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## Chaper 1: What is Smallpox?

### 1.1 The Smallpox Disease

Smallpox is a serious disease which kills up to 30% of the people infected with it. The last known case of smallpox was in 1977 in Somalia. The virus **which** that causes the smallpox disease is variola.<sup>1</sup> The variola virus includes agents from vaccinia, monkeypox and cowpox. The poxvirus genome, the largest of all virions, is a brick-shaped structure with a diameter of about 200 nm, consisting of a single molecule of a double-stranded DNA.<sup>3</sup>

Smallpox causes a severe rash that can have a scarring after effect, high fever, tiredness, excruciating back pains, terrible headaches, and even blindness. Also, vomiting can sometimes occur.

The name smallpox is derived from the Latin word for “spotted” which refers to the raised bumps that appear all over an infected person’s body. The four types of smallpox classifications are:<sup>2</sup>

#### ✦ Variola Major

- Ordinary
  - ◆ Accounts for 90% or more of all smallpox cases
- Modified
  - ◆ Can Occur in a previously vaccinated person; yet a mild case when **if** it does
- Flat
  - ◆ Usually fatal
- Hemorrhagic
  - ◆ Rare and extremely severe

#### ✦ Variola Minor

- Less severe than Variola Major
- Accounts for 1% or less of deaths from the smallpox disease

Table 1 identifies the stages of the smallpox disease.<sup>2</sup>

Table 1: Stages of the Smallpox Disease

Smallpox Disease	
<b>Incubation Period</b> (Duration: 7 to 17 days) <b>Not contagious</b>	<b>Exposure to the virus</b> is followed by an incubation period during which people do not have any symptoms and may feel fine. This incubation period averages about 12 to 14 days but can range from 7 to 17 days. During this time, people are not contagious.
<b>Initial Symptoms (Prodrome)</b> (Duration: 2 to 4 days) <b>Sometimes contagious*</b>	The <b>first symptoms</b> of smallpox include fever, malaise, head and body aches, and sometimes vomiting. The fever is usually high, in the range of 101 to 104 degrees Fahrenheit. At this time, people are usually too sick to carry on their normal activities. This is called the <i>prodrome</i> phase and may last for 2 to 4 days.
<b>Early Rash</b> (Duration: about 4 days) <b>Most contagious</b>  Rash distribution:	<p>A <b>rash emerges</b> first as small red spots on the tongue and in the mouth.</p> <p>These spots develop into sores that break open and spread large amounts of the virus into the mouth and throat. At this time, the person becomes <b>most contagious</b>.</p> <p>Around the time the sores in the mouth break down, a rash appears on the skin, starting on the face and spreading to the arms and legs and then to the hands and feet. Usually the rash spreads to all parts of the body within 24 hours. As the rash appears, the fever usually falls and the person may start to feel better.</p> <p>By the third day of the rash, the rash becomes raised bumps.</p> <p>By the fourth day, the bumps fill with a thick, opaque fluid and often have a depression in the center that looks</p>



[View enlarged image.](#)

like a bellybutton. (This is a major distinguishing characteristic of smallpox.)

Fever often will rise again at this time and remain high until scabs form over the bumps.

#### **Pustular Rash**

(Duration: about 5 days)

**Contagious**

#### **Pustules and Scabs**

(Duration: about 5 days)

**Contagious**

#### **Resolving Scabs**

(Duration: about 6 days)

**Contagious**

#### **Scabs resolved**

**Not contagious**

The bumps become **pustules**—sharply raised, usually round and firm to the touch as if there's a small round object under the skin. People often say the bumps feel like BB pellets embedded in the skin.

The pustules begin to form a crust and then **scab**.

By the end of the second week after the rash appears, most of the sores have scabbed over.

The scabs begin to fall off, leaving marks on the skin that eventually become pitted **scars**. Most scabs will have fallen off three weeks after the rash appears.

The person is contagious to others until all of the scabs have fallen off.

Scabs have fallen off. Person is no longer contagious.

## ***1.2 Transmission of Smallpox***

Typically face-to-face contact for a prolonged period of time will spread the smallpox virus. However, it can also be contracted from direct contact with bodily fluids infected with the virus or anything contaminated by the virus. The smallpox virus is not normally transmitted through air and does not survive for long periods at customary ambient temperatures. Humans are the only natural transporters of the disease. If someone has contracted the virus they are most infectious during the first 7 to 10 days of a rash appearing and remain infectious until the last scab falls off.<sup>2</sup>

## ***1.3 Risk of the Smallpox Infection***

The majority of people who contract smallpox will recover; however there is a 30% chance of death. Survivors of smallpox will be left with permanent scars over a large portion of their body, especially their face and some may be left blind.

If the smallpox virus is released in aerosol form approximately 90% of the virus will be inactivated or dissipated (dies) within the first 24 hours; in the presence of ultraviolet light this percentage increases. The smallpox virus is a fragile virus.

At this time the vaccine is the only preventative medicine for smallpox. Early laboratory tests are being performed, on animals, with a drug called cidofovir that may fight against smallpox, but not enough information is available at this time to really be certain how well it will treat the smallpox disease.

## **Chapter 2: Why Get Vaccinated?**

The purpose of the smallpox vaccine is to protect those people who work with smallpox in laboratories or those who would be first to respond to an outbreak, should it be used as a biological weapon. The smallpox vaccine helps the body develop immunity to smallpox.

Studies conducted after 1967 found that with the available higher concentration vaccines, major reactions could be induced in those persons successfully vaccinated as recently as 3 to 6 months before, and in almost all of those who had experienced smallpox only 1 year previously. The

vaccinia virus does not protect against smallpox as well as natural infection which provides for permanent immunity. However, in most countries, 90% or more of cases were among individuals without vaccination scars. Further surveys have led to vaccine-efficacy ratios of 80% or more among those vaccinated 20 years previously. Additional studies have shown that this protection could not be solely attributed to the vaccine. They discovered that previously vaccinated persons often developed inapparent infection with substantial increases in antibody levels. Immunity was thus a combination of past experiences with both vaccinia and variola infections. Data from countries where smallpox was introduced after an absence of many years indicate that the vaccine provides substantial long-term protection against a fatal outcome. Among 680 cases of variola major occurring after a smallpox breakout, 52% of those who had never been vaccinated, 1.4% among those vaccinated up to 10 years before exposure, and 11.1% among those vaccinated more than 20 years before died. <sup>3</sup> Current data indicates that 95% of those vaccinated are unaffected by the smallpox virus.

