1N1 vaccination campaign is suffering implementation challenges. Delayed vaccine production and the increase in cases across the country has resulted in a very anxious public. [96]

Several outbreaks cited the use of movement restriction to include social distancing, isolation, and quarantine as part of their strategic response actions. [7, 8, 48, 49, 53, 61, 62, 71, 82, 97] Public health professionals supporting the adenovirus 14 outbreak referred to this strategy as the most effective action to reducing disease burden in the BMTs. [82] The most impressive use of the movement restriction was seen during SARS in Toronto. Over 13,000 individuals voluntarily quarantined themselves in their homes for a period of up to 10 days. [48, 72] Only 27 individuals were served a legal quarantine order, which speaks highly of the public messaging provided by city leadership. The logistics of this effort were complicated, as food and medical care had to be provided to those persons in quarantine. [72] In addition, other strategic actions identified in the document review included policy change and/or recommendations, surveillance, contact tracing, hospital alerts, and triage of patients. [8, 48-50, 52, 53, 56, 57, 59-61, 72, 73, 80, 82, 90]

Successfully responding to an outbreak.

Many of the successes have been described above in other emergent themes. Two re-occurring successes documented by the majority of outbreaks were messaging to the public and relationships.

Providing updates and education, from leaders to the public, was mentioned by many as a successful intervention to mitigating disease and stopping the outbreak. [8, 48, 49, 55, 56, 59, 61, 70-75] This messaging provided confidence to the public that their best interest was being considered. The Minnesota state epidemiologist stated that having someone the public trusted offered reassurance that someone credible was in charge. [73] Public messaging was also identified as the reason for the compliance with self quarantine in Toronto. The public reported that they were motivated to protect others. [72]

As mentioned previously, relationships were cited as a critical element to making response easier. The first SME interviewed shared that pre-established relationships with emergency management and law enforcement partners came to her offering assistance in the early days of the city's outbreak. [48] The second SME noted the ease with which communication plans, testing, and functioning in an Incident Command Structure occurred without difficulty because the city had worked and exercised with other city agencies in the past. [49] Other outbreaks referenced creation of multiagency and multidisciplinary groups as a successful strategic action that supported decision making, policy changes, and provided recommendations. [48, 49, 59, 70, 71, 73, 94]

Failures of responses.

No one specific failure was uniformly documented among outbreaks reviewed. Antiquated information technology (IT) was identified as a barrier during SARS, the Dublin measles, and the Edmonton meningitis outbreaks. IT barriers prevented responders from verifying immunization records and tracking cases. [48, 59, 70, 72]

Lack of clear policy on administrative and logistic matters was identified as an issue that took decision makers away from more critical response activities. As an example, Toronto leaders had to deal with the parking issues created with alternate care sites. Secondly, the issue of compensation came to the forefront since there was no policy when employees were asked to quarantine themselves after exposure. [48, 72] The H1N1 outbreak continues to amplify employee policy issues. In some parts of the U.S., health care workers have refused to be vaccinated against H1N1. Some health care systems tried to mandate vaccination. Other systems have put policies in place for unvaccinated health care workers to wear masks during their shifts. [98, 99]

Failure was also attributed to actions or lack of actions that lead to the outbreak itself. Clearly low vaccination rates significantly contribute to possibility of an outbreak. Several documents acknowledged the awareness of low rates of immunizations before the outbreak, yet no action was taken to improve the situation. [55, 57, 59, 62, 66] Secondly, it was noted that limited oversight has contributed to outbreak occurrence. The U.S. monkeypox event is a key example where the lack of regulation allowed for diseased animals to be imported and moved around the country. Furthermore, this led to an inability to track where diseased animals went in the country. Unfortunately, with limited resources to provide oversight and a $3 billion illegal exotic animal trade business we will continue to see these outbreaks initiated by zoonotic disease. [100] Other documented failures included confusion of authorities, premature relaxation of intervention strategies, lack of strict infection control measures, and deficient communications with the media and professionals responding to the outbreak. [7, 48-50, 52, 61, 72]

From the data and themes identified during the document review and interviews, two no-notice infectious disease scenarios were created for use in the key informant interviews in Aim 3 of the study. Table 4.3 describes characteristics of each of the scenarios. They were delivered in a five day format where each day a vignette of information was given. Informants were asked, at the end of the vignette, if they would implement an intervention that affected the publics' health today. Interventions included actions that would affect the health of the public. Examples include the delivery of guidance to the public, movement restriction, or medical countermeasures. Changes in hospital protocol for staff protection or a media story on the outbreak with no guidance to protect individuals were not considered as an intervention that affected the publics' health. A positive indication that an intervention would be attempted prompted the investigator to ask "What information triggered your decision to implement an intervention that affected the publics' health?" A negative response prompted the question to informants, "What additional information would you like to have?" Each key informant was given both scenarios.

Table 4.3. Characteristics of the Disease Scenarios Delivered in Aim 3

	Scenario A	**Scenario B**
Characteristic of Event	Confirmed Disease: Plague	Unconfirmed disease: respiratory disease. The scenario was based on SARS but the key informants were not given that information
Information Source	Early Detection System: City A- BioWatch City B- lab test	EMS and Emergency Room
Symptoms	High fever, chills, and labored breathing	High fever, chills, and headache along with ILI
Information available	City A – BioWatch Actionable Result (BAR) City B – presumptive lab result Both cities – # hospitalizations, lab results, # fatalities,	# Cases, syndromic surveillance data, # hospitalizations, #fatalities
Morbidity and mortality	117 hospital admissions and 15 fatalities	87 hospital admissions and 4 fatalities
Other scenario characteristics	Media requests information from officials, citizens are overwhelming the emergency departments	Media reporting, labs are unable to characterize disease, initial cases are university students, health care workers are affected.

Aim 3

Understand the process by which decision makers choose to implement interventions during a no-notice disease outbreak. Determine what information they need. Determine how their decisions are affected by early biologic detection data.

Interviews were conducted with seventeen key informants, nine from City A and eight from City B. The interviews included questions based on the two no-notice infectious disease scenarios and a set of general interview questions where the investigator learned more about the informants' positions, data availability, confidence in data, decision making processes, and concerns about getting information to inform their decisions.

The informants named 24 responsibility categories to describe their positions. The two most frequent responsibilities identified were planning and command and control/oversight activities. Informants identified individual professional tasks for their positions such as investigating disease, leading a certain program, or managing of activities within their agency. Law enforcement informants included the protection of both their officers and their officers' families as part of their responsibilities. It was explicitly mentioned that it is important to take care of family members so officers come to work. Five key informants made reference to the fact that they do everything or anything their supervisor asks them to do.

Data from the scenarios identified when informants would implement public health interventions and what those interventions were. Secondarily, data were collected on what triggered their decisions. Finally, informants that did implement an intervention on a particular day were asked what additional information they would like to have.

The next four tables will provide data on when informants indicated they would implement an intervention that affects the publics' health. Once an informant indicated they would implement an intervention they were counted as providing interventions on the subsequent days. These informants described both the continuation of the same intervention or the implementation of additional interventions on subsequent days.

The timing for implementation of an intervention has been displayed two different ways. Tables 4.4 and 4.6 compare timing of interventions between cities. A comparison of intervention timing by profession is shown in tables 4.5 and 4.7. A general description of the vignette information provided to informants for each day of the scenario is described in parentheses. It should be noted that in the first scenario (pneumonic plague), some persons in City A did not feel comfortable making a public health decision early in the outbreak and indicated they would follow guidance of public health. Occurrences of these responses have been reflected in table 4.4 and 4.5.

Scenario 1 (pneumonic plague) interventions decisions.

Even though City A had a BioWatch Actionable Result (BAR) on day one, none of the informants indicated they would implement an intervention that affected the publics' health on that day. On the second day, the vignette provided information on suspected plague cases which caused a majority of City A's informants to implement an intervention. In comparison, one of City B's informants implemented an intervention on day 1, three on day 2, and the majority (6 informants) made interventions on day 3. Sixteen of the seventeen key informants indicated they would implement an intervention by day 5 of the scenario. The remaining informant described actions that he would take, such as reviewing the plans for a response, but never declared he would or would not implement an intervention by day 5.

Both cities identified the number of cases of suspected plague on day 2 served as a trigger for them to take action. The increased number of cases continued to serve as a trigger for both cities on days 4 and 5 as well. On day 3, several key informants indicated that the confirmation of plague triggered them to implement an intervention. This concern was continued to day 4 where some key informants indicated the nature of the disease (plague) served as a trigger.

Table 4.4. Informant Responses on Implementation of a Public Health Intervention, Categorized by City for Scenario 1 (Identified Plague)

		Day 1 (Announcement of suspect disease)	Day 2 (Suspect cases hospitalized)	Day 3 (Confirmation of disease, fatality reported, additional hospitalizations, and media inquiry)	Day 4 (Additional fatalities and hospitalizations)	Day 5 (Additional fatalities and hospitalizations; emergency departments overwhelmed)
City A (n=9)	Implement Intervention		5	5	6	8
Trigger			a) # Cases b) Combination of all data / information	a) Confirmation of plague	a) # Cases b) Combination of all data / information c) Nature of disease	a) # Cases b) Data from subject matter experts
	Follow the Guidance of Public Health		2	3	2	
City B (n=8)	Implement Intervention	1	3	6	8	8
Trigger		a) Presumption of plague	a) # Cases b) Nature of disease	a) Confirmation of plague b) Combination of all data / information	a) # Cases b) Deaths c) Nature of disease	a) # Cases
	Follow Guidance of Public Health					

The data in Table 4.5 shows that professionals in health agencies initiated interventions earlier than other informants in both cities. One professional from EMS, police and emergency management said they would follow the guidance of public health. By day 5, all three of these professionals described at least one intervention they would implement which moved them from the column of following the guidance of public health into the implementation column.

Across the professions, the number of cases was routinely identified as a trigger starting on day 2 through day 5. Public health and medical professionals tended to identify the disease (plague) or the nature of the disease as a trigger for implementing an intervention. One key informant identified the presumption of plague as their trigger on day one.

Table 4.5. Informant Responses on Implementation of a Public Health Intervention, Categorized by Profession for Scenario 1 (Identified Plague)

		Day 1 (Announcement of suspect disease)	Day 2 (Suspect cases hospitalized)	Day 3 (Confirmation of disease, fatality reported, additional hospitalizations, and media inquiry)	Day 4 (Additional fatalities and hospitalizations)	Day 5 (Additional fatalities and hospitalizations; emergency departments overwhelmed)
Public / Environmental Health - Practioners (n=4)	Implement Intervention		2	4	4	4
Trigger			a) # Cases	a) Confirmation of plague	a) Nature of disease	No additional triggers specified
	Follow the Guidance of Public Health					
Public / Environmental Health – Administrators (n=3)	Implement Intervention		3	3	3	3
Trigger			a) # Cases	a) Confirmation of plague	a) Combination of all data / information	No additional triggers specified
	Follow Guidance of Public Health					
EMS (n=4)	Implement Intervention	1	3	3	4	4
Trigger		a) Presumption of plague	a) Combination of all data / information b) Nature of disease	a) Combination of all data / information b) Confirmation of plague	a) # Cases	a) # Cases
	Follow Guidance of Public Health		1	1		

Table 4.5. (Continued)

		Day 1 (Announcement of suspect disease)	Day 2 (Suspect cases hospitalized)	Day 3 (Confirmation of disease, fatality reported, additional hospitalizations, and media inquiry)	Day 4 (Additional fatalities and hospitalizations)	Day 5 (Additional fatalities and hospitalizations; emergency departments overwhelmed)
Police (n=2)	Implement Intervention				1	2
Trigger					a) Nature of disease	a) # Cases
	Follow Guidance of Public Health		1	1	1	
Education (n=2)	Implement Intervention			1	2	2
Trigger				a) Did not specify a trigger	a) # Cases b) Death	No additional triggers specified
	Follow Guidance of Public Health					
Emergency Management (n=2)	Implement Intervention					1
Trigger						a) Data from subject matter experts
	Follow Guidance of Public Health				1	

The earliest and most frequent intervention in response to scenario 1 (pneumonic plague), was holding a press conference that provided guidance to the public. Informants also described the implementation of social distancing and prophylaxis by the 5th day of the scenario. Even though informants did not implement interventions on the initial days of the outbreak, they did describe a multitude of actions they would be taking to scope the event and prepare for a response (e.g. disease investigation, review of plans, preparation of public information, heightened surveillance). More than half of the respondents in City A indicated plague was endemic to their community and a BAR for plague would not get them "overly excited". Several informants from different professions, in each city, discussed the fine line between informing the public and creating panic. Police professionals, in particular, were concerned about taking protective measures in their force (i.e. wearing masks) without an assertive media campaign that described why they were taking those precautions as this action would alarm the public.

Scenario 2 (SARS) interventions decisions.

During the first two days of the second scenario, a death was identified as a trigger to implement an intervention. The number of cases was added as a trigger on day 2 by city A and day 3 by city B. On day 2, key informants also triggered an intervention on the infectious nature of the disease. This trigger carried through the remainder of identified triggers. Both cities identified the public reaction as a trigger to implement an intervention on day 4 and 5.

Several informants pointed out that they would not likely be notified of the information that was provided on the first day of the scenario (two deaths from respiratory failure in the university student population). A majority of informants from City B indicated they would implement interventions on day 2 of the scenario. In comparison, City A did not reach a majority of informants implementing interventions until day 3 of the scenario. Interventions described included press conferences with guidance for the public, social distancing to include school closures, medical countermeasures, and quarantine.

Across the professions, the number of cases was identified as a trigger to implement an intervention. The public health and medical professionals suggested disease related triggers such as infectious nature of disease and severity of disease. Law enforcement, emergency operations, education, and emergency management professionals started identifying the public reaction as a trigger to implement an intervention on days 4 and 5.

Table 4.6. Informant Responses on Implementation of a Public Health Intervention, Categorized by City for Scenario 2 (Unidentified SARS).

		Day 1 (Notification of atypical respiratory deaths)	Day 2 (Reporting of increased cases in syndromic surveillance system)	Day 3 (Reporting of respiratory hospitalizations and ventilator usage)	Day 4 (Reporting of respiratory hospitalizations, ventilator usage, and media reporting)	Day 5 (Reporting of respiratory hospitalizations, ventilator usage, fatalities, and overwhelming public concern)
City A (n=9)	Implement Intervention	1	3	6	8	9
Trigger		a) Death	a) Death b) # Cases c) Infectious nature of disease	a) Infectious nature of disease b) Data from subject matter expert	a) # Deaths b) # Cases c) Public reaction	a) # Cases b) Public reaction c) Severity of disease
City B (n=8)	Implement Intervention	1	5	5	6	8
Trigger		a) Death	a) Death b) Infections nature of disease c) Combination of all data / information	a) # Cases b) Infectious nature of disease	a) # Deaths b) # Cases c) Severity of disease d) Public reaction	a) # Cases b)Infectious nature of disease c)Severity of disease d) Public reaction

Similar to the first scenario, key informants from health professions were among the first to implement interventions. Since the origin of the outbreak was identified in the local university, the key informant employed by the university also revealed he would implement an intervention early in the event similar to the health professionals' response. He also noted the dilemma of closing the university only to send exposed individuals into multiple communities where the outbreak could spread rapidly.

Since the second scenario only provided symptoms of the disease and did not name the disease nor provide a clinical diagnosis for cases, several informants said it would be difficult to inform the public when there was little or nothing known about the disease. However, one informant noted sharing information about what was known and unknown to the public was better than not saying anything which may be perceived as hiding things from the community.

Table 4.7. Informant Responses on Implementation of a Public Health Intervention, Categorized by Profession for Scenario 2 (Unidentified SARS).

		Day 1 (Notification of atypical respiratory deaths)	Day 2 (reporting of increased cases in syndromic surveillance system)	Day 3 (reporting of respiratory hospitalizations and ventilator usage)	Day 4 (reporting of respiratory hospitalizations, ventilator usage, and media reporting)	Day 5 (reporting of respiratory hospitalizations, ventilator usage, fatalities, and overwhelming public concern)
Public / Environmental Health - Practioners (n=4)	Implement Intervention	1	4	4	4	4
Trigger		a) Death	a) Death b) Combination of all data / information	a) Infectious nature of disease	a) # Deaths b) Severity of disease	a) Infectious nature of disease b) Severity of disease
Public / Environmental Health – Administrators (n=3)	Implement Intervention		1	3	3	3
Trigger			a) Infectious nature of disease	a) Infectious nature of disease b) Data from subject matter expert	a) # Cases b) # Deaths	a) Severity of disease b) Public reaction
EMS (n=4)	Implement Intervention		2	3	3	4
Trigger			a) # Cases	a) # Cases	a) Public reaction	a) # Cases b) Severity of cases c) Public reaction
Police (n=2)	Implement Intervention				1	2
Trigger					a) Public reaction	a) Public reaction

Table 4.7. (Continued)

		Day 1 (Notification of atypical respiratory deaths)	Day 2 (reporting of increased cases in syndromic surveillance system)	Day 3 (reporting of respiratory hospitalizations and ventilator usage)	Day 4 (reporting of respiratory hospitalizations, ventilator usage, and media reporting)	Day 5 (reporting of respiratory hospitalizations, ventilator usage, fatalities, and overwhelming public concern)
Education (n=2)	Implement Intervention	1	1	1	1	2
Trigger		a) Death	a) Infectious nature of disease	a) # Cases	a) # Cases	a) # Cases b) Infectious nature of disease
Emergency Management (n=2)	Implement Intervention				2	2
Trigger					a) Public reaction	a) Public reaction

After being asked about implementation of an intervention, informants were queried about what triggered their decision to intervene or what additional information they would like. Table 4.8 lists the triggers informants stated as the reason they would implement an intervention(s) and the additional information they would like if they did not implement an intervention on a particular day.

Table 4.8. Key Informant Requests for Additional Information

	Additional information requested
Scenario 1: Identified Plague	- Intelligence - Laboratory results - Epidemiologic data - Clinical data - BioWatch location - Guidance from public health - Guidance from state health
Scenario 2: Unidentified SARS	- Epidemiologic data - Clinical data - Guidance from public health

The second half of the interviews were guided by pre-established questions to understand more about the informant, what data are available to them, decision making processes, and their concerns about receiving data they could use to respond. Responses were merged with data from the scenarios into overarching topics. Through further analysis of the data, several themes emerged. The themes are described in table 4.9.

Table 4.9. Emergent Themes

Themes
1. Data types, sources, and confidence were varied among decision makers.
2. Relationships are key to the notification of and response to an event.
3. Public relations and media are critical pieces of any response.
4. It is not clear who has the authority to make which make decisions regarding public health interventions.
5. Cities had a significant event that initiated their preparedness with a multiagency focus.
6. The 2009 H1N1 pandemic experience tested response and identified lessons observed.

Emergent Themes (Aim 3)

1. Data types, sources, and confidence is varied among decision makers.

City A informants identified seven types of data from 11 sources that would provide early indication and warning of a no-notice infectious disease outbreak. The most reported type of data was a “heads up” notification (4 responses) from a partner in the community (5 responses). One informant that has city surveillance responsibilities, referenced a surveillance system that was set up for the National Special Security Event (NSSE) to provide them early identification and warning of disease. According to him, the capability was unfortunately turned off after the NSSE was over and again they had limited tools to accomplish surveillance for the purpose of early detection of a biological threat. None of the key informants identified BioWatch as a type of data or a source of data. Informants made the following comments about BioWatch:

> *Yes the BioWatch is important but the follow-up information is critical.*
>
> *Looking [at the] bigger picture, the BioWatch system being in place and sounding an alarm is just one piece of information in the decision making process.*
>
> *You know if BioWatch goes off and you immediately say we got a BioWatch [hit], immediately get the SNS started. Then we have just destroyed the tourism trade in the city for the next year and a half, significantly impacting the economy.*

City B key informants named 20 types of data they would receive from 20 potential sources. Of the 20 types of data, only four types of data were mentioned by more than one informant. Similar to City A, the most frequent data type was a “heads up” notification (3 responses). The most frequent source of data was a notification from a community partner (3 responses). Several of the informants cited that they have “good” surveillance systems in the city which have been adopted for state wide use.

Five key informants in City A were confident that the data they received would assist them in responding to a no-notice disease outbreak. The four informants that did not have confidence expressed that their confidence is in personal relationships or only exists if the data are “good”. One informant mentioned they need to rely on personal relationships.

> *I’m more confident about the personal relationships then I am about the surveillance systems just because we haven’t got enough resources to fully staff personnel to be monitoring those systems on an on-going basis. We have limited numbers of data sources feeding in.*

One informant from City A, when asked about his confidence that a BAR would indicate an actual event stated:

> *Not very [confident] because how many BARs have there been in the country and how many true events have there been. I don’t even know if there have been any.*

Seven key informants, in City B, noted they were confident in the data they receive. Four of those specifically used a positive adjective to describe increased confidence (e.g. highly confident). There was no one piece of data or a source of data that multiple informants referenced as being confident in.

Four of the key informants in City A believed they would get data in a timely fashion. In comparison, 7 informants in City B were confident in the timeliness of the data.

Two key informants from City A and four from City B indicated they did not have concerns about the data they named. An informant from City B stated he had no concerns whatsoever and expressed, “I sleep good at night” when asked about concerns with the data. The remainder of informants identified some type or level of concern about receiving data for decision making. Concerns expressed included:

- They would not be notified of data/event
- There would be no recognition of the event
- There would be an inability to manage information
- Technology barriers
- Withholding of information from the city if there was a bioterrorism threat

Informants from both cities referenced the overwhelming amount of information that was provided during the 2009 H1N1 pandemic. Informants shared that they could not keep up with the amount and the quality of data which potentially affected their response.

2. Relationships are key to the notification of and response to an event.

Although there were no specific questions requesting informants to identify or describe relationships, an overwhelming majority felt obligated to mention them. Of the seventeen informants, fifteen referenced the importance of relationships in their responses. Eleven described that relationships are effective in their community because they have been tested during planning, training, and responding over the years. Four informants specifically said that relationships are the key to successful response.

Several described that the personal relationships they have developed with each other have driven an informal communication network to keep each other aware of situations that may need a community response. This was evident when informants were asked about the data types and sources from which they would get data about a biologic event. Seven informants mentioned "heads up" notification as the type of data and eight described partners as the source of their data.

Responders from City A primarily described two types of relationships. The first were occupation-related relationships which have been in place for a long time. These are relationships that are generally within a certain profession (e.g. infectious disease doctors) or a field (e.g. medical community). The second type of relationship was a new one that was generated by the planning and execution of the NSSE in their city. Five of the nine informants in City A described the NSSE as an instigator for bringing the response community together to better understand roles, responsibilities, and gaps in response. Informants commented that they built trust with their partners, during the NSSE preparations, where it had not existed previously. One informant reflected positively that her city was now better prepared for crisis.

