

New England Compounding Center Meningitis Outbreak: A Compounding Public Health Crisis.

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Abstract

The New England Compounding Center's (i.e., NECC) meningitis outbreak represents a major public health crisis of 2012 that led to over 40 deaths, along with infection of several hundred individuals. The outbreak necessitates the need for how such a crisis could be prevented. The research focuses on assessment of the NECC Meningitis Outbreak using the Anticipatory Model of Crisis Management (AMCM). Using the AMCM principles, it was found that NECC did not engage in an adequate vigilant decision making process.

Keywords: Crisis management, Crisis preparedness, Anticipatory model, Meningitis outbreak

1. Introduction

Crises are fairly commonplace in today's society, either because we are more aware of their occurrence through the media, including social media, or because their impacts are often close to home. Although inevitable in organizational life, crises are preventable¹. The idea that crises are avertable represents the hallmark of the anticipatory model of crisis management¹⁻². Notwithstanding, organizations rarely do what it takes to prevent crisis. Some would rather deal with crises after they occur than commit valuable resources to prevent crises from happening. This leads to an assessment and evaluation of the meningitis epidemic fueled by the New England Compounding Center in late 2012. In essence, the goal of this study is to evaluate and assess the management of the meningitis crisis

while offering important implications for crisis managers and practitioners, as well as public health experts.

2. Case overview

New England Compounding Center (NECC) is a pharmaceutical company embroiled in a crisis of great proportion. Since September 21, 2012, more than 30 Americans have died of fungal meningitis and almost 300 people have become infected from tainted steroid injections they received to treat problems with their spines³⁻⁵. NECC is a pharmaceutical company that does compounding, a practice that involves preparing a medication to suit small but specific needs that are unmet by larger pharmaceutical companies. NECC is reported to have shipped close to 18,000 vials of the contaminated steroid to 75 facilities in 23 states, and as a result, many more people stand to be

infected with the fungal contaminated product⁵. The next section presents a brief overview of the anticipatory model of crisis management which is used to analyze the NECC meningitis case.

3. Anticipatory Model of Crisis Management

The anticipatory model of crisis management (AMCM) posits that while one might not be able to prevent all crises from occurring, prevention should be a major priority. The essence of the anticipatory model is that attempts should be made to put in place programs that prevent error, disaster, and crisis while also implementing plans to handle any crises if and when they do occur. An understanding of the AMCM requires a clear definition of organizational crisis, which is as an unpredictable or a major threat that could have a negative effect on the credibility of the organization, the industry or its stakeholders⁶⁻⁸. In keeping with the impact crises can have on public health, crisis is characterized as an event that compromises the health and safety of employees, customers, or and community, that threatens to destroy public trust in the organization, thus damaging the company's reputation⁹. The definition of crisis offered by Pearson et al. reflect the sense that the prevention of crisis not only safeguards the public's health and safety, but also preserves the trust that the public has for the company to prevent crises by ensuring their products are safe and that their business practices and communication with the public are honest. With regard to public health preservation, the anticipatory model implies that best practices are maintained through competent communication within the organization and with the public.

The notion of anticipation deserves attention here. Specifically, an anticipatory focus not only thwarts disasters, but it reduces their magnitude if and when they do happen¹⁰. Furthermore, despite the rare occurrence of many organizational and health crises, the brunt is significant when they do occur, which necessitates an anticipatory approach when planning for them and preparing for their potential impacts. Finally, decision makers should possess a deep understanding and knowledge of conditions, situations, or events that could signal danger or trigger crisis. This understanding

can be achieved through the specific components of AMCM, which are outlined subsequently.

Weick¹¹ warns that the very action that enables people and organizations can also cause destruction. In other words, crisis is not just something that happens to an organization, but rather, organizational members and leaders enact thoughts and engage in actions that can intensify the conditions that make crises more likely to happen. This idea pertains to the principles of enactment and expectation which are germane to the anticipatory model^{1-2,12-13}. Enactment represents a process whereby a given action is brought about¹⁴. In other words, enactment represents any activity that puts a plan into motion, embodies an organizational policy, or reflects a pre-determined response to an event, such as an anticipated crisis. Based on the AMCM, enactments are proactive rather than reactive, meaning that they should not just reflect response to disasters that have already occurred, but are actions that are pre-determined.

