Anthrax: The Precautionary Principle Goes Postal

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The precautionary principle, in its various meanings and guises, has had remarkable success, both in its adoption and its ability to withstand assault from special interests who oppose its implications.[1] This success suggests that something about the principle, where it has achieved currency, is connected to widely shared core values. On the surface those core values are as hallowed and simple as the pieces of wisdom passed from parent to child through the ages—look before you leap, better safe than sorry, a stitch in time saves nine—or a venerable public health cliché—prevention is better than cure. If this were all there were to the precautionary principle, it would still be important: one problem with common sense is that it is not very common so any formulation that aids its application is significant. The precautionary principle could stand on that ground alone. Indeed, the need for an explicit statement of principle grew from clear and obvious threats to the general welfare created by unbridled and irresponsible actions by private interests and public institutions often acting on their behalf.

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But the real world usually resists easy solutions. Does the precautionary principle have additional content that allows us to make operational decisions in hard cases? This article describes some of the principle's underlying values and then examines how these values relate to decisions made in the recent anthrax episode. Its aim is to begin to clarify the deeper structure and scope of the precautionary principle.

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VALUES THAT GUIDE THE PRECAUTIONARY PRINCIPLE

In at least one of its forms, the precautionary principle is guided by four underlying values:[2]

- *Action in the face of uncertainty:* the necessity to make timely decisions affecting public health even in the face of some scientific uncertainty;
- *Transparency:* clarity for the basis of a decision;
- *Inclusiveness:* democratic decision-making by those affected by a decision, with the opportunity to consider a full range of alternatives; and
- *Accountability:* responsibility of actors for preventing harm or minimizing risks to communities affected by their actions.

An overarching value of the principle is the right of all individuals to a healthy and life-sustaining environment for themselves and future generations.

ANTHRAX

After the September 11, 2001 attack on the World Trade Center, we were witness to the first use of anthrax as an instrument of malicious intent, perpetrated by a person or persons unknown. Coping with the anthrax threat, even though the number of cases was small, taxed the public health system and exposed its weaknesses.[3,4] It also required making public policy decisions that could have potentially affected a large number of people. These decisions will be used to examine three of the values underlying the precautionary principle: action in the face of uncertainty; transparency; and inclusiveness.

Anthrax is an ancient disease still shrouded in medical mystery. In part this is because it is primarily a disease of livestock, with serious human cases a thing of the past in this country or a matter of exotic and distant peoples. Since it is extremely rare, it has not received as much attention as some other diseases. Despite its rarity, however, considerable interest has focused on its potential as an agent in biological warfare. An unknown amount of scientific data on the disease is now under wraps and not accessible to the world scientific community.[5]

The basics, however, are relatively straightforward. Anthrax is a disease caused by a bacterium, *Bacillus anthracis*, that exists either in a vulnerable growing and reproducing life stage (its vegetative phase) or in a very resistant, but dormant life stage (a spore form). It is deadly for various animals important in commerce (cattle, goats, sheep) and the spores can remain viable in the soil for decades, and possibly for just as long in the pelts of affected animals. Human infections usually involve the skin (cutaneous anthrax), where a large ulcer forms and becomes covered by a black scab giving the disease one of its names (*anthrax*, meaning "black" in Greek; other names are derived from the occupations of those who principally suffered from the disease: woolsorter's disease and ragpickers disease). On occasion, however, the spores can enter deep into the human lung or gastrointestinal tract and cause inhalation or intestinal anthrax, deadly human diseases with high mortality. These are caused by the same organism as cutaneous anthrax but with a different route of entry.