One of the great things about the [NSSE] is we got to work with partners all over the city. People whose names I had heard but never met. I got to work with [Mary], who is the epidemiologist for [County X]. I would have never worked with [Mary] that much, that often. The great thing about that was if we had a real incident,[Mary] and I would have already had a relationship of trust and awareness because [Mary] and I are like oil and water. If we were thrown together at the last minute she would think I was horrible and I would think she was wacko. We had months to go, wow, your wow. And now if there was an emergency I would go to [Mary]. Who she is and how she works would be something I already knew about. In a real situation we would be ready to go. We know each other, we trust each others. And I don't just mean [Mary] and me, I am just using that as an example. The whole team, we knew each others names. We just have a sense of community we didn't have before. That kind of thing is important.

City B repeatedly referred to their relationships as a unique collaboration that spanned the response community. Many described their community as no place they had ever seen in the country where all responders get along and work together effectively. One informant referred to their relationships as the glue that makes response so successful. Another informant noted that you "can't buy that" as he described the success that relationships have had in their community planning and response.

Several informants in city B, stated relationships grew out of a need to be more responsive to a threat in their community. A bomb threat in the county courthouse was mentioned by many as the initiating force to get response communities together. This domestic terrorist event prior to 9/11 drove planning and funding for collaborative efforts. One informant described their relationships with pride:

I'm proud of this place; we've really come a long way. We work so well together between law enforcement, fire and medical. It is really fun to be here, and we can build great things here and we have. But I can tell you the success are those relationships. You have to have those relationships. If you don't you are screwed.

In addition to city relationships, all but one informant cited some relationship with their respective state. Several described the following activities that included the state:

notification of a case or event to the state, collaborative efforts to respond to the outbreak, laboratory testing, surveillance, and receiving support (e.g. people, equipment, funding). Half of the informants pointed out that they would be getting direction or guidance on how to respond from their state.

> *There are very few decisions that are high profile that we make locally that we don't coordinate with the state because they want to know what's going on.*

Federal relationships were also mentioned by eleven informants. The relationships were described as federal or a specific agency was referenced (e.g. CDC, EPA). Notification of events and receiving guidance from federal partners were the most referred to relationship. Informants also referenced collaboration and support from the federal level.

3. Public relations and media are critical pieces of any response.

The media is a factor in response: good or bad. An overwhelming amount of informants said they would use the media as an intervention to provide guidance to the public. In the plague scenario, five informants from City A said they would implement media releases. An additional 2 informants described their actions included preparing for press releases. Seven informants, in City B, said they would use media as an intervention. Similarly in the SARS scenario, City A had eight informants using the media as an intervention while the last informant mentioned there would be preparations for a press release. Seven informants from city B would use the media as an intervention during this second scenario.

Many informants pointed out that the media would be a factor from the first day of an outbreak. Several shared a concern that if accurate information was not given in a timely manner, the public would panic. One informant commented that the media would be, as is their nature, reporting information regardless of their ability to confirm it. Furthermore, he stated that without balanced commentary from the city leadership or medical community, the public may panic. This reality is what drove most informants to hold or plan for a press conference early in each scenario.

Informants described newspaper, television broadcast news, websites, and information hotlines as the type of media outlets that they would use to provide public guidance. The information hotlines included both a 1-800 call in number for the public to ask questions and a 311 information number where the public could receive automated information and guidance. Spokespersons for media efforts were typically described as a combination of city leaders and public health professionals with no one type of individual being identified predominately by the informants from either city.

Informants shared two kinds of frustration when discussing the media. The first was internal to the responders when information was shared through media before being shared through responder channels. Informants stated they were frustrated or offended when they got updates from the news media before hearing it from their partners. This was seen both horizontally (e.g. across agencies) and vertically (e.g. from federal level to city level). The second frustration was with the media misreporting. One informant said: [articulately what others informants described]

> *The news media doesn't need to be right and their intent isn't to ensure peoples' lives are safe and don't intervene if you don't need to. They want to create their story and they want their story out and want people to listen. We [responders] don't get to do that and we can't be saying things that aren't factual.*

4. It is not clear who has the authority to make which decisions regarding public health interventions.

The investigator asked the informants to describe the process for making decisions in a no-notice infectious disease event. This broad question was answered from a city perspective by some informants and from an agency perspective by others (See Table 4.10). Responses were not consistent in describing who the definitive decision maker was in either city.

Four informants from each city stated decisions were made by a team or ad-hoc group. These groups were described as a compilation of either medical professionals or all emergency responders in their city. Informants from both cities referenced the Incident Command System (ICS) as their unifying structure to respond to an incident in their city. Under ICS, the leader was dependent on the event. For example, if the event was a fire, the fire chief would be running the response. During a biological event, the city health director would be in charge.

Only two informants from City A identified elected leadership in a decision making role. One of those informants also noted that the elected leadership would take their cue from the recommendations by the ad-hoc team and rarely make a decision against that team. Informants that mentioned elected leaders referred to them as a formality or a figure. City B indicated that their elected officials do not have a background in health and would rarely, if ever, disagree with recommendations from public health professionals in response to an infectious disease outbreak.

Table 4.10. Decision Makers Identified for a No-Notice Infectious Disease Outbreak

	City A	City B
Team or ad-hoc group	4	4
Agency director	2	4
Elected officials	2	
Public health		2
Did not articulate a decision maker	2	

5. Cities had a significant event that initiated their preparedness with a multiagency focus.

When asked if there was a significant event that changed their process to prepare for and respond to an event, all informants in City A cited the preparation for a NSSE. Several informants referenced the 18 month preparation allowed them to plan and build relationships that were not previously there. Two informants credited training held outside of the city where plans and response could be tested without distraction as a benefit to building their relationships. It was mentioned that this training allowed them to see how each other would handle themselves under a little bit of pressure. One informant mentioned the preparation allowed the city to plan for reality instead of theoretical threats.

> *The [NSSE] was our chance to really go from talking in the abstract to talking in the particular. It forced us to say what is the difference between three people puking and three hundred thousand people puking? How do you isolate all the [distinguished visitors]? We had sick [distinguished visitors] and we dealt with them. How would you do it if there was a bad thing that happened? It was great. It was a wonderful thing.*

One informant, in City A, also identified pandemic influenza planning as an opportunity to improve their preparedness. Another informant noted that there is continuous adjustment that comes from lessons observed in responding to local events. Responses to events such as suspicious powder or air traveler health alerts, have provided opportunities to learn and make their processes better.

Half of the key informants in City B indicated that a bomb threat in their courthouse initiated change in their processes. The threat was initiated by a disgruntled citizen who walked into the courthouse with a suspected bomb with a weapon of mass destruction (WMD). Informants identified the following gaps that led them to the realization that they were unprepared for a significant event in their city:

- The disgruntled citizen was able to access the city facility with a bomb
- The guards did not have PPE
- There was no way to identify if the disgruntled citizen had a real threat
- Responders had no knowledge of WMD
- They took inappropriate action to deal with a bomb. For example, they set up their command post across the street from the courthouse where they would have been in the blast zone if the bomb was detonated.

One informant further described frustration when city responders were told to step aside by an outside organization that had a specialized team to deal with events of this nature. He revealed that city responders got very territorial and realized they needed to improve their capabilities.

Three informants, from City B, said that all the events that they have responded to have provided them with opportunities gaps that they have used to improve their preparedness and response capabilities. Snowstorms, disease outbreaks, and H1N1 were cited as examples of events that identified problems which they have since corrected.

6. The 2009 H1N1 pandemic experience tested response and identified lessons learned.

The interviews with informants took place during the initial response to H1N1. All seventeen informants referenced this event at some point during the interview. Thirteen of the informants mentioned something that their city did during H1N1. These actions included media releases, conducting daily teleconferences, notification of cases, stand up of emergency operations centers, receipt of the Strategic National Stockpile, use of PPE, and implementation of plans. One informant said H1N1 tested the hard work that had gone into planning for an influenza pandemic.

> *Now H1N1 was a beautiful prompt. Let me tell you, we had so many calls about it. Are we supposed to implement our continuity of operations? It was pretty cool to watch. All these planners suddenly had a chance to dust off their plans and I can't say how many managers called. While they were calling their continuity of operations people say okay this isn't a drill anymore.*

Ten informants compared H1N1 to how they would respond to a future outbreak or had responded to a previous outbreak. Informants also identified the lessons they have observed from H1N1:

- Realization that plans may need to be tweaked but not completely rewritten
- Receipt of SNS requires logistics to include a never before anticipated storage of medical countermeasures
- A plan is needed to decontaminate equipment to include emergency management vehicles
- It is important to provide risk communication to the public to avert panic
- It is beneficial to establish early relationship with the state through the ICS to rapidly share information and resources
- Information overload is a reality, making it difficult to get the appropriate information needed to make decisions.

Predicted and actual patterns.

Prior to the study, predictions were made about the patterns that would emerge from Aim 3. The predictions included both city differences and differences in professions. Below are the predicted pattern (italics) followed by the actual pattern.

1. Decision makers will come from different professional backgrounds.

Yes, decision makers identified by the cities came from different professional backgrounds including health care, public health, public safety, emergency management, and education.

2. Decision makers in City A have been involved in planning for a public health emergency.

All informants indicated some level of planning within their city. City A identified NSSE preparation as their driver for multiagency planning. A majority of informants in City B noted that their planning was initiated by a bomb threat in their court house. The primary push for City B's planning came 10 years prior to City A's execution of the NSSE.

3. There is less variability in the types of data, sources of data, and confidence in the data received by decision makers in City A.

No specific data type or data sources were identified by the majority of informants in either city. The most frequent type of data was a "heads up" personal notification. Response partners and the local health departments were the most frequent responses given when asked to name data sources that were utilized in their city.

More key informants in City B expressed confidence in receiving data to take action during a no-notice infectious disease outbreak. City B also noted more confidence in receiving data in a timely manner.

4. Decision makers in City A take action more rapidly.

A majority of informants from City A implemented an intervention one day sooner in the scenario that identified the disease. In the second scenario, where there was no clinical diagnosis of disease, City B informants implemented interventions earlier.

5. Decision makers in City A have a defined process for responding.

In City A, the BioWatch standard operating procedure initiates follow-up testing and a conference call with responders (to include the CDC). This was the only protocol or defined process for responding. Once this was accomplished, key informants in City A did not identify a defined process for responding. Key informants from both cities noted that response is situationally dependent on the event.

Aim 4

Determine the effectiveness of the timing for taking action.

The execution of the national TOPOFF 3 (Top Officials) exercise identified a significant gap in modeling epidemiologic predictions of infectious disease to be used during a crisis event such as a terrorist-generated pneumonic plague release in the United States. It was realized that the uncertainty during this type of event makes planning and response operations difficult. This realization led to the development of requirements for a new type of epidemiologic model that could provide predictions and analyze courses of action rapidly for decision makers. In model generation, a need was defined for the capability to run models quickly with limited data as all the characteristics are typically unknown in the early hours/days of a crisis. Figure 4.1 diagrams the concept of using epidemiologic modeling in an operational response to better inform decision makers. An example of this concept using a pneumonic plague outbreak is diagramed in Figure 4.2.

Figure 4.1. Concept Diagram Using Epidemiologic Models to Inform Decision Maker Actions.

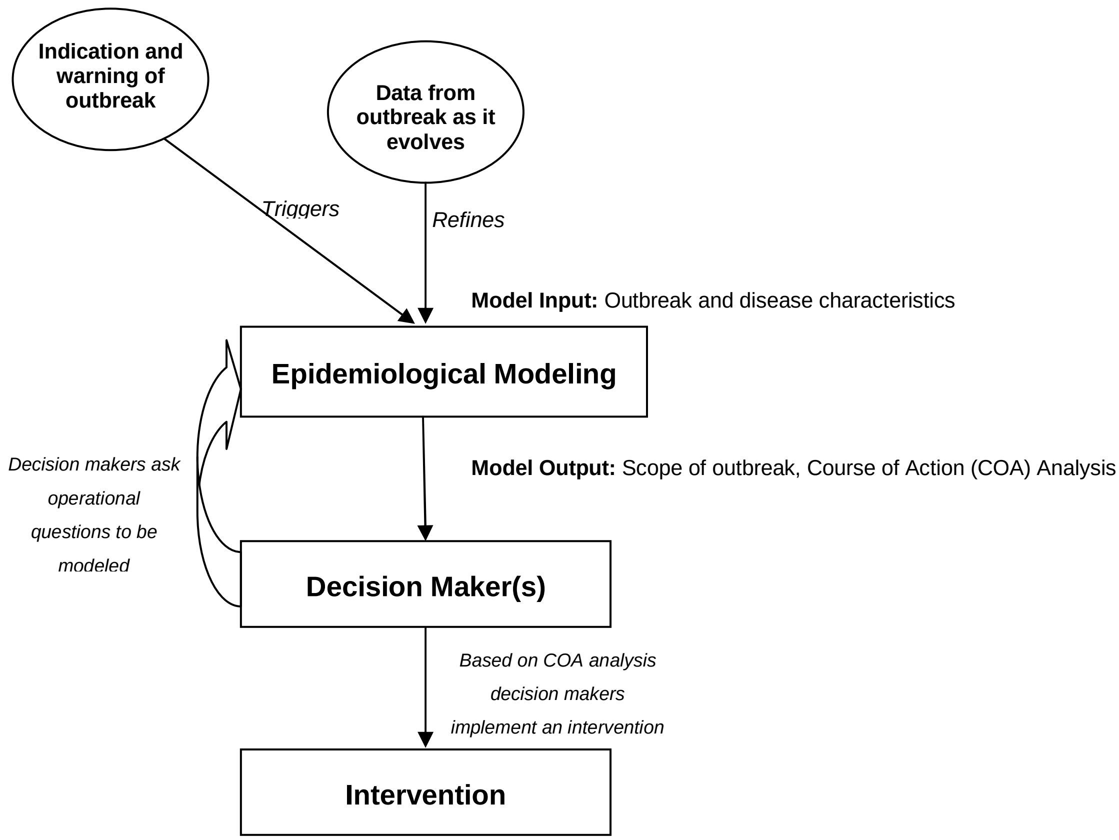
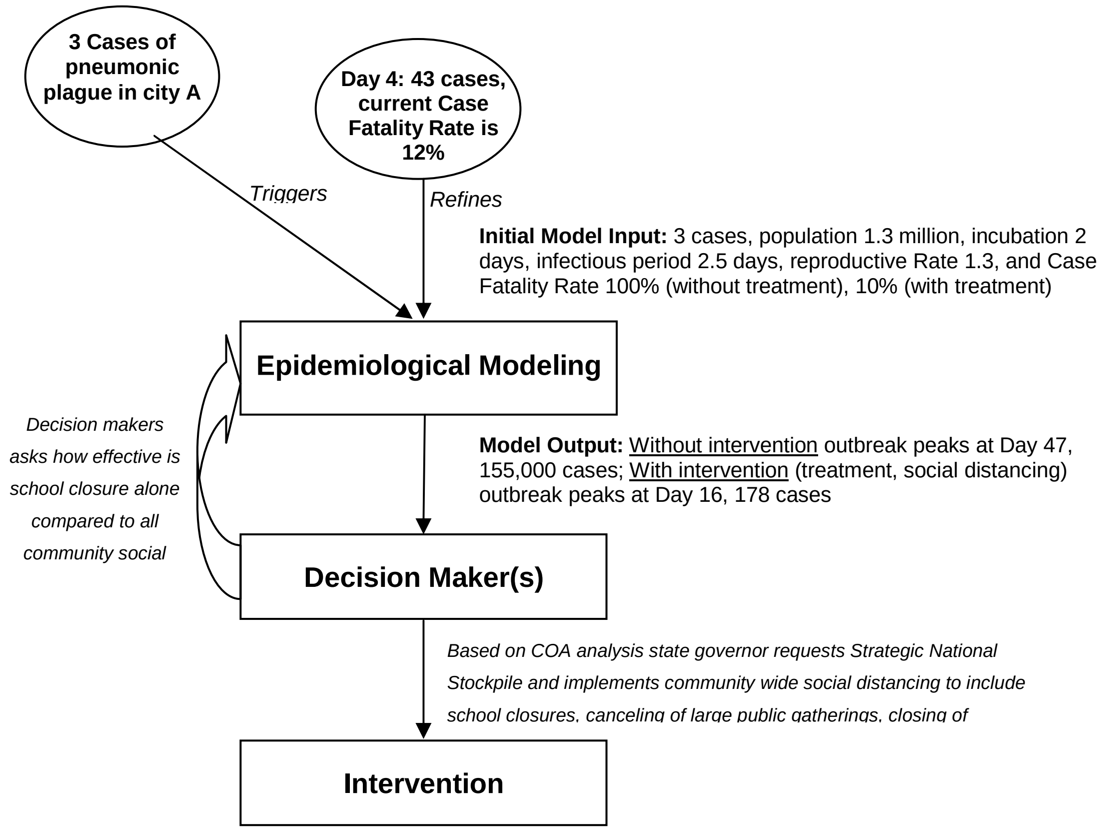


Figure 4.2. Example Diagram Using Epidemiologic Models to Inform Decision Maker Actions.



Based on this concept, the primary requirements generated were:

- Ability to provide disease burden predictions,
- Analyze courses of action,
- Run models within 4 hours,
- Function with limited data, and
- Describe the geographic spread of disease.

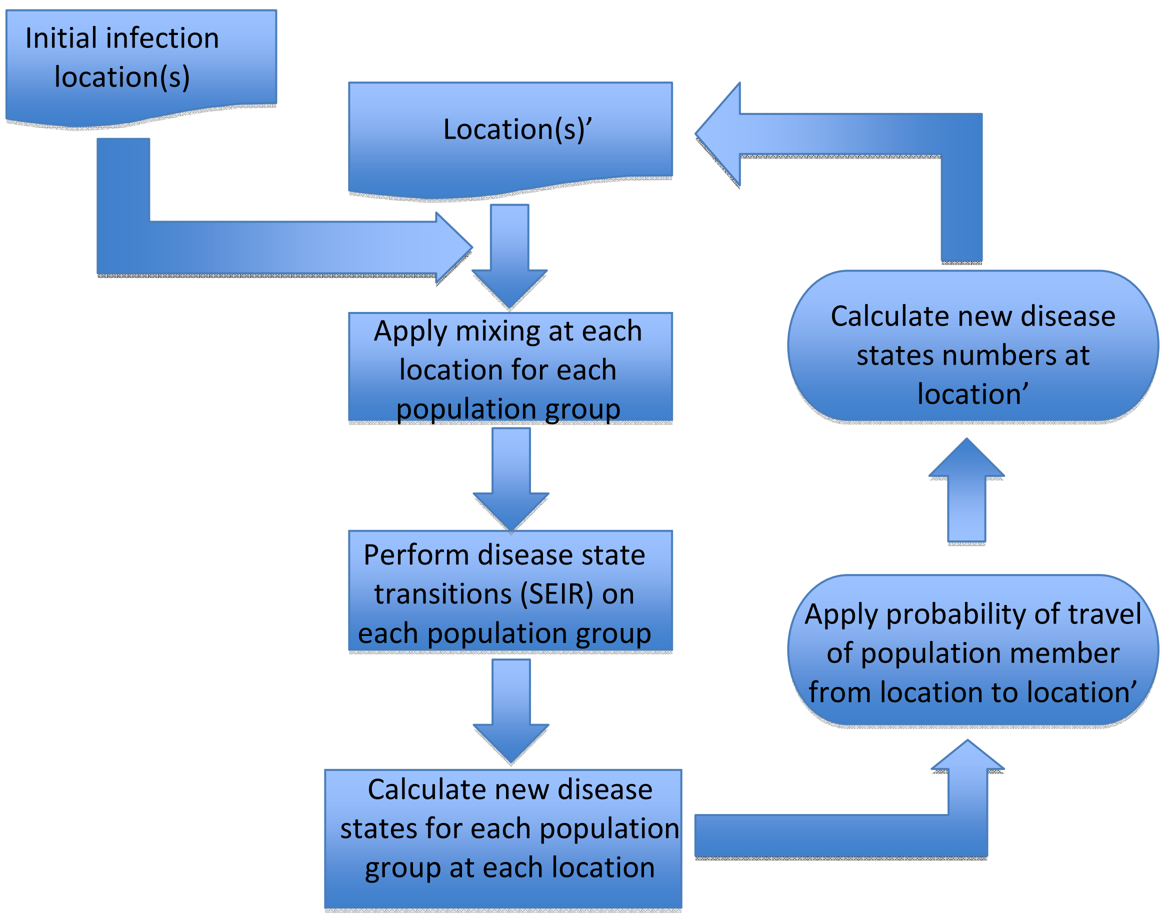
These requirements were used to build an agent-based models and a model simulator to provide rapid, multi-run modeling capability that could be reconfigured as new or revised data were collected (See Appendix F). The capability allows for dynamic analysis required during a crisis as opposed to traditional steady state epidemiologic modeling that needs considerable data and significant run time for analysis. These traditional models are typically used for research or retrospective studies. This model was going through beta-testing and validation while being used for this study.

The model utilizes the Susceptibility-Exposed-Infectious-Recovered (SEIR) disease states to generate the amount of burden in populations. The transitions between the four SEIR states are defined by algebraic functions that describe transition rates and probabilities that individuals or groups mix and become ill based on their movements. The model also allows for intervention strategies to be applied to individuals or groups in the population by changing probabilities. For example effective treatments will change the probability of movement from the infected (I) to recovered (R) disease state based on the therapeutic value of the treatment with respect to the specific disease.

Other examples of probability changes include the movement of individuals or groups of the population from one geographic location to another where the disease is more prevalent, probability of individuals moving from morbidity to mortality, and probability of individuals complying with intervention strategies.

Figure 4.3 diagrams the model as it moves through the simulation. The *location'* is geographic with a known number of individuals in the population (e.g. Hawaii, population 767,300). The initial infection *location* is where the disease cases begin (e.g. Honolulu seeded with 5 cases of disease). The seeded cases are inserted in a specified location where the mixing of populations is modeled. From here, each individual or homogeneous group of individuals is placed into one of the SEIR disease states. Based on the mixing of the population, which occurs randomly, SEIR states are calculated for each individual or group based on probabilities for the disease that is being modeled. For example, a susceptible individual may come in contact with an infected individual moving them into the exposed disease state. When disease states have been assigned, the simulator applies a second probability that the individuals or group of individuals will travel to other defined locations. After the movement occurs, disease states are reassigned, which could move our example individual from exposed to infected. At this point, the modeling cycles starts again.

Figure 4.3. Diagram of Epidemiologic Model Used for Prediction and Course of Action Analysis.



