An Actor-Network Theory Analysis of the Causes of the Cutter Incident

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On my honor as a University student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments.

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Introduction

In April of 1955, the United States' battle against the poliovirus reached an important milestone. Thomas Francis, a respected virologist, presented epidemiology data from the field trials of 1954 suggesting that a new vaccine created by Jonas Salk could help protect people from the crippling effects of polio (Juskewitch et al., 2010). Within days, laboratories around the country began producing mass quantities of this new vaccine. One such lab was the Cutter Laboratory in Berkeley, California. Although many labs produced safe vaccines, the Cutter vaccine was administered to over 300,000 individuals before it was understood that the vaccine still contained live polioviruses (Langmuir et al., 1956). Many individuals who received this vaccine began showing polio symptoms within 4-14 days, and after just a few months, hundreds were paralyzed and eleven were dead. This tragedy is now known as the Cutter Incident, and it sparked a number of administrative changes in the United States (Center for Disease Control and Prevention, 2020).

This incident is traditionally understood in one of two ways. In his widely reviewed book on the broader context of the Cutter Incident, Paul Offit argues that a lack of experience in the laboratory led to the failure (Fitzpatrick, 2006). He cites poor communication with the government, the choice of a particularly virulent viral strain for the vaccine, and inadequate safety testing as primary factors involved in the failure of the Cutter vaccine. Ultimately, Offit narrowly places blame on the Cutter Laboratory itself without considering many other actors involved (Carapetis, 2006).

Similarly, other scholars have narrowly placed blame on the speed of the vaccine project. After all, the average time for a medical discovery to reach patients was 17 years, and this particular vaccine did the same in only 6 years (Juskewitch et al., 2010, p. 183). Juskewitch et al. make this argument in their article, "Lessons from the Salk Polio Vaccine."

Although the accelerated pace of the vaccine project and the inexperience at the Cutter Laboratory played important roles in the polio vaccine network's collapse, these views are simply too focused on individual contributors. If we understand the Cutter Incident only in terms of individual failure, we risk misunderstanding how other influential actors like regulatory legislation and monetary influence contributed to the temporary collapse of the polio vaccine network. Drawing on Actor Network Theory, I argue that the polio vaccine network collapsed not only because of its accelerated pace and Cutter's inexperience, but also because of actions by the National Foundation for Infantile Paralysis (NFIP), the press, and Dr. Jonas Salk.

In what follows, I will first provide relevant background information on polio. Then, I will use Actor Network Theory to describe the heterogeneous structure of the polio vaccine network and its ultimate collapse. This network was large and powerful because it included many human and non-human actors which strived for the common goal of a safe, effective polio vaccine. In this argument, I will draw on government reports on the vaccine and on the field trials of 1954, a law review of the Cutter incident, and contemporary press coverage surrounding the vaccine.

Overview of Poliomyelitis

Poliomyelitis is a complicated viral agent that ravaged the United States during the twentieth century. The first outbreak was recorded in 1894, and it included just over 100 cases, but in 1916, polio infected 27,000 people and killed 6,000 of them (Juskewitch et al., 2010, p. 182). From 1916 onwards, the number of cases fluctuated widely from year to year. The CDC reports a yearly average of 16,000 cases between 1951 and the release of the vaccine in 1955 (CDC, 1999).

People infected with polio could expect to feel classic viral symptoms like fever and sore throat, but 1-2 percent of cases developed paralytic polio (Juskewitch et al., 2010). Those with paralytic polio experienced two phases of symptoms. In the acute phase of paralytic polio, the muscles associated with breathing and normal bodily function were compromised. Many polio patients died of asphyxiation during this initial phase (Juskewitch et al., 2010). In 1927, Drinker and Shaw invented the iron lung to help patients survive the acute phase of polio. This contraption was an intimidating, large machine that helped people breathe when they could not use their diaphragm. It also became a scary icon of the devastating virus (Spencer, 1955). The second phase of polio lasted for the rest of patients' lives. Although breathing and normal bodily functions usually returned, patients could expect to remain paralyzed indefinitely.

Polio also disproportionately affected children, worsening the public outcry for a solution. In 1955, children at 6 years old were two times as likely to develop polio than those at 15 years old (Langmuir et al., 1956, p. 86). Combined with the President Franklin D. Roosevelt's notable case of polio, the public was very aware of its crippling effect.

Literature Review

Although multiple scholars have studied the Cutter crisis of 1955, none have reached as holistic a conclusion as this incident requires. Instead, scholars have tended to narrow their analysis to a single cause of failure. In this section, I will outline one argument posed by an independent group of scholars and one argument released by the government.

