

Critical Infrastructure Protection in the National Capital Region

**Risk-Based Foundations for Resilience and
Sustainability**

**Final Report, Volume 19:
Protecting the Nation's Blood Supply: A
Critical Infrastructure**

September 2005

University Consortium for Infrastructure Protection

Managed by the
Critical Infrastructure Protection Program
School of Law
George Mason University

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Final Report, Volume 19: Protecting the Nation's Blood Supply: A Critical Infrastructure

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September 2005

Arnauld Nicogossian

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– **Notice** –

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Protecting the Nation's Blood Supply: A Critical Infrastructure

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Final Report April 26, 2004

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Executive Summary

Contamination and disruption of the blood supply can have dire consequences for medical safety, patient confidence, and the entire U.S. healthcare industry. The risk of a terrorist infecting the donor pool, igniting an epidemic and threatening patients' lives is the focus of this report. To address this concern, the George Mason University (GMU) research team conducted an extensive literature review, consultations with the sensor development industry, and a series of expert led fact-finding meetings.

The events of September 11, 2001 and the subsequent anthrax crisis, raised concern among several American Red Cross (ARC) experts, notably Mr. Christopher Patton and Mr. William FitzGerald. This led to the first expert meeting and review held on October 30, 2002, jointly sponsored by the School of Public Policy at George Mason University (SPP/GMU) and the American Red Cross. The findings from that meeting set the tone and direction for further research activities. The follow-up research was sponsored by the Critical Infrastructure Protection Project (CIPP) at GMU. The purpose of this research was to conduct an in-depth evaluation of the strengths and vulnerabilities of the existing processes and procedures, and examine the public and health policy issues relevant to the protection of the nation's blood supply. It was anticipated that such an evaluation would result in the identification of potential weaknesses in the collection, processing, and distribution of blood products. This in turn would provide an insight on how to further enhance the safety of blood products and contribute to the protection of public health.

The second fact-finding workshop, convened on Friday, October 31, 2003 at the GMU/SPP Fairfax Campus, identified major technical and policy issues that required further study. The third workshop also held at the Fairfax Campus on January 30, 2004, provided recommendations on potential public policies surrounding the protection of blood and blood products.

In addition to a bio-terrorism event, the research team also addressed the:

- significance and role of opportunistic blood borne pathogens in the development of chronic

and debilitating diseases;

- potential for using blood products to detect sentinel events from bio-terrorism attacks;
- barriers to the implementation of a biomedical monitoring system of blood donors and products;
- formulation of policies necessary to establish such a monitoring system; and
- strengths and weaknesses of existing epidemiological models used for assessing the impacts of bio-terrorism attacks.

All relevant sources of information available to the medical community were reviewed, and a reference database on biological and blood-borne agents was developed. A complete summary of the initial findings from this database were presented to the participants of the workshops as a resource for fact finding and is currently displayed at <http://policy.gmu.edu/oimp/index.htm>.

The findings and recommendations resulting from this research can be summarized as follows:

1. Effective safety and control measures are currently in place to protect the blood supply, distribution, and infrastructure. However these measures might not be immune to a terrorist event.
2. Periodic shortages of blood supply often dictate remedial collection practices which could result in safety and control gaps, leading at best to the destruction of valuable and life saving products, or at worst to potential contamination of the blood products.
3. The most significant threat of concern is the ability to *terrorize the public without actually compromising the collection and distribution chain of blood products*.
4. Even in the absence of a bioterrorism event, active or latent blood-borne infections (as with any transfused or transplanted biological materials) will continue to be a potential source for the transmission of biological agents capable of causing acute illness, iatrogenic complications and chronic disorders.

5. After proper ethical and policy issues are addressed, a registry for blood and blood products, including an epidemiological database of donors and the carrier state of blood-borne pathogens suspected as etiologic agents for chronic diseases, should be initiated, funded and maintained by the federal government. To this end, proper legislation should be enacted to ensure the deployment of such a system.

6. Additional research and development funds should be appropriated to accelerate the development of blood and blood product substitutes.

7. Commercial use of residuals, cells and proteins left over from the processing of blood, should be considered as a potential funding source for establishing the epidemiological surveillance of the baseline blood-borne pathogen carrier status. This surveillance can include specific markers, such as immunoglobulins, cytokines and antigens, in the

population which could help establish trends and detect sudden deviations as a potential "early warning system" based on sentinel events. Such an approach will require a change in policy and potentially the passage of appropriate legislation.

8. The workshop revealed potential deficiencies in modeling capabilities that are intended to support policy and decision-making, as well as the management and implementation of actions intended to reduce and mitigate the impact of terrorist-generated blood-borne infections.

9. Additional research into the potential risks associated with blood-borne infections and prioritizing threats based on these risks is required. Furthermore, policies for implementing a "sentinel monitoring" system are needed, especially in the context of evolving global health interdependencies.

Introduction

Contamination and disruption of the blood supply can have dire consequences for patient confidence and the entire U.S. healthcare industry. The possibility of a terrorist infecting the donor pool, igniting an epidemic and threatening patients' lives is the subject of this research report. To address this concern, a series of expert led fact-finding meetings and an extensive literature review have been undertaken.

The first expert review workshop, held on October 30, 2002, was jointly sponsored by the School of Public Policy at George Mason University (SPP/GMU) and the American Red Cross. The findings from this workshop served as the basis for the current research. The follow-up research was funded under a grant from the Critical Infrastructure Protection Project (CIPP) at GMU. The purpose of the follow-up research was to conduct an in-depth evaluation of the strengths and vulnerabilities of the existing processes and procedures, and examine the policy issues relevant to the protection of the nation's blood supply. It was anticipated that such an evaluation would result in the identification of possible weaknesses in the collection, processing and distribution of blood products. This in turn would provide insights into further enhancing the

safety of blood products and contribute to the protection of the public health.

The second fact finding workshop was convened on Friday, October 31, 2003 at GMU's Fairfax Campus. This one-day event was co-sponsored by the University's Office for International Medical Policy (OIMP), College of Arts and Sciences, and the National Center for Biodefense. Additional participants represented the American Red Cross, Naval Medical Research Center, INOVA Health Care System, Rapid Biotest, New World Healthcare Solutions, Inc., Spectral Diagnostics, and Quality Antisera.

The third workshop, primarily focused on policy review, was held at the Fairfax Campus on January 30, 2004. The purpose was to establish policy concepts surrounding the protection of blood, blood products and supply.

It is postulated that a clandestine bioterrorist attack using agents such as anthrax (*Bacillus anthracis*) or smallpox (*Variola virus*) would not be recognized until a large segment of the target population became infect-

ed. After symptoms are manifest, treatment is much more problematic. The disease, if communicable and of a longer incubation period, would have had days or weeks to spread through the population. It is also recognized that many existing and emerging infections cannot only cause periodic epidemics, but over time can result in the development of chronic and debilitating disorders such as heart disease, liver, stomach or blood cancers, arthritis and neurological disorders.

It is suspected that some of these infections are transmitted through blood contact (such as naturally occurring vectors, contact with infected individuals, transfusion of blood products, or tissue transplants) and can remain asymptomatic for long periods of time before the illness becomes manifest. Fortunately, the blood-banking infrastructure within the United States is quite safe, due to the regulations and procedures designed to monitor the collection and delivery of its products.

"The blood supply plays a critical role in the American health care system. While the United States is recognized as having one of the safest blood supplies in the world, assuring this safety poses formidable challenges. Each year, approximately 14 million units of whole blood are drawn from about 8 million volunteer donors to make products that are transfused into more than 3.5 million Americans. Some of this blood, and an additional 12 million units of source plasma, is further processed into products referred to as derivatives."¹

The events of September 11, 2001 demonstrated that periods of critical blood shortages are followed by a glut of blood donations in the aftermath of disasters.² Protracted military engagements abroad with periodic surge of casualties also require collection and overseas shipment and distribution of blood products. These events have the potential to introduce safety gaps in the collection, processing and distribution of blood products.

The blood banking industry collects and tests approximately 40,000 to 45,000 units of blood per day from healthy volunteer donors. It is plausible that in the event of a clandestine release of bio-weapons, especially those with long incubation periods, one or more

infected individuals would donate blood during the pre-symptomatic phase of the infection. It is unknown whether upgrading the current blood banking infrastructure to provide for the detection of a range of bio-weapons would make it possible for the potential outbreak of a disease to be detected early enough so that intervention would be successful with minimal societal and economic impacts. Additionally such an intervention might carry with it a significant penalty in reducing the number of qualified blood donors, hence creating a severe blood products shortage.

Today, there is no source of accurate information on the carrier status of blood-borne pathogens in the general population. A registry designed to identify baseline blood levels in the population does not exist. In 1997 the Food and Drug Administration (FDA) working with the Centers for Disease Control (CDC) and the National Institutes of Health (NIH) took steps to further strengthen the safety of blood products. Since then, the testing for seven pathogens has been prescribed, in addition to the screening of prospective blood donors by administering questionnaires. These measures have been particularly important at the peak of certain infections such as West Nile Encephalitis or SARS. It should also be noted that there is a national tissue and organ registry that can lend itself to reasonable epidemiological surveillance.