Weick¹¹ supports extending the notion of enactment to consequences from such actions. For example, failure to put in place a crisis plan might hinder eventual crisis management. With enactment conceived as a retrospective sense-making process, the model contends that the notion of "anticipation" (of crisis) in and of itself is an action, given that it determines the subsequent choices an organization makes based on available information. Justification of this argument lies in the fact that decision-makers often find themselves in situations where they have to anticipate opportunities, threats, and weaknesses in their environment and then take appropriate measures to safeguard their interests. Therefore, the model asserts that decision-makers' actions or inactions with anticipation would result in different outcomes.

Expectation, a second AMCM principle, involves assumptions that people make about certain situations, environments, technologies, or their combination^{1-2, 10, 12-13}. For example, expectations about the potential occurrence of a crisis would determine whether or not a preventive countermeasure is put in place. Notwithstanding, assumptions have the potential to bring about a self-fulfilling prophecy. For example, when organizational decision-makers assume that a technology is fail safe, they err and might relax other safety measures such that

additional counter measures are never put in place to create necessary redundant procedures^{1-2, 10, 12}.

The third element in the model is the idea of control, which is the degree of power an organization has over events or crises. A multifaceted term, control is used to describe how well organizations and decision makers are in command of crisis situations, as well as conditions that might lead to crisis. Control, however, is measured in relative terms, which include the perceptions of stakeholders and the public¹⁰. For example, if it is discovered that a shipment of medicine leaving a factory is tainted, control might refer to the company's ability to stop the shipment before it hits pharmacy shelves. The control component intertwines with expectation and enactment to the extent that expectations influence enactments (decisions or actions) and actions exert control over crisis situations. Acknowledging the notion of control enhances the ability to prepare and implement effective crisis-management programs, including positive media relations, information dissemination, and adaptability to make changes when necessary.

In sum, crisis prevention requires a thorough understanding of the complexity of relationships and their environmental contexts. Nevertheless, enactment, expectation, and control must be acknowledged to understand the process^{1,11}. While enactment consists of specific actions, expectation about an object determines the type of action taken in the enactment process and provides organizations the needed control to handle a crisis. Furthermore, control reflects an organization or decision-maker's ability to respond to an expectation with the appropriate enactment. Taken together these factors constitute the crisis anticipation process where managers foresee the occurrence of crisis and work to eliminate or reduce the degree of the catastrophe. The relational perspective as it pertains to public health is useful to facilitate the pre-crisis planning stage of crisis communication. Beyond gaining and maintaining the public trust, crisis prevention can be a matter of life and death for community members.

4. Methods

As is traditionally the norm in crisis management research, the method employed in this study consists of a case study, namely the NECC. In an attempt to trace steps, missteps, and processes culminating in the eventual crisis at NECC, the researchers utilize and analyze available news materials from media outlets including blogs, news reports, reports of interviews from government agencies (e.g., Centers for Disease Control and Prevention, Federal Bureau of Investigations, etc.) and stories. Scholars and crisis communication researchers have employed this particular method for decades^{9,15-19}. Furthermore, the use of case studies is considered crucial to crisis management and theory development²⁰, and case studies often necessitate the use of any news articles and documents that provide context. Therefore, the NECC meningitis case materials or information were viewed to create a timeline of events surrounding and leading to the eventual crisis (i.e., deaths and illnesses). Analyzing and creating timelines regarding news stories provided the researchers an opportunity to go back in time and assess what went wrong. This analysis also enabled them to identify windows of opportunity where NECC could have engaged in crisis planning and/or put in place an adequate crisis management program.

Moreover, the creation of the timeline provides a systematic approach that uses assumptions and premises of the anticipatory model of crisis management (AMCM), which were used to analyze and evaluate NECC's crisis communication and management. Thus, the study assesses and evaluates available news materials and interviews from government agencies through the lens of AMCM. From the analysis, discussions and recommendations were offered. The next section offers results from the analysis and evaluation of the NECC meningitis crisis.

5. Analysis and Evaluation of NECC Meningitis Case

The NECC meningitis outbreak offers critical lessons and links between crisis preparation and issues management. While crisis management involves three major stages including pre-crisis, during crisis, and post crisis, issues management focuses on public policy processes to advance organizational interests²¹⁻²², as well as protect the health and safety of the public. While crisis management encompasses all crisis stages, issues management is a proactive method of

crisis preparedness and prevention, hence focusing on the pre-crisis stage.