This model was used to run the two no-notice infectious disease scenarios provided during the informant interviews in Aim 3. The epidemiologic characteristics of pneumonic plague and SARS were defined by reference literature. [28, 101-104] Parameters used fell within the ranges identified in the references and served as inputs for the model runs (See Table 4.11)

Table 4.11. Epidemiologic Characteristics and Parameters Used as Inputs for Epidemiologic Modeling

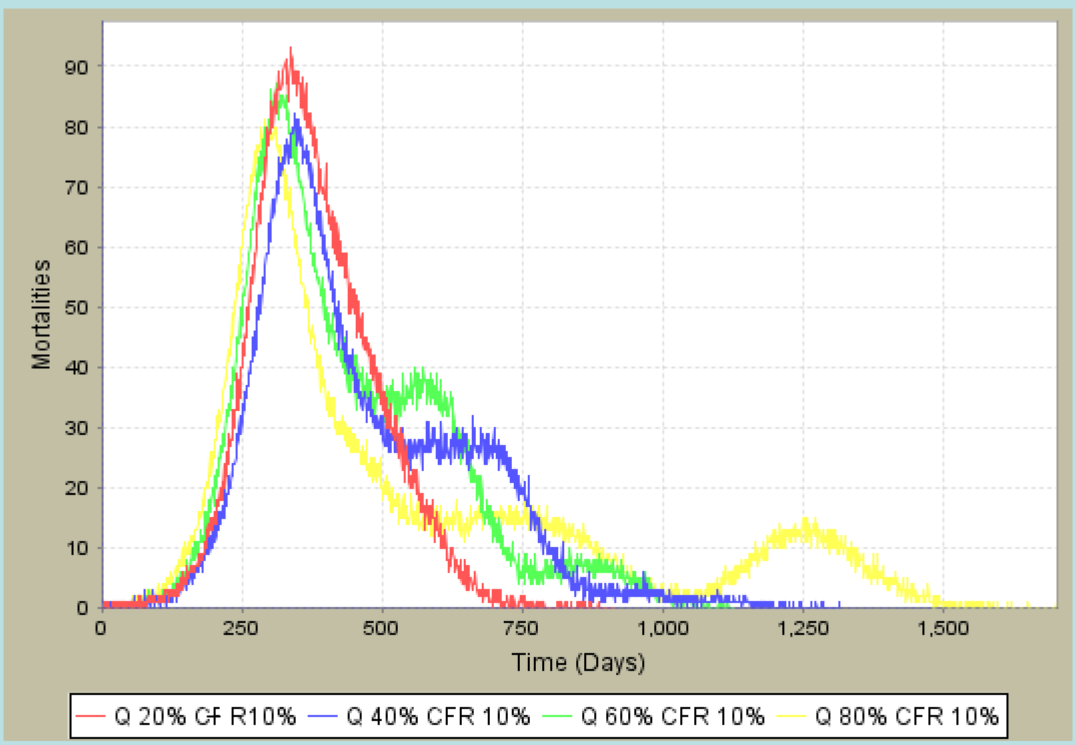
Characteristic	Parameter
Pneumonic Plague	
Incubation Period	2.0 Days
Infectious Period	2.5 Days
Reproductive Rate	1.3
Case Fatality Rate	100% without treatment; 1% with treatment
SARS	
Incubation Period	4.5 Days
Infectious Period	10 Days
Reproductive Rate	3
Case Fatality Rate	15%

After the model runs to predict disease burden without intervention were accomplished, intervention strategies were modeled to identify optimal Courses of Action (COA) and timing for intervention. The model output and subsequent analysis highlighted a difference between expected and actual results. Further discussions with committee members lead the investigator back to the primary developer/modeler in an attempt to find explanations for the results generated. Upon further review, it was determined that the model had flaws in the algorithms when calculating disease burden for certain Case Fatality Rate (CFR) parameters and when applying intervention strategies. Results from both scenarios are provided below followed by a discussion of the model flaws identified during this study.

Model output for plague scenario.

Treatment was applied to individual cases when they were identified as infected and social distancing was applied at 20%, 40%, 60%, and 80 % compliance. Social distancing was accomplished by decreasing the probability that any individual will come in contact with any other individual. Graph 4.1 shows how the combination of interventions affects the morbidity in the modeled outbreak. Treatment was provided to patients with 90% effectiveness for all runs. As expected a 80% compliance rate and treatment combination was the most optimal COA.

Graph 4.1. Comparison of Treatment and Social Distancing at Varying Compliance Percentages.



Where: Q% = Social distancing at % compliance
CFR 10% = Treatment given decreasing Case Fatality Rate to 10%

The investigator used a 60% social distancing compliance rate to determine how the delayed start of social distancing, as the only intervention, affected the morbidity in the population. Each simulation ran separately as noted by the difference in Days of Simulation output however a model flaw created a consistent negative morbidity and equal mortality numbers for the peak day of the outbreak (See Table 4.12). It was expected that morbidity would be varied with an optimal day for implementation being apparent based on morbidity and mortality numbers.

Table 4.12. Comparison of Social Distancing with a 60% compliance rate implemented at different days after initiation of outbreak.

Social Distancing Compliance (60%) / Day Implemented	Number of Days Until the Epidemic is Over	Morbidity on Peak Day of Outbreak	Mortality on Peak Day of Outbreak
Social Distancing (60 %) / Day 1	14	-115	237
Social Distancing (60 %) / Day 2	16	-115	237
Social Distancing (60 %) / Day 3	11	-115	237
Social Distancing (60 %) / Day 4	17	-115	237
Social Distancing (60 %) / Day 5	11	-115	237

Graph 4.2 visualizes a portion of the table above displaying the mortality given an intervention of social distancing at 60% compliance with varying days of implementation. It was expected that the peak day of mortality along with subsequent days would be varied between the implementation start days. The graph shows that the varying implementation days produce the same mortality numbers which added to the suspicion that the model had flaws.

Graph 4.2. Comparison of Social Distancing with a 60% Compliance Rate Implemented at Different Days After Initiation of Outbreak.

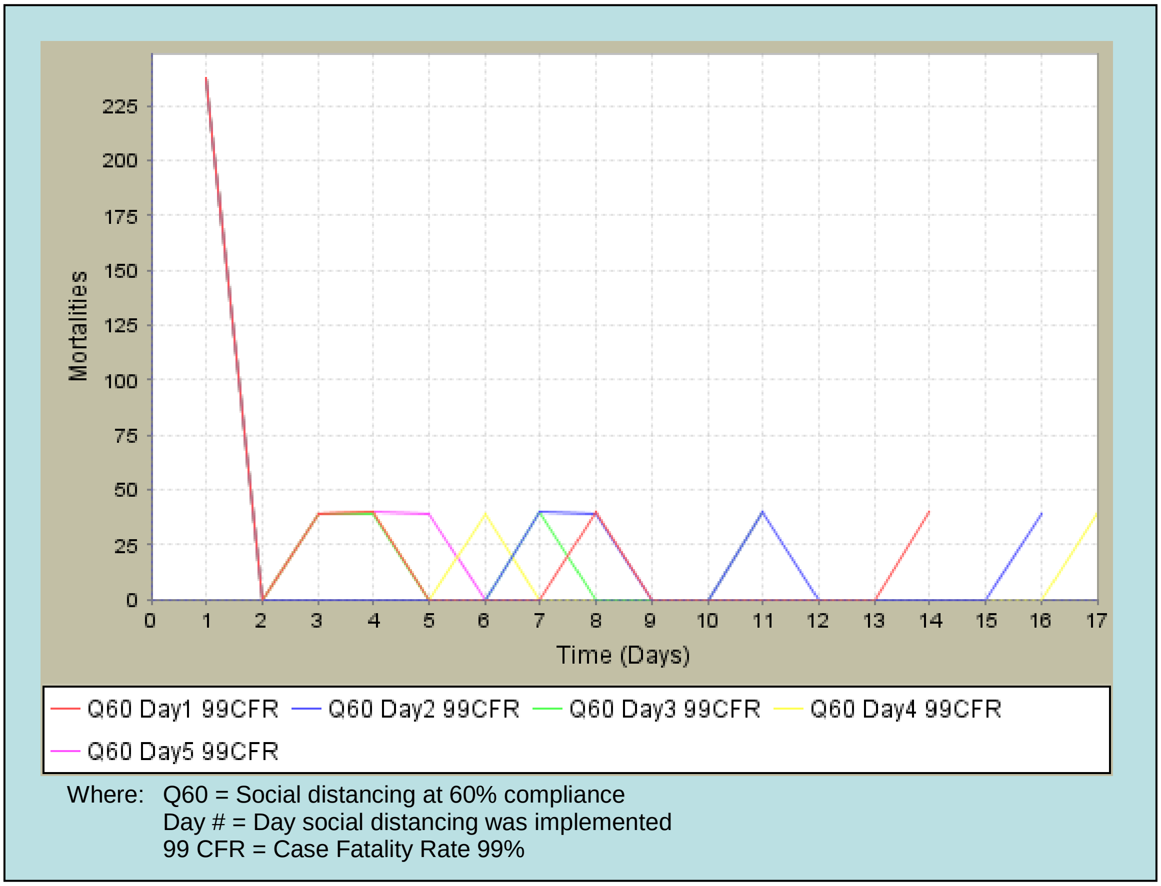


Table 4.13 provides model output for the combined application of social distancing at 60% compliance at varying implementation days and treatment provided to those who are identified as infected. The investigator anticipated the model output would have different mortality numbers with one implementation day standing out as optimal. While the combination of treatment and social distancing on day 1 appears to be the optimal choice, the generation of same result for days 2 – 5 is suspicious.

Table 4.13. Comparison of Treatment and Social Distancing with a 60% Compliance Rate Implemented at Different Days After Initiation of Outbreak.

Treatment Provided and Social Distancing Compliance (60%) / Day Implemented	Mortality on Peak Day of Outbreak
Treatment & Social Distancing / D1	89
Treatment & Social Distancing / D2	237
Treatment & Social Distancing / D3	237
Treatment & Social Distancing / D4	237
Treatment & Social Distancing / D5	237

Model output for SARS scenario.

Only social distancing was applied to the SARS outbreak since no treatment or vaccine existed during the outbreak in 2003. The first model runs varied the compliance of social distancing at 20%, 40%, 60%, and 80 % (See Table 4.14). It was expected that compliance at 80% would reveal the best result. This was true for the morbidity however the 20% compliance rate showed the best result in the mortality output. Another unexpected result was that no intervention generated the second lowest mortality. Even after multiple model runs, there was no obvious trend that a higher rate of compliance resulted in optimal output. These results heightened the investigators awareness that an error in the model existed.

Table 4.14. Comparison of Social Distancing with Varying Levels of Compliance Rate.

Social Distancing % Compliance	Number of Days Until the Epidemic is Over	Morbidity	Mortality
Social Distancing 20%	376	35765	1180
Social Distancing 40%	376	37003	1330
Social Distancing 60%	434	36157	1299
Social Distancing 80%	441	32782	1242
No intervention	379	37056	1227

Like the plague model runs, social distancing for the SARS runs were held at 60% compliance while the day of implementation was varied (See Table 4.15). Although it may be feasible that implementation of social distancing on the fourth day could be the most optimal, the minimal difference in the output during repeated runs echoed concerns from the plague results.

Table 4.15. Comparison of Social Distancing with a 60% Compliance Rate Implemented at Different Days After Initiation of Outbreak.

Social Distancing Compliance (60%) / Day Implemented	Number of Days Until the Epidemic is Over	Morbidity	Mortality
Social Distancing (60%) / Day 1	447	34088	1226
Social Distancing (60%) / Day 2	439	34358	1235
Social Distancing (60%) / Day 3	419	34232	1230
Social Distancing (60%) / Day 4	440	34054	1224
Social Distancing (60%) / Day 5	420	34545	1242

Model flaws.

The first model issue identified is a defect in the software based on an incomplete understanding of how to apply SEIR differential equations. When the CFR for a disease is high, the model calculates a negative morbidity. The CFR for plague is .99 to 1.00 without treatment. [102] When the scenario was modeled with a) no intervention and b) social distancing only the morbidity output was a negative number. Due to the flaw, disease burden could not be calculated and comparison of interventions was not feasible.

The second issue was a flaw created during the assignment of disease states (SEIR), once the probability that a person in a SEIR category moves from one location to another location. The algorithm incorrectly assigned disease states of individuals coming in contact with others. This creates miscalculation in the effectiveness of social distancing among the populations. Effectiveness and optimal timing for social distancing could not be determined.

Due to the flaws in the algorithms, it was determined that the model in its current state could not be used for the plague and SARS outbreak scenarios. If the model had run optimally, the investigator would have expected to use the results to provide COA analysis to the informants to assess how they would use the data to potentially alter their decisions to mitigate disease in their city.

Use case for utilization of epidemiologic models in decision making.

Due to the model flaws the output was not provided back to the key informants to understand if the data would alter their decision making. The following use case (i.e. description of interaction between user and system) has been provided to demonstrate the utility of epidemiologic modeling in decision making during a no-notice infectious disease outbreak. Three decision making cycles are presented with each containing: a) a description of the indication and warning of events, b) epidemiologic model output, c) analysis of model output, and d) the decision maker's actions for each cycle. The example sequence starts with the identification of disease cases which triggers epidemiologic modeling. The starting parameters of the use case are ten cases in a city of 377,925 individuals with epidemiological parameters that resemble influenza.

Decision making cycle 1.

Indication and warning of disease: 10 infectious diseases cases identified in city A. Policy question, "Is social distancing an effective strategy to implement to reduce disease burden in this city?"

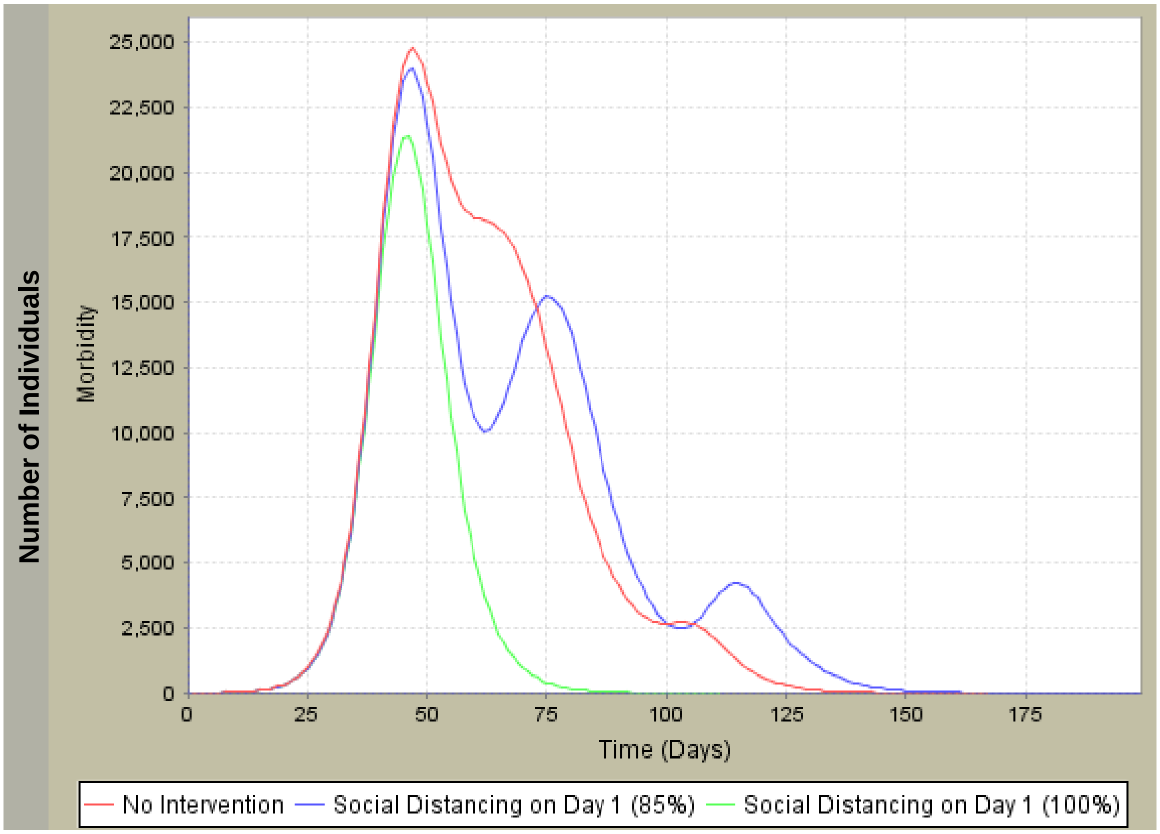
Epidemiologic modeling: Graph 4.3 displays the affect social distancing (i.e. limiting individuals from coming in contact with one another) has on the outbreak by comparing no intervention with social distancing measures applied with 85% and 100% effectiveness implemented on day 1 of the outbreak.

Analysis: This data indicates that social distancing is an effective strategy that will lower the number of overall cases in a community. It demonstrates that 100% social distancing is the most effective target to obtain. Based on logistics and human behavior, 100% compliance may be an unreasonable so a target of 85% could be chosen as a more realistic goal.

Decision maker action(s): Decision makers chose two activities that are based on the model output and analysis. They are:

> *Intervention:* Decision maker directs planning for immediate implementation of social distancing by closing city schools, restaurants, entertainment venues, and large gatherings.
>
> *Additional modeling:* Decision maker requests modeling the affects social distancing has when implemented on days 1, 5, and 10 of the outbreak. Policy question, “If we are unable to implement social distancing until day 10, is it still worth it?”

Graph 4.3. The Affect Social Distancing, with 100% and 85% Compliance, has on the Overall Disease Burden in City A



Decision making cycle 2.

Model request: The model was run with social distancing implemented on different days after the initial identification of cases to determine the impact on overall disease burden. Output of the model run is reflected in Graph 4.4.

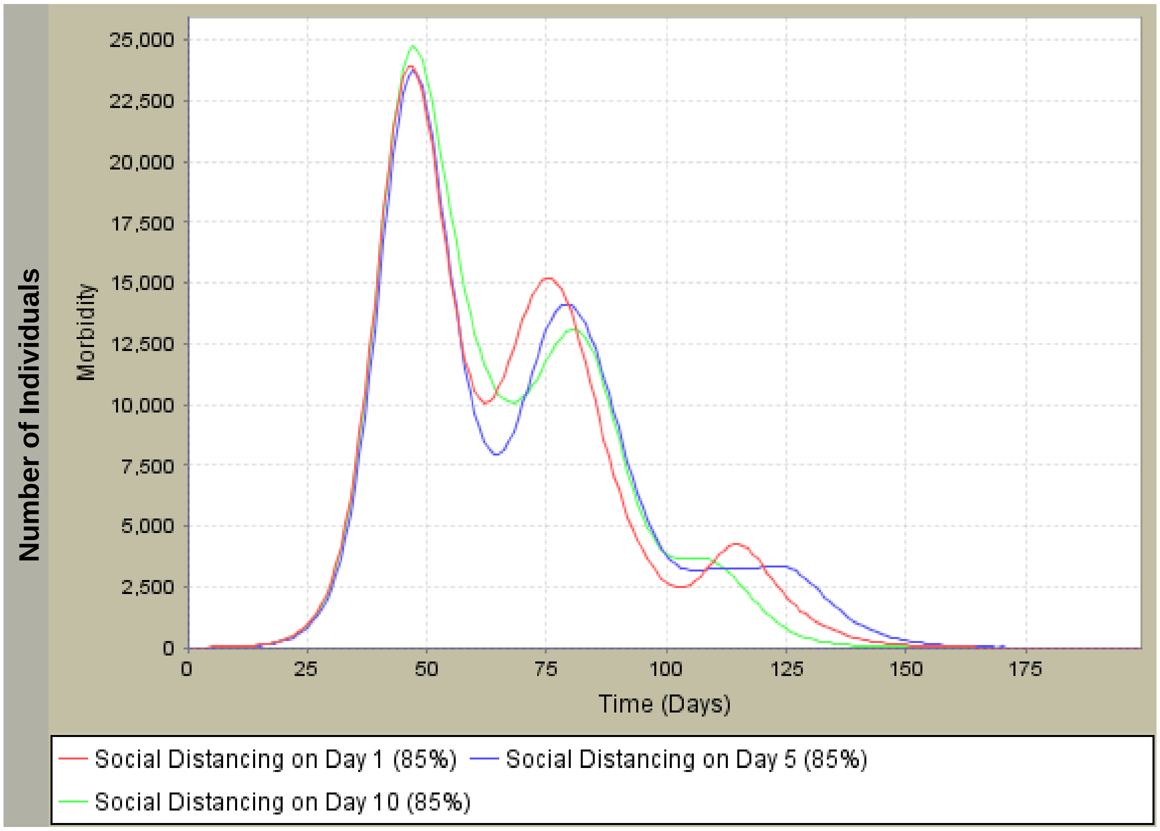
Epidemiologic modeling: The model output indicates that social distancing with 85% effectiveness remains valuable if implemented on day 1, 5, or 10 (See Graph 4.2). The displayed model runs showed the difference in overall disease burden between the three different implementation days was 1,172 cases.

Analysis: These data indicate that social distancing is an effective strategy to implement even if it is delayed until day 10. This delay may be a reality due to the logistics of implementing city wide social distancing measures.

Decision maker action(s):

> *Intervention*. Decision maker directs implementation of social distancing for the city by closing schools, restaurants, entertainment venues, and large gatherings as soon as possible.
>
> *Additional modeling.* Decision maker requests modeling of the impact of treatment from the city pharmaceutical stockpile on the overall outbreak. Policy question, "Should we treat only our population or share our stockpile with neighboring cities to treat their populations?"

Graph 4.4. Comparison of the Affect Social Distancing has on the Overall Disease Burden in City A when Implemented on Day 1, day 5, and day 10



Decision making cycle 3.

Model request: The model was run to compare treatment of cases in City A only and treatment of cases in Cities A, B, and C. Output of the model run is reflected in Graph 4.5.

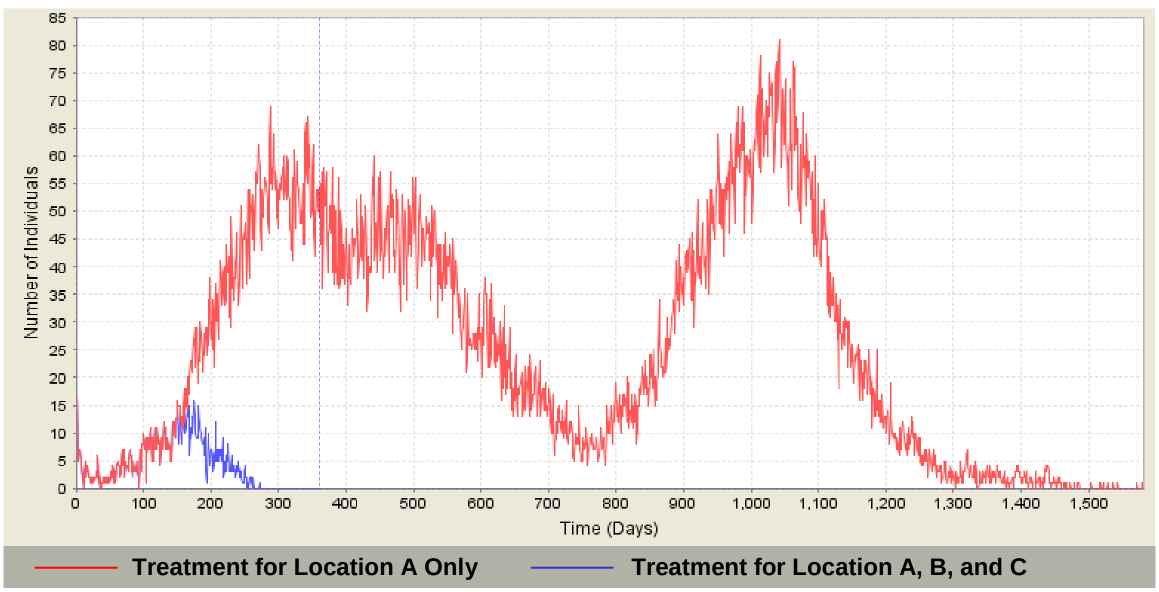
Epidemiologic modeling: The model output indicates that in an environment where there has been no border closing between cities, treating only cases in City A will result in secondary waves of disease. If treatment is provided for all cases in cities A, B, and C the outbreak will subside in all three cities.