One scholarly example of this type of narrow thinking is in “Lessons from the Salk Polio Vaccine: Methods for and Risks of Rapid Translation” by Juskewitch et al. The article opens with a quick overview of the virus itself and the vaccine’s field trials, but its main argument is that the Cutter incident was “a result of its rapid [transition from discovery to implementation].” These authors support their argument by citing the factors which accelerated the vaccine production, but they maintain that speed was the main cause of the collapse. Although the network might have reached a more stable equilibrium if given more time, this argument is undeveloped, and it misses many actors involved in the collapse of the polio vaccine network.

Another relevant work in the realm of the Cutter incident is the Public Health Service’s official “Surveillance of Poliomyelitis in the United States in 1955.” This investigation was written by Langmuir, Nathanson, and Hall on behalf of the government. It was intended to inform “hesitant parents or community groups” that considered getting the vaccine. Their evaluation avoids placing blame in any meaningful way except for the cursory statement that “few plans had been made to conduct controlled studies of the effectiveness of the vaccines” in use during the Cutter incident. That is to say, the government did not adequately plan to test the vaccines released to the public. Just like the argument made by Juskewitch et al., this argument only considers a single actor involved in the failure of the network. As such, it is far too narrow.

In what follows, I will bridge the gap left by the authors mentioned above. My argument will synthesize and broaden the narrow claims that speed led to the Cutter incident and that poor government planning led to the Cutter incident.

Conceptual Framework

My analysis of the Cutter incident draws on the many human and non-human actors involved in the development of the polio vaccine. As such, the science, technology and society (STS) concept of Actor Network Theory (ANT) will allow me to effectively decompose and explore the various connections between these actors. The main idea of ANT is that engineers exercise power and influence by building and maintaining effective actor networks. This process is known as heterogeneous engineering because it involves both human and non-human actors united toward a common goal (Cressman, 2009). Powerful networks draw their power from the strong connections between various actors instead of individual capability, so an isolated actor holds little influence. Along these lines in his overview of ANT, Darryl Cressman asserts that "we should not ask if this network is more powerful than another; rather, we should ask if this association is stronger than another one" (Cressman, 2009).

The process of forming and maintaining an actor network is called translation, as established by Michel Callon. This process includes four steps (Callon, 1984). My argument will follow the polio vaccine network through translation, so I will outline the steps below. The first step is known as problemitization, and during it, the network builder identifies both the problem and the actors needed to solve it. Next is interressement, in which the network builders recruit human and non-human actors to join the network. Third is enrolment, when network builders assign roles to the actors of the network. These actors must accept and perform these roles for the network to function successfully. The last step of the translation process is called mobilisation, when network builders solidify their role as the spokespeople for other actors in the network. After translation, a successful network can be viewed as a black-box, which produces its output in a coherent, stable way (Callon, 1984).

Analysis of the Polio Vaccine Network

Actor and Problem Identification

In this section, I will identify the central actors in the polio vaccine network, and I will describe their relevance within the network. This will help clarify the Cutter situation and demystify its causes. The network builder and thus a very important actor in the polio vaccine network is (i) *the National Foundation for Infantile Paralysis* (NFIP). They are the obvious network builder because they identified the problem and recruited relevant actors to solve it. The NFIP was created by President Franklin D. Roosevelt in 1938 to ensure that "every responsible research agency in [the United States] is adequately financed to carry out investigations into the cause of infantile paralysis and the methods by which it may be prevented" (Brandt, 1978). As such, the goal of the network was defined. With this broad goal in mind, the NFIP began to identify the other actors needed to solve the problem.

The NFIP identified six other actors necessary to solve the problem at hand: (ii) *the American public*, (iii) *the press*, (iv) *scientists*, (v) *the government*, (vi) *the poliovirus* itself, and (vii) *independent laboratories* (Brandt, 1978, Juskewitch et al. 2010). The American public would become both the user and the financial supporter of the network, so they constitute an important actor. The press also played an important role in the network because they distributed relevant information from the NFIP to the public. Scientists would be responsible for research and development of a solution to the problem, and the government would oversee their activity. The poliovirus itself is a relevant actor because it causes infantile paralysis, which is the root of the problem at hand. Interestingly, it was also fundamental to the vaccine formula. Finally, independent laboratories are important actors because they would help meet the inevitably large public demand for the vaccine. With the goal defined and the actors identified, the NFIP began the process of recruitment for the polio vaccine network.