So far it is not clear whether such a measure will be adequate to safeguard the blood-derived products. Given the US involvement in the global war on terrorism, and the potential future reliance on imported blood products, such a registry, coupled with monitoring, might be advisable if supported by federal funds and oversight. However, such an undertaking might result in negative outcome(s), such as a reduction in product availability and/or the reluctance of blood donors to be monitored by public health/government authorities.

In depth literature searches on blood-borne pathogens which could serve as bio-weapons and/or result in chronic and debilitating diseases, were reviewed and analyzed. A literature database was created and served as a reference for the workshop participants. A sample of the bibliographic database is presented in Appendix C.

¹Testimony on FDA's Regulation of Blood, Blood Products, and Plasma by Michael A. Friedman, M.D., Lead Deputy Commissioner, Food and Drug Administration, U.S. Department of Health and Human Services, Before the House Committee on Government Reform and Oversight, Subcommittee on Human Resources and Intergovernmental Relations, June 5, 1997.

²Starr G. *Blood: An Epic History of Medicine and Commerce*. Perennial Publications 2002.

Workshop Design and Objectives

The workshops combined plenary sessions and individual discussion groups addressing the following areas:

- Examining the feasibility and utility for monitoring blood products;
- Assessing the adequacy of existing epidemiological models; and,
- Identifying barriers and policies to implementing a program for improving the safety of blood collection and blood products manufacturing.

Specific objectives of the workshops were to:

1. Discuss means for protecting blood products from new and re-emerging infectious diseases and bio-weapons.
2. Examine the feasibility of safeguarding the society as a whole, using monitoring and periodic testing of the blood supply as an early epidemiological warning system, including policy and/or legal considerations necessary to overcome existing barriers.
3. Review compiled information and identify additional pathogens which can be transmitted through blood products and which are implicated in the development of chronic and debilitating medical disorders.
4. Evaluate the adequacy of existing epidemiological models designed to assess societal and economic impacts of such events.

The initial plenary session acquainted the participants with the research team findings, recommendations, and information on blood-borne pathogens obtained from the literature review. Participants were assigned to individual discussion groups based on their expertise and interests. Facilitators were then identified for each group³, whose role was to frame and guide the discourse. Following the plenary session of the second workshop, three working groups met individually to examine and discuss specific topics of interest. The three groups reconvened for a working lunch to facilitate interactions between the group members needing to address and clarify interdisciplinary issues.

Following lunch the small groups reconvened for additional deliberations and presentation of recommendations. All participants joined for the afternoon plenary session to report on the group findings, recommendations and to identify follow-up activities necessary to conclude this project.

Group Discussion Design: Each participant was provided a handout with questions to facilitate discussions and establish common terms of reference during deliberations (Appendix D). For clarity, the topics were organized into the three discussion areas. However, all groups were encouraged to consider all the issues found in the discussion guide.

Morning Plenary Session

During his presentation, Dr. Nicogossian discussed the importance and relevance of this research, highlighted new and re-emerging infections (epidemics/pandemics), and identified recently documented worldwide outbreaks and spread of infections. These findings also served as the basis for formulating specific questions for the participants of this workshop (see Appendix D).

The results of the first workshop were summarized as follows:

- Within the next 5-10 years novel technologies (e.g. bio-sensors and markers) will significantly shorten the time lapse between the collection of blood and the availability of the resulting products by as much as 80%, thus removing the need for costly storage of blood products, a portion of

³Each participant was provided a handout with questions to facilitate discussions and to establish common terms of reference (Appendix D). For clarity, the discussion points were organized based upon the three discussion areas, however, all groups were encouraged to consider issues throughout the discussion guide. The role of the facilitators was to frame and guide the fact finding and recommendations.

which is discarded at a later date.

- In the near term this type of technology, if properly deployed and operated, could contribute to the early detection of bio-weapons by monitoring transmissible infections in the blood of donors.
- Many pathogens can be transmitted by blood products, especially cellular components, and will remain silent in the host for years and on occasion, produce chronic diseases.

Dr. Aiguo Wu from the National Center for Biodefense, College of Arts and Sciences, GMU, reviewed the health risks of blood-borne pathogens. He indicated that the U.S blood supply is highly regulated at many levels:

- Donor screening;
- Donor deferral registries to eliminate unsuitable donors from future blood donations;
- Testing the donated blood;
- Quarantining donated blood until its safety is established by all required tests and control procedures;
- Monitoring and investigating problems occurring in blood donation/transfusion to correct deficiencies.

He identified the blood-borne pathogens that are important in biomedical research today and include, but are not limited to:

- Human Immunodeficiency Virus (HIV)
- Hepatitis B Virus (HBV)
- Hepatitis C Virus (HCV)

Similarly, blood-borne pathogens used in bio-warfare can be divided into four categories:

Bacteria:

- Anthrax (Bacillus Anthracis)
- Tuberculosis (Mycobacterium)
- Plague (Yersinia pestis)
- Diarrheal Diseases (Salmonella, Shigella, Cholera)
- Tularemia (Francisella Tularensis)

Toxins

- Botulism = Clostridium botulinum
- Enterotoxins = Staphylococci
- Clostridium Perfringens Toxins
- Ricin = Castor beans

Viruses

- Smallpox
- Camelpox
- Ebola and Marburg
- Venezuela Equine Encephalitis
- Humanized Viruses (infecting humans)
- Yellow fever Virus
- West Nile Virus
- Severe Acute Respiratory Syndrome (SARS)

Rickettsia

- Q fever

Dr. Wu stated that tests for these pathogens are generally very sensitive and that pathogens can be identified even when they exist in very small amounts.

During the discussion it was noted that terrorists may choose to use agents that are not routinely tested for, or which can cause chronic diseases that are not tested for either. One area for further research will be to develop recommendations for what should be added to the test template based upon risk-benefit ratios. Several interesting questions were raised --- Is it feasible to test for 50 agents simultaneously? What is the cost? And more importantly, what will we do with the information once we have it?

Considerable time was devoted to the discussion of impact of blood-borne pathogens, the testing protocols and the deferral of the blood donor pool. There are currently many reasons for donor deferral based upon disease, travel or lifestyle. Everyone has some level of infection (carrier status for pathogens) in their blood. If testing becomes more sophisticated and accurate, with the improved ability to detect these infections, it is possible that the entire donor pool could be ultimately disqualified. A potential scenario could be: An outbreak of Small Pox occurs and the United States performs mass Small Pox vaccinations. All of these vaccinated individuals will become ineligible to donate blood, which in turn will

create a crisis for the blood supply industry. A terrorist wouldn't even have to employ a biological agent to succeed in disrupting the system. Very simply, the fear of contamination would cause the U.S to take proactive measures to protect the public health, which could subsequently decimate the blood donor pool.

In addition to the importance of preserving the donor pool, the preservation of the manufacturing infrastructure was also identified as a critical element of protecting the nation's blood supply. The infrastruc-

ture consists of several Regional Collection sites and laboratories that have high dependency on the electrical power grid and the water supply. Examples of problems in this area included the August 2003 power grid failure in the Northeast. The blood processing facilities had backup power generation capabilities but did not adequately plan for the total loss of water. Another example was the wildfires in the San Diego area. These fires caused a significant drop in the humidity levels leading to water supply shortages, that disrupted blood-processing operations in the affected areas.

Discussion Group Sessions and Structure

Following the first plenary session and general discussions, the participants broke into 3 small groups. Each group was asked to address specific aspects necessary to protect the nation's blood supply. These topics consisted of: (1) Policy and Legal Considerations, (2) Medical and Technological Feasibility, and (3) Improving Epidemiological

Models. Participants were initially assigned to a group based upon their areas of interest or expertise, but were also provided the opportunity to switch groups if they felt they would be able to contribute more effectively in another discussion.

The participants in each group were:

Group 1: Policy and Legal Considerations	Group 2: Medical and Technological Feasibility	Group 3: Improving Epidemiological Models
Facilitator: Connie McNeely	Facilitator: Vikas Chandhoke	Facilitator: Ted Woodcock
Wing Chan	George K. Anderson	Ken Button
William FitzGerald	Dan Freilich	Allan Morrison
Lee Fritschler	Paul Hemmes	Laurie Schintler
Karen Plante	Mike Huchital	Tom Zimmerman
Kevin Thomas	Chris Patton	Lindsay Poulin (Executive Coordinator)
Adriana Kocornik-Mina (Executive Coordinator)	Geoffrey Seaman	
	Gretchen Ehle (Executive Coordinator)	
	Amy Springfloat (Executive Coordinator)	

Group I: Policy and Legal Considerations

The group first addressed the status of existing risks to and vulnerability of the blood products industry. The conclusion was reached that there are three distinct aspects of vulnerabilities that must be addressed:

1. the potential for terrorists to contaminate the blood supply;
2. the possibility of disrupting the collection and/or distribution systems; and,
3. the potential for depleting the donor pool.