Analysis: The resurgence of cases in city A is due to the populations of cities B and C infecting susceptible individuals in city A as they interact. Providing treatment to all cases in all three cities is the most effective strategy to ending the outbreak.

Decision maker action(s).

<u>*Intervention*</u>*:* Meet with decision makers in cities B and C to determine their available treatment supply. If their supply is limited, determine how much will be required and if it is feasible to share City A's stockpile with cities B and C.

Graph 4.5. Comparison of Number of Individuals Infected by Treating Cases in City A Only and Treating Cases in Cities A, B, and C



CHAPTER V: DISCUSSION

The primary dissertation question for this study was to determine the effects early biological detection data had on decision makers' action to minimize the consequences of no-notice infectious disease outbreaks. To fully understand the decision makers and the data available to assist in making decisions, several strategies -- SME interviews, document review, key information interviews, and epidemiologic modeling -- were employed.

The goal of SMEs interviews and the document review of past outbreaks were to provide insights on the characteristics of outbreaks to include understanding the successes and failures of the responses. This provided information to build realistic scenarios used in key informant interviews. These interviews were performed to determine how decision makers respond in a no-notice infectious disease outbreak, as well as comprehend their process for making decisions, what information they needed, and how data affects their decisions. The data provided an opportunity to compare a city with and a city without early biological detection capability. Finally, the goal of epidemiologic modeling was to better understand how the timing of interventions affected disease burden and an analysis of what public health interventions could mitigate disease. The results can be summarized as follows:

1. Data from the early biological detection system did not support decision makers' actions. Other formal and informal data and information does inform decision makers.

2. The strength of a response comes from relationships built by decision makers in multidisciplinary networks and planning or responding to events.

3. Decision makers come from multiple agencies and disciplines.

4. The media is a factor which should be embraced, planned for, and included in testing response.

5. Operational epidemiologic models would be a beneficial addition to the toolkit of responders. Improvements and validation of models should continue.

Cities across this country face an ever increasing set of biological threats to their communities. The hazards come from emerging and reemerging agents, as well as vaccine preventable diseases delivered by Mother Nature or by terrorists. This post 9/11 environment has contributed to the unprecedented amount of concerns we face. In an attempt to minimize human suffering there have been efforts in policy and funding to create early indications of disease. Homeland Security Presidential Directives 10 and 21, as well as the Pandemic and All Hazard Preparedness Act, are the primary drivers to move toward capabilities that would warn of disease early in order to provide rapid prevention, treatment and mitigation of a significant outbreak. [105-107] Since 2001, administrations have attempted to increase preparedness by providing $54.39 billion. The Obama administration proposed $6.05 billion in support of FY2010 biodefense activities. [108]

This study assessed the value of an early detection system, BioWatch, to determine if the capability triggered actions by decision makers to protect their citizens. BioWatch is one of the biodefense activities that has been funded with Department of Homeland Security management. The FY2010 proposed budget for this BioWatch is programmed at $94.5 million to support baseline capabilities for first- and second-generation collectors, support field testers, and procure third generation systems. [108]

In this study, the BioWatch system did not prove to trigger informants to implement public health measures upon notification of a BAR. Specifically, in the scenario using BioWatch as the alarm to indicate disease, informants from City A, who have the sensors, did not implement any interventions when the BAR occurred. Five of the informants did indicate an intervention on the subsequent day (day 2) of the scenario triggered by suspect cases identified in the clinical care system. Only one of those five indicated that the BAR, along with the suspected cases and the nature of the disease, would trigger them into an intervention. Of the interventions mentioned on day 2, four informants stated holding a press conference and one described dispensing medication. These results are contrary to the stated purpose of BioWatch, which is to identify a biological threat and treat exposed persons. [109] By comparison, half of the informants from City B noted that they would implement an intervention by day 2 also. City B does not have the BioWatch system.

To reinforce the scenario findings, informants in City A did not mention BioWatch as either a data type or data sources when asked what types and sources of date would alert them of a potential infectious disease outbreak. This was a surprising response, as the system's mission describes the capability as an early warning system to detect aerosolized biological agents in order to speed response and recovery efforts. [109]

Furthermore, informants in City A referenced that the system has alarmed several times across the nation without actually detecting a single concerning event since its origination in 2003. The system did alarm during the NSSE held in City A, which created frustration and miscommunication between local, state, and federal responders over an environmental agent endemic to the region. [110] Like the incident in City A, the BARs across the country have typically been the result of organisms that already exist in the environment. Policy questions regarding maintaining or expansion of the program need to consider the results of the program to date, the complicating factor of endemic agents, and what the expectation is of decision makers when they receive warning of a biologic agent in their community. Does the system provide benefit to a city detecting low probability/ high consequence threats or does it result in extra effort and time wasted by the local responder community only to prove no threat exists? Unofficial sources have cited the annual cost of the system at $1 million dollars to operate in each city. [111]

The architecture for this system was designed to detect a large biological release, outside in the specific geographic locations where the sensor resides in approximately 30 cities in the United States. It should be questioned if this architecture is best suited against the threat the nation faces which may be small releases in a variety of venues which includes smaller urban areas, inside buildings or in underground transportation systems. Are there better means of detecting biological threats? Ultimately it comes down to a cost benefit analysis which will determine if the juice is worth the squeeze. On the other hand, the existence of a detection system may serve as a deterrent to terrorists to release biological weapons of mass destruction. Is that worth $94 million dollars?

As expected, this study confirmed that data and information are important to making decisions to implement interventions during a no-notice infectious disease outbreak. The discovery from the findings was that informal, in addition to formal, data shared between trusted colleagues may serve as an early indicator of an outbreak.

It was particularly informative that informants primarily identified personal notifications as both a data type and a data source. Both cities conveyed a sense of trust in their partners to inform them of something that appeared out of the ordinary. In City A, this confidence was shared by those informants belonging to the public health and medical communities. In City B, however, the sense of sharing information as a “heads up” was referenced consistently by all types of responders including the informants representing primary and secondary education systems. All of these personal networks were informal in nature and appeared to function with ease and little or no evidence of “turf” issues.

During the scenarios, informants consistently identified the numbers of cases and deaths, throughout the days of the scenario, as a trigger to implement an intervention. For the plague scenario the number of cases each day served as a trigger consistently in both cities and among professionals. On day 3 of the scenario plague was confirmed as the biological agent creating the outbreak. This information was identified as a trigger by public health and medical professionals in both cities due to the nature of the disease. The SARS scenario did not name the disease but only characterized the event to the informants. Death was noted as a trigger on the first day of the scenario by public health and education professionals. The education professional’s trigger was due to the fact that the death was on the college campus. During the second and third days of the scenario informants from both cities indicated their trigger for an intervention was based on rising case numbers and the nature of the disease which appeared to be infectious. On day four of the SARS scenario informants were told that the media was reporting on the event. This information triggered EMS, law enforcement, and emergency operations professionals to take action based on the public reaction of the outbreak.

When informants did not trigger an intervention on a particular day, they noted that they would need additional information before they took action. Information requested included intelligence, laboratory results, epidemiologic characteristics, and clinical data.

From the data provided it is apparent that number of individuals affected (morbidity and mortality) serves as trigger for implementation of interventions. In addition, public health professions are motivated to apply interventions due to the nature of particular diseases. Professionals with daily public interaction highlighted public reaction as a trigger for their intervention. This leads to the need for early communication with the media to assist in communication with the public without the creation of fear.

Interestingly, informants also looked for guidance from other places such as another agency or higher level of government. It is common sense to assume that professionals from law enforcement look to the public health professions for an infectious disease outbreak; however, it is unclear the reasons why they requested guidance from a higher level of government. I was surprised by this, considering SMEs were present in both communities to offer guidance on the outbreak. Perhaps this was a result from a culture of professional courtesy, or possibly, it has formed from lessons learned over the years. Another explanation may be the potential need for the advanced capability and resources that reside in state and federal agencies, which may drive locals to involve them early in a response.

Responses to questions related to the types and sources of data that exists in their community revealed that there are numerous types of data that come from a variety of sources. Informants did not uniformly identify a set list of data types or sources. Often the naming of a type or source was by only one individual which leads me to believe there is not a robust understanding of the data structure in either city. Secondly, the data types and sources are not necessarily linked to each other and they may be known to only a few in the community. Finally, the preponderance of responses only identified traditional health data as the primary means for finding an infectious disease outbreak.

These constraints pose a significant challenge for communities in getting early indications that a biological threat exists in their backyard. As an example, there may be hints of an infectious disease outbreak percolating in various traditional and non-traditional data streams. There may be two cases of disease with respiratory symptoms seen in Dr. Smith's Clinic, one admission to the hospital for upper respiratory illness, and an increase in the sale of over the counter pharmaceuticals. Additionally, law enforcement communities may have a report of a domestic terrorist threat that they have deemed not credible. Regrettably, none of these warnings would break their own respective threshold to identify a significant event; nor are they linked together to provide a responder a complete picture of what is happening in the city. In this example, fusion of data across disciplines would assist in completing the picture of potential health threats in a community. Perhaps this fusion is currently occurring informally through the "heads up" notifications as described by community partners. While this informal network was described as successful, it should be looked at to determine if it can be formalized to assure all appropriate decision makers are getting the right information, at the right time, to make the right decision.

Engagement of formalizing should be accomplished with mindfulness. The federal government has attempted it with the creation of the DHS led National Biosurveillance Information System. Unfortunately, after 4 years the system still lacks the definition of capabilities required for a successful nationwide biosurveillance system. [112] Based upon personal involvement, there have been too many stops and starts without accomplishing the initial hard work to design and develop a system that has been built to fuse data from a variety sources.

The results of this study point to the need for communities to understand what their information requirements are to support response in a no-notice infectious disease outbreak. Once that is accomplished, an identification of existing data types and sources should be mapped to determine gaps between required need and the current data architecture. These steps need to be closely followed by education and training initiatives to inform decision makers on the data available to them and how they can use the data to take appropriate action during a crisis.

Another finding from this study recognizes the importance of relationships in emergency preparedness and response. This reinforces the well known quote in preparedness communities that, "a disaster is no place to exchange business cards"; meaning it is easier to respond when you know each other before the incident. It was overwhelmingly apparent from the SME interviews, document review, and key informant interviews that relationships were beneficial to successful responses. These relationships occurred within professions and among multiple disciplines. It was evident that there is a trust associated with these relationships. Informants alluded to this trust when they described confidence in others' abilities based upon their expertise or a colleague's successful response to previous events. This concept of relationships was supported when questions regarding the decision making process revealed that a formal or ad hoc team comes together to make collaborative decisions. These decision making bodies were portrayed as teams made up of multiple disciplines and/or multiple agencies.

It was apparent that the genesis of these relationships and collaborative response approaches were driven by some event. Planning for the execution of a NSSE drove City A to build relationships in order to be prepared for a disaster. This was referenced by all informants during interviews and when responding to a question that asked for identification of a significant event that changed their processes for responding to a public health crisis. There were specific mentions and an underlying tone in other responses that relationships were not strong in the city prior to planning for the NSSE. Some informants stated that relationships were weak or even nonexistent prior to the event.

Informants divulged that this weak collaboration was, on many occasions, prohibitive to effectively responding in their community. The first issue associated with this was a perceived lack of confidence among responders. This was driven by not knowing the response players and a misunderstanding of roles. After the NSSE, informants noted that they got to know their response counterparts on a personal basis.

This, along with an understanding of what each other does, generated trust. It was noticeable that first names were used when positive relationships were discussed. Secondly, prior to the NSSE, the issue of turf was an inhibitor to the development of relationships. As an example, the development of protocols for response to a suspicious white powder event required professionals from the health sector, emergency services, and law enforcement. A lack of clear authority for these events drove differences in how agencies handled these incidents. The differences created frustration and the proverbial finger-pointing among agencies. Planning for the NSSE exposed these gaps, differences, and opinions for all to reflect and take appropriate action to fix potential problems that would be highlighted by the disaster in their city during the NSSE.

A real event instigated City B to improve response capabilities and build their relationships. A domestic terrorist entered one of their county buildings with a bomb which served as their wake-up call pre- 9/11. After the event, individuals from the various response organizations came together to brainstorm a better concept for response, developed a structure, and then sought federal dollars to fund their efforts. In addition to the real threat, this city seemed to be motivated to overcome the reality that they were not viewed by federal government officials as a city of significance that could be targeted for a terrorist attack like New York City or Chicago. Therefore, they had not received the funding or capabilities that large cities had post 9/11.

There is a strong vibe in this city that professions with response roles were a team that continuously watched out for another without question. Descriptors of their relationships included words like “proud” and “keys to success”. The city’s collaboration has been positively referenced as “unique” and “like no other place in the country”.

Based on the two cities, actual incidents and preparation for large events appear to serve as a forcing function for cities to build relationships, review plans, de-conflict roles, and test their capability against reality verses theoretical discussions. No one would advocate that actual disasters occur in our nation's cities to better prepare them for something worse. However, we can recommend that cities be selected to host exercises and self-nominate to host significant events to increase their capacity to effectively respond to a disaster. Fortunately, opportunities to implement this concept already exist.

It is rumored among homeland security professionals that over 4,000 preparedness exercises are conducted in the United States each year. At least one of these is a Tier 1 National Level Exercise (NLE) which is directed by the White House and mandates full participation by the U.S. Government. The physical location of the exercise event(s) always includes a city(s) located within the U.S. These cities are involved in exercise preparation 18-24 months prior to the exercise which gives them an opportunity to plan for and test their capabilities.

A second opportunity comes from hosting significant events. Large events may be given a Special Event Assessment Rating 1 or 2 rating, which indicates they may be a target for disaster. Subsets of these are designated as NSSEs based on three criteria; (1) anticipated attendance by dignitaries; (2) size of event; and (3) significance of the event. Some of these designated events consistently take place in the same location, such as the Presidential inauguration or the State of the Union Address in Washington, DC. Other events rotate to different cities. In the past, the Super Bowl, G8 summits, and the Democratic and Republican National Conventions have been hosted in a variety of cities. Each year there are a couple events that receive a high SEAR or NSSE designation. To host a designated event, cities must self-nominate and be selected. Unfortunately, many cities do not nominate themselves due to the cost of planning and execution. On occasion, there may be some federal financial support, but often it is too little and many times too late.

To improve nationwide preparedness we can take advantage of these already occurring exercises and NSSEs. DHS should consider selecting cities not previously used in a major exercise as the locations for upcoming NLEs. Secondly, the United States Congress should identify funding sources to increase the number of cities self-nominating to host NSSEs. These efforts would allow cities to increase their readiness and enhance relationship building which ultimately leads to a higher level of country wide preparedness.

Yet another finding revealed that decision makers who would respond to a no-notice infectious disease outbreak come from multiple disciplines. Even if the event is related to the health of the population, more than health leaders are involved in the response. This is a result of the activities that would be required to mitigate disease in the population. City emergency management directors identified decision makers came from public/environmental health, health care, public safety, and emergency management for a no-notice infectious disease outbreak. In addition, education systems were identified by City B as part of the decision making community even though they are not traditionally thought of as responders. It was outside the scope of this study to understand why they were considered decision makers for a public health response. However, considerations for their inclusion may be a societal concern that children should be protected or the significant impact a university population has on a community.

The results from key informant interviews identified that either pre-established or ad hoc teams are being used during response to make decisions. This team-based approach insures that all perspectives supporting a response might be heard and considered. An example of team based decision making is the establishment of mass vaccination clinics for a new virus, such as H1N1. The health director may identify the medical equipment and number of health professionals required. The police chief may offer suitable locations for the clinics based on public safety. Finally, the public transportation director identifies the use of city buses to assist in getting citizens to the clinics.

Decision makers are also established by the structure of the city. The cities studied had different structures that defined some of their decision making. In City A, the public health agency does not belong to the city but is owned by one of the health care systems. Another city agency must delegate the authority to the public health agency. Recommendations from the public health agency are brought to an ad hoc, multidisciplinary executive team, and possibly the mayor, for decision.

City B’s structure also had some uniqueness in their local structure. The EMS system and a significant portion of the county health department staff were employed by one of the local health care systems. Only health department staff members with regulatory or director positions were employed by the city.

Major decisions affecting public health (e.g. establish city quarantine) would be brought forward to city commissioners based on recommendations from the public health director or a team of emergency responders. It was noted that the recommendations were typically not deviated from by the commissioners, as none of them had a background in emergency response or public health emergencies.

Political leadership was not initially identified as part of the decision making community for a public health emergency in either city. Furthermore, the majority of informants did not include elected officials when describing the decision making process in their city. If elected officials were mentioned, it was only in terms of providing a “blessing” of recommendations brought forward by the response professionals.

This study also found that the media is a factor that cannot be dismissed or ignored during a public health crisis. Data from SME interviews, document reviews, and key informant interviews spoke to both the benefits and drawbacks of the media. The primary advantage of the media was their capability to rapidly disseminate information to the masses. Their primary detriment was revealed in their quest to deliver breaking news stories.

Informants repeatedly cited they would, and have used the media as an intervention to provide guidance to the public. Examples of this guidance included telling citizens what symptoms to look for, what preventive actions they should be taking individually, and when to seek clinical care. Informants referenced two reasons for utilizing the media early. The first was their capability to reach the entire community rapidly. This is intuitive since it is stereotypical behavior of the American public to turn to the media for information. The other driving factor cited was getting ahead of misreporting by the media. Informants felt engaging with the media at the outset of an outbreak would decrease the inaccurate or conflicting information that would be reported.

The media is part of our American culture that operates 24 hours a day, seven days a week, and 365 days a year. It cannot be avoided, so in the best interest of efficient response, it should be embraced. Organizations have made this realization and employ public information officers within agencies and cities to assure public messaging is accomplished in conjunction with response activities. Cities across the country have also established joint information centers, typically located within their emergency management departments, to coordinate the efforts of all responders, decreasing the potential for contradictory information and guidance to the public.

Finally, the epidemiologic model failure was a finding that allowed for documentation of IT flaws that limit its use in operations. A description of model runs, the intent of use in this study, and the flawed output has been documented and provided to the modelers both verbally and in writing. A description of the model failure has also been shared with the Department of Defense sponsor. Follow-up discussions with the modelers led to the creation of a proposal to fix documented flaws at an estimate of $810,000. A secondary $3.59 million proposal was developed to incorporate both the repairs and to build enhancements in the model. These proposals have been submitted to homeland defense and security agencies and are awaiting award.

Prior to knowing about the model flaws, all key informants were asked about their willingness to review epidemiological modeling output and assess whether their decisions to implement a public health intervention, in response to the scenarios, would change. All indicated they would participate in this phase of the study. Several commented that having a rapid modeling and analysis capability would be beneficial to have in their response toolkit.

A personal experience with recent operational epidemiologic modeling may provide insight that activity and advancement is worthwhile. On the second day of the 2009 H1N1 influenza pandemic, epidemiologists from U.S. Northern Command (USNORTHCOM) and the Department of Health and Human Services (DHHS) collaborated on modeling the potential disease burden with the information that was available. A 24 hour modeling cycle was created to account for the continual influx of new and changing data. Initially, only two models could meet the rapid turn around time to get updated data, run a model(s), analyze the output, and provide information back to the requesting agencies namely, USNORTHCOM and DHHS. As the outbreak progressed, additional models became available and the requesting organizations asked that modeling include COA analysis for public health interventions. This collaborative activity occurred for four weeks. As a member of USNORTHCOM, I can offer that the data were widely shared across the Department of Defense (DOD) to include the Secretary. Output and analysis was also requested by and provided to the White House Homeland Security Council. In the Command, the data were used by planners and operators to publish the military operation plan that was used to execute DOD response to the event. COA analysis was used by senior leadership in the Command to inform their decisions on implementing public health interventions and medical countermeasures.

The Department of Homeland Security (DHS) has also recently realized the need for this new and unique operational epidemiologic modeling capability. In late August of 2009, they posted a Broad Agency Announcement (BAA) for modeling capability during crisis situations. [113] The Department has initially allocated $2.5 million dollars to the effort with additional follow-on year option money available. This BAA is built on the requirement that products and services in support of crisis response need to be conducted in less than four hours to meet the leadership decision cycles. Awards will be announced in February 2010.

Conclusion

The purpose of this study was to determine if decision makers' implementation of public health interventions was affected by early biological data. The findings suggest that data from sensors designed to provide the earliest indication of disease did not serve as triggers for implementing a public health intervention to mitigate a no-notice infectious disease.

Early biologic detection data are critical to rapidly mitigating human suffering and loss of life during an infectious disease outbreak. Despite this finding, the results recognized that there are tools and activities that contribute to successful identification and response to a no-notice infectious disease outbreak. This study revealed that data may not only be found in formal sensors and electronic tools but could come from curious public health professionals, astute clinicians, or city responders.

Secondly, relationships were defined as a significant contributor to successfully responding to incidents. These relationships were established as the result of an incident or in preparation to host a major event in their city. In an attempt to increase nationwide preparedness, there should be dedicated effort to select cities to host NSSEs and serve as exercise locations in the National Exercise Program that have not previously prepared or been significantly tested.

Finally, the study offered a realization that there are different kinds of decision makers in a city that would be involved in response to a no-notice infectious disease outbreak. It was outside the scope of this research to understand the roles and effectiveness that these decision makers have.

Limitations

There are several limitations for this study and its findings. First, the documents reviewed may have lacked completeness of information or data describing the outbreak and response characteristics. There may have also been under-reporting of failures in response. Secondly, some outbreaks may have been unintentionally excluded if there was no published documentation of the event or its response.

The second limitation was identified during the SME interviews. Two SMEs were intentionally selected based on the significance of the outbreak they responded to. This, along with their willingness to participate, introduced a selection bias. In addition, the ability to correctly remember the characteristics of the outbreak and how their city responded may have resulted in a recall bias. Triangulation of data using publicly available descriptions of the outbreak and response were used to validate SME responses.