Actor Recruitment & Role Assignment

In this section, I will describe how the NFIP recruited the relevant actors and assigned them roles, and I will start with the American public. The NFIP developed a strong financial and emotional connection to the American public that laid the foundation for all other connections within the network. Basil O'Connor, President Roosevelt's former law partner, led the NFIP and spearheaded a very successful fundraising campaign to recruit the public. This campaign was innovative because it involved people of all socioeconomic status, not just the wealthy. For example, the NFIP once asked the American public to send dimes directly to the white house in celebration of President Roosevelt's birthday. After more than 2,600,000 dimes marched into the White House, the NFIP earned the nickname "March of Dimes" (Brandt, 1978). This financial connection grounded the NFIP, which was not funded by the government. The connection between the NFIP and the American public was also emotional because of the nature of the disease. Images of people fighting for their life in the iron lung, stories of paralyzed children, and press conferences from the President brought polio painfully into the public eye. The public yearned for an end to the crippling disease (Spencer, 1955).

Although it is not certain, it can be reasonably assumed that the NFIP recruited the press in a more passive way than they did the public. The press naturally covered the NFIP and its activity because polio was a relevant topic at the time. Press coverage from the Saturday Evening Post and the New York Times will be considered in what follows.

To recruit scientists, the NFIP awarded large, long-term grants to researchers and institutions that studied polio. These scientists came from many different universities and labs, and they recruited the polio virus, in turn. The successes of relevant scientists will be considered in the proceeding section (Brandt, 1978). Notably, without the widespread public support that the NFIP enjoyed, they could not have paid the scientists in the same way.

The connection between the government and the NFIP was a weak one in comparison to other connections in the polio vaccine network, and the NFIP did not formally recruit them until the vaccine was already to be tested. The Food and Drug Administration's only legal requirement was that drugs were safe, not effective. This meant that they had no legal obligation to oversee trials and testing meant to ensure the effectiveness of the vaccine. However, the NFIP required that vaccine manufacturers test all product in a federal lab before using it in the field trials of 1954 (Brandt, 1978).

The last actor that the NFIP recruited for the polio vaccine network was the independent vaccine manufacturers' laboratories. This recruitment was similar to that of the scientists because it was mostly monetary. The NFIP paid labs to produce the vaccine in large quantities after it was discovered (Brandt, 1978). After the NFIP recruited these five actors, the network could function as intended.

Role Performance

In this section, I will explain how each actor performed their assigned role. Many relevant actors' performances shifted during the successful field trials of 1954, so I will split each actors' actions into pre-trial and post-trial. The field trials are not directly relevant to this paper, but they included over 1.8 million children and constitute one of the largest clinical trials in history (Meldrum, 1998).

The scientists in the polio network made a number of significant advances which enabled the field trials to take place. In 1949, the three types of poliovirus were identified, and polio was cultivated in nonnervous tissue for the first time. (Juskewitch et al., 2010). Two years later, Dr. Jonas Salk began the search for a vaccine, and "within a year he had successfully immunized monkeys in his laboratory" (Brandt, 1978). During the months leading up to the trials, however, some scientists remained skeptical of Salk's vaccine. For example, Dr. Albert Milzer had trouble creating the vaccine in his lab at the University of Chicago, and he found live virus in his final product multiple times (Brandt, 1978). Also, Dr. Albert Sabin, a competitor of Salk, consistently criticized Salk's vaccine. In contrast, Salk gave the public "every possible assurance" that his vaccine would be safe. After the field trials, the scientific community remained uncertain. Sabin continued to attack the vaccine while Salk proclaimed his confidence.

The NFIP established new regulations and made important organizational changes before the field trials. For example, they hired Thomas Francis, a respected virologist, to lead the charge. His experience with the field trials of the flu vaccine boosted public confidence in the whole project (Meldrum, 1998). The NFIP also tightened the testing policy for the vaccines that would be used in the trials. They required all vaccine lots to be tested by the manufacturer, the Salk labs, and a lab in the United States Public Health Service (USPHS). Also, they required that each manufacturer produce 11 consecutive "clean" lots of vaccine for their product to be accepted (Brandt, 1978). After the trials' success, the NFIP dropped the triple testing protocol and the consecutive batch requirement. All they required was that each manufacturer submit a written protocol to the USPHS (Brandt, 1978).