Anthrax is not spread from human to human. Moreover the inhalational form of the disease, its most dangerous form, is so rare that only 18 cases were reported in the United States in the entire 20th century.[6] Exactly why this form of anthrax is rare is unknown. Inhalation anthrax seems difficult to contract, but not because the organism itself is rare: it is relatively common in the environment of many U.S. states, especially in the south west. It may be that most people, for some reason, are not susceptible to the disease.[7] Studies in factories and mills where infected hides were treated, for example, indicated that the average factory worker might breathe 400 to 500 individual spores deep into their lungs per shift. Yet almost no workers contracted inhalation anthrax, although cutaneous anthrax was relatively common.[8] Despite this apparent innate resistance of many, it is likely true that with a large enough exposure, most people will become sick with inhalation anthrax, and of these most will die (until the recent cases, case fatality of inhalation anthrax was 80% to 90%). Moreover, as with chemical agents, some people will be especially susceptible to much lower doses.[4]

Since anthrax is inexpensive and easy to produce, stable and persistent in the environment, and not contagious, it has been considered an ideal bioweapon that could decimate and demoralize opposing forces on the battlefield. The United States and the Soviet Union, among other countries, carried out active offensive and defensive programs involving anthrax spores specially "weaponized" to infect as many people as possible via the airborne route.[9] It now appears that some of the weaponized material developed in the U.S. program has fallen into the hands of a person or persons intent on using it as a weapon of terror or intimidation.[10,11] However, for the purposes of this article, the origin of the material is not important, since the focus is on how important public health decisions relate to the values underlying the precautionary principle.

This article examines three separate, but related, aspects of the anthrax response:

- Whether and whom to treat with postexposure prophylaxis with antibiotics;
- Whether to shut down the postal system when the danger of massive cross-contamination of the mails was first raised; and
- Whether and whom to treat with anthrax vaccine after the recommended course of postexposure prophylaxis with antibiotics was over.

The anthrax episode might not appear similar to the larger and longer-term decisions traditionally addressed by the precautionary principle. The contemplated use of prophylactic antibiotics on a population basis is itself a serious public health decision, bringing with it not only a hazard of unwanted side effects of the medication to those treated, but more relevantly, the danger presented to the general population. Such use could promote the emergence and spread of many other antibiotic resistant organisms. Currently, antimicrobial agents, such as ciprofloxacin (cipro), are among the most important for many infections that have become resistant to other antibiotics. They are widely used in intestinal and urinary tract maladies. Loss of efficacy would affect many more than those undergoing postexposure prophylaxis. Although the use of this drug for anthrax prophylaxis has been confined to only several thousand people, it could have potentially reached many times that.

Shutting down the U.S. postal system is clearly a public policy decision with far-reaching implications.[2] An alternative, which was adopted, was to embargo selected mail and irradiate it. Workers handling this irradiated mail are now complaining of nausea, breathing problems, and throat irritation possibly connected with the material that enclosed it during the irradiation process.[12]

Finally, the offered provision of the anthrax vaccine as an adjunct to postexposure prophylaxis brings up interesting questions of what the objective of inclusiveness means in public policy-making in these and other instances.

Who was at risk? Postexposure prophylaxis

Experiments with monkeys in the U.S. biological warfare program convincingly established that timely postexposure treatment with antibiotics, to which the anthrax organism was sensitive, could greatly diminish or even eliminate the lethality of inhalation anthrax. Monkeys are expensive, so the trials were small, and there is still uncertainty in the estimate of efficacy of the antibiotics (ciprofloxacin, doxycycline, penicillin, and similarly acting drugs). It is clear, however, that they decrease the risk of dying, probably by a very large margin, if the animal has been sufficiently exposed to anthrax spores and the antibiotic is given soon enough.[13]

Yet, public health authorities are uncertain as to what constitutes "sufficient" exposure. From the outset of recent events, whether from ignorance of the scientific literature or from a misplaced desire to calm public concern, public health authorities—through official spokespeople or on their own—insisted that the threshold for infecting someone with anthrax was a dose to the lungs of 8,000 to 10,000 spores. This seemingly large amount is not likely encountered through casual or even direct contact with a letter containing powdered anthrax spores.[14] While these numbers soon took on a life of their own, they unfortunately had no basis in the scientific literature.