Third, a relatively small sample, sampling methodology, and participation may have introduced selection bias during key informant interviews. The purposeful sampling partially addressed this limitation by selection of decision makers representing various agencies in each city as defined in Chapter 3 of this study. Key informants undoubtedly, and likely without intention, injected bias into their response. Their personal views, political opinion, or a lack of awareness may have contributed to the bias. On a few occasions, informants refrained from answering questions because they stated they did not have the knowledge to provide a confident response. During two interviews, key informants brought another employee to either amplify the detail for the program in question or to provide historical data, since the key informant had only been in place 6 months. The investigator asked for clarification when responses among city informants were inconsistent. Publically available data served to validate informant responses.

The fourth limitation was the failure to model the no-notice infectious disease scenarios. These data were intended to be provided to key informants to discuss if they would alter their decision based on the model outcomes. The failures have been documented and provided to the primary modeler as well as the Department of Defense agency sponsoring the model development.

Finally, the purposeful selection of the two cities may have introduced a bias to results based on their geographic location and culture. Selection of these cities did however, take into account size and structure to be representative of metropolitan areas in the country.

Implications for future study

To continue the advancement of preparedness and response for public health disasters, especially no-notice infectious disease outbreaks, findings from this dissertation suggest at least four recommendations for future study:

1. *Analyze data types and sources to determine the most valuable for both early warning of disease and decision making.* This study learned that both formal and informal categories of data exist and are used in communities. Future research should conduct an analysis of these to determine what are the most critical to identification of disease and response to events. This knowledge would inform the funding of information systems and processes most advantageous in community settings.

2. *Determine where authority exists, both real and perceived*. The findings of this dissertation revealed that decision makers exist both formally and informally. Formal authority may be held in an elected official position but the decisions made to mitigate a public health crisis reside within a single individual or an informal team of responders. Analysis of who has real authority and perceived authority to make decisions would have implications for training, preparation, and execution of a response.
3. *Assess how decision making may be informed by predictive epidemiologic modeling.* While modeling was attempted in this study, no findings were obtained. The methodology from this study can be used and enhanced for future research to determine if having predictive disease burden and COA analysis available to decision makers positively affects their decision making.
4. *Development of an evaluation mechanism to determine city preparedness.* Measures that currently exist are immature and do not adequately assess a city's ability to come together as a team and execute a response that protects their citizens from human suffering and loss of life. Development and employment of robust measures would offer evaluation which could be used to identify and correct gaps in preparedness.

CHAPTER VI: PLAN FOR ACTION

The findings of this study suggest many opportunities exist to improve the preparedness of our nation's cities against a no-notice infectious disease outbreak. This plan for change will discuss two actions that can readily be taken as first steps to improve preparedness. The first is a multi-step process to meet the information requirements of decision makers. The second conveys the need, to the U.S. Congress, for funding that supports nationwide preparedness.

Action 1 - Steps to build a robust information network.

As discussed earlier, having information available to decision makers improves their ability to implement the most appropriate courses of action during a public health response. The key informant responses highlighted both the need for information and a better understanding of what data are available in a community. To assist communities, this plan for change describes necessary steps to developing a more robust information network making use of data from multiple sources, to provide early warning of disease and provide decision makers data upon which to inform their actions.

Step 1: Find a champion and build a citywide stakeholder group.

The first phase of this effort is to determine who is best suited to champion this effort. This advocate should have a significant role in community response, exhibit a firm understanding of the environment and players, comprehend how data would be valuable to response, and most importantly, have the time to dedicate to seeing the effort through to completion.

The role of the champion, first and foremost, is to support and promote this activity as a beneficial step in enhancing preparedness in the community. To this end, they will need to assist in defining the work group, assuring that the appropriate players are at the table. Responsibilities may include, but are not limited to, scheduling/hosting meetings, facilitating the stakeholder group through assessments, and developing recommendations.

The makeup of this stakeholder group should include both individuals in decision making roles in response to a public health disaster and individuals that own data and information that would assist in making decisions to mitigate human suffering and minimize impact on the city (e.g. environmental, economic). At a minimum, decision makers in the stakeholder group must include elected officials and directors of response departments. In addition, educational systems, owners of critical services (e.g. waste management), large businesses residing in the community, and non-governmental agencies (e.g. churches) should be considered to participate in the stakeholder group.

After the initial list of stakeholders is developed, there should be a second list developed to find groups or organizations that own data that would be beneficial in a response. It is possible that those identified through the second list have already been added to the group through the determination of decision makers.

Step 2: Determine information requirements in a public health emergency.

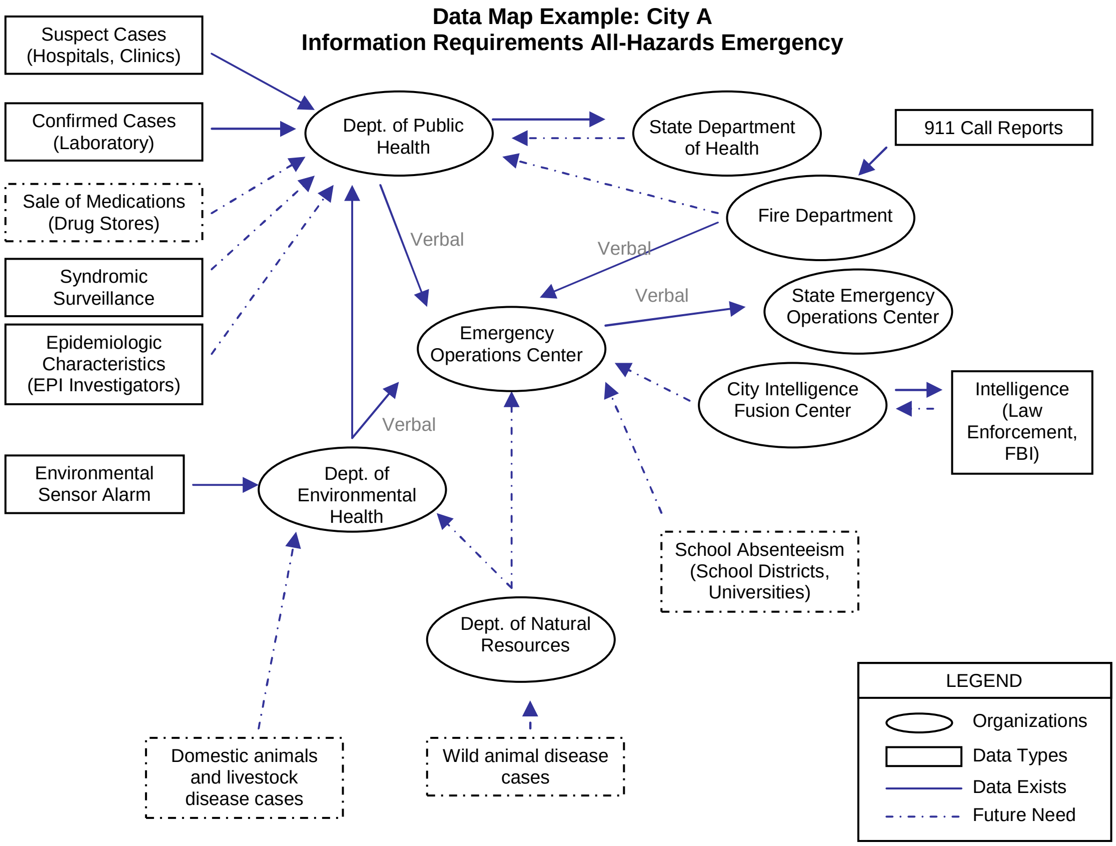
To fully understand what information decision makers would like to have during a public health emergency, a face-to-face session to determine the information requirements needs to be accomplished. To get stakeholders in the mindset of response, it is suggested that this requirements generation is done using disaster scenarios. This tactic provides a sense of reality, allowing stakeholders to ask the questions they would ask during actual response. As a result, information requirements will be made clearer. The two scenarios built, based on the review of previous outbreaks, proved to be realistic of what could actually occur in a community. Information on data availability and information required was easily generated during these scenarios delivered during the key informant interviews. The scenarios have been included in Appendix G for use during this phase. National planning scenarios could be utilized to identify information requirements based on other types of public health disasters.

In addition to the goal of building information requirements, documentation of data that does and does not exist should be accomplished. This is most easily done as the stakeholders move through the scenarios. It will be beneficial to have at least two scribes capturing data types, sources, and gaps as they are described. Appendix H is a template for data collection. It may be modified to meet local need.

Step 3: Build an information map of data types and sources

Using the data documented during the generation of information requirements, develop a map of both current and future data that is required. The map should designate data ownership and how the information flows at a minimum. Figure 6.1 provides an example of what a city information map might look like. This activity will provide a clear picture of gaps that exist, based on current data infrastructure and the information requirements generated.

Figure 6.1. Example Information Map of Data



Step 4: Accomplish an analysis to determine priority level of gap, requirements necessary to correct gap, and potential barriers.

Once the gaps have been identified, the stakeholder group should reconvene to determine the priority of the gap, activities necessary to correct it, and potential issues that would prohibit closure of each gap. First, stakeholders should assign each gap a priority to determine how critical it is to decision making and operational response. The group can establish their own priority ratings based on the complexity of analysis they would like to apply. Secondly, stakeholders should identify all the actions necessary to close the gap. This becomes the task list that members will take action on to close the gap. This may include assessment of information technology (IT), grant writing, changes in policy, education and training, or creation of standard operation procedures. Finally, in reviewing the activities that need to occur, the group should honestly assess what barriers may exist to closing the gap and brainstorm how they can be overcome. For instance, if funding is a barrier to purchase of IT software that allows for the rapid transfer of data, stakeholders may want to determine if there is grant funding available through preparedness dollars to procure the software.

Step 5: Build a ranked task list to close gaps.

Rank the gaps and their associated task lists determined in step 4. It is important to consider that not all high priority gaps may fall into the top echelon of the ranked task list. Stakeholders must consider the feasibility of tasks associated with each gap along with cost estimates to accomplish them. Another important component to consider when ranking gaps is the potential barriers to successfully closing the gap. If the barrier is too great at the time of ranking, it may appropriately fall lower on the list. Once the order has been set, the stakeholder group must determine what gaps they are able to close in the upcoming year. In some communities this may be two, while other locations may be able to close out their entire list.

Step 6: Create work groups to tackle tasks

To accomplish the task list for each of the selected gaps chosen for the upcoming year, a work group should be established. These groups should have representation from multiple agencies that have a vested interest in the gap being closed. Once membership has been determined, a work plan for individual groups can be established with timelines for completion.

At anytime a significant barrier arises within the work groups, to stop the progress of the activity without resolution, it should be brought to the stakeholder champion. At that time, it can be determined if it should be brought to the entire stakeholder committee for assessment of ways to move forward.

Step 7: Hold annual checkup: report out, evaluate

One year from initiation of the work groups, an annual meeting should be held to assess progress to date. Each workgroup should be given an opportunity to report out to all the stakeholders. Reports should include: tasks accomplished, description of barriers encountered along with solution set to overcome that barrier, and timeline to completion.

Step 8: Refine task list and reprioritize goals for the next year.

The task lists and ranking of gaps should be reviewed and reprioritized at the annual meeting since the environment will have undoubtedly changed over the past year. Limiting barriers, such as an obstinate political party in office, may no longer be an issue and the gap could be easily resolved in the upcoming year. Another example may be funding changes at local, state, and federal levels that remove or add barriers to forward progress.

Action 2 – Convey a funding need to policy makers to improve nationwide Preparedness

The results of this research revealed that cities were more prepared for disasters when they had a seminal event in their city or had been engaged in significant preparation for a large scale event. These occurrences served as a forcing function to improve response plans, build necessary multiagency relationships, and exercise capabilities to find gaps that must be addressed to assure a successful response.

A multitude of reports and evaluations analyzing our country have exposed chinks in the preparedness armour of our cities. To assist in the repair, we can provide communities an occasion to plan for the reality of a potential disaster as opposed to traditional planning for theoretical, undefined incidents. We are fortunate an opportunity already exists to enhance the preparation of our cities. Each year, cities nominate themselves to host NSSEs. Most often, little or no money is received to support the event, which leaves many cities unwilling to submit themselves for consideration. Using the grant approach already articulated, monies could be granted to cities selected to host a NSSE.

To initiate this grant effort, the introduction of a bill requesting that grants be rapidly available to eligible entities (cities selected to host National Special Security Events) is needed. This rapid availability of funds would be to assist in improvement of preparedness among our U.S. cities, subsequently increasing our nationwide preparedness with the successful execution of each NSSE. Two memos have been written to request initiation of this action in the 111th Congress. (See Appendix I)

The first memo is addressed to Representative Bennie Thompson who serves as the Chair of the House Committee on Homeland Security. In the 110th Congress, Rep. Thompson sponsored two bills that provided amendments to the Robert T. Stafford Disaster Relief and Emergency Assistance Act. The first established a grant program for pre-disaster hazard mitigation enhancement, and for other purposes. The second established a grant program to assist innovative natural disaster first responder programs, and for other purposes. As the Chairman, Rep. Thompson has listed eight priorities of the committee for the 111th Congress. One of these is to strengthen our nation in response, resilience, and recovery. Both this goal and the nature of previously sponsored bills identify Rep. Thompson as a likely supporter of this request.

The second memo is address to Senator Joseph Lieberman, who chairs the Senate Committee on Homeland Security and Governmental Affairs. Sen. Lieberman’s committee just approved the Weapons of Mass Destruction Prevention and Preparedness Act. Fostering community preparedness is found in the language of this act. Like Rep. Thompson, Sen. Lieberman’s historical actions and his position as the Chair of the Senate Committee on Homeland Security and Governmental Affairs points to the likelihood that he would be support this request.

APPENDIX A

Interview Guide – Subject Matter Experts (Aim 2)

The following questions were used to guide interviews with subject matter experts that had responded to a no-notice infectious disease outbreak. The prompts following each question were used if additional clarity is needed about the question

1) What position did you have when you were involved in responding to [name of the no-notice disease infectious disease outbreak]. What were your responsibilities?
   a) What type of organization do you work for?
   b) What activities did you have to accomplish?

2) Tell me about [name of the no-notice disease infectious disease outbreak].
   a) Why was the event concerning?
   b) What was your level of activity (constant, daily, weekly)?
   c) How many people did it affect?
   d) Did the outbreak have transmissibility or infectivity?
   e) Was it affecting healthcare delivery?

3) How did you first learn of the [name of the no-notice disease infectious disease outbreak]
   a) Healthcare providers?
   b) Hospitals?
   c) Sensor data?
   d) Media?

4) What information did you receive about the [name of the no-notice disease infectious disease outbreak]?
   a) Case reports?
   b) Surveillance data?
   c) Sensor data?
   d) Media?

5) What influenced the decision to implement public health interventions?
   a) Case reports?
   b) Disease characteristics such as rapid spreading?
   c) Politics?
   d) Plan that had pre-identified trigger points for interventions?
   e) Concerned citizens?
   f) Media reporting?

6) Who were the decision makers during the outbreak?
   a) Health departments?
   b) Healthcare providers?
   c) Government?

d) Emergency personnel?

7) What was the outcome of the event?
   a) How long did it last?
   b) How many people were affected?
   c) What in the system failed?
   d) What was the cost to respond to the event?

8) Tell me about the lessons that were learned during the event?

APPENDIX B

Interview Guide – Decision Makers (Aim 3)

The following questions were used to guide interviews with decision makers. The prompts following each question were only be used if additional clarity was needed about the question.

1) What is your position title? What roles do you have in responding to a public health emergency?
   a) What type of organization do you work for? (Government, private or nonprofit?)
   b) What are your responsibilities?

2) How have you been involved in planning for public health emergencies such as an infectious disease outbreak in your city? What was your role?
   a) Was the planning a result of receiving federal monies or programs?
   b) Who initiated the planning?
   c) How big has your role been? (minimal or significant?)

3) What data or information do you receive about public health issues such as infectious disease outbreaks? Tell me about the kinds of data or information you receive?
   a) Biologic detection data?
   b) Environmental sampling?
   c) Reports from the health department or Health Alert Networks?
   d) 911 reports?
   e) Case reporting from healthcare providers?

4) From which sources would you receive this data?
   a) From the health department?
   b) From healthcare providers?
   c) From government officials?
   d) From detection systems such as air samplers?
   e) From the media?
   f) Others?

The next set of questions will reference a no-notice infectious disease outbreak which is defined as an infectious disease outbreak discovered in a community without prior knowledge that the biological agent was active in the population.

5) How confident are you that the data you receive during a no-notice infectious disease outbreak would assist you in decisions to implement public health interventions such as movement restriction? Which data sources are you most confident in?
   a) Are you confident that the data will be accurate?
   b) Has the confidence level of data been pre-determined, for instance air sampling data is always considered confirmed?

6) Are there any data in particular that would cause you to take immediate action to mitigate the effects on health during a no-notice infectious disease outbreak?
   a) Is there a specific source or type of data that would require immediate action?
   b) Does having confirmed data change your timeline for response?
   c) Would you respond immediately if the data indicated a terrorist attack?

7) How confident are you that you will receive data in time to respond to a no-notice infectious disease outbreak?
   a) Is information provided to you soon enough for your response?
   b) Is information delayed or filtered? If so, how?

8) Describe your process for making decisions during a no-notice infectious disease outbreak.
   a) Is there a plan? If so, how is it documented?
   b) Has the process been agreed to? If so, who has agreed to the process?

9) Tell me how confident you are that this city would receive information on a no-notice infectious disease outbreak and be able to provide a coordinated response.
   a) Does the city get information to coordinate a response?
   b) Give an example

10) Describe your concerns, if any, about receiving information or coordinating a response to a no-notice infectious disease outbreak in your city.
   a) Is the information reported to decision makers? If so, how?
   b) Does the information arrive in time to take action? If not, please elaborate.
   c) Do you have confidence in the data you receive? If not, why not?
   d) Are there any barriers? If so, please describe.
   e) Are there any issues within your organization or another that pose a barrier?
   f) Are there any political issues that come into play and pose a barrier?
   g) Are there any other complications you can cite that pose a barrier to you receiving or coordinating a response?

11) Tell me about a time where you had to take action to minimize the consequences of a disease outbreak.
   a) Did you have the information you needed? If not, what was missing and why?
   b) Did you feel pressured to make a decision? If so, why?
   c) Did the plan the city had assist in making decisions? If not, why not?
   d) What concerns did you have during that event?

12) Has there been a significant event that has changed your process for receiving data or responding to public health emergencies? If so, please describe it.
   a) Was it natural, intentional, or accidental?
   b) Have there been changes in leadership as a result? If so, why? Please describe the change.
   c) Have there been changes in laws, regulations or policies as a result? If so, why? Please describe the changes.

13) Is there anything else you would like to add?

14) May I contact you after I model the scenarios to determine optimal intervention strategies?

Thank you for your time. If you have any questions please feel free to contact me.

APPENDIX C
Key Informant Interviews
Coding Manual / Definitions

Information needs
These codes refers to the additional information key informants said they would like to have in order to make decisions for implementation of an intervention during a no-notice infectious disease outbreak.

Information Sharing
These codes refer to the partners and/or organizations that key informants said they would share information with for a no-notice infectious disease outbreak.

Interventions
These codes refer to the activities that key informants said they would implement that prevent or mitigate an adverse outcome in the public's health.

Actions
These codes refer to the actions key informants said they would take to prepare for response activities as an agency or a collective group of responders (e.g. review an agency plan for a public health emergency). These actions do not affect the public's health and are not considered interventions.

Data
These codes refer to the types of data that key informants said they would receive or had access to.

Data Source
These codes refer to the sources (e.g. agency, system) that data originates from to provide information on a no-notice infectious disease outbreak.

Roles
These codes refer to the roles key informants indicated they held in their respective agencies.

Relationships
These codes refer to the identification of relations between individuals or organizations that are involved in response activities.

Trigger
These codes refer to the things that initiated an implementation of a public health intervention.

Notification
These codes refer to the process of how responders are notified that a no-notice infectious disease outbreak may exist.

Decision Maker
These codes refer to the individuals who make the decisions to implement an intervention that affects the public's health.

Plan
These codes refer to involvement in creation or maintenance of a plan for an emergency in their community.

Communication Mechanisms
These codes refer how information is shared (e.g. email).

Confidence
These codes refer to the level of confidence in the availability and timeliness of data that would assist in the response of a no-notice infectious disease outbreak.

Immediate Action
These codes refer to the events that would lead decision makers to take immediate action or implement interventions to mitigate adverse outcomes.

Concerns
These codes refer to any identified concerns related to receiving information or coordinating a response to a no-notice infectious disease outbreak.

Examples
These codes refer to examples of events where actions and/or interventions had to be accomplished to minimize the consequences of a disease outbreak.

Significant Events
These codes refer to the significant events in key informant communities that lead to changes in processes to respond.

H1N1
These codes refer to any discussion related to the 2009 H1N1 influenza outbreak and response.

Other
These codes are miscellaneous.

APPENDIX D

Consent Form

University of North Carolina-Chapel Hill
Consent to Participate in a Research Study
Adult Participants

IRB Study #____________________
Consent Form Version Date: 26 February 2009

Title of Study: Effects of early biological detection data on decision makers' actions to minimize the consequences of no-notice infectious disease outbreaks.

Principal Investigator: Amy Kircher
UNC-Chapel Hill Department: Health Policy and Management
UNC-Chapel Hill Phone number: (919) 843-4621
Faculty Advisor: Dr. Suzanne Havala Hobbs
Study Contact telephone number: 719-492-4086
Study Contact email: kircher@email.unc.edu

<u>What are some general things you should know about research studies?</u>
You are being asked to take part in a research study. To join the study is voluntary. You may refuse to join, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study. You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

<u>What is the purpose of this study?</u>
The purpose of this research is to determine how information from an early detection system, like the BioWatch program, affects emergency preparedness and response communities' decision making process.

<u>How many people will take part in this study?</u>
If you decide to be in this study, you will be one of 20individuals interviewed for this research study.

How long will your part in this study last?
The interview should take approximately 60 minutes. If you agree, you may be asked to respond to questions in a follow-up phone conversation lasting no more than 30 minute.

What will happen if you take part in the study?
You will be asked to respond to questions based on two scenarios and then a few questions about the decision making process in your city. If you do not want to comment on any of the questions posed, you do not have to answer.

What are the possible benefits from being in this study?
Research is designed to benefit society by discovering new knowledge. You may not benefit personally from being in this research study.

What are the possible risks or discomforts involved from being in this study?
There may be uncommon or previously unknown risks. You should report any problems to the researcher. However, I do not foresee any risks to you at this time.

How will your privacy be protected?
All the information I receive during the interview will be separated from identifying information, including your name. The data will be strictly confidential and will be secured. I will not identify you or use any information that would make it possible for anyone to identify you in any presentation or written reports about this study. If it is okay with you, I might want to use direct quotes from you, but these would only be quoted as coming from "a person" or a person of a certain label or title, like "one woman said." When I finish with all the interviews from participants, I will group all the responses together for any publication or presentation. There will be no way to identify individual participants.

I will not record your name with your responses so identification of any individual is highly unlikely. There are no other expected risks to you for helping me with this study. Other than informing the fields of public health and emergency preparedness, there are also no expected benefits for you either.