In assessing the meningitis outbreak one needs to look at policies or rules in effect governing compounding pharmacies. In so doing, it has been suggested that one of the policy issues that contribute to the crisis is the current administration's recent tightening of oversight of the manufacturing of generic versions of sterile injectable drugs⁵. The tightening was called for due to legitimate concerns that the Food and Drug Administration (FDA) had about the reliability of the manufacturing facilities. However, it is argued that while the new regulation is aimed at safety issues, it has also created shortages of drugs. Consequently, the shortages have forced doctors to seek needed medicines from compounding pharmacies, which are less regulated than the generic drug firms⁵. Notwithstanding this argument, the recent outbreak of meningitis has emboldened government agencies in instituting even tighter laws and regulations. For instance, Federal health agencies (e.g., Food and Drug Administration, Centers for Disease Control and Prevention) are focused on recalling the drugs, and Congress members are called for investigations and the creation of new laws and tightened controls over compounding pharmacies⁵.

An investigation of the role of compounding pharmacies such as NECC indicates that compounding medicines never go through formal FDA review. Compounders frequently distribute these unapproved, older medicines. However, many of the drugs used by compounders have been on the market for decades. These drugs have established proven efficacy with little to no side effects and have been in existence before the establishment of the modern FDA review requirements. These drugs include sterile, injected drugs, such as the steroid behind the meningitis outbreak⁵. The point being made by Gotlieb is that tough oversight comes with or results in product shortages. However, we beg to differ because the first responsibility of a government agency is to preserve and protect the safety of the public. We are not arguing that government agencies never go overboard in their regulatory practices. Instead, we contend that ensuring manufacturing facilities are in compliance and are operated safely is not too much to

ask any pharmaceutical or medical company, especially a compounding pharmaceutical company like NECC. After all, the principle of non malfeasance – which focuses on the intent to not engage in harm or bring injury to others is at the core of assessing medical operational guidelines¹⁶.

This case study analysis reveals that NECC may have failed this test of non malfeasance by not adhering to the basic rule governing compounders, which is never to circumvent basic pharmacy compounding to full-scale manufacturing^{5,23}. In other words, a compounding pharmacy must follow specific prescriptions being compounded rather than make a large batch and ship the products without prescription. To this end, Hicks²³ reports that Massachusetts state regulators accused NECC of violating state laws by not requiring patient prescriptions before shipping products. Essentially, this practice raised questions about the pharmacy's operation. As a result, NECC is said to engage in drug manufacturing (regulated by FDA) rather than compounding (not regulated by FDA). As a result, NECC found itself under investigation and was subject to calls for further investigations by State Representative Edward Makey and Governor Deval Patrick, along with U.S. Attorney Carmenn Ortiz. Furthermore, the entire NECC entity has been called into question and greater scrutiny due to the meningitis crisis. The FDA is now investigating the company's medication pipelines, including treatments used during heart surgery, for possible contamination attributed to a different fungal meningitis in at least two patients²³.

6. NECC response to crisis

NECC's response to the meningitis crisis has been, for the most part, nonexistent at worst and lackluster at best. As a whole, their response violates the basic tenets of the Anticipatory Model of Crisis Management, which is to anticipate and prepare for crisis in an effort to buffer the impact of crisis upon occurrence. In the days following the outbreak of fungal meningitis, NECC was nowhere to be found. As a matter of fact, it was reported that after the FDA raided its facilities, the company reacted to the raid through its attorney and unplugged its website for several days until October 6, 2012, when it replaced its website with a statement about the recall²³⁻²⁴. As of October 17, the website has never been updated. NECC maintains that the recall came "out of an abundance of caution due to the

potential risk of contamination. While there is no indication at this time of any contamination in other NECC products, this recall is being taken as a precautionary measure."²⁵.

The lack of direct communication from NECC to the public and other stakeholders conveys a lack of care. Also, not admitting that the FDA recall was based on the meningitis outbreak resulting from the contaminated vials is a pattern of behavior that showed NECC's deliberate attempts to be deceptive to the general public in an effort to circumvent potential lawsuits and impending prosecution¹⁶. The claim that the steroid recall by the FDA is precautionary is questionable, especially given that over 300 people have been infected and more than 30 have died²³. More importantly, the resulting behavior by the NECC is less than vigilant; it neither conforms to good public relations practices nor conveys good corporate citizenry.

With regard to principles of the anticipatory model, NECC have failed to analyze potential consequences of a failure to accept responsibility, and they pursued a silence strategy. A vigilant and prior assessment of such a strategy would have suggested that it is only a matter of time before affected members of the public would start filing lawsuits, as is currently the case^{3,16,23}. It would have been more prudent for NECC to be out in the public helping affected people and conveying the impression that the company is doing everything in its power to make things right rather than keeping silent. Furthermore, silence and denial usually embolden other stakeholders, and especially whistleblowers, to come forward either to get their media time or to vilify the company. At the same time, organizations that remain out of sight in times of crisis are perceived to be guilty and attract more lawsuits and closer media scrutiny as did Exxon, Shell, and BP^{16,19,23}. It also appears that NECC did very little to help itself. A report indicated that when investigators raided its facilities, it was unimaginable what they found in what was supposed to be a sterile facility²⁵. For instance, mats at sterile entrances used to wipe dirt, dust, and other possible contaminants from shoes were dirty and soiled with assorted debris, according to Dr. Madeline Biondolillo of the Massachusetts Department of Public Health²⁵.