The best published data on the susceptibility of humans to inhalation anthrax comes from three sources: (*a*) older literature on occupational exposure to those who work with animals hides;[6,15,16] (*b*) the extrapolation from aerosol challenge studies on monkeys;[17] and (*c*) an often cited study, published in the journal *Science* in 1994, on the epidemiology of an outbreak of inhalation anthrax resulting in the death of 66 people in the Soviet city of Sverdlovsk (now Yekaterinberg).[18]

The most reassuring of the data come from older occupational studies where goat hide workers were found to be routinely exposed to an estimated 500 to 600 anthrax spores daily, in particles of a size that could penetrate deeply into their lungs.[6] Despite this opportunity for routine exposure, inhalation anthrax almost never occurred until a cluster of four cases appeared in 1957, prompting a detailed investigation of these mills. By the time of the study, about half of the goat hide workers were vaccinated against anthrax, so the relationship to the current situation is unclear. One conclusion might be that day in and day out exposure to 500 respirable spores was essentially safe.

Another perspective is provided by the aerosol challenge studies on monkeys, which involved exposure to a range of spore numbers.[15] The results of these studies are given in the customary terms of the number of spores that would infect and kill *half* of those exposed—the so-called LD50 (lethal dose 50%). Some of the best data (based on over 1,200 monkeys) suggested an LD50 from 2,000 to 8,000 spores, with a single estimate of a little over 4,000 spores. Whatever the true number, the LD50 is just one point on a distribution, not a threshold.

The most troubling data come from Sverdlovsk,

where an unknown amount of anthrax spores inadvertently escaped from a weapons factory and lethally infected an estimated 2% of a downwind population.[16] In this instance, the escape of *Bacillus anthracis* spores in Sverdlovsk did not cause half of the estimated exposed population to perish, "only" 2%. Using a mathematical model based on extrapolating from the monkey data,[15] the authors of the 1994 paper calculated that the amount released might have been as much as a gram (1/28 of an ounce) or as little as a few thousandths of that amount. The infective dose of spores sufficient to kill 2% of the exposed individuals calculated in this study might have been as little as nine spores. Whether these calculations are exactly correct or not, the threshold, if indeed there even is one, could not be as many as 8,000 spores as some unnamed experts contended. These experts mistook a dose that infects 50% of the population for one that infects none (a threshold).

Furthermore, what is also evident in the Sverdlovsk data—corroborating everything we know about environmental and infectious disease epidemiology and animal data—is that not everyone is at the same risk, even given the same exposure. Age, sex, occupational and smoking history, and probably genetic differences all affect any particular person's risk in ways we still do not understand. These variables mean some people might be much more sensitive than others, and a threshold of 8,000 spores for the average person, even if correct, would not likely be true for the many who are more sensitive than the average.

In the setting of an exposure of hundreds of people to aerosolized spores, as in large mail processing centers, inhalation of even very small numbers of aerosolized spores might result in potentially fatal disease in a fraction, although perhaps only a small fraction, of the exposed individuals. But if large numbers of people are exposed, for example 1,000 or more, then even a small fraction, such as 2%, results in 20 affected individuals. At the Brentwood mail facility, where four postal workers became ill and two died of inhalation anthrax, more than 1,000 workers were present in the room where a contaminated letter ran through the machines. Should all of these workers have been considered exposed from the outset and been offered a 60-day course of antibiotic? A public policy decision, made under conditions of uncertainty, was needed.

Shutting down the postal system

Within weeks of the first anthrax cases federal officials became aware that anthrax spores could escape from unopened envelopes, expose postal workers, and present the risk of cross-contaminating other mail. Exposures from unopened mail had infected seven postal workers in Washington D.C. and New Jersey with inhalation anthrax and given cutaneous anthrax to a number of others. Since mail frequently travels in a circuitous and unpredictable manner, it might not be possible to know which parts of the system had become contaminated and which had not. There were already reports of contamination in facilities distant from New York or Washington D.C., where contaminated mail had been routed.

Officials did not know the extent of this contamination, nor the risks presented by any contamination that did exist. Already the comfortable but erroneous notion of a high exposure threshold was looking shaky, although, publicly, the 8,000 to 10,000 spore threshold fiction was still being maintained. After a period of public indecisiveness and false reassurances, there was evident need to "get it right" in a firm and confident manner. (According to *The New York Times,* the CDC's acting deputy director of infectious disease, now the CDC Director, "felt huge pressure to act decisively, even as events in Washington had made it clear to them that decisiveness was hardly warranted.")[2] Public trust and credibility were diminishing in a way that might make any decision irrelevant if the perception grew that what was being sent through the mail system was too dangerous to use or to handle. In addition, a large number of postal workers were potentially at risk.