1. Contamination - It was agreed that there is currently a well developed level of control and accountability. Human errors are, perhaps, the greatest risk. Contamination could occur internally, either inadvertently or intentionally. Chain of custody is tight and storage processes would be difficult to breach. The blood supply is likely one of the more secure elements within the healthcare system.

2. Disrupting Collection or Distribution - The group proposed that the most significant issue to be concerned with is the ability and/or potential for terrorizing the public without actually compromising the blood products and their supply and distribution chain. It is the "kill versus scare" scenario. If public confidence was compromised, there may be systemic impact equal to physical damage to the blood supply.

Additionally, ill-intentioned persons could target other infrastructures that have cascading effects of disrupting the blood supply. Utilities infrastructure and transportation networks are the most obvious. Utilities, water supply and transportation networks are the most obvious ones. Any deterioration of public confidence in the quality and availability of blood could be devastating to the healthcare system.

3. Depleting the Donor Pool - There are baseline levels of pathogen markers in everyone's blood. Blood is not a sterile product. As technology advances, and testing of blood for pathogens improves, we will undoubtedly see the extent to which this is true. In the United States, blood donors are currently deferred for a number of reasons. Forward-reaching policies should address the potential for screening to become "too good," thus eliminating most donors. An important aspect of this policy will be to decide what blood product substitutes should be researched and developed. Should genetic engineering technology be applied to this problem? Should each person periodically donate his/her own blood to be stored for a future time of need? What are the societal and economic impacts of such screening approaches and policies?

4. Extended Testing of Blood Donors and/or Products - The issue of who is financially liable for any screening or testing within the system was discussed at length. The general agreement was that invariably the cost for any additional testing would be passed on to consumers. But any costs associated with surveillance testing should be the responsibility of the government. Generally, advancing technology results in decreasing costs, but introduction of new tests into the blood products production process will ultimately result in increased costs.

Other policy concerns that will require further exploration are those related to systematic discrimination in deferral of donors. What domestic and international laws or treaties might be required? As these and other issues are debated, it is imperative that the clinical regulation (FDA) be kept separate from security regulation (DHS). The ethics of applying new knowledge and technologies to make blood products safer should be addressed prior to their implementation.

Group 2: Medical and Technological Feasibility

Progress in rapid diagnostic capacity for multiple pathogens and associated technological advances are proceeding at an accelerated pace. Currently available technology can be readily adapted to existing protocols for blood donors and product testing. Screening, testing protocols, and processes were discussed as well as the costs associated with various testing options.

To ensure the safety of blood products, the sensitivity and specificity of the diagnostic procedures will have to be accurate enough to reduce false positive and false negative results. The location of such testing along the continuum of the blood collection system is also a major consideration. The ideal option would be to test at point of collection, but in the current configuration the implementation cost to enhance the infrastructure and the training will be prohibitive. There is already a rather effective mechanism in place for testing, hence the merits of expanding this system need further evaluation of threats and cost effectiveness analysis.

Demonstrating this testing as an effective sentinel system will be a complex process. To be funded, it would have to be proven to have greater utility than clinical and symptomatic indicators. To be a sentinel indicator there must be a high level of reliability and reproducibility of results.

The recommendations from this group were:

1. Additional testing for detecting blood-borne agents is more a sentinel detection issue than a blood bank issue.
2. Phase 1 of the project should be first conducted at the four main blood collection/processing centers, if implemented.
3. Additional research is required to assess what is currently known of the behavior of the blood-borne pathogens presented - to this end available primate and human studies should be reevaluated (the GMU Bio-defense Center should conduct such research.)
4. More information on communicable diseases (highest priority) that can be weaponized should be collected, evaluated and prioritized. Toxins are a lower priority.
5. Screening/testing for these pathogens will provide an extra layer of security - early warning and/or deter terrorist activity (terrorists will know what the donors are screened for).
6. Technology Issues:
 - a. The blood banking community should be involved in the decision making process to identify technology needs, development, insertion and timing.
 - b. Setting up an infrastructure (complementary to the blood banking industry) for screening the public with regard to bio-terrorism should be carefully assessed.
 - c. Acquiring federal support for expanding these facilities across the country will be necessary, requiring resources above the current funding of similar projects by the National Institutes of Health and CDC.
7. A careful evaluation of the fundamentals of the technology will require a careful identification of:
 - a. Best practices;
 - b. Needs for multiple and redundant technologies applied to the same sample; and
 - c. Ethical issues with new technology use and societal impact.

Group 3: Improving the Epidemiological Models

Dr. Woodcock presented a review of the literature pertaining to disease models, discussed and displayed intervention models, and identified some economic impacts of bio-terror attacks. The vulnerabilities of the nation's blood supply identified by the epidemiological modeling discussion group were:

- Terrorist contamination of blood with biological and chemical agents at a collection point or in blood banks.
- Contaminated blood could act as a randomly distributed disease vector affecting medical and other first-responder personnel and patients.
- Perceived contamination would inhibit public acceptance of use of blood for surgery and other medical purposes.
- Evidence suggests there should be new require-

ments for new rapid monitoring and detection devices, integrated command, control, and communication and crisis management facilities.

- Studies could be supported with enhanced epidemiological models that also include economic and other impacts.

Three dynamics-based system models of a notional disease describe:

- A disease process involving infection, recovery, and death.
- Disease modified by restorative medical care activities.
- Disease modified by preventive public health and restorative medical care activities.

Modeling the Disease, Recovery, and Intervention Process

A relatively simple model of the spread of disease within a susceptible population with subsequent recovery or death was produced and demonstrated to the workshop participants. The model displayed the impact of the timing and magnitude of preventative measures on the spread of infection within a

susceptible population. This model was implemented in STELLA™, a commercial-off-the-shelf systems dynamics modeling facility. The model also contained a relatively simple representation of the impact of public health and other measures in preventing disease spread.

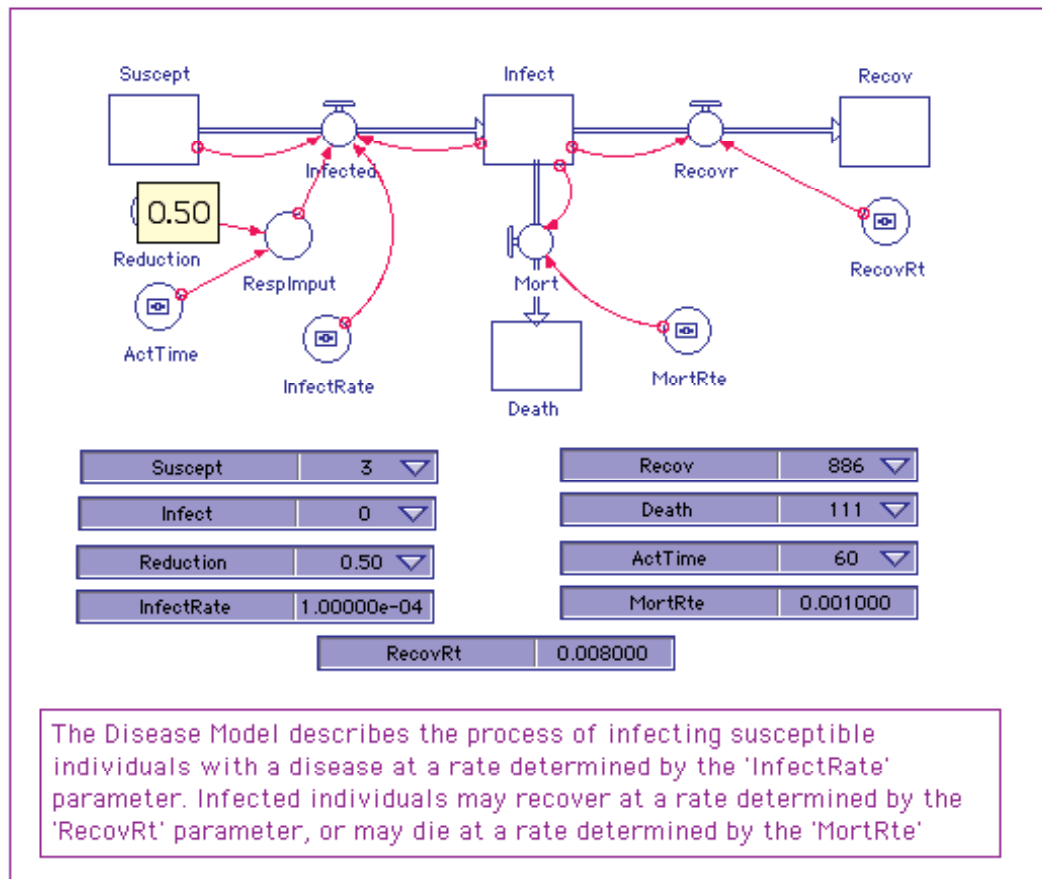


Figure 1: A relatively simple systems dynamics-based model representing the process of disease infection, recovery, and death as well as the impact of public health measures aimed at preventing the spread of disease.