Perhaps the most damaging evidence is meningitis-linked fungus (i.e., visible black fungus) found in unopened vials that were shipped to several states²⁵⁻²⁷, which by any standard is unjustifiable and constitutes irresponsible behavior on the part of NECC. Clarke and McLaughlin⁴ report that the problem of unsanitary and questionable practices at NECC dates back to 1999 with the most recent reprimand occurring in 2006 when NECC was evaluated by an outside firm that found inadequate documentation and process controls involving sterilization at NECC. It stands to reason that a company that underwent a severe reprimand in 2006 would be more vigilant and take necessary and periodic measures to make sure that it never repeated the same mistake that could ultimately force it out of business.

Unfortunately, this was not the path NECC chose. Sheldon Bradshaw (a former FDA Chief Counsel), who signed the enforcement letter in 2006 warning NECC about potential microbial contamination, puts it succinctly when interviewed on CBS's 60 Minutes: "Well, it's clear the company [NECC] made a conscious effort to disregard that warning letter because only a few years later they were engaged in the very behavior the FDA warned them about"²⁸. During that same broadcast, a former NECC employee indicated that he witnessed technicians handling drug vials without hair nets or gloves. Another former employee indicted the owners by indicating that the company's owners discussed as far back as 2009 as to whether NECC had crossed the line from compounding, which involves mixing approved drugs for individual prescriptions which is allowed to manufacturing, which would require more oversight. Sheldon Bradshaw suggested that NECC is among other large drug manufacturers who operate under the pretense of traditional pharmacy compounding but are clearly violating the law, and that they do so simply because they think they can get away with it²⁸ (Doane, 2012).

The above illustrates the AMCM principle of expectation and enactment about crisis facilitate or hinder crisis preparedness and response^{1-2,12}. For instance, the fact that NECC management considered the possibility of crossing the line between small-scale compounding to large-scale manufacturing suggests they were aware of the possibility of breaking the law. Notwithstanding, there is something to be said about the fact that it is possible that

some of the employees in the *60 Minutes* interview may be disgruntled, but the public's perception in times of crisis is more likely to be anti-establishment or anti-organization than favorable. At the same time, the impression that NECC management continues to operate its business as usual and consequently, it has managed to get away with some violations up to that point, might continue to operate with the expectation of going undetected. Otherwise, NECC would have taken the necessary steps to go through FDA requirements for manufacturing or take corrective measures. This would appear as a faulty assumption on the part of NECC and its management. As is the case with any faulty assumption, it often results in fallible enactment or actions whose consequences can be dire^{2,11,13,16}. From another standpoint, the AMCM contends that assumptions and expectations presented by the model constitute vigilant decision making^{13,29} only when decision makers like NECC are able to efficiently and effectively analyze and evaluate outcomes¹. Furthermore, some scholars have discussed the fact that most crises are preceded by clear warning signals but often frequently ignored^{22,30-31}. Unfortunately, NECC fell short as did other organizations, given that it did not appropriately anticipate any negative consequences from blurring the line between pharmaceutical compounding and manufacturing. Similarly, failure to engage in appropriate precautionary measures undermines the degree of control that the organization has over the crisis and its management^{1-2,10,13}.

In terms of AMCM's principle of control, NECC engaged in some missteps that made it lose control in its crisis management effort. For instance, its decision not to take seriously the FDA warnings in 2004 and 2006 creates the perception that the company does not care²⁸. The failure to engage or enact a voluntary recall of its steroidal injection as soon as the first victim died, and the decision to wait for directions from the FDA, and then suggesting that the FDA's recall is only a precaution does not bode well for the company^{12,16,23}. The failure to engage the public and communicate in a manner that demonstrates care to victims and stakeholders did not represent a competent control of the crisis^{16,19}. Also, the fact that one of the co-owners of

NECC (i.e., Conigliaro) operates a company that recycles foam insulation that is run from the same complex as the NECC²⁸ violates safety requirements that a sterile pharmaceutical operation demands.