On October 22, 2001, according to *The New York Times,* a public policy decision, under conditions of uncertainty, was made in a small conference room by a handful of CDC scientists who knew that their recommendations would likely carry the force of law in this crisis.[2] Certain lots of mail were impounded for later treatment by irradiation and the rest of the postal system stayed open.

Anthrax vaccine

The recommendations for postexposure prophylaxis with antibiotics were for a course of treatment of 60 days. This was based upon experience with monkeys, which indicated that some exposed animals whose treatment was discontinued at 30 days went on to develop fatal anthrax. Those animals died, presumably, because the spores were "hiding" ungerminated in the lungs until much later, when they reverted to the vegetative phase—the form in which they are susceptible to antibiotics. Data from Sverdlovsk showed the last case appeared 43 days after the putative exposure. Hence, it seemed that, with a small cushion, 60 days would suffice. However, independent data also indicated that some spores could remain viable within an animal

lung for up to 100 days. If this was so, there might be no time limit on the risk after antibiotics were discontinued.

The only additional data that seemed to bear on how long to treat exposed individuals prophylactically involved the same animal trials that produced the recommendation for a 60-day course of treatment with antibiotics.[11] Those trials used small treatment groups of 10 monkeys each. One of those groups was treated both with anthrax vaccine and the antibiotic doxycycline. The other groups were treated only with doxycycline, ciprofloxacin or were untreated. Animals in the untreated group had high mortality, but in the treated groups only one animal (of ten) or none died, a clear demonstration of efficacy of postexposure treatment. The group in which no animals died was treated with both vaccine and doxycycline, while one animal died in each of the groups treated only with the antibiotic. This was not a statistically significant difference between the treatment groups, since in such small groups of animals the difference between one death and no deaths could easily have been the result of random sampling.

But it was still a data point. And there was some plausibility to the notion that the initial period of antibiotic treatment gave the body time to develop vaccine stimulated antibodies, thus affording long term protection after discontinuing the drug. Consequently, as the 60-day period of antibiotic prophylaxis for postal workers and congressional staff was elapsing, federal officials decided to offer anthrax vaccine to any congressional or postal employee who wished it. The stockpiled vaccine was in short supply and, at the time of the decision, there was no new source, so the offer was a major policy decision.

The offer, however, came with no recommendations, but instead, a series of caveats. Federal officials stressed, for example, that there was always some risk of side effects with the use of any vaccine and that the efficacy of the combined vaccine and antibiotic regimen was untested in humans. In other words, buyer beware. Moreover, there were persistent rumors that this vaccine, which had been used in the Gulf War, was the cause, or at least one of the causes of Gulf War illness, a contention denied by the military. In addition, federal officials had asserted that the danger from anthrax exposures was now negligible, a claim reminiscent of their earlier denial of an anthrax risk to postal workers that turned out to be far from negligible.

The pros and cons of using the vaccine were described in some detail to those at risk and in the media. But the reaction of the postal workers to the offer of a vaccine for an untested use was immediate and vigorous. Accusing the government of using them as sacrificial lambs and guinea pigs, postal union officials angrily rejected the offer.

On its surface the decision had the ultimate in democratic attributes: control remained with individuals most affected, after consultation with their own experts (their doctors). This inclusiveness was not appreciated by the affected parties.

Anthrax and the many faces of uncertainty

For the initial postexposure prophylaxis of the Brentwood postal workers, an overt decision was made not to treat them, based on an incorrect belief about the degree of risk. The error about the quantity of spores needed for infection was compounded by a failure to appreciate the potential for exposure, despite the documented exposure in Senator Daschle's office. There was also a failure to perform the same kind of exposure assessment at Brentwood as in the congressional offices, where nasal swabs were done as a way to estimate the extent of spore dissemination in the offices.