The structure of the implemented systems dynamics model (Figure 1) shows flow-related processes where susceptible individuals become infected and either recover or die at rates determined by a set of user-selected model coefficient values. The model includes a process that represents the impact of disease prevention activities caused by the intervention of public health-related actions. A notional 1000 susceptible individuals were assumed to be potential candidates for infection in each run of the study.

Elapsed time for each of the sample runs of the model was assumed to be 1000 time steps. Model parameter values could be selected to represent the characteristics of specific diseases. Actual values used in the following discussion do not represent any specific disease, and are used here for demonstration purposes only. No actual medical results should be assumed based on the model output. Selected model-generated outputs are presented and discussed below.

In the case shown in Figures 2, 3, 4, and 5, an infection rate coefficient of 0.001 (or 0.1%) per time step, recovery rate coefficient was 0.008 (or 0.8%) and the mortality rate coefficient was 0.001 (0.1%). The peak of infection occurs at approximately 100 time steps (Figure 2). Preventative

measures taken at notional time step 120 that are assumed to prevent 90% of the spread of infection (Reduction coefficient = 0.1) have almost no impact on the spread of the disease since very few of the susceptible individuals remain to be infected at that time.

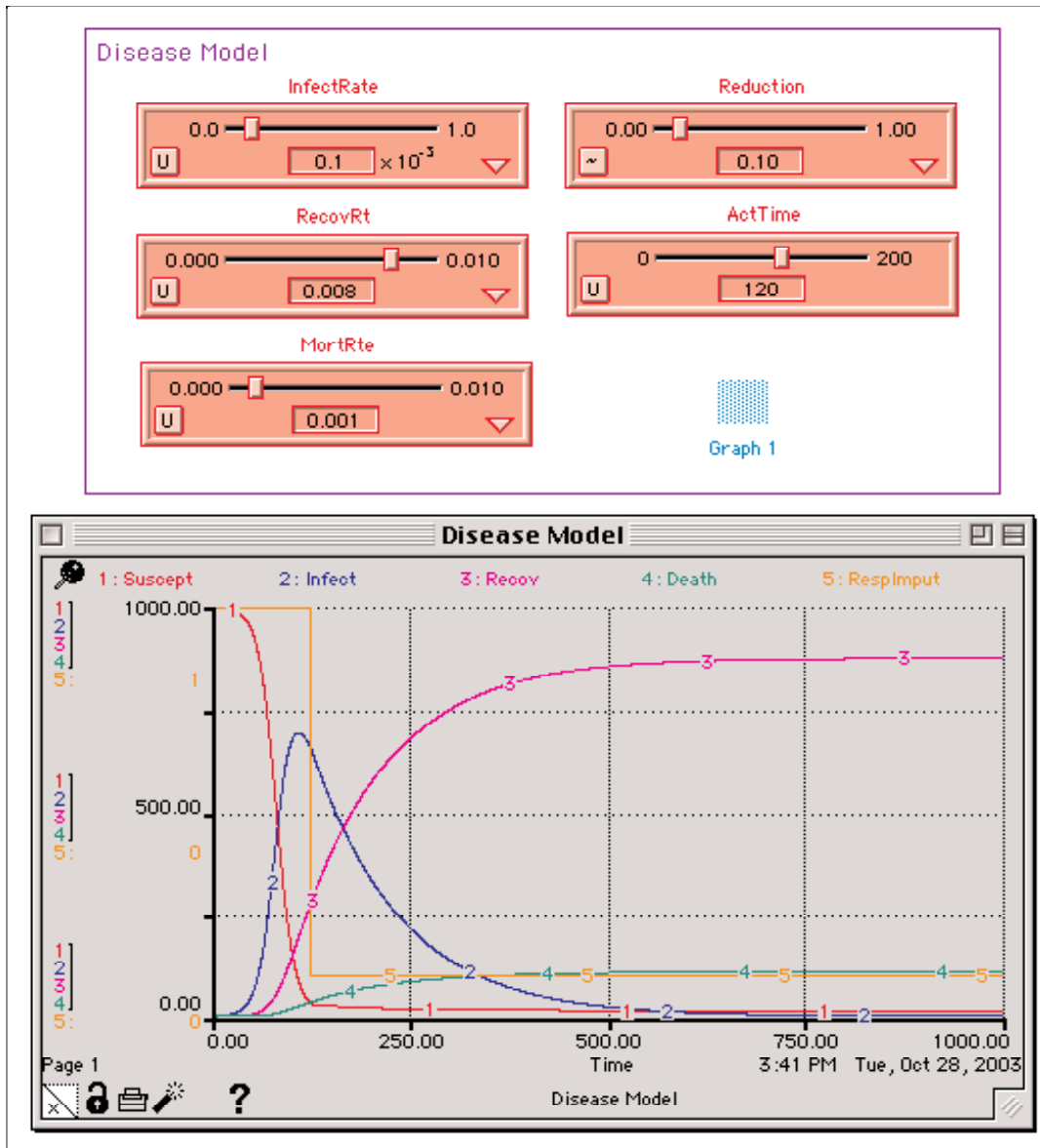


Figure 2: Delay in public health-based intervention beyond the peak of the infection to time step 120 can result in even massive amounts (90%) of preventative measures from having an effect on the overall spread of the disease.

By contrast, intervention at time step 80 (Figure 3) creates conditions where some 200 susceptible individuals do not become infected. Public health intervention at the 90% level at time step 40 can prevent most of a disease outbreak from taking place (Figure 4). In that case, some 700 of 1000 susceptible individuals were prevented from becoming infected. Reducing the level of inter-

vention even early on in the outbreak of a disease can significantly reduce the effectiveness of disease prevention activities. As shown in Figure 5 a 50% public health effort at time step 40 fails to prevent almost all susceptible individuals from becoming infected despite the fact that a 90% effort at the same time prevents 700 infections (Figure 4).

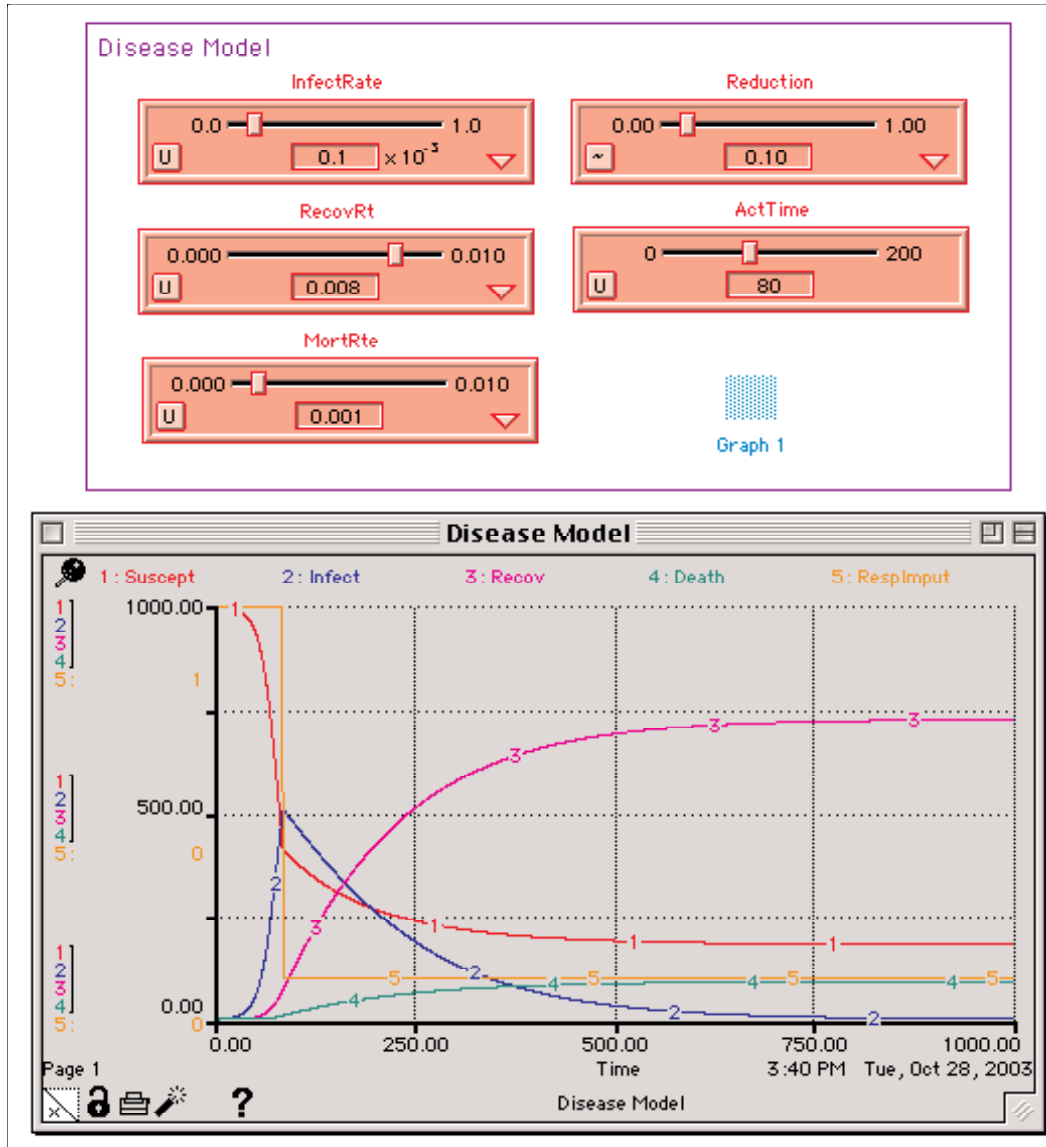


Figure 3: Intervention at time step 80 of 90% preventative measures prevents some 200 out of 1000 susceptible individuals from becoming infected.