## 2.1 Smallpox Vaccine Safety

The smallpox vaccine is the best protection currently available against a smallpox outbreak. The risks associated with the vaccine are much less than the risks from contracting the smallpox virus. It only takes one person to become infected and it will be considered to be a national health emergency.

There are risks associated with the smallpox vaccine which are detailed in section 3.9.

Statistics show that about 1,000 people out of 1 million vaccinated experienced serious reactions such as erythema multiforme, which is an allergic reaction, sometimes toxic, at the vaccine site.<sup>4</sup> Other reactions include those mentioned in section 3.9. Careful screening of vaccine recipients is required to determine who may be at increased risk.

Should a severe reaction occur Vaccinia Immune Globulin (VIG) and cidofovir may be administered under the investigational new drug protocol. By the start of January 2003 there will have been over 2,700 treatment doses of VIG (which covers predicted reactions of more than 27 million people) and 3,500 doses of cidofovir (which covers over 15 million predicted reactions).<sup>5</sup>

## Chapter 3: The Smallpox Vaccine

After 1977 the routine vaccination against smallpox was eliminated when it was felt there was no longer a danger of conceiving the virus. That is no longer the case as we are now faced with the threat of biological terrorism using the smallpox virus. The cost for smallpox control in the United States during 1968, including the costs of quarantine services, was estimated to be \$150 million. There are tradeoffs between the costs and potential benefits of the vaccine. The interest of the patient (minimization of side effects) and that of the whole of society (overall reduction of vulnerability to the disease) are possibly at odds with each other. Policymakers must address funding for mass vaccination as well as consider which services will no longer be available in order to fund mass vaccination.<sup>11</sup>

### 3.1 About the Vaccine

Sometime before AD 1000, in India, the vaccine was first discovered by deliberately inoculating scabs or pustular material from infected persons into the skin or nasal insufflation of those being vaccinated. This method of vaccination was called variolation. Later material was taken from lesions formed from the cowpox virus and used as a vaccine for smallpox due to their similarities. The use of cowpox was opposed by religious leaders and antivaccinationist societies because it entailed infecting humans with an animal disease.<sup>3</sup>

The vaccine comes from a virus called vaccinia, which is similar to smallpox but not as harmful. The vaccine is not dead yet *does not* contain the smallpox virus and can not give you the smallpox virus.<sup>4</sup> Most vaccine now available is grown on the skin of a calf and harvested after sacrifice of the animal. The vaccine is purified by the addition of fluorocarbon and differential centrifugation, and its bacterial content is reduced by the addition of phenol. Peptone is added as a stabilizing agent, and the vaccine is freeze-dried. Because of its source, the vaccine inevitably contains some bacteria, but properly prepared, the number of bacteria is 10/mL or less. Microbiological examination must confirm that none is a human pathogen.<sup>3</sup>

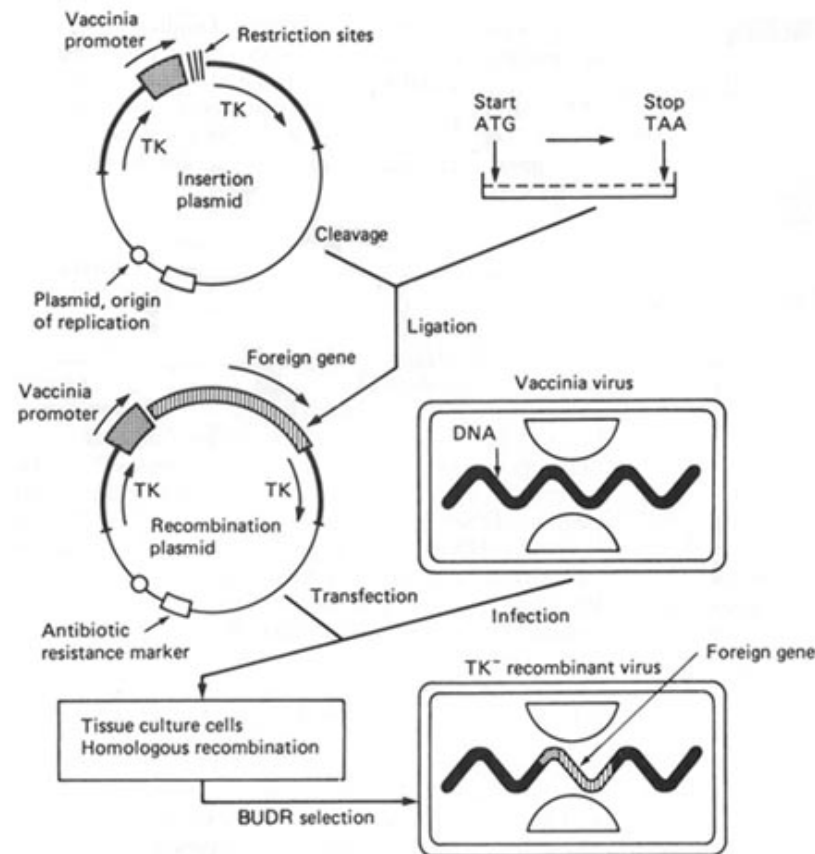
An individual's response to revaccination depends on the level of immunity. Erythema may develop within 24 to 48 hours as a delayed hypersensitivity reaction. Anyone with some residual cell-mediated immunity, but not enough to inhibit viral replication, develop erythema and sometimes a pustule at the site of a vaccination, both of which dissipate more rapidly than in a primary vaccination reaction. Those with substantial immunity may experience no more than the hypersensitivity reaction. A hypersensitivity reaction can also occur due to the use of an impotent

vaccine. Anyone who experiences a hypersensitivity reaction is advised to repeat the vaccination.<sup>(3)</sup>

Recent tests have shown that diluted smallpox vaccine is just as effective as the full-strength vaccine in providing for immunity.<sup>(5)</sup> This will help the vaccine go even farther.

Shortly after the World Health Assembly recommended ceasing production of the smallpox vaccination, proposals were made to use alternative combinations of the vaccinia viruses for immunization against other infectious diseases. How these alternative combinations are generated is depicted in [Figure 1](#).