The precautionary principle conveys that it is permissible, even desirable, to take actions to safeguard the public even when full and verified scientific knowledge is absent, i.e., when there is uncertainty. This article distinguishes four kinds of uncertainty for the purpose of this analysis:

1. *True uncertainty.* This is an actual lack of data about important parameters, for example, in this case, the minimal infective dose.
2. *True uncertainty supplanted by false knowledge.* This is a false belief about what the data actually showed, in this case, that the minimal infective dose was 8,000 to 10,000 spores.
3. *Manufactured uncertainty.* This is common in many environmental disputes, where the strategy is to cast doubt on well founded scientific judgments that have uncomfortable implications. This is knowledge, masked by a false uncertainty.
4. *Systematic uncertainty.* Sometimes information is available about some things or populations and not others, or information is available to some and not others. In such instances we should ask how it is we know about some kinds of information and not other comparable information. In the case of anthrax, the ultrahazardous nature of the material was known to bioweapons experts, but not, apparently, to public health experts. The widespread exposure from the Daschle letter was documented for congres-

sional staffers, but not for Brentwood postal workers.

The anthrax situation involved uncertainty of types 2 and 4. In the context of those uncertainties, an action (in this case, a lack of action) was taken. Should all the Brentwood postal workers have been given prophylactic ciprofloxacin? Such action might have saved the two postal workers who later died. And it could be considered reasonable on the grounds of what was known shortly after the letter to Senator Daschle's office was opened and found to have exposed more than 30 people. The Daschle letter could have, perhaps should have, alerted public health authorities that they Andy Stirling and David Gee investigate the complex relationship among science, precaution, and public policy. Based on various examples, they propose means for more effectively applying precaution in science policy. were dealing with an ultrahazardous form of anthrax powder—one capable of exposing almost everyone in a multilevel office suite merely as a result of opening a single letter. This fact was presumably known to weaponeers who design such material explicitly for increasing the potential for exposure. The exposures in Senator Daschle's office were detected by using nasal swabs—an imprecise method that tells little about risk other than indicating that exposure has occurred—and was therefore abandoned by the CDC for routine use. But because more than 30 people had spores in their nasal passages, all congressional staffers in and near the offices of Senator Daschle were swabbed and provided a prophylactic regimen of ciprofloxacin. The Brentwood employees were not swabbed, so there was not the same evidence of widespread exposure to prompt prophylaxis as in Senator Daschle's office.

The failure to have any exposure information for the postal workers illustrates type 4 uncertainty, an uncertainty borne of a differential incentive to develop information. There were incentives to develop as much information about exposure as possible in the congressional offices, where powerful individuals and their staff members did work that could be temporarily halted with little consequence to the general public and the economy. For the postal workers, neither factor operated to get exposure information. In the CDC's view, evidence of widespread exposure would not have told them anything more about the risks of that exposure (which they incorrectly believed to be negligible), but would have had a major impact on the operations of and public confidence in the postal system.

An area where further work might be useful is in understanding the effects of different kinds of uncertainty on how the precautionary principle should be operationalized. Are some types of uncertainty more reliable clues to action than others? For example, manufactured uncertainty would seem to be a prompt for more vigorous and urgent action than true uncertainty, although one can think of many instances where this would not be determinative. The most difficult problems concern cases where all the various options carry with them uncertainties about substantial harm. Is it the case, then, that the precautionary principle is of limited use when no course of action would clearly be dominant in avoiding serious consequences?

Anthrax, transparency, and inclusiveness

The larger decision to keep the postal system open was made in the face of genuine uncertainty about the meaning and risks of cross-contamination (type 1 uncertainty). But the postal workers and the general public were not consulted or presented with a full range of alternatives. Nor was there transparency in the decision-making process beyond media discussion. So in this case, major objectives of the precautionary principle were not fulfilled.

It is always best to consider all plausible alternatives, but delay entails its own risks. Shutting down the postal system had risks to health and welfare—most of them difficult to quantify, but surely significant. The adopted alternative—embargoing selected batches of mail and irradiating them—may also have been problematic. Other choices that emerged (chemical treatments, for example) were similar in risks. When there are no good choices, some of the value of transparency also disappears.