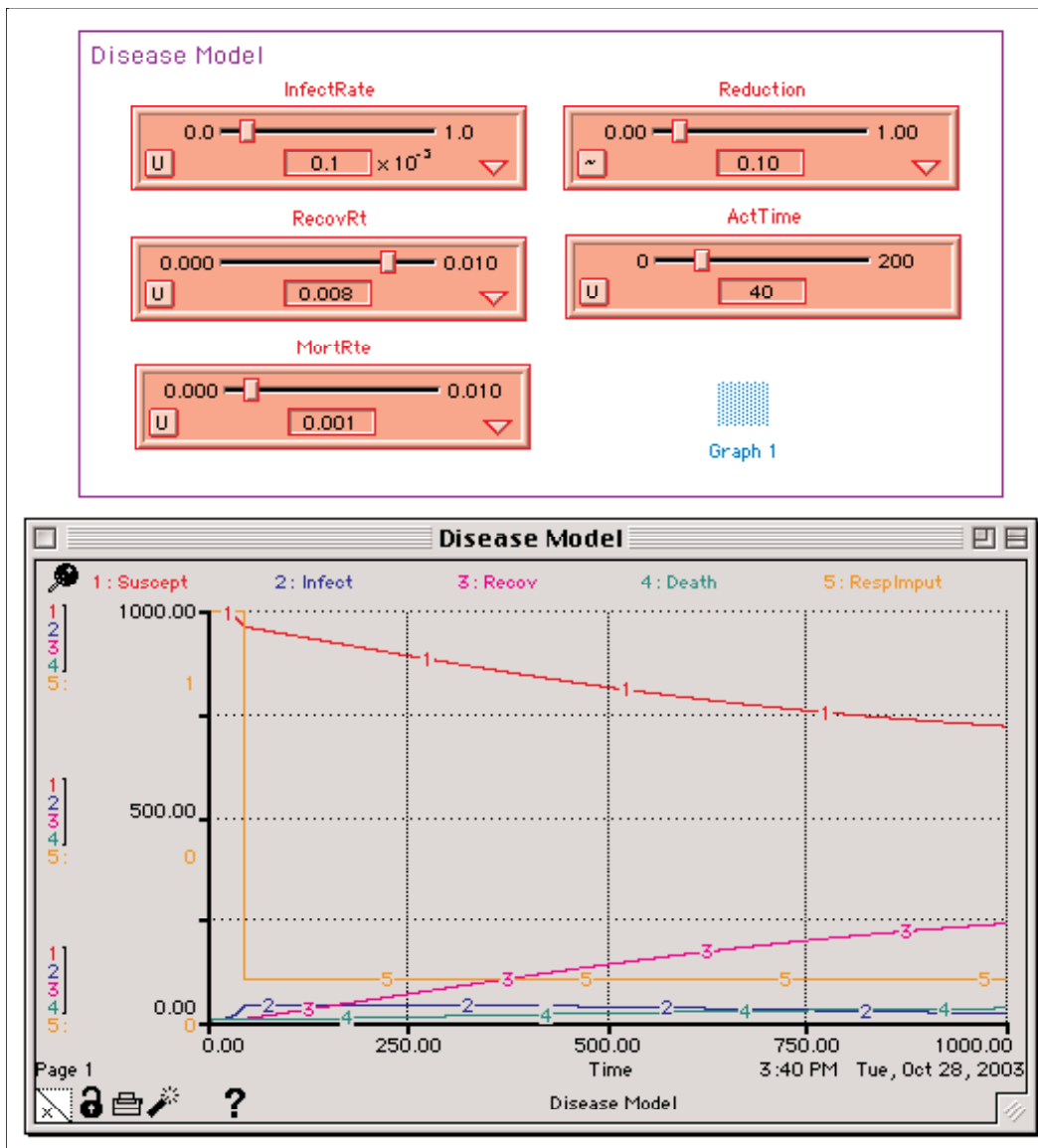
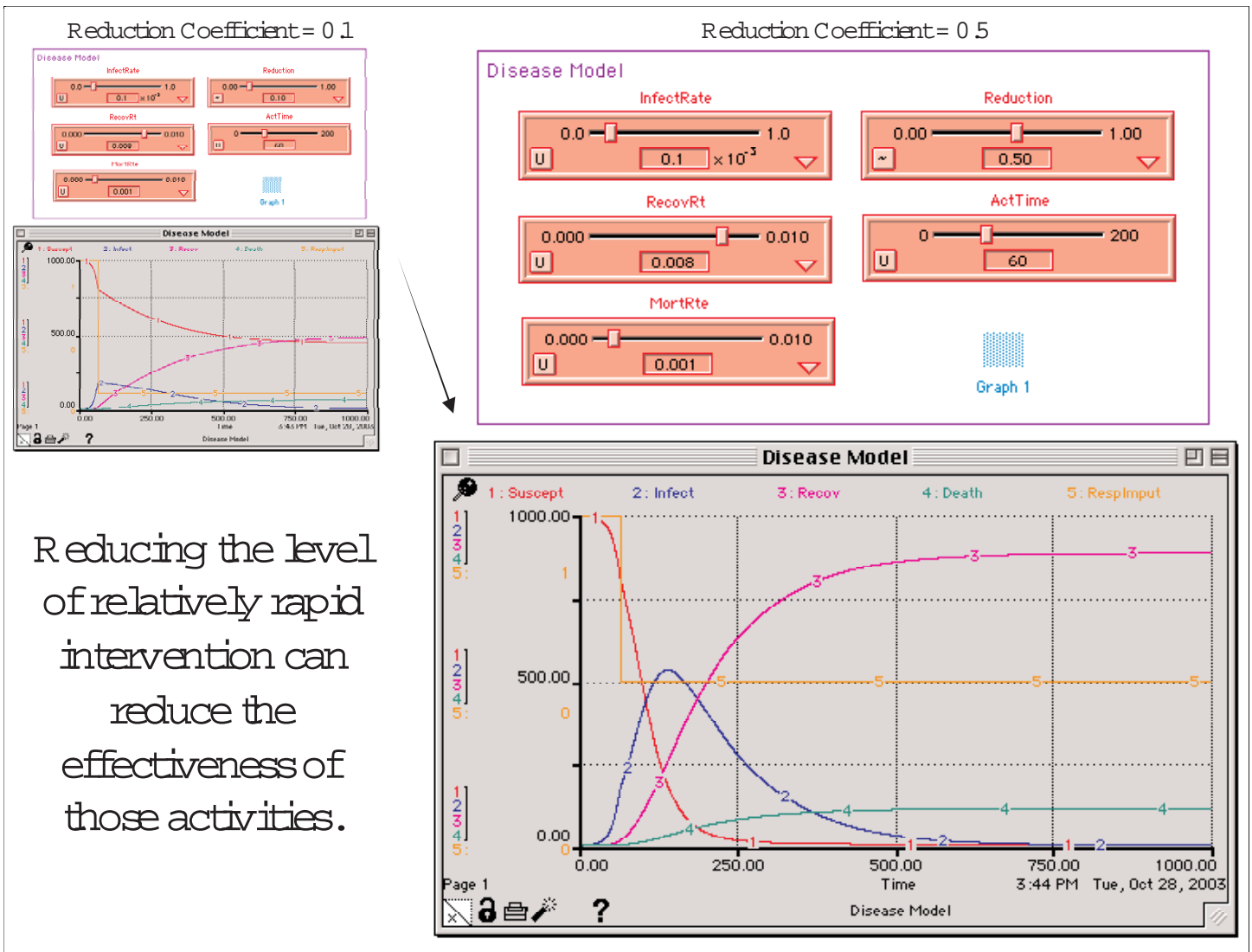


Figure 4: Public health intervention at the 90% level at time step 40 can prevented some 700 of a total 1000 susceptible individuals from becoming infected.



Reducing the level of relatively rapid intervention can reduce the effectiveness of those activities.