**Figure 1: Alternative Combinations of the Vaccinia Virus**



### 3.2 Length of Protection

The vaccine protects an individual for 3-5 years from infection with decreasing immunity after that and can protect you from serious illness and death for ten or more years.<sup>(1)</sup> If a person is re-vaccinated at a later time the length of immunity increases.

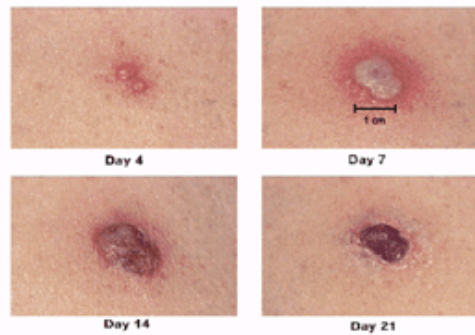
### 3.3 Receiving the Vaccination

Receiving the vaccination *prior to* being exposed to the virus protects most people from contributing the virus. If a person is exposed to the virus and are vaccinated *within 3 days* of initial exposure it may still prevent the disease or at least minimize the effect from the disease. Even being vaccinated *within one week* upon exposure can lessen the effects.<sup>(1)</sup>

The vaccine is administered through skin surface with use of a bifurcated (two-pronged) needle dipped into the vaccine solution. The vaccine is usually given in the lateral surface of the upper arm, and 5 to 15 rapid strokes are made. These strokes are sufficiently vigorous that within 20 to 30 seconds, a trace of blood appears at the vaccination site.<sup>(3)</sup> A successful vaccination will produce a red and itchy bump at the vaccine site in 3-4 days. Within a week the bump becomes a pus filled blister that begins to drain. In the second week a scab will form which will fall off in the third week to leave a scar. Figure 2 illustrates what the vaccination lesion looks like through the first 21 days.<sup>(4)</sup>

**Figure 2: Vaccination Lesions**

### Smallpox vaccination site Days 4 through 21



[View enlarged image.](#)

### 3.4 Availability

The number of production laboratories diminished from 76 in 1977 to 11 in 1985. The few remaining laboratories are in the industrialized countries and are engaged only in the preparation of finished vaccine from bulk preparations harvested in quantity some years ago and preserved by freezing. The virus grown in tissue culture is available in the Netherlands (Lister strain) and Japan (LC 16m8 strain); other countries use vaccine grown on calf skin (primarily Lister and New York City Board of Health strains).<sup>3</sup> Freeze-dried smallpox vaccines are the most stable of currently available vaccines.

Routine vaccination stopped after 1972 when the disease was considered to be eradicated in the United States. Since the events of September – October 2001 the U.S. government has ordered production of the smallpox vaccination in quantities large enough to immunize the American public should a smallpox outbreak occur. Currently the U.S. has access to enough of the vaccine to effectively respond to a smallpox outbreak in the United States.<sup>4</sup> However, at the present time, the smallpox vaccine is not available to the general public and is being kept for emergency outbreak use only.

### 3.5 Ring Vaccination

In a study conducted by scientists from Yale and the Massachusetts Institute of Technology a mathematical model was employed to compare vaccination plans in the response to 1,000 people in a large city being infected with smallpox. The results showed that mass vaccination would result in 1,830 cases and 560 deaths and the outbreak would last for 115 days. Ring vaccination would result in 367,000 cases of smallpox and 110,000 deaths in an outbreak that would last 350 days. Besides the noticeable benefits of mass vaccination it would also eliminate the variola virus as a concern for biological warfare as well as eliminate necessary plans of action should an outbreak occur. The strain on resources would certainly be eased by mass vaccination. Ring vaccination was called for in the guidelines by the CDC due to inoculation being possible up to four days after exposure. The ring vaccination, as can be seen by the mobilization and deployment plans of the CDC are not easy to implement. If attacks occur in multiple locations the situation could exceed the capacity of the CDC and local health officials to carry out the plan.

The risk associated with mass vaccination is that the number of deaths would be sure to be higher than anticipated not only due to the vaccinia itself but from the adverse side effects induced in those individuals who are already at higher risk due to other medical conditions or drugs.

Upon a deliberate release of smallpox health outcomes have been predicted for quarantine, vaccination and a combination of both. Theoretically smallpox could be halted by quarantine alone, but its very difficult to enforce if at least 50% of the U.S. population is put at risk from the release of the virus. Historically, mass vaccination has not been completely successful either in prohibiting the transmission of the disease, therefore its recommended that a combination of both be put into place.<sup>11</sup> This supports the plan that the CDC has enacted.

### 3.6 Mobilization and Deployment

A senior level war exercise was performed, called “Dark Winter”, which staged an outbreak of smallpox on December 9, 2002 to test U.S. reaction to the deliberate use of variola as a biological weapon. The key players served in high level government and military positions and were given the responsibility of determining who would receive vaccinations, developing strategies and instituting procedures to contain the effects of the disease.

This test was not very successful and proved that managing such an attack had to considerably more well planned and organized than that of managing a natural occurrence of smallpox.<sup>11</sup>

Throughout the smallpox eradication program, vaccination of close contacts to smallpox cases played the most important role in stopping

transmission of disease. This strategy may be supplemented with broader vaccination campaigns to increase the level of community immunity to smallpox. However, targeted vaccination of close contacts is the mainstay of smallpox outbreak control as it assures those with the greatest risk of developing and transmitting smallpox will be vaccinated. Prioritizing vaccination based on risk of exposure can help minimize vaccination of those at risk for serious adverse events. The following activities must take place to support vaccination administration in a smallpox emergency:

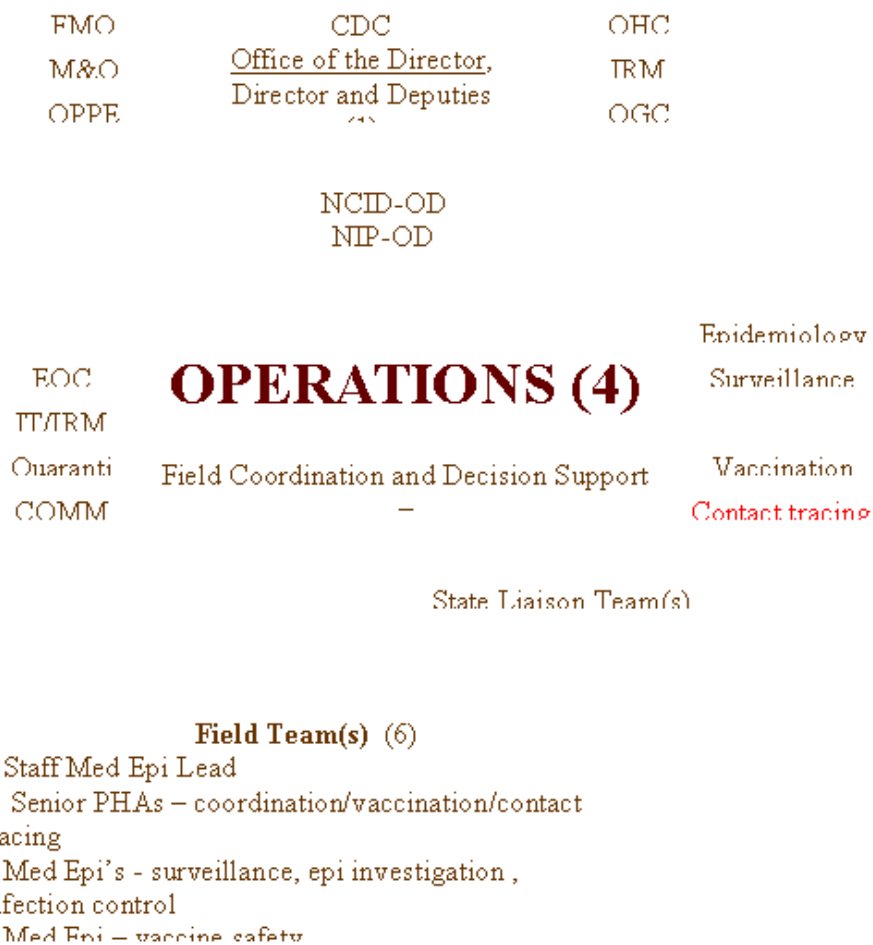
- \* Controlled, non-hospital vaccination sites for close contacts must be established in case large-scale vaccination campaigns must be implemented.
- \* Establish a system for tracking adverse effects, reporting, and treatment of those who received the vaccine.

The primary strategy for surveillance and containment is to identify cases of smallpox, isolate the cases (people), and vaccinate anyone who has already or will come into contact with the cases. This strategy sometimes has been referred to as “Contact Identification” or “Ring Vaccination.” Individuals most likely to come into contact with an asymptomatic (not exhibiting signs or symptoms of smallpox) contact to a smallpox case (i.e., household members of a contact) should also be vaccinated to prevent infection of those individuals, should the initial smallpox contact later develop the disease. In addition, contagious individuals (those with clinical smallpox) must be isolated to prevent contact with non-vaccinated or susceptible individuals during their period of infectiousness. Health-care and public health workers who will be evaluating, treating, transporting, or interviewing potential smallpox cases or administering smallpox vaccine will also need to be vaccinated. The final stage is vaccinating all others who have a probability of contact with smallpox patients or infectious materials.<sup>7)</sup>

Vaccine delivery will be prioritized for areas/states with confirmed cases of smallpox and/or confirmed contacts to smallpox cases. States with probable cases will also have priority over states with no cases.<sup>8)</sup>

The following figure shows an organization chart illustrates the stakeholders affected by a confirmed outbreak of smallpox:

**Figure 3: Flow Chart of CDC Personnel Organization/Mobilization**



### *3.7 Ethics of Receiving the Vaccine*

On July 12, 1974, the National Research Act was signed into law creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Commission had a duty to identify the basic ethical principles for the conduct of biomedical and behavioral research that involved human subjects and to develop guidelines should such research be conducted. The Commission was to consider:

- ✦ The boundaries between biomedical and behavioral research and the accepted and routine practice of medicine
- ✦ The role of assessment of risk-benefit criteria in the determination of the appropriate human subject to be used in the research
- ✦ Guidelines for selecting human subjects
- ✦ The Nature and definition of informed consent in research settings

Through scientific research there have been many social benefits that arose and also some troubling ethical dilemmas. In complex situations broader ethical principles should be applied. The Belmont Report's objective is to provide a framework which should guide the resolution of ethical problems arising from research involving human subjects.

The purpose of medical practice is to provide diagnosis, preventative treatment or therapy to an individual. Research on an individual designates an activity to test an hypothesis, permit conclusions to be drawn and therapy to develop or contribute to generalized knowledge. A procedure that is new and could possible therefore be termed "experimental" does not mean it is research. The rule is that if there is anything deemed research in a procedure it should be reviewed for the protection of the human subjects.

The ethical principles refer to those general judgments that serve as a basic justification for the ethical prescriptions and evaluations of human actions. The basic ethical principles are relevant to research with human subjects: the principles of respect of persons, beneficence and justice. Respect for persons incorporates that individuals should be treated as autonomous agents and that persons lacking the ability of autonomy be entitled to protection. The moral requirements derived from this ethical principle are the acknowledgment of autonomy and requirement to protect those with diminished autonomy. To respect a person's autonomy means that their opinions and choices are to be considered, while refraining from inhibiting their actions. The lack of respect for a person's autonomy would be to minimize the person's considered judgments, deny them freedom to act on their judgments, or to deliberately withhold information necessary for them to make a judgment when there is no compelling reason to do so. The amount of protection provided for those who lack the ability to make autonomous judgment should depend on the risk of harm and the likelihood of

benefit.

Informed consent is another aspect of respect and should include information, comprehension and voluntariness. Information provided to the reasonable volunteer should be such that the person knows the procedure is not necessary for their care nor fully understood and by their participation they are helping to further the knowledge of the researchers (and themselves). The subjects should understand clearly the benefits and especially the range of risks for their participation. If incomplete disclosure is necessary to the research being performed, subjects must be informed that not all information is being provided to them for the benefit of the research itself.

Beneficence includes respecting individuals decisions, protecting them from harm and securing their well-being. Beneficence in human research is a strict obligation and means not to harm human subjects and to maximize possible benefits while minimizing possible harms. However, in medical research learning what is harmful (or beneficial) often puts subjects in harms way. The Hippocratic Oath requires physicians to benefit their patients “according to their best judgment.” Physicians have a moral obligation to best determine when benefits outweigh the risks involved, and when the risks are too great to seek the benefits.