The incorrect information about the threshold for anthrax infection as the basis for the decision was shared with the postal employees, at least to the extent of alleging it was part of the scientific knowledge base. If we assume that the data from the Sverdlovsk study was not deliberately withheld, or in the confusion of the moment didn't get to the decision makers, we are left with a kind of transparency to the extent that decision makers shared whatever information they believed to be true. Sharing false information is not usually of much help, even when done with the best of intentions. Transparency can only take us so far. It is not a cure, although an important value to strive for.

Sometimes transparency means sharing ignorance. In many cases, it is important for all concerned to be aware of what we don't know as much as what we do know. However, when the full scope of that ignorance was shared with postal workers in the context of offering them anthrax vaccine, their response was resentment and fury.

Unfortunately the whole notion of transparency is not as transparent as we might wish, despite its surface appearance. Indeed it is most often the "obvious" notions that hide the most difficulty under the surface, their very obviousness resisting the kinds of analysis that are most needed. I suggest something of the kind is at work in the notion of transparency. We need further analysis.

The same might be said of the notion of inclusiveness. The decision to keep the postal service open was hardly inclusive. Postal workers did not have their own medical experts, who, in any case, would likely have been as mistaken as anyone else about what the actual risks were. On the other hand, in a fast moving and fluid situation, to require some kind of formal stakeholder process is neither realistic nor probably desirable. Given the situation, it is an important question whether most postal workers were necessarily looking for a place at the decision-making table, or rather wishing, as did any other segment of the general public, their interests were considered and guarded with the same zeal as anyone else's, in particular, members of congress and their staffs. Clearly people differ in the extent to which they want actual control. We shouldn't assume, however, that such control is universally desired or desired by any one person at all times.

On the other hand, it is possible that at least two members of the public contracted inhalation anthrax from cross-contamination and died, although their exposures may have occurred before anyone knew of the problem and would not have been affected by any decision to shut down the system. Including postal workers in the decision-making would almost certainly have resulted in a shutdown. The calculus from their point of view was quite clear: why should they take even the smallest chance so that the mail would go through? In this case, the inclusiveness objective of the precautionary principle would have been determinative. But what of the other stakeholders: the general population and enterprises whose mail would be stopped?

The vaccine dilemma reveals an important aspect of inclusiveness. The failure was not failure to include those affected. The failure was in the credibility and trust invested in the decision makers.

In recent discussions of the precautionary principle, there has been more of an emphasis on the "democratic" part of democratic decision-making as part of transparency and inclusiveness. This emphasis has the effect of highlighting power relationships, especially in regards to who has the best access to information, influence, and resources in our society. Clearly, such factors affect decision-making. Also, they likely affected the different ways Senate staff and postal workers were treated, and the reaction of postal workers to events. But given the lack of options that were clearly better than all others, this has the effect of converting the decision to one about political power. It may be that this is in fact part of the content of the precautionary principle. If it is, we should be clear about it.

CONCLUSION

This article examined three values that underlie the precautionary principle: action in the face of uncertainty; transparent decision-making; and inclusion of those affected in the decision-making process. Though desirable objectives, none are panaceas, individually or collectively. Uncertainty is a more complex notion than a simple formulation credits. There are many cases, perhaps the majority of them, where no single course of action clearly embodies the least risk. We are not helped in how to act in the face of such uncertainty. Also, the examples presented here suggest that in such cases neither transparency nor inclusiveness is a cure. Hard cases are hard cases because there is no formula that solves them.

The precautionary principle has shown itself a durable and important tool in pointing us toward courses of action that will maximize our chances of a safe and healthy environment as we negotiate a complicated political, social, and technological landscape. When we confront cases where the safest path forward is harder to discern, we need to sharpen and clarify the foundations of the precautionary principle. The principle has proved its worth and seriousness. We need to strengthen its intellectual and theoretical basis as we face new challenges. Difficult theoretical work remains to be done.

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