Data will be password protected and secured in a locked container. Only the principle investigator will have access to your name and contact information.

Participants will not be identified in any report or publication about this study, unless requested to be identified. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies for purposes such as quality control or safety.

To assure you data is captured and transcribed appropriately I would like to record this session. All audio recordings will be secured in a locked container. At the end of the study the recordings will be destroyed. You may at any time request me to stop the recording device.

Check the line that best matches your choice:
_____ OK to record me during the study
_____ Not OK to record me during the study

Will you receive anything for being in this study?
You will not receive anything for taking part in this study.

Will it cost you anything to be in this study?
There will be no costs for being in the study

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions, or concerns, you should contact me using the information at the top of this consent form.

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject you may contact, anonymously if you wish, the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

- -

Title of Study: Effects of early biological detection data on decision makers' actions to minimize the consequences of no-notice infectious disease outbreaks.

Principal Investigator: Amy Kircher

Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

____ __________________
Signature of Research Participant Date

____
Printed Name of Research Participant

Signature of Research Team Member Obtaining Consent | Date

Printed Name of Research Team Member Obtaining Consent

APPENDIX E

Document Review of No-Notice Infectious Disease Outbreaks

Outbreak	
Measles: NJ, US (1985-86)[55, 92]	
Epidemiologic Characteristics	Traditional measles disease outbreak in young children. The outbreak was sudden and spread rapidly among a typically unaffected population of infants and toddlers. Complications as a result of the disease included pneumonia, otitis media, diarrhea, and encephalitis. Transmission of the disease was aided by exposure to infected cases in hospitals, emergency rooms, physician's offices, schools, and day care centers. The outbreak resulted in 334 cases and 70 hospitalizations.
Political Environment	The Immunization Practices Advisory Committee recommends children are vaccinated against measles at 15 months due to their low probability of exposure. During the outbreak in New Jersey, the recommended age for vaccination was lowered to 12 months in an attempt to protect infants. The continuation of cases 5 months after the start of the outbreak led to the recommendation that the infants 6 months and older be vaccinated with revaccination at 15 months. Of the individuals affected, 100 cases were under 16 months.
Social Environment	The vaccination rate of young children in the New Jersey was known to be low even though the recommendation for the first measles vaccination was 15 months. The lack of uniform requirements for admission to pre-schools and day cares in addition to the large undocumented alien population likely contributed to low rate which assisted the transmission of disease a younger population. Even when the outbreak was publicized and the recommended age for vaccination age was dropped the public response was minimal. Knowing that vaccinations were key to preventing disease burden in the younger population, the State Health Department expressed their frustration in the lack of public response.
Economic Environment	The state provided free vaccinations to persons that did not have the recommended measles immunizations.
Organization Environment	
Information Available	Clinical data and lab results as patients presented for medical care. In New Jersey, Measles is on the list of diseases to be reported immediately to the local health department.
Strategic Actions	Actions taken to mitigate and stop the outbreak included: intensified surveillance to find new cases, public media campaigns to update and provide guidance to the public, audits of school and daycare center vaccination records, were available, and free vaccination clinics. Additionally, mid-way through outbreak, the recommended age for measles vaccination was lowered to 12 months and finally to 6 months after the outbreak did not subside.

Success/Failures	Failures (1) Without mandatory requirements imposed by licensing agencies of pre-schools and day care centers, there were no requirements for vaccinations prior to admission which contributed to lower vaccination rates. (2) Lack of strict infection control protocols by medical facilities created a an opportune place for transmission of disease.
Decision Maker(s)	City Health and Human services, New Jersey Department of Health and Senior Services.
Lesson Identified	(1) Pre-school populations were susceptible to disease and contributed to spreading the disease to the unvaccinated population of children under 16 months; (2) Lack of public response to vaccination efforts did increase the likelihood of additional vaccine-preventable outbreaks; (3) There needs to be increased efforts to vaccinate hard to reach age groups.
Meningitis: MN, US (1995) [73, 78]	
Epidemiologic Characteristics	A Neisseria meningitidis outbreak which triggered two community clusters in on a one month time frame. The outbreak was identified when 3 cases were admitted to hospital in serious or critical condition within a 12 hour time period. After an initial immunization campaign of 3,300 individuals, a high student was admitted to the hospital with rapidly progressing meningococcal disease. The individual subsequently died which led to a larger immunization campaign. Source of initial transmission was a party the weekend before the outbreak. The outbreak resulted in 334 cases and 70 hospitalizations. 9 cases and 1 death. Neisseria meningitidis, Group C had recently been identified by The Journal of the American Medical Association as an emerging public health emergency due to the disease's ability to strike healthy people at random.
Political Environment	Established and positive relationships existed between the Governor and the Minnesota Department of Health. The Governor verbally shared his support of the department to the public through media venues. The response included rapid delivery of the antibiotic rifampin which could be used to reduce transmission. In the state, dispensing of medication could only be accomplished by a registered pharmacist. The amount of pharmacists available to support the response was a rate limiting factor. To overcome the barrier, special emergency permission was requested and granted from the Board of Pharmacy to have public health personnel assist in counting rifampin pills.
Social Environment	The nature of infectious disease and perception that the outbreak was not easily controlled increased the concern in the community. This fear drove human behavior changes such as diversion of truckers from their traditional transportation routes to avoid driving through the community, canceling of sporting events in the state, and cancelation of motel reservations in the city. Public panic became more evident when the death in a high school student was an announced. Parents of school students were scared and upset. They questioned public health officials' decisions

	to keep the school open. They demanded answers as to decisions to vaccinate only select populations and delay the start of antibiotics. The state epidemiologist was called arrogant and uncaring by members of the public. The media criticized public health professionals for providing mixed messages. The outbreak coincided with television news ratings month. The story gained immediate media attention and satellite media trucks came to capture the sweeps month story. In the race for a story, media outlets provided inaccurate information creating confusion in the community.
Economic Environment	A relatively rare vaccine was available for purchase from Pennsylvania. The $22/person vaccine was purchased for and administered to high school students. The price tag to vaccinate 30,000 individuals was 1.2 million dollars. In comparison, the annual budget of the Acute Diseases Epidemiology Section in the Minnesota Department of Health (MDH) was 2.2 million dollars. Initially the burden of the cost was to be absorbed by the epidemiology section however the state legislature approved an emergency appropriation to cover the purchase in the end. The hospital treating patients did not receive any reimbursement for the outbreak and incurred a significant financial hit.
Organization Environment	Local public health officials and hospital staffs requested state assistance upon identification of the first cases. State public health professionals came to city to support outbreak response. They focused on leading the locals to consensus on how to proceed with outbreak response rather than directing them how to respond. The month long outbreak required over 600 individuals to assist in the response. Health care professionals, especially pharmacists were called in from other parts of the state to assist in response activities.
Information Available	Clinical data and lab results as patients presented for medical care. Meningitis is a reportable disease to the MDH within one day.
Strategic Actions	Actions taken to mitigate and stop the outbreak included: Vaccination campaign to vaccinate 30,000 individuals (city population 55,000), antibiotic distribution, contact tracing, education campaign for citizens and elected officials, and establishment of phone banks.
Success/Failures	Failures (1) Local and state health professionals were not able to identify the source of the outbreak or the links among victims leading to continued cases in the community. Successes (1) Public health professionals were able to vaccinate 30,000 members of the community rapidly.
Decision Maker(s)	Local county health department, Minnesota Department of Health

Lesson Identified	(1) Vaccination clinics in controlled settings such as school were ideal; (2) A spokesperson that the public has confidence in is necessary to reduce panic; (3) The media will report what information they have even if it is inaccurate; (4) The logistics of mass vaccination required thorough planning to include non-clinical components such as traffic patterns; (5) Infectious disease with high severity created panic in a community; (6) It was difficult to communicate updates and guidance with responders who were working 18 hour days; (7) Emergency rooms needed to set up separate triage system to find and isolate potential cases.
Measles: Dublin, Ireland (December 1999 – July 2000) [59, 85, 86, 89]	
Epidemiologic Characteristics	Traditional measles disease that spread rapidly due to a large population of unvaccinated children. Characteristics of childhood hospital admissions included dehydration, pneumonia, and tracheitis. The outbreak resulted in 1407 cases, 111 hospitalizations, 13 ICU patients (all unvaccinated), and 3 deaths.
Political Environment	MMR immunizations were recommended at 15 months with a second dose administered at 4 to 5 years. During the outbreak the age for the first MMR vaccine dose was reduced to 12 months in one eastern region of the city and to 6 months in northern region of the city. An editorial in the National Disease Surveillance Report suggested that to increase the vaccination rate a serious consideration be given to no fault compensation for children who suffer a rare adverse reaction from a state sponsored vaccines.
Social Environment	Vaccination rates in effected area were <70 % for measles whereas the national vaccination was 79%. At the time, none of the country's regional health boards had reported reaching the recommended vaccination level of 95%. Several factors may have contributed to the low vaccine rate to include parental forgetfulness, apathy, and concerns about side effects. In addition, an increase in immigration to northern Dublin was noted as important factor to low immunization rates. Public perception on the safety of vaccines may be influenced by scientific literature and a regional example. An article published in the Lancet in 1998 suggested MMR vaccine may be related to autism. Secondly, the 1992 case of an individual, from Ireland, that incurred severe brain damage after receiving a toxic dose of pertussis vaccine may have influenced decisions to be vaccinated.
Economic Environment	
Organization Environment	Regional Health Authorities are comprised of several Area Health Boards. The Area Health Boards made intervention decisions based on their population and how the outbreak was affecting them. A multiagency team with professionals from local, regional, and national health agencies was established to coordinate the outbreak response. The group consisted of senior area medical officers, directors of public health nursing, general managers, the Regional General Practice Unit, the Consultant Clinical Microbiologist and Infection Control Sister, the Director of the National Disease

	Surveillance Centre, and a virologist from the Virus Reference Laboratory. The group met every 2-3 weeks to review the epidemiological data and determine intervention measures.
Information Available	Clinical data available for those admitted to children's hospital. Disease reporting data. Measles is a notifiable disease in Ireland.
Strategic Actions	Actions taken to mitigate and stop the outbreak included: Vaccination campaign for previously unvaccinated children and infants greater than 6 months, messaging directed to parents of children without records of immunization and parents of pre-school children to see their general practitioner for vaccination, designation of a measles ward in the hospital to minimize transmission, closure of the hospital school and playroom, and media campaign to educate the public.
Success/Failures	Failures (1) Parents did not have children vaccinated for a variety of reasons; (2) Younger doctors and nurses did not typically see the disease so identification and recognition of severity was limited. Successes (1) Multiagency establishment of a multidisciplinary outbreak control team to coordinate the response; (2) Rapid implementation of public health measures by the Area Health Boards to reduce the number of new cases.
Decision Maker(s)	Area Health Boards, Regional Health Authorities, Health Service Executive
Lesson Identified	(1) Limited notification of measles cases made it difficult to understand the true disease burden in the population; (2) Poor vaccination records created difficulty in identifying who to target for vaccine campaigns; (3) Perpetual lack of action on declining vaccination rates allowed for transmission of disease; (4) Lack of computerized child health system limited the coordination of response among Area Health Boards.
Measles: Netherlands (June 1999- May 2000) [56, 65, 66, 87]	
Epidemiologic Characteristics	Traditional measles disease with 16% of cases reporting one or more complications. Individuals hospitalized were admitted for pneumonia, dehydration, encephalitis, high fever, shortness of breath, severe otitis media, croup, and other non-specified reasons. Unvaccinated individuals accounted for 94% of the cases. Among the population of unvaccinated cases, 83% claimed religious or fundamental objections. Unvaccinated individuals were 224 times more likely to get measles than vaccinated individuals. Vaccinated individuals that were infected primarily resided in areas with low vaccination coverage. The low occurrence of cases in vaccinated communities points to the sufficiency of herd immunity to minimize disease transmission. Transmission of the disease was slow in the summer months but increased as children began school in the fall. Median age of cases was 6 years old. The outbreak spread throughout the country affecting one third of all municipalities. The outbreak resulted in 3292 cases, 157 estimated hospitalizations and 3 deaths.
Political Environment	Measles is not mandatory for entrance to school in the Netherlands. The Dutch health ministry provided public messaging urging parents to get their children vaccinated to mitigate the outbreak.

Social Environment	Measles vaccination coverage rate in the Netherlands is high (94-96%).Vaccine coverage, in the affected area, ranged from 53 – 90% in municipalities with a high percentage of residents who were members of a religious group that refrains from vaccinations. Measles outbreaks have occurred every 5-7 years among unvaccinated communities since the vaccination was introduced in 1976.
Economic Environment	
Organization Environment	The national public health agency collects the vaccination status of all Dutch inhabitants routinely in a computerized database. Data is reported annually at municipal, provincial, and national level. Local public health officials and the Ministry of Health were involved in the outbreak response however the characteristics of their relationship were not addressed in the documents reviewed.
Information Available	Routine measles surveillance data, data obtained for the case register that was established for this outbreak by the National Coordination Center for Communicable Disease Outbreak Management, clinical data, and physician annotated data on case complications. Measles is a notifiable disease in the Netherlands with cases being reported by physicians to the local Municipal Health Services (MHS).
Strategic Actions	Actions taken to mitigate and stop the outbreak included: Contact tracing, vaccination of susceptible contacts, outbreak alert to hospitals, active surveillance through general practitioners, creation of vaccine clinics to accomplish catch-up measles vaccinations at Municipal Health Services and Mother/Child clinics, and public media campaign to urge parents to complete vaccination and discuss the issues with an under vaccinated population.
Success/Failures	In documented reports of the outbreak there were no citations of successes or failures. It could be assumed that the large unvaccinated population led to the scale of the outbreak. Public health professionals are challenged in this situation as the majority of the infected population claimed religious or fundamental objections to being vaccinated.
Decision Maker(s)	Local public health departments, Netherlands National Institute for Public Health and Environment.
Lesson Identified	(1) The increase of cases at the beginning of the school year indicated the school setting was an opportune environment for transmission; (2) Unvaccinated populations are susceptible to outbreaks and pose a risk to vaccinated persons living within those populations.
Meningitis: Edmonton, Alberta, Canada (December 1999 - April 2001)[54, 70, 79, 83]	
Epidemiologic Characteristics	Outbreak generated by a strain of Neisseria meningitides not previously seen in Edmonton. Initial cases began in December of 1999 with a second spike of cases occurring in the fall of 2000. Symptoms of the disease included headache, fever, sensorial disturbances, neck and back stiffness. While 70% of cases made a full recovery, others experienced complications resulting in amputations, severe scars and other sequelae such as knee pain, neurologic problems, decreased hearing, decreased sensation at the extremities, and stiffness in hands. A review of modifiable risk factors showed that attendance at raves and having a maternal smoker in the house significantly increased the likelihood of disease. The outbreak primarily affected those less than 24 years of age. The

	outbreak resulted in 61 cases and 2 deaths.
Political Environment	A multi-agency expert advisory committee on outbreak response was established to review the epidemiology and determine recommendations and policies to stop the outbreak.
Social Environment	The population of the region is 827,507 with residences mixed in metropolitan and rural settings. Public fear was initiated with the deaths of 2 teenage students. As the disease burden increased in the community, the public demanded that children over the age of 2 years be vaccinated as opposed to the initial target vaccine population of 15-19 year olds.
Economic Environment	Vaccine was available on a staggered base which established the dates of the vaccination clinics. Regions with the highest risk received vaccine first.
Organization Environment	Roles and responsibilities were established for the vaccination campaign from the provincial level down to the regional health authorities. This clarity assisted in effectively administering vaccine to over 200,000 individuals. Shortfalls in staffing were identified and additional resources were found to pack and deliver the vaccine to the clinics.
Information Available	Clinical data and lab results as patients presented for medical care.
Strategic Actions	Actions taken to mitigate and stop the outbreak included: Contact tracing, administration of antibiotics to cases, and 3 separate vaccination campaigns. The initial campaign vaccinated 168,000 individuals ages 2-19 years (Feb). The second vaccine campaign expanded the target age to 2-24 years vaccinating an additional 60,000 individuals (Fall 2000). The final vaccination campaign offered vaccine to 2 year olds not previously eligible (April 2001). All campaigns combined provided coverage for 87% of the target population.
Success/Failures	Failures (1) Even though public health professionals targeted 20-24 years to be vaccinated; this population of young adults did not come in to the clinics to be vaccinated leaving them vulnerable. Successes (1) The vaccination of 76% of the target population was due to collaboration of responders at all levels and communication with public. Completion of the campaign brought the region back to pre-outbreak rates for meningitis.
Decision Maker(s)	Edmonton Capital Health, Alberta Health and Wellness

Lesson Identified	(1) Creation of modifiable data collection templates for altered based on their population would have been helpful to capture nuances of disease burden in a specific area; (2) Cost of the media campaign for vaccinations would have been reduced by centralizing work at the province; (3) Organizers of vaccine clinics had to be flexible and prepared to change based on the evolving situation; (4) Using electronic bulletin boards was successful in non-emergency times; (5) Development of more robust computational tracking systems to increase efficiency is needed; (6) Involvement of the First Nation and Inuit Health Branch in all decision-making and implementation was critical; (7) Preparation for close out issues of the campaign was necessary as members of the public will have questions when the campaign is over.
Pertussis: Fond du Lac County, WI, US (May 2003 – February 2004) [60, 61, 90]	
Epidemiologic Characteristics	A highly communicable and vaccine treatable outbreak of pertussis, starting in the adolescent population and spread into the community. The initial phase of disease, and most infectious stage, is similar to the common cold with cough setting in several days later. Symptoms of the disease included cough, paroxysms, whoop, vomit, sleep disturbance. The initial cases of prolonged cough occurred in May however diagnosis of pertussis was not reported until July. The source of outbreak was high school weight room. A resurgence of the outbreak in October among children, middle school students and adults indicated transmission beyond the initial high school population. Only 7 cases of pertussis have been reported in Fond du Lac County between 1998 and 2002. Greater than 70% of cases were in individuals 10-19 years old. The outbreak resulted in 313 suspect cases and 0 deaths. Susceptibility to pertussis had been attributed to the waning immunity after vaccination or natural infection. According to CDC data, 2004 was the third annual increase in reported pertussis, primarily in the adolescent and adult communities.
Political Environment	This outbreak occurred before the pertussis booster vaccine (Tdap) was licensed for adolescents and adults in the US. Licensure came for this population came in 2005 after the outbreak.
Social Environment	The source of the outbreak occurred in the largest high school and school district in the county. Each of the district schools which included 3 high schools, 6 middle schools, and 11 elementary schools reported pertussis cases during the outbreak. The outbreak created substantial impact on schools and families due to the intensive public health measures to stop transmission. Pertussis was perceived, by older individuals who were previously vaccinated, to be a milder disease which may lead to the delayed recognition of cases in schools.
Economic Environment	At least half of the economic burden of the disease was related to public health activities including surveillance, testing, and preventive treatment. The estimated cost of $1989/ case did not include administrative disruption (school, social, athletic) or personal protective equipment. The estimated response cost for the county's largest hospital was at least $78,000. Their costs included medication for staff, laboratory testing, emergency room and urgent care assessment of illness, leave for furloughed staff, replacement workers, personal protective equipment, outbreak-related administration, and public relation costs.

Organization Environment	The outbreak was labor and resource intensive as it continued and peaked in the fall of 2003 with the start of school and extracurricular activities. The county was involved in intensive control measures for 2 months to finally stop the outbreak. In recent years the health care community had expanded capability to detect cases and outbreaks using better testing such as polymerase chain reaction (PCR) and diagnostic serology. While the increased detection of cases was been positive, the workload burden placed on public health professionals with no additional resources was significant.
Information Available	Reports of suspect cases to county health department by health care providers, laboratories, schools, and day care centers, and others with knowledge of pertussis; investigation data gained from interviews with patients and parents; vaccination records from the Wisconsin Immunization Registry; Clinical data and lab results as patients presented for medical care.
Strategic Actions	Actions taken to mitigate and stop the outbreak included: Recommendation of prophylaxis for any persons that had been in the high school weight room more than 6 hours; screening of persons with cough prior to utilization of the high school weight room, health alerts for clinicians to monitor for, diagnose, and treat pertussis, press releases to educate the public on disease and transmission; active surveillance of disease among close contacts of infected individuals; aggressive testing and treatment of cases, prophylaxis of contacts, county health department physician alert advocating that clinicians monitor and treat households with children younger than 6 months due the risk of severe disease; voluntary social distancing of cases from school, work, and social activities for 5 days. There were 5000 persons treated or prophylaxed in the community (19% of population).
Success/Failures	Failures (1) Public health did not recommend and the high school did not implement strict interventions early in the high school weight room; (2) Even with the recommendations from public health, health care workers did not initiate community wide testing until 4 months after identification of outbreak in high school. Successes (1) Public health's institution of a community wide screening; (2) Health care worker implementation of diagnosis and treatment protocols for pertussis especially in families with children younger than 6 months.
Decision Maker(s)	Fond du Lac County Public Health Department, Wisconsin Division of Public Health
Lesson Identified	(1) Development and implementation of testing protocols to identify and treat cases as soon as possible was most successful; (2) Delayed implementation of preventive measures and case findings led to subsequent outbreaks in the community; (3) The outbreak highlighted the need for booster vaccinations in adolescents and adults; (4) There was a need for national and state guidelines to prevent and control of pertussis.
Monkeypox: Midwest US (2003) [52, 69, 88, 100]	
Epidemiologic Characteristics	The first community-acquired human cases of monkeypox in the United States. This pox like illness resembles small pox with rash and fever symptoms. The outbreak was linked to infected prairie dogs that had been in close contact with exotic rodents imported from Ghana. Individuals were exposed to infected prairie dogs, on premises where prairie dogs were kept, and/or exposure to persons with monkeypox. Initially the differential diagnosis for the first cases included tularemia and plague. At the time of the outbreak there was no proven treatment for monkeypox. Two cases in Wisconsin

	healthcare workers are suspected of being infected by patients indicating the first person-to-person transmission in the United States. The outbreak resulted in 72 cases and 10 hospitalizations.
Political Environment	As a result of the 2001 anthrax attacks public officials were on a heightened alert for biological weapons. A pox-like illness raised immediate concern of bioterrorism which increased the amount of agencies involved in response. Several recommendations and policies were implemented for medical care and to stop the transmission of disease among the animal population. They included: - Interim recommendations from the CDC, advising individuals with a high risk of exposure receive the smallpox vaccine and cidofovir, a drug that has showed potential beneficial in treatment. - State and federal policies restricting the movement of animals. - Food and Drug Administration (FDA) and CDC ban on the importation of implicated animal species.
Social Environment	Public concern was heightened as the fear of bioterrorism after 9/11 was a reality. In addition, this event followed the identification of SARS which already had the public anxious.
Economic Environment	The commerce of exotic animal importation had become a significant factor in the global spread of disease. At the time of the monkeypox outbreak, illegal trade of plants and animals was estimated to be $3 billion dollars in the United States.
Organization Environment	Limited oversight of animals into the country is a combination of factors to include the fragmentation of regulation between agencies. While the USDA has responsibilities to bar diseased animals from entry to the country in effort to protect farm animals they do little surveillance and detection of disease that may affect human health. The US Fish and Wildlife service has a similar responsibility but focuses on protecting native species. They have some authority but lack the resources to adequately regulate importation of disease that may affect native species.
Information Available	Both clinical, epidemiological, and laboratory data was available upon presentation of cases. Atypically large amount of data was collected since this was a smallpox-related illness which raised immediate concern of bioterrorism.
Strategic Actions	Actions taken to mitigate and stop the outbreak included: Contact tracing, administration of medical countermeasures to include the smallpox vaccine given pre- and post-exposure, patient isolation, patient triage in decontamination suite of emergency department, trace-back and trace-forward of animals, banned importation of animals, animal premise quarantine, animal euthanasia, and restriction on movement of infected animal species.
Success/Failures	Failures (1) Animals importers in Texas did not keep distribution records of 23% of the animals from the infected shipment from Ghana; (2) Owners of prairie dogs did not keep records of animal deaths or those moved through animal swap meets making it impossible to find additional infected animals.