Justice in research on human subjects considers fairness in distribution and what is deserved. An injustice occurs when a benefit is denied to a person who is entitled to that benefit without good reason or when some risk has been unduly imposed on an individual. Justice implies that equals ought to be treated equally. Risks and benefits ought to be provided to each person in equal shares, provided to each person dependent on individual need, provided to each person based on individual effort, provided to each person according to their contribution to society, and to each person on merit. Selection of research subjects should not only include those who are most easily accessible, those who are in a compromised position, or those who are easily manipulated. Research on human subjects needs to include all those who are considered to be beneficiaries and not only those who can afford the advantages.

Finally any morally justifiable research should not contain the brutal or inhumane treatment of subjects, risks should be reduced to the minimum to achieve the research objective, of major risk is involved information, comprehension and voluntariness must be manifested to include justification of the risk, appropriateness of involving vulnerable populations must be demonstrated, and risk and benefits must be clearly spelled out in the informed consent process.<sup>6</sup>

### ***3.8 Risks of Receiving the Vaccine***

The risk of serious harm or death from the smallpox vaccine is very small. Mild to moderate reactions consist of a mild rash, lasting 2-4 days, a fever over 100°F which occurs in approximately 10% of people, or blisters on parts of your body other than where the vaccine was distributed which occurs in approximately 1 out of every 1,900 people. About one-third of those who receive the vaccine miss work due to feeling sick or may have trouble sleeping temporarily. Moderate to severe reactions require immediate medical attention and may be manifested in an eye infection, which could lead to loss of vision or a rash over the entire body, which appears on 1 out of every 4,000 people vaccinated. Severe to life threatening reactions occur with those people cancer, who have or weakened immune systems. Severe and life threatening reactions include severe rashes which can lead to scarring or death, encephalitis which is a severe reaction in the brain that can lead to permanent brain damage or death, or a severe infection at the site of the vaccination that also leads to scarring or death. However, for every one million people vaccinated only fourteen to fifty-two will have a life threatening reaction and only 1-2 will die.<sup>1</sup>

Three types of skin reactions may occur following receipt of the vaccine in various levels of severity. The skin infections that may occur are:<sup>3</sup>

- ✦ Eczema vaccinatum, associated with abnormal host reactions. Occurs in people with eczema. The vaccinated area becomes inflamed, and may spread to normal skin. Symptoms are usually severe and include high temperature and enlarged lymph nodes, however the vaccinia immune globulin will reduce mortality.
- ✦ Progressive vaccinia, associated with abnormal host reactions. Occurs in people with immune system deficiencies. The vaccination site does not heal and secondary lesions sometimes appear elsewhere on the body and then gradually spread. Methisazone may be slightly effective in treatment, unfortunately one third of those who contract this reaction die.
- ✦ Generalized vaccinia, in which many lesions appear in multiple locations of the body. Nothing tragic happens and they follow the same path as the lesion that typically appears after vaccination.

## **Chapter 4: Who Should Get Vaccinated and When?**

If there is no outbreak of smallpox those who work with vaccinia infected or contaminated laboratory animals or handle cultures, and public personnel between the ages of 18-65 who would be first to respond to an outbreak should still be vaccinated.<sup>1</sup>

Should an outbreak occur those directly exposed should be vaccinated as soon as possible, or those at risk of becoming exposed should be

vaccinated as soon as possible upon becoming aware of the existence of the virus.

#### **4.1 Vaccination On Children Under 5**

The Advisory Committee on Immunization Practices (ACIP) met on January 14, 2003 to consider whether a child under the age of 1 year would be a contraindication to the smallpox vaccine. Approved wording from the committee meeting was: *"The ACIP does not recommend vaccination of children and adolescents less than 18 years in the current pre-vaccination program, and smallpox vaccine is contraindicated for infants less than 1 year of age. The presence of an adolescent or child (including an infant) in the household, however, is not a contraindication to vaccination of other members of the household. Data suggests that the risk of serious complications from transmission from an adult to a child is extremely small. However, the ACIP recognizes that some programs may defer vaccination of household contacts of infants less than 1 year of age because of data suggesting a higher risk of adverse events among primary vaccinees in this age group, compared with that among older children."* (5) Parents of young children who are vaccinated need to be extra careful not to infect the children and be sure to keep any articles which might be contaminated out of the reach of children.

The ethical principle of beneficence is found in research involving children. Testing the smallpox vaccine on children could provide the benefit that they too could be made immune to the disease; however it is unknown how much risk is involved in vaccinating children. The risk needs to be weighed against the benefit in this case as well as to the future benefit of children in this age group.

#### **4.2 Priority Groups**

Centuries ago when the vaccine first became available it was mostly used among middle- and upper-income groups in or near cities where the vaccine was produced and in more prosperous countries resulting in the less socioeconomic urban areas having higher infection rates. (3) However, this is morally unethical to offer the vaccine to only those well-to-do families while letting the lower income families contract the disease and suffer the consequences. The CDC has put together guidelines for identifying priority groups to be vaccinated and they are as follows:

- Face-to-face contacts of less than 6.5 feet (or 2 meters) to include any household agents that have come into contact with a smallpox victim after the onset of a fever.
- Anyone exposed to the initial release of the virus
- Those who live with someone in contact with smallpox patients
- Persons directly involved with the smallpox virus and its treatment or transportation
- Laboratory personnel who work with the virus
- Those who have access to or come into direct contact with contaminated materials
- Personnel working in isolation and quarantine centers or interviewing possible smallpox patients
- Persons allowed access to designated facilities for treatment of smallpox or administration of the smallpox vaccine
- Anyone who might be in close proximity to an aerosol release of the virus (8)

#### **4.3 Who Should Not Get Vaccinated or Should Wait**

In a non emergency situation where no outbreak has been identified those with eczema, atopic dermatitis, or a past history of either of these should refrain from receiving the vaccine. If a skin condition is present that causes breaks in the skin, this condition should be given time to clear up before receiving the vaccination. Anyone with diseases such as HIV/AIDS and systemic lupus erythematosus, or cancers such as leukemia, lymphoma and most other cancers, or have been in cancer treatment in the past three months, or drugs which effect the immune system should avoid the smallpox vaccine. Also, anyone under twelve months of age should refrain from receiving the vaccine. The Advisory Committee on Immunization Practices advises that anyone under eighteen years of age should not be vaccinated in a non-emergency situation. Women who receive the vaccine should refrain from becoming pregnant for four weeks afterwards because they risk infecting the fetus with the virus. If you are in close contact with someone in the above mentioned categories, you also should not be vaccinated due to the risk it imposes on those individuals. Others who should not receive the vaccine include breastfeeding mothers, those using steroid drops in their eyes, anyone moderately or severely ill at the time of their scheduled vaccination, anyone who has had an adverse reaction to polymyxin B, streptomycin, chlortetracycline, neomycin, or a previous dose of the vaccine that was life threatening. (1)

Should a smallpox outbreak occur these restrictions may be no longer be applied.