7. Implications

Crisis preparedness is important and essential for any organization, particularly when public health is at stake. An organization need not wait for crisis to occur before developing a crisis management plan. It appears that NECC, despite several warning signs, considered itself invulnerable to crisis. Vigilant anticipation requires more than just organizing far in advance and preparing speeches to minimize crisis effects on an organization³². Successful anticipation and vigilance involves risk assessment and critical evaluation of potential vulnerabilities from different causes of actions and inactions. Effective and proactive communication is important to maintain with the affected publics and stakeholders in times of crisis. Failure to select appropriate spokespersons other than lawyers can hinder any crisis management effort. Lawyers or legal counsel are paid to deal with liability, but adequate crisis management goes beyond liability avoidance; it must convey sincerity, adherence to the principle of non malfeasance, and genuine apology. The moment of crisis is not the time to put financial considerations ahead of public safety¹⁶. From a pre-crisis standpoint, it is important that organizations identify potential source(s) of crisis and develop a plan of action to prevent them and consequently enact the plan when a crisis occurs.

In the case of NECC, contamination prevention is one such area of crisis management, and efforts or programs ought to be in place to put sanitation as a top priority and not wait until regulators identify problems. Furthermore, operating in tandem within the boundary of regulations is prudent. If the management can catch itself or speculate that there is the potential of violating the law, chances are it is. Therefore, the management must take appropriate measures to ensure that the company is in compliance. Doing the right thing might be difficult at first, but in the long run it would save the company from a bigger headache. Thus, it is imperative that organizations should make every effort to do things right the first time.

The NECC meningitis outbreak crisis underscores the importance of prevention and crisis management to safeguard and protect the community from a public health standpoint. The protection can be done from an issues management perspective, which emphasizes the need for increased regulations and the demand for stricter compliance with current regulations to protect the public and health consumers. The public needs to demand better from pharmaceutical companies and retail pharmacies regarding how their medications, and in particular compounding medicine, might affect them. Lack of knowledge and information from this standpoint is likely to result in more episodes like the meningitis outbreak that will further put the public and their health at risk. Moreover, the risk might not necessarily be limited to compounded drugs but other manufactured medicines, as illustrated in the Johnson and Johnson phantom recall case¹⁶.

In essence, the NECC crisis is only symptomatic of what could potentially unfold in the public health arena. The overall goal of public health is to educate the public on matters of health and safety whenever necessary, monitor industrial health standards, and prevent or at least control the outbreak of illness and infection³³. NECC has a responsibility to the public to process and disseminate products that are safe and effective, and to take the best measures possible not to hamper the health of the population segment that needs their drugs. Moreover, NECC has the obligation to be transparent about product flaws that may have unfortunately made their way to the market. Given these responsibilities and obligations, this study contends that NECC failed in its part to promote and safeguard public health. Hence individuals, government agencies, and communities at large would be better served in identifying such potential sources of healthcare crises and develop appropriate steps to safeguard against them as specified by the tenets of AMCM.

Finally, this case brings to the forefront that issues management and crisis management often go hand in hand. Issues management, in essence, represents a strategic approach to crisis management, and in terms of AMCM and crisis prevention, crisis is indicative of a distinct pattern of unfolding occurrences, and the

patterns are identifiable even prior to a triggering event^{2,22}. For instance, in the case of NECC, there are the warnings based on FDA regulations and guidelines for pharmaceutical compounders versus manufacturers, and then there are previous violations and compliance notifications prior to the actual cases of fungal meningitis infection. These circumstances could have prompted NECC to make some pivotal decisions to prevent a full-scale meningitis outbreak¹⁶. How organizations choose to respond to a crisis could make or break the success of its crisis management plan because publics are more likely to remember not only that the crisis occurred, but more importantly, how an organization responded to the crisis.

8. Limitations

This present study utilizes a case study methodological approach. As is with any case study approach, generalization is problematic and should be done with caution. More empirical studies should be conducted as to the specific causes of miscommunication with the public and the lacking precautionary measures. Nevertheless, the attempt to understand what happened with the NECC, regardless of methodology, still offers crisis managers a general glimpse of what to do and what not to in crisis planning and management. As discussed in the paper, the idea of anticipation of crisis potentials and possibilities is something from which any organization, regardless of size, can benefit. Furthermore, anticipation by itself is not sufficient until organizational leaders develop a plan of actions to prevent or at least minimize catastrophe should crisis ensue. Finally, waiting for crisis to occur before engaging a crisis plan is reactionary rather than proactive. These conclusions, regardless of idiosyncrasies of organizations or environments, are valuable to any crisis prevention and management.

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