	Successes (1) Significant resources available to find and treat cases, (2) Implementation of recommendations and policies by the federal departments.
Decision Maker(s)	County Health Departments, State Health Departments, CDC, and FDA.
Lesson Identified	(1) Strong working relationship between public health and private healthcare led to rapid identification and treatment of cases; (2) Without rapid diagnostic test it was difficult to rule out cases; (3) Guidance and policy is required for how to provide workman's compensation for suspect cases that were sent home to minimize potential spread of disease; (4) There is a public health threat from importation of exotic pets into the United States; (5) Healthcare providers must stay vigilant in identifying new or emerging diseases.
Severe Acute Respiratory Syndrome (SARS): Toronto, Canada (2003-04) [48, 50, 72, 80, 81, 97]	
Epidemiologic Characteristics	A global outbreak created by a novel respiratory virus that exhibited rapid human to human transmission through direct contact. Symptoms of the disease included: high fever, chills, malaise, myalgia, headache and dry cough. Cases often lead to pneumonia. Epidemiologic analysis identified that some infected individuals, “superspreaders”, transmitted the disease more efficiently than others creating a larger number of secondary cases. The highly transmissible disease exhibited a reproductive rate of 2-3 which does not include the "superspreaders". The disease was initially difficult to diagnosis with no diagnostic test so diagnosis made on clinical presentation. The index case of outbreak was given a differential diagnosis of tuberculosis for 4 days before clinicians realized they may have a new virus that they had not yet seen. Within weeks SARS was globalized, spreading from the Guangdong province of China to 37 countries. The outbreak resulted in 228 cases and 38 deaths in Toronto.
Political Environment	The high rate of morbidity and mortality created significant concern in the political community as the disease was exhibiting characteristics of the 1918 influenza pandemic where approximately 40 million people died. After the first month of disease in Toronto, the Premier of Ontario declared a provincial public health emergency which put all of Toronto’s hospitals into code orange. This action canceled all surgical procedures, limited emergency access, and the cancellation of appointments and elective procedures. In additional all visitation was banned including family members attempting to see their dying relatives. A WHO travel advisory to Toronto was issued as the first wave of the outbreak appeared to be ending. This advisory had not been coordinated with government officials, as is protocol. This prompted local and federal officials to go to Geneva to meet with WHO officials in effort to reassure them about their containment measures. Seven days later the ban was lifted but the damage was already done as conferences and travel to the region continued to be canceled. This potential loss of jobs and commerce led the provincial government to initiate marketing campaigns to reassure

	potential visitors that Toronto was safe. The media faulted politicians for not being more visible. While there was consistent communication between political and public health leaders the public perception was they were not involved. The politicians' rebuttal to the media were public statements claiming complete confidence in public health professionals and continued presence in press events. To demonstrate their faith in public health measures, politicians began making appearances in places considered unsafe, such a Chinese restaurants.
Social Environment	The scientific uncertainty of the disease drove public perception and human behavior. The public reacted to the outbreak with fear as the disease seemed to cause serious disease in healthy individuals. The public shunned individuals, communities, and commerce they thought to be the source of the disease. The events of 9/11 and the Amerithrax events of 2001 may have also contributed to fear of a new disease. The media propagated this fear by using the words like "mystery disease" and "deadly" in their headlines to describe the event. The continuous media coverage and official press conferences led to conflicting information and confusing guidance for the public. Each evening senior health officials would provide updates with calmness and reassurance that public health measures were working to mitigate the disease. In contradiction, other health care specialists or news reporters would give conflicting data or an opposing perspective which led to public perception that there was a lack of leadership and an attempt to cover up a more severe outbreak. The announcement of the second wave of the outbreak seemed to prove the critics recognition of failures to control the disease. When asked to assist in mitigation of the disease the public responded positively. Of the over 13,000 individuals asked to self quarantine for 10 days, there were only 27 isolation orders that were issued to mandate individuals into quarantine. A retrospective study noted that citizens cited their primary reason for going into quarantine was protection of others.
Economic Environment	The economic impact of SARS was disproportionate in comparison to other outbreaks. It is estimated that the uncertainty and risks associated with the disease led to indirect costs in addition to medical and public health costs. The primary indirect cost of the outbreak was attributed to the travel restriction imposed on the country by the WHO. Studies have estimated the economic cost of SARS to be between 30 and 100 billion dollars globally, which average out to be 3-10 million dollars per case.
Organization Environment	In the last century with the development of vaccine, eradication of smallpox, and use of antibiotics to treat TB and STDs there was a sense that infectious disease was controlled. A shift in public health practice moved to behavior modification such as tobacco cessation programs. Funding dedicated to infectious disease surveillance and control dried up. This was felt in Toronto as the capabilities and capacity to deal with a large scale infectious disease event did not exist.

	There are several examples where pre-crisis planning could have assisted the city in finding gaps and planning a response. First, the surveillance tracking system was antiquated and staff moved to paper tracking of cases. Secondly, a lack of testing capacity delayed diagnosis which necessitated the need for volunteers from other health units in the region to assist. The capacity of resources was further diminished when healthcare workers exposed to the disease had to be placed in a10-day quarantine. Finally, crisis planning was required to implement a major quarantine in the city. Toronto had the authority to quarantine but there was little experience in the logistics of imposing a quarantine which included the medical care and feeding of individuals put in quarantine. Due to the national and international concerns of SARS, the WHO, Health Canada and provincial health agencies were involved in decision making for activities in Toronto which lead to confusion on roles and authority. Senior health leaders in Toronto became frustrated when they had to provide information and updates to various levels of government and agencies. Part of the conflict may have come from differences in perspective over who developed programs and delivered services in the country. Politicians from the national and provincial did not agree and in one instance left the country at risk when pandemic influenza planning was not accomplished. This pre-event planning for a pandemic would have assisted the city as response strategies and implementation plans would have been developed vice created in the middle of the crisis. Healthcare workers were significantly affected during the outbreak with 78 of the 228 cases reported. In follow-up studies, infection control practices were identified as a contributing factor to the large number of healthcare worker infections. Some medical facilities did not institute strict infection control measures and in other cases, workers choose not to follow the measures to protect themselves. Another contributing factor was the number of healthcare workers that were ill that felt either committed to stay on the job or were concerned about retribution if they left work. Their decision not only exposed patients but their co-workers. Communication has been defined as in issue at various levels during the outbreak. First city officials had several agencies at various levels (provincial, national, and international) to report information to. Messaging to staff was equally difficult as healthcare workers were involved in the response 18-20 hours per day which left no time for updates. A senior health official in the city reported that their healthcare workers were “offended” that they had to get updates from the media.
Information Available	Clinical and epidemiological data was available upon presentation of case. Laboratory confirmation of cases was available once tests were developed. Global case reporting was provided by the WHO. The media reported on potential cases they captured through official reporting and investigative journalism.

Strategic Actions	Actions taken to mitigate and stop the outbreak included: Press conferences with guidance to the public, establishment of a public health hotline (fielded 300,000 calls), contact tracing (23,000), 10-day home quarantine of exposed persons (13,374), social distancing, cancelation of elective procedures in medical facilities, implementation of strict infection control procedures, and imposed travel restrictions (WHO).
Success/Failures	Failures (1) Medical facilities prematurely relaxed infection control measures; (2) Healthcare workers continued to work in medical facilities when they were ill; (3) Initially there was a delay in identification of cases due to the lack of diagnostic tests which did not exist due to the novelty of the disease; (4) Lack of coordination between federal and provincial health which provided additional burden on Toronto Public Health. Successes (1) Toronto Public Health accomplished active surveillance through contact tracing; (2) Toronto Public Health got 13,374 individuals to home quarantine themselves; (3) Toronto Public Health was complimented on their clear messaging to the public which ultimately led to the compliance of public health measures.
Decision Maker(s)	Toronto Public Health Department, Ontario Ministry of Health, Health Canada, and World Health Organization.
Lesson Identified	(1) Acceptance and compliance of interventions by the public was critical to ending the outbreak; (2) Global communications assisted responders with the rapid sharing of scientific information and ability to coordinate a global response; (3) Lack of defined lines of authority and responsibilities created confusion and frustration for responders and the public; (4) Without maintenance and upgrades technology was antiquated and serve little use in the emergency (e.g. surveillance system); (5) Communicating guidance to multiple ethnicities was challenging; (6) Lack of instruction on the importance and use of personal protective equipment led to cases in the responder community; (7) Relaxation of interventions prematurely led to additional outbreaks; (8) There was no process for communicating with those involved in the response so they have situation awareness and learn about any changes to protocol; (9) Multiple agencies were required to manage the outbreak including those outside the medical and public health profession; (10) There is a need to change the attitude from response to preparedness, a more strategic approach to planning for infectious disease outbreaks; and (11) Occupational health had a significant role in assuring workers are safe and protected; healthcare workers needed guidelines that do not penalize them for staying home.
Mumps: UK (2004-2005) [57, 67, 91]	
Epidemiologic Characteristics	Tradition mumps disease, typically diagnosed by the onset of unilateral or bilateral swelling of the parotid or other salivary gland lasting more than 2 days without known cause. Symptoms of the disease include fever, headache, malaise, myalgia, respiratory symptoms, and parotitis. Prior to the MMR vaccination, mumps led to viral meningitis as a complication and was the leading cause of hearing loss in children in the UK. The majority of cases occurred in individuals 15-24 years old. Of the age cohort primarily affected, 3.3% had two doses MMR vaccine and 30.1% had one dose MMR vaccine. Cases continued until the third quarter of 2005 when summer vacation began. The outbreak resulted in 56,390 cases.

Political Environment	WHO recommends a vaccine coverage rate of 90% to prevent outbreaks of mumps. Coverage in the UK fell to about 80% among 2 year olds in 2003-04. In some areas, vaccine rates were as low as 60% in 2 year olds.
Social Environment	The majority of cases affected were too old for MMR vaccinations when introduced in 1988 and were too young to be exposed to mumps when it was an endemic childhood disease. Public opinion varied wildly as the outbreak continued. Citizens claimed the vaccine/autism scare as rationale for not vaccinating their children while other parents were angry they had not known that their children needed the second dose of the vaccine. Some expressed frustration at those persons not being vaccinated which, in their opinion, led to a higher risk for outbreaks for all.
Economic Environment	Vaccine and education information was provided by the Department of Health so no cost was incurred by citizens.
Organization Environment	The entire health system from the general practitioner through to the Health Secretary was involved in some aspect of the response. The UK Health Secretary spoke on the British Broadcasting System ((BBC) television programming to advocate that parents of young adults be vaccinated against mumps. The Department of Health went to the general practitioner community recommending that all children be vaccinated even if they were above the normal age.
Information Available	Both clinical and epidemiological data was available upon presentation of case. Mumps is a notifiable disease in the UK. Typically general practitioners serve as the population that notifies.
Strategic Actions	Actions taken to mitigate and stop the outbreak included: The documented strategy was focused on vaccination campaigns. A catch-up vaccination campaign was initiated for those that had not received both doses of MMR vaccine. In addition, the UK Health Protection Agency encouraged local public health to vaccinate all students with 2 doses of MMR prior to leaving for summer vacation. Prior to fall admission, Universities advised first year students to receive MMR vaccination.
Success/Failures	Documentation of the outbreak did not identify success or failures of the response.
Decision Maker(s)	Local health services, UK Health Protection Agency.
Lesson Identified	(1) Susceptibility exists in populations that have not been vaccinated and do not have immunity through exposure; (2) Requiring immunizations for children and young adults is critical to decreasing the risk for national outbreaks.

Mumps: Multistate, US (January - June 2006) [7, 58, 63, 64, 71]	
Epidemiologic Characteristics	Tradition mumps disease that primarily affected vaccinated college students in Midwest states in the US. Symptoms of the disease include fever, headache, malaise, myalgia, respiratory symptoms, and parotitis. Where vaccination status was known, 84% of the 18 – 24 year-old cases had the 2-dose series of MMR vaccine. Multiple factors likely contributed to the scale of the outbreak to include inadequate vaccination levels, vaccine failure, difference in disease strain and vaccine strain, the high density college campus environment increasing opportunity for transmission, less than 100% vaccine effectiveness, waning immunity, and misdiagnosis. This mumps outbreak produced the largest number of cases reported since 1987. Prior to the outbreak, less than 300 cases were reported annually since 2001. The mumps genotype was associated with the large outbreak in the UK in the 2004-2005. In the 2006, 6584 cases and 85 hospitalizations were reported in the United States. The majority of these cases were found in 8 Midwest states.
Political Environment	Only 25 states require a 2 dose series of MMR vaccination as part of their college admission requirements (only 3 of the 11 states affected had the requirement). As a result of the outbreak, states, the American College Health Association, and CDC recommended a 2-dose MMR vaccine requirement for students in a university setting. The Iowa Department of Public Health issued vaccine recommendations targeting high risk populations to include college students and health care workers. Due to the success of the MMR 2-dose vaccination program initiated in 1998, the US set a goal to eliminate endemic mumps by 2010. This outbreak identifies gaps to obtaining this goal.
Social Environment	College students served as the primary population affected by this mumps outbreak. The source of transmission was traced back to air travel. At least 11 persons infected with mumps were identified as having traveled on commercial flights. Contact tracing of air passengers subsequently identified 575 persons that were potentially exposed during these flights. Mumps outbreaks may continue to be imported in the US since 43% of the global countries do not vaccinate against mumps.
Economic Environment	One cited reason contributing to the outbreak is the waning of the vaccination over time. This has led to discussion if a third “booster” vaccine would be cost effective. At the time of this writing, there is not a recommendation for a third vaccine.
Organization Environment	Local health departments, state health departments, and the CDC worked collaboratively to control the spread of the outbreak and determine why the outbreak occurred in a highly vaccinated population.
Information Available	Both clinical and epidemiological data was available upon presentation of case. Mumps is a notifiable in the US through the National Notifiable Diseases Surveillance System.
Strategic Actions	Actions taken to mitigate and stop the outbreak included: Vaccination campaigns in communities and on college campuses, isolation of cases, contact tracing specifically in air passengers, and a public media campaign to educate and provide guidance on the outbreak.

Success/Failures	Failures (1) Delayed recognition of mumps by younger physicians that may not have seen mumps or not suspected it in vaccinated individuals; (2) Isolation phase was not strictly followed by college populations. Successes (1) Appropriate messaging to college age students (e.g. email); (2) Centralizing lab testing; (3) Collaboration with local and state health (e.g. active surveillance)
Decision Maker(s)	Local health departments, state health departments and CDC.
Lesson Identified	(1) The 2-dose series of MMR vaccination is not 100% effective and may have added to the sustainment of transmission; (2) Decreasing immunity may be a factor in vaccinated individuals being infected; (3) Diagnosis of mumps cases was difficult in the vaccinated population as there was not test that would reliably detect infection; (4) Rapid transmission of disease is made more efficient by air travel.
Measles: Switzerland (November 2006 - April 2008) [62, 68, 74, 114]	
Epidemiologic Characteristics	Uncharacteristically long outbreak of traditional measles disease initiated in school age children. Source of outbreak is unknown. The genetic sequence was identical to a measles outbreak occurring in Japan at the same time which suggests a link. Disease spread from Lucerne to all Swiss cantons and then onto other European countries and the US. Median age of cases was 11 years old. Unvaccinated or partially vaccinated individuals accounted for 98% of cases. Hospitalizations occurred in 8% of cases due to disease complications. The outbreak resulted in 2250 cases and 0 deaths.
Political Environment	Due to the European Football Championships being hosted by Austria and Switzerland, joint guidance from both countries and the WHO European Regional Office was released to minimize the risk of transmission and prevent further international spread. Guidance recommended that anyone planning to attend check their vaccine status and if necessary get measles vaccination prior to travel. German officials suggested that mobile vaccination clinics be placed at the stadium so attendees could receive at least the first shot of a 2-shot series. Swiss public health officials disagreed with the suggestion citing it would not be good for the football games and may scare attendees.
Social Environment	Measles vaccine coverage in Switzerland was 86% for the first dose and 70% for second dose. Parental opposition to vaccination, for religious or fundamental reasons, is the primary reason for the unvaccinated population. In additional to religious and fundamental opposition to getting shots, some parents remained concerned about the side effects. It had been cited that the parents host measles parties to get their children exposed and infected early in childhood. The outbreak was brought to the forefront of the European community as the European Football Championships were to be hosted in June 2008 in Switzerland where 5 million fans would be in attendance.
Economic Environment	With the public media campaign, vaccine sales increased among the Swiss population.
Organization Environment	Individual cantons are responsible for the controlling outbreaks in Switzerland. There was a variation in the level and type of measures taken across the cantons. Due to the international spread, public health authorities in countries affected by the outbreak (Switzerland, Austria, Germany, and Norway)

	adopted measures at the local and state levels.
Information Available	Both clinical and epidemiological data was available upon presentation of case.
Strategic Actions	Actions taken to mitigate and stop the outbreak included: Public media campaign, contact tracing, recommendation of immunizations for anyone born after 1963, student exclusion from school if sibling was infected, and in some locations there were school closures.
Success/Failures	In documented reports of the outbreak there was not identification of successes or failures. It could be assumed that the large unvaccinated population led to the scale of the outbreak however failure can be placed on the public health system as the unvaccinated populations claimed religious or fundamental objections to being vaccinated.
Decision Maker(s)	Local canton public health, Swiss Federal Office of Public Health, other European nations public health departments, and the WHO European Regional Office
Lesson Identified	(1) Significant length of outbreak due to geographically dispersed population of unvaccinated individuals that allowed outbreak to move slowly without running out of susceptible individuals.
Adenovirus 14: Lackland Air Force Base (LAFB), TX, US (2007) [53, 82, 115, 116]	
Epidemiologic Characteristics	Rarely reported, emerging adenovirus strain that can cause severe and at times fatal respiratory illnesses in all ages. Treatment is primarily supportive as no antiviral drug has shown effective against adenovirus 14. Symptoms range from common cold to pneumonia, croup, and bronchitis. Males were 5 times more likely to be infected. This outbreak demonstrated efficient human to human spread in the Basic Military Recruit (BMT) population. The outbreak resulted in 551 suspected cases, 27 hospitalizations, and 1 death.
Political Environment	The military has established notifiable diseases that all service medical facilities must comply with. In addition, each installation must comply with the regulations of the state in which they reside. While Adenovirus is not a reportable disease in Texas, the state does require that any outbreaks, exotic diseases, and unusual group expressions of disease must be reported.
Social Environment	BMTs have physically and mentally intensive 6.5 week training. Each week 600-900 BMTs are added to those in training totaling 3500-4500 BMTs. Trainees are grouped into flights of 50-60 persons that train and live together. The culture drives BMTs to be strong and competitive. This often leads to an under representation of disease and injury. Local media reported the outbreak as “Boot Camp Flu”. One local website indicated that the media was not notified of the death in a recruit which was atypical based on previous engagement between the installation and local media. LAFB did provide responses when questioned by local media.
Economic Environment	Medical care is provided for all BMTs through the Department of Defense Military Health System. All members have full access to care and no out of expenses are incurred by members. LAFB’s medical facility, Wilford Hall, is the largest in the Air Force.

Organization Environment	In addition to clinical medical support, Air Force installations have public health officers who report case, manage outbreaks, and submit requests for assistance that move up the chain of command from the installation to their Major Command and finally to Air Force Headquarters. Public health officers at LAFB requested assistance from the Texas Department of State Health Services and the CDC.
Information Available	Febrile respiratory surveillance, administrative records on BMTs, clinical data, and lab results.
Strategic Actions	Actions taken to mitigate and stop the outbreak included: Provision of additional hand-sanitizing stations, sanitization of common surfaces, education to recruits and staff, implementation of contact and droplet precautions for hospitalized patients, testing of all health-care workers working in the units where trainees had been admitted, and confinement of febrile, respiratory patients to one dorm where surgical masks were worn.
Success/Failures	Failures (1) BMTs may not have reported illness or presented for medical care as this may delay training (cultural issue). Successes (1) Continuous active surveillance of recruits led to the early identification of outbreak; (2) Creation of a bed rest flight where cases could be isolated and rest.
Decision Maker(s)	LAFB Public Health, Texas Department of State Health Services, Centers for Disease Control and Prevention
Lesson Identified	(1) Unclear how to best control the outbreak since standard hand washing and surface/equipment disinfectant did not seem to decrease the caseload; (2) Identification of suspect patients may have led to reduction in severity of disease in patients; (3) Medical bay where BMTs were allowed to rest may have contributed to decreasing the severity of disease but did not appear to significantly decrease transmission.
H1N1: US (2009) [8, 49, 75, 94, 95, 117, 118]	
Epidemiologic Characteristics	Novel strain of influenza A, H1N1. Characteristic of seasonal flu with few folks showing signs of immunity (elderly only). Symptoms include fever, cough, vomiting, and shortness of breath. Median age affected is 16 years old. The majority of hospitalizations and deaths have had underlying medical conditions. The Federal Drug Administration approved vaccine licenses for four manufacturers five months after the outbreak. All preliminary data on vaccines have showed them to be effective and safe. It is predicted that H1N1 will circulate with seasonal flu during the 2009-2010 season. This outbreak continues as of mid-October 2009 with over 15,000 hospitalizations and over 1500 deaths in the US.
Political Environment	In the first week of the outbreak, senior government officials held a press briefing hosted by the White House. The press brief emphasized that a goal of the administration was to provide timely and clear information to the public. In addition to publicizing government actions, senior officials noted the individual responsibility each citizen has to mitigating disease which includes good hygiene and public health practices. In the first press brief, CDC indicated that they expected guidance and recommendations to change as they learned more about the disease. The Homeland Security Council created an interagency group of senior federal experts to coordinate between departments and agencies the federal response

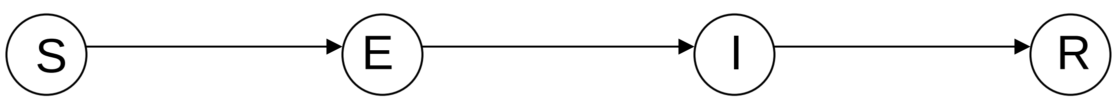
	The President addressed the nation in his weekly address during the second week of the outbreak in the US. He stressed that the response would be guided by science and that all individuals have a responsibility to protect ourselves and our communities. The President reinforced his commitment to speak clear and honest about the response. The Department of Health and Human Services (DHHS) declared a public health emergency 3 days after the first cases were identified. The Department expressed the declaration was standard operating procedures and not a declaration of crisis. This declaration allowed resources to be made available as well as the purchase additional antivirals. CDC has been actively providing guidance to health-care workers, public health officials, schools, universities, child care centers, and businesses.
Social Environment	The US, along with the global community, had been preparing for a possible influenza pandemic since the H5N1 avian influenza strain was identified. This preparation led to earlier notification along with a rapid and collaborative global response to H1N1. The identification of disease in Mexico and the US immediately removed any disease containment activities. The public has expressed concern over the safety of the H1N1 vaccine. A Harvard survey of US citizens found 41% of persons would get the vaccine and 51% of parents would get it for their children. The percentages increase in both populations if there illness and/or deaths occurring in their community. Those surveyed listed the following reasons for not getting the vaccination: side effects, availability of an effective medication to treat the disease, low risk of being infected, and lack of trust in public health officials that the correct safety information will be given. Additionally there is a residual concern from the 1976 vaccine that caused Guillain-Barre disease. Only 31% regarded the vaccine as safe.
Economic Environment	For the past year, the US has been faced with an economic recession. Despite this environment, Congress approved $7.65 billion for the pandemic flu response. The money was directed primarily to the DHHS and CDC for surveillance, stockpiles of drugs, and the development and implementation of vaccine. The funding also included $350 million to assist state and local capacity. In addition, $50 million was identified to assist other countries respond to the flu.
Organization Environment	Local and state health departments, US Government, and World Health Organization The President's Council of Advisors on Science and Technology praised the Federal Government's response to outbreak. They cited high level cooperation, depth of thinking, level of energy, and work toward mitigating potential pitfalls.
Information Available	Open source media accounts of disease in Mexico, CDC's National Influenza Surveillance System, clinical data, lab tests that indicated un-typeable influenza A, and contact tracing data.