## Chapter 5: After the Vaccination

At the vaccination site a blister will likely form which turns into a scab and eventually leaves a scar. Swelling for 2-4 weeks can occur in the lymph nodes after blistering. Itching at the site of the vaccination, fatigue, a mild fever, a headache, or muscle aches may also occur following receipt of the vaccination.

After being vaccinated the vaccinia virus may be spread to other people or other parts of your body, until the scab falls off. The vaccination site should be covered so as not to irritate the site or the scab. After changing any bandages or touching the vaccination site you should wash your hands prior to touching any other part of your body, especially eyes. Never put ointment on the vaccination site. The used bandages and the scab, when it falls off, should be placed in a sealable bag. All towels, clothes and anything else that might have into contact with the site should be laundered immediately. After 7 days you should have the vaccination site checked to confirm that it is doing its job.<sup>1</sup>

## Chapter 6: How Serious is the Threat of Smallpox?

Throughout the 1970's the Soviet Union possessed more than 20 tons of the variola virus and by 1990 was capable of manufacturing 80 to 100 tons of the virus per year. There are claims that these stores have been destroyed, yet there is no way to prove such a claim. Officially the virus is held only in the United States and Russia; it's considered a principal threat to world's health. Since there is uncertainty whether others besides the U.S. and Russia possess the virus its difficult to assess the seriousness of the threat. Furthermore, the transmission rate of variola depends on several social and biological factors. These facts make it difficult to calculate the risk-benefit of mass vaccination as well as assess how great the threat is.<sup>11</sup> A threat does not seem to exist of accidentally or naturally contracting the smallpox disease since its eradication prior to 1980. However, with the threat of biological terrorism on the horizon the U.S. government has put into effect a nationwide smallpox response plan designed to quickly contain the smallpox outbreak and vaccinate people who may be at risk on contracting the disease. The plan includes healthcare teams that would be first to respond to a smallpox emergency and which team members have previously, yet recently, been vaccinated. Included in early vaccination would also be military and civilian personnel deployed to high risk areas. The deliberate release of the disease is the only way of contracting the disease at this time and that is now regarded as a serious possibility. The Centers for Disease Control and Prevention consider the smallpox virus to be a Category A agent, which means that it poses a highly negative threat to the health and wellbeing of the American public as well as having the potential for quick large-scale dissemination. Other Category A agents include, anthrax, plague, botulism, tularemia, and viral hemorrhagic fevers.<sup>5</sup>

It is thought, by some, that by isolating those individuals with confirmed or suspected cases this could lead to greater exposure for non-infected individuals and therefore leading to an increase in smallpox infection. Due to the fact that this vaccine causes illness and in very small instances death it should not be mandatory for people to receive the vaccine as that violates their freedom of conscience. The government has a right to keep those individuals in their homes, without a court order, who are assumed to have been exposed to the virus and who refuse the vaccination resulting in a loss of freedom of movement for those individuals.

Should smallpox be used as a biological weapon there are serious concerns to consider, such as:

- ◆ The length of the incubation period unless it's released via an aerosol in which case the incubation period is shorter than that of the standard incubation period. People are contagious during the late stages of this period even though they may be asymptomatic, therefore permitting transmission of the disease up to two days after exposure.
- ◆ The clinical characteristics of smallpox are severe in that the duration of the illness is long, care for the infected persons is very resource intensive and treatment and healing can take months. This is why strict isolation is mandated.
- ◆ The symptoms of smallpox are similar to those of other viral illnesses, such as influenza which can delay an accurate diagnosis.
- ◆ Corpses of those who have died from smallpox may remain infectious for days to months depending on the climate.

## Chapter 7: Risks of Biological Warfare

### 7.1 Ethics vs. Justice

It is thought that by isolating individuals who have been confirmed of having smallpox and those that are suspected of having smallpox that you

increase the chances of infecting non-infected individuals therefore increasing the population of those infected.

Many moral rights are also thought to be violated by mandatory vaccination requirements. The freedom of conscience appears to be violated if one can not choose to be vaccinated based on the known information that a small percentage of people will die from adverse reactions or at the very least many will be ill for a short period of time. According to the CDC Isolation and Quarantine Guidelines, Guide C, government officials are allowed to detain in their homes, without a court order, those individuals suspected of being exposed to the virus and refusing to be vaccinated resulting in a loss of freedom of movement for those individuals. On the other side, because law enforcement has a right to remove a person from their home in the case where they have been confirmed to have smallpox in order to move them into a designated isolation and quarantine facility violates due process rights and security of home.

## 7.2 View On War By St. Thomas Aquinas

According to St. Thomas Aquinas war is always a sin because:

- ✦ To wage war would be sinful because punishment is not inflicted except for sin. God would have the right to punish those who wage war, therefore making war unlawful.
- ✦ War is contrary to the Divine precept that says “But I say to you not to resist evil” and “Not revenging yourselves, my dearly beloved, but give place unto wrath.” According to this Divine precept war is sinful.
- ✦ Peace is considered to be a virtue and war is contrary to that virtue, therefore war is always a sin.
- ✦ Those who are slain in war are deprived of an ecclesiastical burial therefore making war a sin.