Figure 5: A 50% public health effort at time step 40 fails to prevent almost all susceptible individuals from becoming infected.

These studies with a simple systems dynamics-based disease model reinforce the role of the dynamics of the disease process as the critical factor in determining the nature of the measures needed to prevent or mitigate the impact of disease. The development and fielding of public health and other facilities that can permit early detection and rapid and massive response to outbreaks of disease are critical in order to permit survival from disease outbreaks. Such diseases might be caused by terrorist actions and could involve contamination of the nation's blood supply. It is clear that the formation of an integrated response environment involving medical and other personnel is of critical importance.

Motivation for making the necessary investment can come from studies, such as those reported above, in which the economic impact of particular types of disease outbreaks are considered in the overall development of public policies aimed at insuring societal protection. Such policies will drive the allocation of funds during the national and state budget processes. The ability to estimate the economic impact of particular types of bio-terrorist attacks and the cost-effectiveness of different types of protective measures would provide significant advantages to policy- and decision-makers and to those responsible for the design, management, and implementation of protective measures against bio-terrorist actions.

Epidemiological Modeling

A review of the literature (Ref. 8 - 11) associated with epidemiological research related to bio-terrorist actions was accomplished. In a study titled "Modeling the Consequences of Bioterrorism Response," Giovachino and Carey (2001) identify actions made in response to bio-terrorist attacks and present a spreadsheet tool or simulation model that estimates the number of casualties from a hypothetical bio-terrorist attack based on the time it takes to initiate medical intervention. The study uses as a metric the number of preventable deaths at different delay times and how many people would die given different speeds of response to the hypothetical biological attacks.

Key events in determining the success of a response to bio-terrorist acts identified by Giovachino and Carey include the need to recognize that an unusual medical event is taking place. This would be followed by obtaining laboratory confirmation that a patient has been impacted by a bio-terrorist agent such as anthrax. Determining if nearby facilities or entities are also reporting similar cases would provide evidence of the extensiveness of a possible attack. An estimation of the size of the affected population could be obtained by carrying out rapid epidemiological analysis, and would identify the location and time of infection.

Specialized medical response personnel should be able to advise public officials on what information needs to be presented to the public to prevent panic, advisability of quarantine, administration of prophylactic treatment(s) to asymptomatic and sick individuals, etc. Rapid provision of prophylaxis should be made to essential personnel (hospital workers, police, firefighters, and their families). Response activities should also include setting up phone and internet access to permit rapid transfer of essential information, and the establishment of mass prophylaxis sites, providing personnel, obtaining appropriate supplies and preparations to distribute medicine. Other considerations should include the identification of and provision of prophylaxis to home-bound individuals, determining if decontamination is necessary and identifying type of decontamination activities, and identifying precautions to be taken for very young and elderly.

In a study titled "Modeling Potential Responses to Smallpox as Bioterrorist Weapon," Meltzer et al. (2000), it was assumed that 100 persons are initially infected and an additional 3 persons were infected per infectious person. The research indicated that quarantine would stop disease transmission but would require a minimum removal rate of 50% with overt symptoms. Vaccination would stop the outbreak in 365 days only if disease transmission was reduced to some 0.85 per persons infected. Combined, the vaccinations and quarantine would stop the outbreak if daily quarantine rates of 25% and vaccination reduced transmission by some 33%. In that case, 365 days would be needed to stop the outbreak, in which 4200 cases would occur. Meltzer et al. discuss historical data which suggest that 2,155 smallpox vaccine doses per case were given to stop outbreaks.

In another study of a model for smallpox vaccination policy, Bozzette et al. (2003) report that vaccination of contacts must be accompanied by effective isolation, and would result in 7 deaths involving the release of variola virus from a laboratory. They estimate potential deaths in several different scenarios. Particularly they estimate 19 deaths in a human vector scenario, 300 deaths in a building attack scenario. Estimated 2735 deaths in a low impact airport attack (involving 10 airports, 200K, some virus aerosol) and an estimated 54,729 deaths in a high impact airport attack (involving 10 airports, 200K, high level of virus aerosol). They report that immediate vaccination in the affected region would provide little relief and further, that prior vaccination of healthcare workers provides some relief, could cause 482 deaths nationally, and would save lives if the probability of a building attack was greater than 0.22 or the probability of a high-impact airport attack was 0.002.

Kauffman et al. (2001) in a study titled "The Economic Impact of a Bioterrorist Attack: Are Prevention and Postattack Intervention Programs Justified?" examples provided the justification for preparedness measures against bio-terrorist attacks. Their model-based analysis demonstrated that the economic impact of aerosolized anthrax, brucellosis and other attacks in the suburbs of a big city was \$4777.4M per 100,000 population (brucel-

losis scenario) to \$28.2B per 100,000 population (anthrax scenario). Their work indicates that rapid

implementation of a post-attack prophylaxis is the most important means of reducing those losses.

Improving Current Epidemiological Models

The need to provide model-based facilities that represent the impact of different types of disease resulting from bio-terrorist actions triggered a review of the existing research literature on that topic. Workshop participants undertook a discussion of the need to provide enhanced epidemiological models that include the economic impact of particular types of disease on societal processes. Questions addressed during the model-related portion of the workshop included the following:

- (1) What are the shortcomings of currently used predictive models?
- (2) How could existing models be strengthened by adding additional societal and economic dimensions and processes?
- (3) What additional parameters and economic factors should be considered?

While the results of the discussions were rather limited due to the time available for discussion, some important observations were made that could provide guidance for the development of an enhanced set of models.

The discovery of anthrax in a US Post Office Facility and in the Senate Office Building created severe disruption to government activities and to the businesses and other entities relying on the timely delivery of mail as well as to other entities. It was observed that some economic impacts of attacks on the national blood supply, or on other targets, include the direct costs of illness, incapacity, and death. There is also a need to include the indirect costs of societal disruption that would impact government, health care, manufacturing and service businesses, utilities, transport, educational, and other entities. Models should include

the economic impacts of disease on those entities through the effect on the denial of personnel and capabilities as well as the co-lateral economic impacts of denial of service and access to facilities. In the case of protecting the national blood supply from terrorist actions, the costs of producing and fielding new capabilities responsive to blood contamination as well as the intangible cost of undermining trust in the security of the national blood supply should be included.

The systems dynamics models presented, as well as many if not almost all other disease models, are time-dependent models and do not represent the impact of spatial factors on the spread and containment of disease. It is evident that disease impact models, particularly involving contamination of the national blood supply, need to incorporate both time- and space- dependent processes of contamination and response. Models should be enhanced to include an adequate representation of the processes and mechanisms aimed at detecting, managing, and implementing actions intended to limit and mitigate the impact of terrorist-generated diseases. In particular, the concept of distributed supplies and layered defense of the blood supply and other sensitive entities should be introduced. Models should also include the economic effects of the co-lateral impacts of blood supply contamination and those of other disease-related processes.

With regard to public policy and decision-making, there is a need to incorporate the concepts of risk acceptance and rejection and the impact of such policies on the overall societal risk within the overall political process of a nation or state. Other analyses could provide the basis for undertaking a cost-benefit analysis of particular risk-related strategies. Leadership by non-technical individuals in areas requiring an immediate grasp of complicat-

ed scientific, technical, biological, medical, and mathematical concepts can be facilitated by the provision of graphical, model-generated, map-based, and other technologies. There is also a need for situation assessment involving models to support the assessment of the biological and medical impacts of disease contami-

nation. Other models should support the integration of distributed information in central policy and decision-making facilities. There is also a need to model public information distribution and the role of the media and public opinion in responding to blood supply contamination and/or other bio-terrorist activities.

Afternoon Plenary Session - Summary of Findings

The consensus recommendations are as follows:

1. Disruption of the blood distribution system is a greater terrorism risk than the possibility of infecting the blood supply. The current system is very sufficient. It is complex and comprehensive. The greatest vulnerability is probably human error, which is addressed through competency monitoring, simulation, reviews and training. "Sentinel testing" is an attractive concept and should be implemented in order to achieve a greater security in the post September 11, 2001 era.
2. Policies and procedures currently in place for safeguarding the blood supply are adequate; however the safeguards at the points of collection and distribution can be breached.
3. Concern over bio-terrorist events creating a shortage of blood products (insufficient blood donor pool) is real. There is a socio-economic status relationship to blood donation (disparity).
4. Balancing the need for mandatory disclosure versus the right to privacy (rights of individuals versus the society as a whole) should be a major consideration.
5. The blood banking system is only one of the elements of a "sentinel system." A global policy on biological sampling rather than new blood banking policies should be considered.
6. Health status changes (carrier status) in the population at risk is inadequate. Quantification of this risk will guide the formulation of proper medical policies.
7. Roles and responsibilities of different agencies need further clarification if a monitoring system is established. For example the Food and Drug Administration (FDA) regulates the scientific and technical aspects of pharmaceuticals and medical devices while the Department of Homeland Security (DHS) would be concerned with product distribution and facility protection.
8. The concept of sentinel testing is an acceptable approach to monitoring and managing the threats associated with contamination of blood collection and product industry.
9. The types of pathogens that might be considered as a bio-weapon threat, will carry high infectivity and high mortality risks.
10. Screening of donors can be used as a deterrent to terrorist threat. When establishing monitoring systems, careful consideration should be given to the place of the testing: central versus point of care location. Additional attention should be devoted to the assessment of the value of near-real-time diagnosis, and how such testing could contribute to the stemming of a public health crisis and an increase in public confidence.
11. Nucleic Amplification Testing (NAT), when available, should be utilized and integrated into the blood banking system.