Strategic Actions	Actions taken to mitigate and stop the outbreak included: School closures, expanded testing, antiviral treatment of cases and prophylaxis for contacts, quarantine of exposed contacts, guidance on stay home policies for ill persons, recommendations for personal hygiene, and media campaign to educate and provide guidance to the public.
Success/Failures	Since the outbreak continues there is a paucity of documented successes and failures. Verbally the following successes have been cited: (1) communication to the public about what was known and guidance for personal protection; (2) rapid implementation and continually adjustment of appropriate public health interventions.
Decision Maker(s)	Local public health departments, state health departments, CDC, DHHS, and WHO.
Lesson Identified	(1) Flexibility and the ability to rapidly adjust is key when responding to unknown disease (2) Media is a tool that can assist in providing information and education; (3) Messaging to educate the public is difficult and even with concerted effort may result in less than ideal human behavior.

APPENDIX F
Hybrid Agent-Based Disease Model Technical Notes[119]

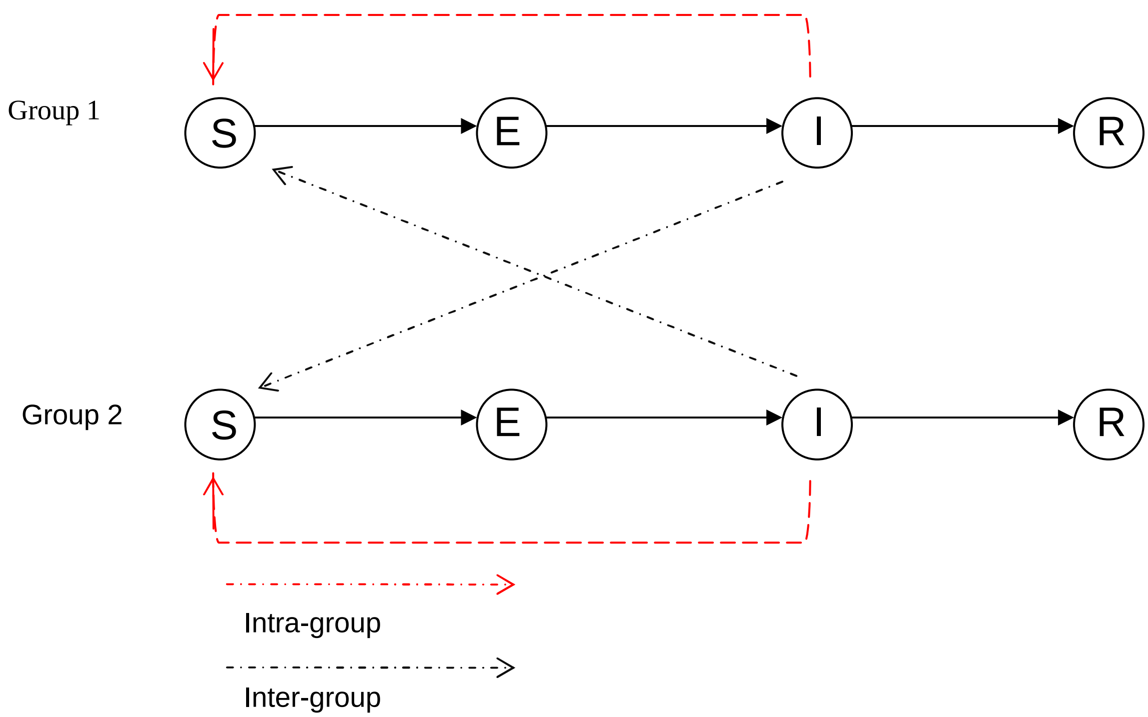
The goal of an operation epidemiologic model is to predict disease burden and provide a Courses of Actions analysis (COA) to decision makers on interventions that may mitigate disease in a population. The hybrid agent- based model used in this study provides a platform to characterize a biological event. This hybrid approach combines aspects from stochastic models that involve random variables to estimate probability of outcomes and deterministic models where event variable alter according to mathematical formulas. The benefit of this approach is the rapid analysis of interventions to find optimal COAs.

The model utilizes the SEIR compartment methodologies to simulate infectious disease outbreaks in a population. Simulated individuals or groups move through the SEIR disease states where, based on probability, they could become exposed and subsequently infected and finally recover. The recovered compartment includes both simulated individuals that have had their health restored and those that have died from the disease.

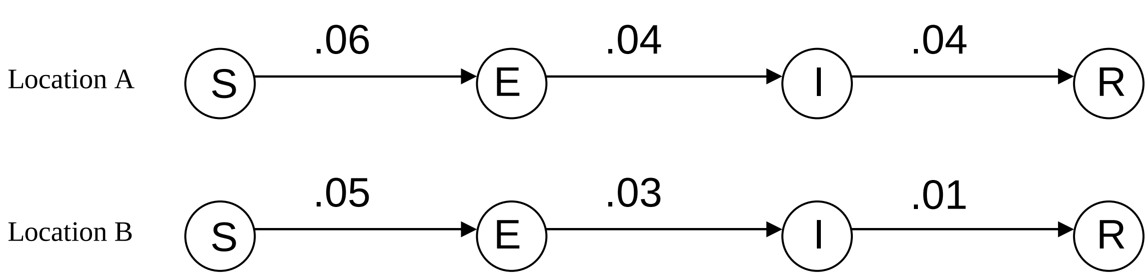


where S = Susceptible
E = Exposed
I = Infected
R = Recovered

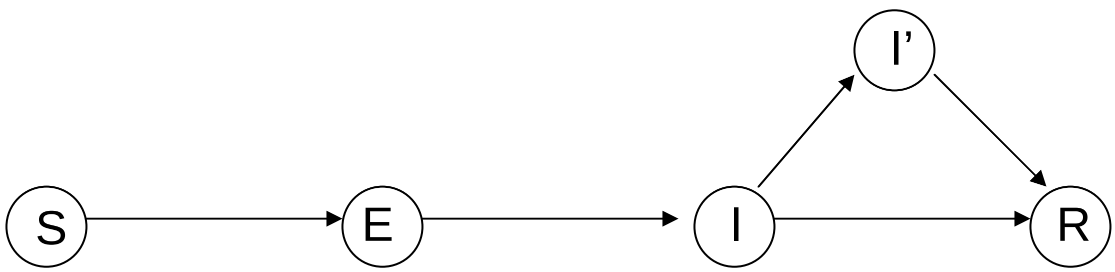
The model places individuals into groups. Individuals within these groups randomly mix and have a probability of movement to another location where they become part of another group, a secondary group. Mixing of the population occurs within each group (intra-group mixing) where the SEIR algorithm applied. It is followed by mixing between different locations (inter-group mixing) where the SEIR algorithm is applied.



Each location has rates of disease transition assigned to it. When an individual goes to that location the rates of disease transition apply per that location. The rates at each location can be different from one another as shown below using example rates.



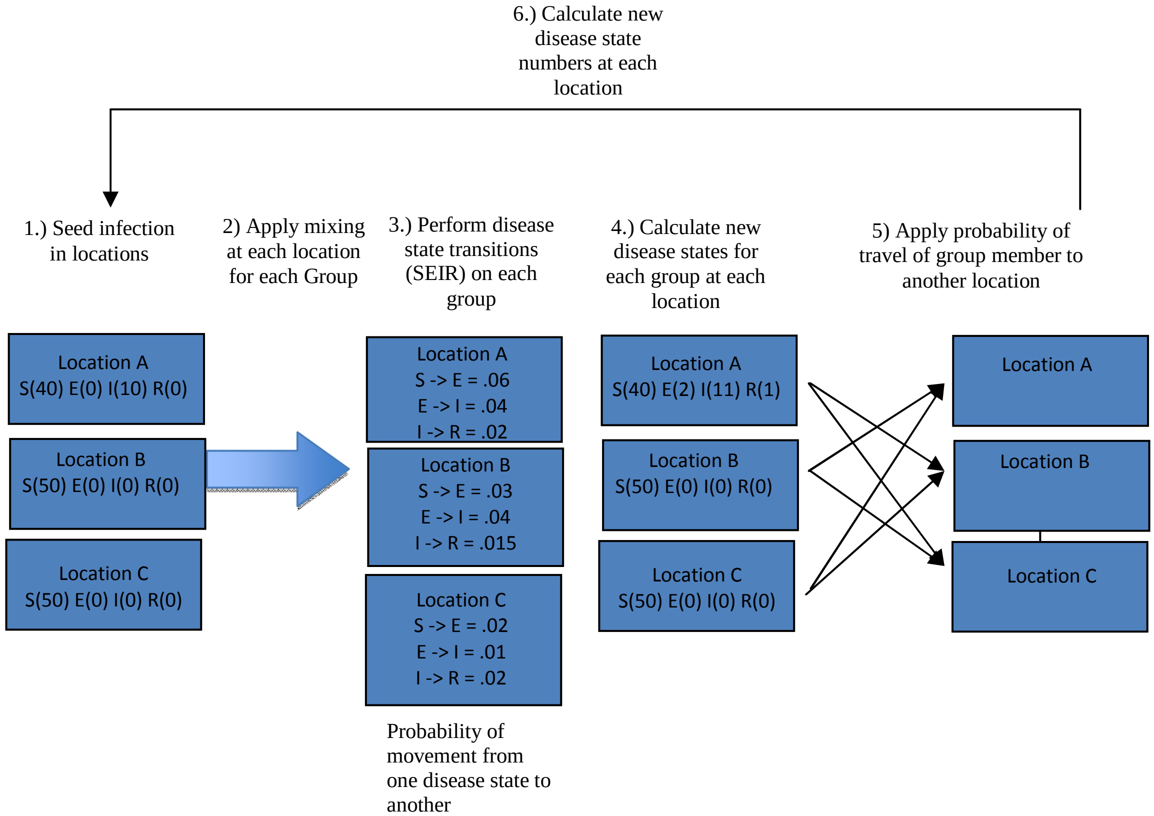
The model has the capability to apply intervention strategies in attempt to mitigate disease burden in the population. At the time of this study, medical countermeasures (i.e. treatment) and social distancing were options that could be applied to the population. A treatment applied to the population created another disease state, I'. The user has the ability to set an effective rate for the treatment when applied to individuals in the infectious disease state (I). Infectious individuals (I) who receive treatment (I') decrease the time they spend moving from the infectious to the recovered disease state. Application of treatment also decreases the probably that infectious individuals die.



When applying social distancing, the user has the ability to set the compliance of the population to adhere to this intervention. The application of social distancing decreases the probability that any individual will come in contact with any other individual. This activity shuts down the social networks of individuals.

The model functions in a step wise fashion as mixing of the population and disease transitions occur. An example of this process is diagramed below. The user defines epidemiologic parameters when setting up the model simulation. These include incubation period, infectious period, reproductive rate, and case fatality rate. To begin the model, the user seeds the disease by determining the number of cases in a location (See step 1). Once the disease has been seeded, a random mixing of the population begins at each location. Once completed disease states are applied to each group. This leads to the calculation of new disease states for each group at each location. A probability of traveling from one location to another is then applied. Once the movement has occurred based on probability, new disease states are calculated for each location and the process starts over again.

Interventions can be applied when the model run is being set up or at a given time within a current model run (e.g. application of treatment on day 5) to determine the effect of the intervention.



APPENDIX G

No-Notice Infectious Disease Scenarios

Scenario A: Pneumonic Plague

Background: The scenario is set at present day. Currently there are no known responses being conducted by the city's operations center. At present, there are no known health concerns in the community.

Day 1:

- At 1700, a local hospital or a BioWatch Actionable Result notified the city leadership that they had a presumptive positive case of plague. Confirmatory tests are currently underway.
  - "Would you implement an intervention that affects the public's health today?"
    - Yes: "What interventions would you implement"
    - Yes: "What prompted your decision to take action?"
    - No: "What additional information would you like to have?"
  - "Who else would you be sharing this information with or consulting?"

Day 2:

- At 1200, 3 persons with atypical symptoms are admitted to 2 local hospitals with high fever, chills, and labored breathing.
- At 1800, another 5 cases with similar symptoms have been admitted to the same hospitals.
  - Would you implement an intervention that affects the public's health today?"
    - Yes: "What interventions would you implement"
    - Yes: "What prompted your decision to take action?"
    - No: "What additional information would you like to have?"
  - "Who else would you be sharing this information with or consulting?"

Day 3:

- At 0800, confirmatory tests are positive for plague

- At 1000, a fatality is reported in one of the atypical admissions yesterday; an additional 7 persons have been admitted similar to the atypical admissions yesterday.
- At 1500, local media is requesting information on a significant amount of persons presenting to local emergency rooms with a mystery disease. The reporter is asking: Do you know the cause of the illness? What steps are you taking to find out? How do you know that your healthcare workers are safe?

  - Would you implement an intervention that affects the public's health today?"
    - Yes: "What interventions would you implement"
    - Yes: "What prompted your decision to take action?"
    - No: "What additional information would you like to have?"
  - "Who else would you be sharing this information with or consulting?"

Day 4:

- At 0800, 3 of the atypical admissions have died over the night, 2 of the 4 fatalities have tested positive for pneumonic plague
- At 1400, 35 additional persons have been admitted to area hospitals with a suspected plague diagnosis

  - Would you implement an intervention that affects the public's health today?"
    - Yes: "What interventions would you implement"
    - Yes: "What prompted your decision to take action?"
    - No: "What additional information would you like to have?"
  - "Who else would you be sharing this information with or consulting?"

Day 5

- At 0800, 67 cases have been admitted to local hospitals with 11 fatalities.
- At 1200, Ambulances delivering patients are having a difficult time getting close to emergency department ramp as people are milling around. The ambulance crews radio the Emergency Department to request assistance in clearing a "pathway."
- The phones in the command center are ringing constantly – you are having difficulty communicating with area medical facilities because internal and external lines are jammed with volume.

  - Would you implement an intervention that affects the public's health today?"
    - Yes: "What interventions would you implement"
    - Yes: "What prompted your decision to take action?"

        - No: “What additional information would you like to have?”
    - “Who else would you be sharing this information with or consulting?

Scenario B: Unknown Respiratory Virus

Background: The scenario is set in December. Currently there are no atypical operations being conducted in the city’s operations center for the season. The community is seeing normal levels of seasonal influenza circulating in the population.

Day 1:

- Between 0800 and 1000, EMS transports to university students in respiratory distress. Both individuals have subsequently died in the hospital. There are no known underlying medical conditions in either of the two students. The hospital lab has been unable to characterize a causative reason for the deaths.

    - Would you implement an intervention that affects the public’s health today?”
        - Yes: “What interventions would you implement”
        - Yes: “What prompted your decision to take action?”
        - No: “What additional information would you like to have?”
    - “Who else would you be sharing this information with or consulting?”

Day 2:

- At 0800, local university reports it has seen a higher than average number of Influenza-Like-Illness (ILI) cases in the past week. Students reporting to the student health center are three times higher than the typical amount of visits for this time of year.
- At 1700, local syndromic surveillance system reports an above average ILI rate for the clinics and hospitals surrounding local university
-
    - “Would you implement an intervention that affects the public’s health today?”
        - Yes: “What interventions would you implement”
        - Yes: “What prompted your decision to take action?”
        - No: “What additional information would you like to have?”
    - “Who else would you be sharing this information with or consulting?”
        -

Day 3:

- At 0800, the hospital that cared for 2 university student fatalities reports 10 admissions for similar symptoms over the past 2 days. They have also admitted two additional persons with similar symptoms. One admission is a nurse in the hospital and the second admission is a bartender at local pub near the university. The causative agent has yet to be characterized. Symptoms of those admitted have included a high fever, chills, and headache along with ILI. One person has been placed on a ventilator.

    - Would you implement an intervention that affects the public's health today?"
        - Yes: "What interventions would you implement"
        - Yes: "What prompted your decision to take action?"
        - No: "What additional information would you like to have?"
    - "Who else would you be sharing this information with or consulting?"

Day 4:

- At 0800, local hospitals have reported 25 admissions overnight, 3 were put on ventilators for respiratory distress. Ages of those admitted were 5 – 50 years old.
- Specimens from the University students are being tested at local labs. The agent remains uncharacterized.
- At 1800, local media is reporting a disease affecting the community. The newscast identifies the University as the source of disease.

    - Would you implement an intervention that affects the public's health today?"
        - Yes: "What interventions would you implement"
        - Yes: "What prompted your decision to take action?"
        - No: "What additional information would you like to have?"
    - "Who else would you be sharing this information with or consulting?"

Day 5

- At 0800, 50 additional cases have been admitted to local hospitals with 10 persons on ventilators and 2 deaths from respiratory failure.
- At 1200, Emergency rooms are overflowing. Local clinics have reported that their phone lines are full with persons trying to get access to their physician.
- The phones in the command center are ringing constantly – citizens are asking for guidance on the current situation.

    - Would you implement an intervention that affects the public's health today?"
        - Yes: "What interventions would you implement"

    - Yes: “What prompted your decision to take action?”
    - No: “What additional information would you like to have?”
- “Who else would you be sharing this information with or consulting?”

APPENDIX H

Information Requirement and Data Collection Template

Information Requirement	Data Type	Data Source	Decision Impact	Availability	Method
Example Input					
Percentage of absenteeism in school system	Personal notification	Community partner	Higher incidence of disease may require school closures	Verbal only	Phone or email
Clinical characteristics of undiagnosed disease	Clinical	Local hospitals	Clinical characteristics may require specialized equipment or personnel	Yes	Electronic
Indication of terrorist nexus	Intelligence	FBI	Changes in triage upon entrance to clinical facility	No	NA

APPENDIX I
Memorandums to Members of the 111th US Congress

The Honorable Bennie Thompson
2432 Rayburn House Office Building
Washington, DC 20515

5 April 2010

Dear Representative,

As the Chair of the House Homeland Security Committee, I thought you would be interested in the findings of my doctoral dissertation. The results of my research revealed that cities were more prepared for disasters when they had a seminal incident in their city or had been engaged in significant preparation for a large scale event. These occurrences served as a forcing function to improve response plans, build necessary multiagency relationships, and exercise capabilities to find gaps that must be addressed to assure a successful response.

A multitude of reporting and evaluations have exposed chinks in the preparedness amour of our cities. These can be repaired by providing communities an occasion to plan for the reality of a potential disaster as opposed to planning for theoretical, undefined incidents. Fortunately an opportunity already exists to enhance the preparation of our cities. Through the selection of cities to host a National Security Special Event (NSSE) we offer those awardees that reality to plan and mend the armour. Cities unfortunately are not nominating themselves to host NSSE level events due to the significant cost to plan and execute them.

I have noted that one of the points in your plan for the 111th Congress is to strengthen our nation in response, resilience, and recovery. In support of that goal, I ask that you consider introduction of a bill that will make grants rapidly available to eligible entities (cities selected to host National Special Security Events) to assist in improvement of preparedness among our US cities subsequently increasing our nationwide preparedness with the successful execution of each NSSE. This critical activity will drive cities to self-nominate and be selected to host significant events ultimately improving their preparedness.

Sincerely,

Amy Kircher, DrPH, MPH
2610 Old Broadmoor Road
Colorado Springs, CO 80906
jakircher@comcast.net

The Honorable Joseph Lieberman
706 Hart Office Building
Washington, DC 20510

5 April 2010

Dear Senator,

As the Chair of the Senate Committee on Homeland Security and Governmental Affairs, I thought you would be interested in the findings of my doctoral dissertation. The results of my research revealed that cities were more prepared for disasters when they had a seminal event in their city or had been engaged in significant preparation for a large scale event. These occurrences served as a forcing function to improve response plans, build necessary multiagency relationships, and exercise capabilities to find gaps that must be addressed to assure a successful response.

A multitude of reporting and evaluations have exposed chinks in the preparedness amour of our cities. These can be repaired by providing communities an occasion to plan for the reality of a potential disaster as opposed to planning for theoretical, undefined incidents. Fortunately an opportunity already exists to enhance the preparation of our cities. Through the selection of cities to host a National Security Special Event (NSSE) we offer those awardees that reality to plan and mend the armour. Cities unfortunately are not nominating themselves to host NSSE level events due to the significant cost to plan and execute them.

I have noted that the Committee's approval of the Weapons of Mass Destruction Prevention and Preparedness Act. In support of that act, specifically fostering community preparedness, I ask that you consider introduction of a bill that will make grants rapidly available to eligible entities (cities selected to host National Special Security Events) to assist in improvement of preparedness among our US cities subsequently increasing our nationwide preparedness with the successful execution of each NSSE. This critical activity will drive cities to self-nominate and be selected to host significant events ultimately improving their preparedness.

Sincerely,

Amy Kircher, DrPH, MPH
2610 Old Broadmoor Road
Colorado Springs, CO 80906
jakircher@comcast.net

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