In order for war to be just three things must be necessary. First, the authority of the sovereign has the obligation to protect the people against attack from external enemies and therefore is the only power that can wage war against those external enemies. Secondly, a just cause is required meaning those that are attacked have committed a wrong. Thirdly, the reason for waging war must be for the advancement of good and avoidance of evil. It is unethical to lay ambushes in war which is exactly what biological warfare threatens to do. Ambushes are a kind of deception and deception is unjust therefore making ambushes unlawful. Also, since deception is opposed to faithfulness and it is wrong to lie, even to one’s enemy, it would seem unlawful to deceive one’s enemy by ambushing them. Since no country wishes to be ambushed they should not ambush another; this follows from the Golden Rule. Deception comes in two forms; first, by being told something false or by the breaking of a promise, both of which are unethical. There are certain “rights of wars and covenants” and ambushing does not appeal to these. The second method of deception comes from not being told the purpose or meaning of something. Although the U.S. is aware of the purpose of biological warfare it is hard to understand the reason for such an attack. The second method of deception, in wartime, occasionally is justified if it is for the purpose of protection or the greater common good as in a soldier not telling the enemy of his plans to prevent an attack.<sup>9</sup>

## 7.3 Ethics of War and Peace

War is an actual, intentional and widespread armed conflict between political communities. To engage in war requires a conscious commitment, and a significant mobilization, on the part of the fighting political communities. Another definition of war is "an act of violence intended to compel our opponent to fulfill our will." In other words, it is a continuation of policy by other means. There exist three major philosophical views of the ethics of engaging in war and they are: JUST WAR THEORY; REALISM; and PACIFISM. The core differences in each of these is that the just war theory says that states can have moral justification for resorting to armed force in the international system making ware, sometimes, morally right. Otherwise stated it says that war is an ethically appropriate use of mass political violence. According to realism power and national security motivate states during wartime and thus moral appeals are strictly wishful thinking. Morality of warfare is pure talk: ethics has nothing to do with global politics, where only the strongest and most deceitful survive. The pacifists believe that war should not be resorted to.

The just ware theory can be divided into three parts: 1) the justice of resorting to war in the first place (*jus ad bellum*), 2) the justice of conduct during wartime (*jus in bello*), 3) the justice of peace agreements and the termination of war (*jus post bellum*). For war to be justified a political community, or state, must fulfill all of the following six requirements:

- Just cause to include self-defense from an external attack; the protection of innocent people; and punishment for wrongdoing. The key principle of just cause, and just war theory is the justification of fundamental rights and the protection of those who have such rights from serious, standard threats to them. Fundamental rights are those human rights The human rights such as life, liberty and subsistence.

Therefore states have the right to make their own political decisions for protection of their own people, within their own borders. The aggressor forfeits its state's rights.

- The motivation or right intention for engaging in war must be morally appropriate.
- A state may go to war only if the decision has been made by the appropriate authorities, according to the proper process, and made public to its own people and to the enemy state(s).
- A state may only go to war, as a last resort, if all other methods of attempting to obtain peace have been exhausted.
- A state may only resort to war if it will have a measurable impact on the situation.
- A state must weigh the benefits to the costs and if the benefits are proportional to, or "worth", the costs war may be waged.

During war justified ends may only be pursued through justified means. This responsibility lies in the hands of those responsible for executing the war and must adhere to these three rules:

- War measures can only target those that are engaged in doing harm.
- Force used should be proportional to the end that is sought therefore ruling out weapons of mass destruction such as the smallpox virus.
- Weapons which are considered to be evil, such as mass rape campaigns; genocide or ethnic cleansing; torturing captured enemy soldiers; and using weapons whose effects cannot be controlled, like chemical or biological agents should not be used in the act of war.

In the event that war may be terminated and peaceful times may once again be sought after there are rules that should be followed, which are:

- Just cause for termination of war include: the elimination of aggression and the restoration of the victim's right. The aggressor must also be willing to accept the terms of surrender which include ceasing all hostilities, providing a formal apology to the victim and renouncing the gains of its aggression. Also the aggressor must be willing to submit to reasonable principles of punishment, including compensation, war crimes trials, and perhaps rehabilitation.
- Revenge is prohibited and equal treatment with regards to punishment of its own people for war crimes must be applied.
- The terms of peace must be publicly announced by an authority of the state.
- Undue and unfair hardship is not to be brought upon the civilian population in particular: punishment should be focused only upon those most responsible for the aggression.
- The people of the defeated aggressor should never have to forfeit their human rights; thus the terms of peace must be proportional to the end of reasonable rights justification.

In contrast realists believe that war should be waged only if it makes sense in terms of national self-interest; and that, once war has begun, a state ought to do whatever it can to win. There are two distinct types of realism, descriptive and prescriptive. Descriptive realism says that states, as a matter of fact, either do not (for reasons of motivation) or cannot (for reasons of competitive struggle) behave morally, and thus moral discourse surrounding interstate conflict is empty, the product of a category mistake. Morality doesn't exist for states because of their defensive function and the harsh environment in which they must survive. Prescriptive realism claims that a state ought to behave amorally in the international arena. In other words, a state should leave its morality at home when considering war on an international stage.

The final view on war is viewed by the pacifist who objects to all killing and especially to the mass killing, for political reasons, which is what war is all about. A pacifist believes that there are no moral reasons to go to war; war is always wrong.<sup>10</sup>

These last two sections seem a bit out of place.

## Chapter 8: My Decision

### 8.1 Should You or Shouldn't You Be Vaccinated For Smallpox?

If you are infected with smallpox you are almost surely to not survive; however, if you have cancer, have recently received chemotherapy or steroid drugs or have other symptoms mentioned in 4.3 and you are vaccinated you also may not survive. Barring any pre-existing health conditions the vaccine does have some adverse side effects but these subside after a minimal amount of time and rarely results in death. The vaccination increases your chances of not being infected with smallpox should this disease be used as a biological weapon. As for the scarring that remains after the vaccination, well most people have a scar from something, whether its from a severe abrasion, surgery, childbirth, etc. so what's one more if it'll save

your life.

As of today this vaccine is not publicly available so this decision doesn't have to be made immediately but you should definitely give it some consideration as to what you would do if the vaccine was made publicly available prior to an outbreak.

## ***8.2 Professional Issues***

The vaccine typically causes a mild rash, but other symptoms may occur as well as mentioned in 3.8. The vaccine may even make you feel poorly enough to miss work (or school) for a few days. All this seems tolerable in order to stay alive.

Those people who are responsible for mobilization and deployment, 3.6, must be well trained and know their emergency response routine without thinking about it. This routine takes a lot of repetitive practice, like any deployment of a highly sensitive initiative would.

The effects of the vaccination on children needs to be studied more deeply so that our younger population may also benefit from being vaccinated, otherwise they will not survive an inoculation.

Enough of the vaccine must be manufactured not only to protect the American people but those people of our allied nations, as well.

The threat of biological warfare using smallpox needs to be thoroughly investigated since it is believed that only the U.S. and Russia have the virus.