Conclusions and Recommendations

As a result of this research it was found that the safety of the nation's blood supply though robust, nevertheless appears to be vulnerable to attack(s) from terrorists and other entities. Contaminated blood could act as a randomly distributed disease vector affecting medical and other first-response personnel and patients. Terror-motivated contamination of blood with biological and/or chemical agents could take place at blood collection points, in blood banks, or during transportation and delivery. Perceived contamination of the blood supply would inhibit public confidence in the use of blood for surgery and other medical purposes and could create widespread panic and societal disorder.

Blood is a life-saving product, and the preservation of the blood infrastructure is a major international concern. The World Health Organization has established a Blood Transfusion Safety Team (BTST) to address world wide problems of infection transmission through blood transfusions. The BTST found that "... 80% of the world's population does not have access to reliable and safe blood. With the rapid spread of the AIDS pandemic, there is an urgent need to ensure the safety of all blood and blood products. The first step in reducing the risk of transmission of infectious diseases through blood is to select voluntary non-remunerated donors from low-risk populations who give blood on a regular basis as these individuals are at a lower risk of transmitting transfusion-transmissible infections than are family/replacement donors, or paid donors. However, even with the most careful selection, some donors will prove to be seropositive for HIV or other infectious agents. Therefore, rigorous screening of all donated blood is required to ensure the safety of the blood supply. Unfortunately not all donations in all countries are screened. It is estimated that 43% of the blood collected in developing countries is not tested for transfusion transmissible infections (HIV, HCV, HBV, Syphilis, Chagas disease). Globally, 5-10% of HIV infections are caused by unsafe blood and blood products."

Movement of blood and blood products globally will continue to present a potential danger for transfusion

transmission of pathogens especially in the modern days of rapid international travel and potential for injuries and illnesses requiring such life saving intervention outside the U.S.A. This is especially true in the cases of extreme sports and tourism, and medical tourism (where individuals are seeking low cost medical treatments abroad). It can also be a potential route for a bioterrorist attempt to contaminate the national blood supply chain. During the course of this research, a West Nile Encephalitis and the variant Creutzfeldt-JaKobs disease (VCJD) contamination of blood products and tissue/organ transplants resulted in transmission of these infections to several recipients.

Today significant expenditures are associated with the collection, processing and distribution of blood products. The current annual estimate for the blood and blood product market in the United States is \$6-7 billion, and the global market is estimated at \$10 billion in annual expenditures for blood products.

There is a critical requirement for new rapid monitoring and detection devices and integrated command, control, and communication and crisis management facilities that could detect, respond to, and mitigate the impact of terrorist contamination of the nation's blood supply.

Issues regarding blood product contamination with HIV, Hepatitis and, more recently, by West Nile Encephalitis, did result in highly publicized debates, law suits and, in some cases, loss of public confidence. Current estimates for the cost of collecting and processing one pint of blood ranges from \$193 by some small blood banks to \$220 by large national banking operations. This cost continues to increase and potential shortages due to deferrals and surges might result in safety gaps which need to be seriously addressed. Recently, the World Health Organization (WHO) recommended that people with potential exposure to SARS be deferred from blood donation. However, at the collection stations, the methods for detection and diagnosis of exposures to infectious agents are quite rudimentary (i.e. health questionnaire and temperature checks during suspected events/epidemics).

The implication of certain blood-borne agents as etiological/predisposing factors for chronic diseases, coupled with the advances in rapid screening/ diagnostic technology, warrants a reexamination of the testing procedures and protocols at the blood collection sites. Introduction of such modalities will not only improve the quality of the products, but enhance the quality of healthcare delivery as a whole. Obviously the downside of such an approach may be the reduction of the pool of blood donors and the creation of an acute shortage in this critical product.

A major focus of the industry is to accelerate the development of blood product substitutes. Clearly these products must have universal compatibility (reducing the chances for iatrogenic events due to human errors), be pure and nontoxic (free of infectious agents), possess storability and shelf life (prevent gluts and /or shortages), have a proven predictability of action (minimize latent complications), and the necessary biostability after use to remain in the recipient's circulation and not to be rapidly metabolized and excreted. The current market for such products is projected to reach \$5-8 billion within the next five years. In recent years, the U.S. military has invested more than \$100 million in blood substitute research and development. We estimate Federal research expenditures are approaching \$1 billion. Obviously a rapid infusion of research and development funds into this program, proper priority, and focus will contribute significantly towards protecting this critical infrastructure in the post September 11, 2001(References 1-7).

New model-based tools for risk assessment and policy definition should:

- Incorporate both time- and space-dependent processes of contamination and response in models.
- Include concept of distributed supplies and layered defense of the blood supply should be introduced.
- Model co-lateral impacts of blood supply contamination.
- Establish risk acceptance and rejection concepts.
- Consider models of biological contamination assessment and of the integration of distributed information in central policy and decision-making

facilities.

- Allow for modeling public information distribution and the role of public opinion in responding to blood supply contamination.

The following recommendations are based on the above findings and observations:

1. Effective safety and control measures are currently in place to protect the blood supply, distribution, and infrastructure. However these measures might not be immune to a terrorist event.
2. Periodic shortages of blood supply often dictate remedial collection practices which could result in safety and control gaps, leading at best to the destruction of valuable and life saving products, or at worst to potential contamination of the blood products.
3. The most significant issue to be concerned with is the ability for *terrorizing the public without actually compromising the collection and distribution chain of blood products*.
4. Even in the absence of a bioterrorism event, active or latent blood-borne infections (as with any transfused or transplanted biological materials) will continue to be a potential source for the transmission of biological agents capable of causing acute illness, iatrogenic complications and chronic disorders.
5. After proper ethical and policy issues are addressed, a registry for blood and blood products, including an epidemiological database of donors and carrier state of blood-borne pathogens suspected as etiologic agents for chronic diseases, should be initiated, funded and maintained by the federal government. To this end, proper legislation should be enacted to ensure the deployment of such a system.
6. Additional research and development funds should be appropriated to accelerate the development of blood and blood product substitutes.

7. Commercial use of residuals, left over from the processing of blood, should be considered as a potential funding source for establishing the epidemiological surveillance of the baseline blood-borne pathogen carrier status. This surveillance can include specific markers, such as immunoglobulines and antigens, in the population which could help establish trends and detect deviations as a potential "early warning system" based on sentinel events. Such an approach will require a change in policy and potentially the passage of appropriate legislation.
8. The workshop revealed potential deficiencies in the modeling capabilities that are intended to support policy and decision-making as well as the management and implementation of actions intended to reduce and mitigate the impact of terrorist-generated blood-borne infections.
9. Additional research into the potential risks associated with blood-borne infections and prioritizing threats based on these risks is required. Furthermore, policies for implementing a "sentinel monitoring" system are needed, especially in the context of evolving global health interdependencies.

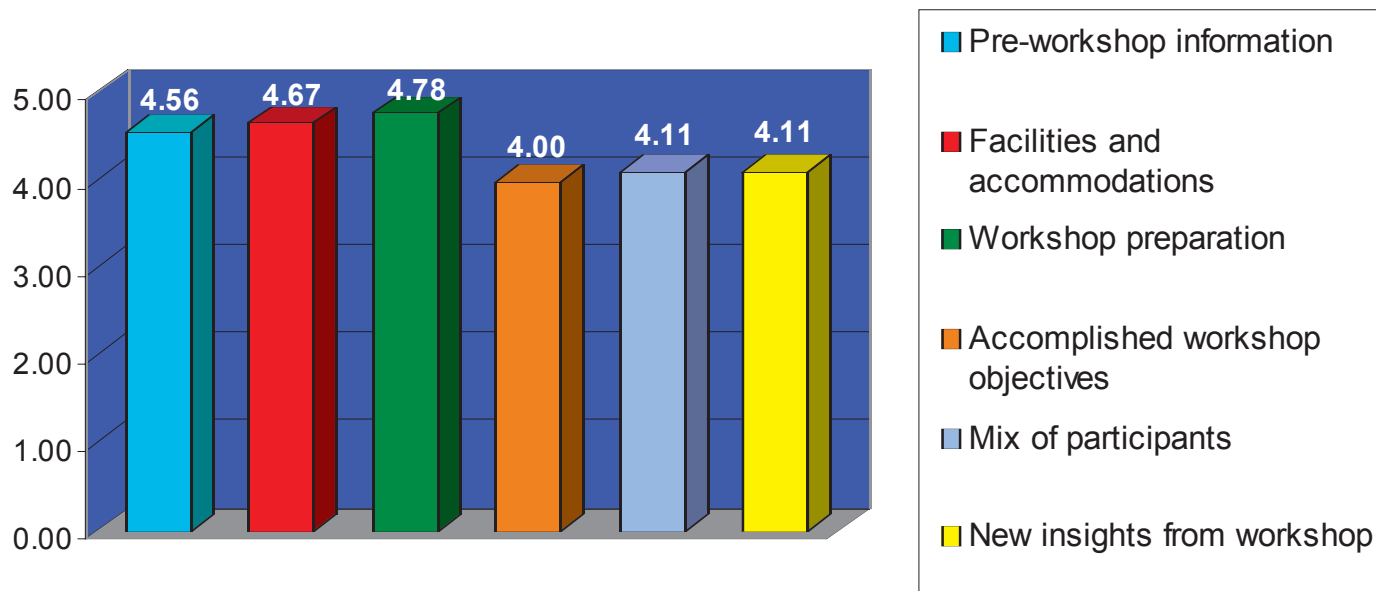
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Workshop Evaluation