The government completely depended on the NFIP for its role in the vaccine network because it had no legal requirement to oversee the vaccine. Although the NFIP required manufacturers to test their product in the USPHS lab, the USPHS had no legal means by which it could postpone the trials (Brandt, 1978). Despite Dr. William Workman's "serious doubts about the abilities of the manufacturers to produce consistently safe vaccine," the USPHS released a statement on April 25, 1954 approving the NFIP's plans for the field trials. Even this statement seemed like a formality because the trials were slated to proceed the following day anyway (Brandt, 1978). After the trials, the government's main task was to award federal licenses to vaccine manufacturers that they believed could create safe vaccines. They signed six of these licenses, one of which went to the Cutter Laboratory. They also had the power to "spot test" batches of finished vaccine for the final rollout, but they chose not to (Brandt, 1978).

The laboratories played a critical role in the network because they had to physically produce the vaccine. I will narrow my discussion here to the Cutter laboratory. Cutter faithfully followed all the testing requirements put forth by the NFIP leading up to the field trials, and they did not even break any laws after the trials. In civil court, Cutter was not found to be at fault for the injuries they caused (Yale Law Journal, 1955). However, they did make some questionable choices in the gray area between legal and moral action. For example, they chose to only report to the USPHS on their successful lots of vaccine and simply throw out the 9 out of 27 lots containing live virus (Brandt, 1978). They also chose not to ask for help from Salk with their production methods.

The press covered the whole process extensively from vaccine development to official rollout. Journalists from the New York Times portrayed Salk as a hero and as having "scored one of the greatest triumphs in the history of medicine" even before the trials had commenced (Brandt, 1978). The NFIP's president, Basil O'Connor, fanned this flame of confidence by asserting that the fight against polio was on the "verge of victory" with the unproven vaccine (Brandt, 1978). In the midst of all this positive news, the American public yearned for the vaccine. It is notable that the public optimism which stimulated the NFIP's balance sheet was the same thing clouding its scientific judgement.

Failures and Inefficiencies

Now that the performance of every relevant actor has been explained, I will identify the actions that contributed to the Cutter incident. First, this network lacked clear communication between the scientific community and those pushing for the trials. Widespread hesitancy about the vaccine was neglected leading up to the trials and vaccine rollout. Instead of an individual failure, this is an inefficiency of the entire network. There are many paths by which this information could have been relayed.

Second, the NFIP and USPHS failed to maintain acceptable standards for the vaccine in question. The choice to drop the triple testing and the consecutive batch requirement jeopardized the entire network. This failure also applies to the laboratories themselves; low standards for testing do not preclude Cutter from judgement. Their choice to relay only positive information, to ask no one for help, and to simply throw away dirty lots of vaccine is deserving of blame. If polio had any higher of an incidence rate, this mistake could have killed significantly more people.

Third, the government is at fault for choosing not to perform spot tests on the vaccine produced in the independent laboratories. In lieu of formal testing requirements, the need for these spot tests was higher than before.

Fourth, the NFIP should be blamed for confusing its fundraising campaign with scientific opinion. All of the optimism that they pumped into the public to get more fundraising dollars worked against their clear scientific judgement. In this same light, the press can also be held accountable for reporting so exclusively on the positive side of the vaccine. The American public yearned for the vaccine because much of what they read touted its success.

Acknowledgement and Response

As I have argued above, there are multiple important actors which contributed to the collapse of the polio vaccine network. This viewpoint contrasts the viewpoint held by Juskewitch et al. in their paper "Lessons from the Salk Polio Vaccine." They argue that the "serious consequence" of the polio vaccine project was a "result of its rapid translation" from laboratory to bedside. This cursory view fails to consider the significant impact of the specific strain of vaccine that the Cutter laboratory attempted to deactivate for their vaccine. According to analysis done by the chief of the Poliomyelitis Surveillance Unit, the strain used in the Cutter labs contained high concentrations of the Mahoney strain of poliovirus. This strain was "more virulent" and produced "massive viremia and a high rate of fatal paralysis" when given to monkeys in laboratory tests (Nathanson and Langmuir, 1965). This particular strain at least increased the severity of the Cutter incident, and it has nothing to do with the speed of the project.

Conclusion

The Cutter incident was a tragedy in modern medicine with a complicated set of causes, and in this paper, I used the STS concept of Actor Network Theory to systematically analyze the contributors. Press coverage, government documentation, and civil law proceedings helped inform my argument that leading scientists, the Cutter lab, the NFIP, the government, and the press all played a part in the collapse of the network they comprised. This argument is important because if we continue to see the Cutter incident as caused individually by one particular actor, then we cannot understand how the other important actors in the network contributed to its failure.

Word Count: 3639

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