What happens when the one surgeon that is needed to perform an operation is not able to perform his duties as a physician because of adverse side effects from the vaccination, whether they be mild or severe?

## ***8.3 Legal/Policy Issues***

Policy issues are addressed in detail in the CDC document referenced several times within this document.

The issues of whether to mass vaccinate the American population, use isolation and quarantine only, or a combination of both of those methods as either prevention from smallpox or containment should an outbreak occur must be addressed and voted on by the American public. I don't feel its right for someone in a high position in the government and/or medical field to decide what to do for the entire population, this is American let's take a vote.

The policy instated that all military and medical personnel be vaccinated has some ethical consequences due to the violation of those individuals right to choose whether to accept the vaccine or not. It inflicts harm on people who may not be willing participants.

The various legal/policy issues that have been put into place which force quarantine and isolation of confirmed or suspected cases violates some ethical principles as well. See Chapter 6.

What happens if a medical person who has been vaccinated accidentally has the bandage covering the vaccinated site falls off and contaminates the bedding or clothing of a patient? Worse yet, what if it touches a sick person's skin that is already weakened from medication and/or their ailments and they become infected?

## ***8.4 Ethical Issues***

When quarantined you lose your right to freedom. Should you be suspected of being infected and be removed from your home without a court order that is a violation of the law and once again a loss of freedom. The loss of a right to choose whether or not to be vaccinated is a loss of conscience and that was taken away from medical and military personnel. Although it's believed to be of beneficence to vaccinate those who might initially come into contact with the virus because they are being kept out of harms way, it still needs to be their choice. Besides, there is still a small percentage of the population who will die from the vaccine therefore resulting in a loss of their life, which they have a right to.

Many other ethical issues surround the idea of biological warfare, as well. 7

## ***8.5 Stakeholders***

- All of those people who prepared and were involved in the preparation and creation of the CDC Guidelines.
- All medical personnel
- All military personnel
- Society as a whole and all of its members who may or may not be vaccinated
- All of those responsible for implementing the mobilization and deployment plan for protection against the virus should the virus get

released.

## 8.6 Possible Actions

- ✦ Make the vaccine publicly available on a limited basis for those who wish to be vaccinated while leaving in tact the CDC Guidelines as they are written, yet still mandating that medical and military personnel be vaccinated since they'll be first to respond to an outbreak.
- ✦ Change the CDC Guidelines and put into effect a mass vaccination plan
- ✦ Keep the CDC Guidelines as they are which include Ring Vaccination principles along with isolation and quarantine guidelines
- ✦ Develop a new CDC to include a combination of both mass vaccination and the current guidelines.

## 8.7 The Final Decision

My final decision would be in support of making the vaccine publicly available for those who elect to be vaccinated prior to a real threat of infection from smallpox while leaving the current CDC guidelines unchanged.

- ✦ Consequences
  - Those people who wished to be vaccinated could do so to put them at ease and to not live with the fear that they might be one of the first ones infected should the virus be released. Peace of mind and feeling safe from a dreadful disease supports those virtues which people hold dear.
  - The medical community would have time to care for those people who might suffer from serious side effects, along with performing their normal day-to-day duties of caring for others under their responsibility. Resources would be more readily available to manage adverse reactions.
  - The CDC Guidelines would not have to be modified therefore allowing for those responsible for carrying out those guidelines to continue practicing the motions without disruption.
  - There will be some disruption in the medical facilities operations while everyone is being vaccinated
  - Military personnel may not be able to perform their designated functions for a minimal time period upon being vaccinated.
- ✦ Individual Rights/Fairness
  - By allowing people to choose whether or not to be vaccinated you are providing them the freedom of choice which they deserve since there are uncomfortable side effects and some will be harmed worse than others from it or could be deceased from the vaccination.
  - The rights of those required to be vaccinated have been taken away without their consent.
  - Should the U.S. be attacked with the smallpox virus everyone will essentially lose their freedom and will no longer be able to live happily in their homes, cities or country.
  - Also, if the U.S. retaliates to such an attack those individuals who think that war is unethical will feel violated by their government and will lose faith and trust in their decisions in the future.
  - Those not known to be infected with the virus should have a choice to be vaccinated or not and not be at risk of having their basic rights of freedom and autonomy be violated because someone else suspects them of being infected. Paranoia could cause those in charge to suspect more people than what is actually infected to be infected, thereby increasing the quantity of infections by isolating and quarantining the uninfected with the virus.
- ✦ Common Good
  - By selecting this option the resources needed to care for those who may encounter severe adverse effects from the vaccination will not be drained and will be free to continue to perform their regular duties.
  - It will allow the CDC Guidelines to be practiced by those responsible for implementing them so that, should the time come to have to use those guidelines, they'll be ready to support the territories and people who need them to act quickly without having to think or read a manual. A smooth dispatch of these plans will prevent from adding to the chaos that will already exist from the terrorizing acts of infecting the country with smallpox.
  - From a utilitarian viewpoint, this decision would have the best overall consequences for everyone concerned by not vaccinating those who are at a higher risk of adverse effects from the vaccine yet vaccinating those who could suffer from infection and are the highest risk of being contaminated.

- Certainly awareness to the reactions to the vaccine and to the virus itself is critical for everyone to make an informed decision.

As for my view on biological warfare, I disagree with the altruistic viewpoint due to the fact that from that viewpoint it would be alright for biological warfare to be waged on the U.S. since it would be doing what is in the interest of those who wish to harm us with disregard for the lives that would be sacrificed. Ethical egoism would dissuade war due to the fact others would be harmed by the actions of war. The categorical imperative should be upheld when considering engaging in war and what actions we take when retaliating to war waged upon us. During war our natural virtues are put to the test as the aggressor seems not to be a virtuous being. It is the responsibility of our government, according to the Principle of Utility, to make a decision which results in the best overall consequences when having to decide between alternative actions and social policies. I believe that if we follow the rules of ethical engagement of war that the U.S. should engage in war. I only hope our president is an ethical man.

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This is a VERY thorough paper. My only suggestion is to eliminate 7.2, 7.3, as they really don't fit. They can simply be referenced in the decision making process.

Your use of HTML is short of the mark. You should provide a link from each reference to the citation page. This way the user can click on the reference and immediately see what the citation is. Also you should use your references in order and make duplicate references to multiply used references.

Grade H-85, C-100, R-98