We used a self-administered questionnaire to evaluate the organization and conduct of the workshop. The GMU research team was excluded from this evaluation process. The overall return rate of the questionnaire was 64%. Participants were asked to rate various aspects of the workshop preparations and conduct

on a scale from 1 to 5, with 1 being unsatisfactory and 5 being highly satisfactory. Mean scores for responses to individual questions are summarized in the table below. Mean scores ranged from a low of 4.00 (accomplished workshop objectives) to a high of 4.78 (workshop preparation).



The evaluation form invited participants to comment on areas where improvements may be made. Comments included:

- Input would be helpful from the FDA, CDC, and/or NIH on issues such as medical devices, vaccines, temporarily/permanently deferred donors, foreign visitors, epidemiological surveillance system for early warning.
- Social, political and economic barriers to effective

monitoring and collection must be taken more seriously.

- Involve experts from the United States Army Medical Research Institute of Infectious Diseases (USAMRID) and the Naval Medical Research Center (NMRC).
- Politics and implementation strategies should be included in the discussion more fully. In addition to actually protecting the blood supply, how do we assure the public that it is safe?

APPENDIX A.**AGENDA**

- 09:00 **Welcoming Remarks**
Kingsley Haynes, Dean, School of Public Policy, GMU
- 09:05 **Workshop Objectives and Expectations**
Arnauld Nicogossian**, Vikas Chandhoke
- 09:20 **Critical Infrastructure Protection Project Overview**
Kip Thomas
- 09:30 **Plenary Session I**
Vikas Chandhoke, Arnauld Nicogossian, Aiguo Wu
- Workshop Objectives, Background Information and Expectations
-Charge to Breakout Sessions Participants
-Discussions
- 11:00 **Morning Break and Refreshments**
- 11:15 **Working Group Sessions and Discussions**
- | <u>Session 1</u> | <u>Session 2</u> | <u>Session 3</u> |
|------------------------------------|---|--|
| Policy and Legal
Considerations | Medical and
Technological
Feasibility | Improving the
Epidemiological
Models |
| Connie McNeely* | Vikas Chandhoke* | Ted Woodcock* |
- 12:30 **Working Lunch** - Interdisciplinary Discussions
- 13:30 **Resume Break-Out Sessions**
- 14:30 **Afternoon Break and Refreshments**
- 14:45 **Plenary Session 2** - Reports from Break-out sessions
- 15:30 **Discussions**
- 16:00 **Summary, Conclusions, Recommendations**
- 16:30 **Adjournment**

* Group Facilitators

**Workshop Facilitator

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**These individuals participated in the third workshop to finalize the policy recommendations.*

APPENDIX C. SELECT REFERENCE LIST FROM PROJECT LITERATURE DATABASE

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Also available are Protocols from the Laboratory Response Network (LRN) for *Francisella tularensis*, *Yersinia Pestis*, *Bacillus anthracis*, *Clostridium botulinum* Toxin, and *Brucella* Species.

Additionally we prepared three documents for use by the participants. "Role of Pathogens in Chronic Diseases" discusses the health effects of chronic

and infectious diseases on public health, and identifies infectious agents. The document contains charts with a listing of pathogens and their related disease description, source and transmission information, basis for diagnosis, descriptive of pathogen in the blood, and treatment notes. A Bioterrorism Literature Review, and Summary Tables related to Biological Warfare Agents were also provided in participant packets.

APPENDIX D. DISCUSSION GUIDE

CONCEPTS TO GUIDE DISCUSSIONS

As you approach your discussions, please give consideration to the following issues. Feel free to make notes on these pages (and additional pages if needed) and turn these sheets into the research team before departing. Please note that all the concepts below may be appropriately considered by any group.

Policies and Legislative Considerations	Remarks
<p>What is (are) the overall risk(s) and probability of bio-terrorism events (threat assessment and modeling)?</p> <p>Who bears the costs? (private, federal government, state and local governments, or the consumer)</p> <p>Who regulates? (state, federal) What type of policies should be considered, debated and enacted?</p> <p>Who should be responsible (liable) and accountable?</p> <p>Degree of donor's privacy and information disclosure? Should the disclosure be mandatory and the individual's right to privacy be waived? Assess ways in which informed consent and reporting will affect the status of voluntary blood donation process.</p> <p>What are the policies and legalities that apply to those tests that are false positive or false negative? What policies or laws should be proposed and/or enacted? What liabilities, impediments and outcomes should be considered (positive or negative)?</p> <p>What other disciplines might benefit from this activity?</p> <p>Will the implementation of such a system serve as a deterrent to terrorism?? What issues exist regarding the sharing of technology and security requirements?</p> <p>What considerations should govern establishment of a blood donor and blood product National Registry Program? Previous participants suggested that consideration be given to the establishment of a historical repository of blood samples from different collection areas, and that additional testing be done for those infectious pathogens which are known to cause cancers and other chronic debilitating disorders, thus improving the general public health programs.</p> <p>Are there potential models that might be used in the evaluation process?</p> <p>What are the economic impacts? (Scaring off donors, increasing the cost of blood products, reliance on international products, impacting blood banking system.)</p>	

Medical and Technological Feasibility	Remarks
<p>What technology is under evaluation and/or development that may benefit this topic?</p>	
<p>Sensitivity and specificity of currently used tests and/or screening procedures?</p>	
<p>Possibility of non-specific screening, i.e., (two step process, IgM + IgG, cytokines, immune markers, followed by a specific laboratory screen).</p>	
<p>Use of information technology and cluster analysis methodology for epidemiological surveillance.</p>	
<p>Identify key players and opportunities for partnerships between government, private sector and academia.</p>	
<p>How safe is safe enough? Where do we draw the line?</p>	
<p>What pathogens should we monitor and/or test for?</p>	
<p>Testing individual donor's blood vs. using pooled sample batches first?</p>	
<p>Testing all nationwide blood collection centers and/or choosing only a few centers in areas with high population density, where the probability of early detection is higher (sentinel system)? (Agro-terrorism to be factored as well)</p>	
<p>If new tests are introduced, should we also retest the presently stored blood supplies (e.g. frozen products)?</p>	
<p>Disposal of contaminated blood. How and when, and the need to store samples for historical purposes.</p>	
<p>Monitoring and/or surveillance of blood donors to develop an epidemiological database and establish a national pathogen antibody baseline.</p>	

APPENDIX E.

Protecting the Nation's Blood Supply						
October 31, 2003						
Workshop Evaluation and Feedback						
Please assess the following aspects of the Protecting the Nation's Blood Supply workshop.						
Please circle your satisfaction level on a scale of 1 to 5, with 5 being the most satisfied.						
Please evaluate the following:		Unsatisfactory		Highly satisfactory		
The adequacy and usefulness of the pre-workshop information.	N/A	1	2	3	4	5
The adequacy and appropriateness of the facilities and accommodations.	N/A	1	2	3	4	5
The overall preparations for the workshop.	N/A	1	2	3	4	5
Are you satisfied that the workshop accomplished the established objectives?	N/A	1	2	3	4	5
Are you satisfied that the skill mix of participants was adequate to address the established agenda items?	N/A	1	2	3	4	5
Did you gain new insights from the interactions at the workshop?	N/A	1	2	3	4	5
Were there any topics or issues that were not on the discussion agenda, or did not receive adequate attention during this workshop? Please elaborate.						

This workshop will focus on the significance and role of opportunistic blood-borne pathogens in the development of chronic and debilitating diseases; the potential for using blood products to detect sentinel events from bioterrorism attacks; the barriers to the implementation of a biomedical monitoring system of blood donors and products; the formulation of policies necessary to establish such a monitoring system; and the evaluation of the strength and weaknesses of existing epidemiological models used for assessing the impacts of bioterrorism events.

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