Executive Summary

Dangerous pathogens and toxins are odorless, colorless, and tasteless, and they know no borders. Bioagents are readily available in the modern world and are relatively inexpensive to produce, store and transport from one country to another. Yet they can be toxic, transmissible and lethal. Many view the potential threat of bioterrorism as a growing one, due to the advances in biotechnology, the increased availability of dual-use materials and the ease of transporting biological agents across borders. Compared to the resources spent on nuclear and chemical terrorism, relatively little is being done to fight this threat. Only 1.5 percent of the $20 billion that the G8 Global Partnership agreed to spend on reducing the risk of weapons or materials of mass destruction falling into the hands of terrorists has been devoted to bio-related programs. Thus the upcoming G8 Summit in St. Petersburg presents a unique opportunity for the Russian President to take initiatives on this vital issue.

This Strategic Study on Bioterrorism was conducted to increase the awareness of the threat of bioterror and to identify means by which States can prevent and respond to such threats to increase their biosecurity. It addressed bio-threat and response scenarios, risk assessment, modern diagnostic techniques and methods to strengthen capabilities for early detection, surveillance and response to natural and bioterror disease outbreaks, the technical issues to be solved and political, social and psychological aspects of bioterrorism. The Group recommended that in order to prevent dangerous microorganisms from falling into the hands of terrorists, it is essential to secure and consolidate them in certified facilities or destroy them. This can be achieved through bilateral arrangements or through the G8 Global Partnership. In addition, the Group agreed that because the first alarm of a bio-attack will probably be sick patients in the hospital, it is critical to enhance the early detection of microorganisms in the environment and the rapid diagnosis of patients. European countries (such as France, Germany, Switzerland, Sweden and the United Kingdom) that have substantial biotechnology industries and experience working on biodefense and with infectious diseases could work with the Russian Federation to increase security and accounting of pathogen collections, and to strengthen export control restrictions. 1

Participants in the study included 20 high level bio-experts from the Russian Federation and other European countries who provided their extensive expertise upon which the study is based. Although they came from diverse professional and cultural backgrounds,

the resulting collaboration provided a greater understanding of the mutual threat posed by natural and man-made diseases as well as concrete recommendations for future activities. The experts established a dialogue on bioterror as a basis for sharing knowledge, identifying future areas of cooperation and creating mutual confidence on a sensitive subject. A crucial element in building such confidence would be to develop common standards on biosafety and biosecurity.
LIST OF RECOMMENDATIONS

1. The Group recommends that a team of international experts conduct a comprehensive study on how to counter the most significant deficiencies in the area of biosafety and biosecurity. The study would provide a roadmap and overall strategy of where resources should be allocated to counter the threats and risks. It should consider the whole chain from prevention, protection and crisis management to consequence management.

2. Due to the difference of views on standards of biosafety and biosecurity, the Group recommends working towards a common understanding of biosafety and biosecurity as a critical element of the confidence building process. Comparing national regulations on biosafety and biosecurity could be a first step in this direction. Enforcing adequate laws would help to prevent, disrupt and carry out an investigation of a bioterror attack. The Group also recommended addressing at the intergovernmental level the possibilities of exchanging national inventories of dangerous pathogens. The European Commission could address in its Seventh Framework Programme the issues of biosafety and biosecurity, as well as monitoring of the environment and the food supply.

3. The Group recommends that Russia and other European countries continue to cooperate on securing and consolidating vulnerable stocks in certified facilities or destroying them, either through the G8 Global Partnership against the Spread of Weapons and Materials of Mass Destruction or through bilateral arrangements.

4. As the Russian Federation is the President of the G8 during the year 2006, the participants in this study recommend that the declared priority, fighting against infectious diseases, should receive additional attention and funding within the Global Partnership.

5. The Group recommends that various regulations and legal systems regarding licensing, first responders, protection of the population, etc. be adapted to each other, with the goal of being prepared to cope with a bioterror event as rapidly as possible. Russia and other European countries should collaborate further in the areas of prevention, crisis management and recovery.

6. The Group recommends that contacts be established among the life science research, development and industrial institutions in Russia and other European countries on specific projects. It recommends convening meetings of government officials, expert communities, agencies and industry from different countries in order to initiate specific co-operative projects on medical countermeasures based on biotechnology against bioterrorist attacks and welcomes business investments in that field. For example, centers of excellence could be established in Moscow and Puschino for storing strains and mastering the technology of hybridomas and monoclonal antibody production. These centers would support other European countries and provide cultures, expertise, advice and training. The Group recommends that Russia and the EU explore the potential for cooperation on emerging technologies and initiate such cooperation where possible.
7. The Group realizes that disease surveillance can be a cornerstone in mitigating the effects of a bio-terrorist attack and recommends strengthening national and international capabilities for disease surveillance of intentional releases of pathogens and toxins as well as natural outbreaks. The global surveillance capability is far from even and could benefit from strengthened activities of the World Health Organization in Russia and other areas. In addition, Russia could develop a system such as phage detection to differentiate between a terrorist event and a natural outbreak. The Group recommends that the standards and procedures for rapid reporting on symptoms and diagnoses in Russia and other European countries be studied and eventually harmonized. Health providers should be trained and syndromic surveillance methods developed to detect changes in the patterns of reported symptoms and diagnoses that might indicate an outbreak.

8. In order to promote a regeneration of the sciences following the economic decline in Russia, the Group recommends that there be an increase in the exchange of researchers among scientific institutions in Russia and other European countries as part of a long-term cooperative project. Such exchange represents an important confidence building and transparency measure. It helps to multiply and rationalize efforts aimed at solving existing problems and stimulates general development of science. The Group recommends promoting scientific exchange and collaboration in the following areas:

- Developing and improving drugs and other prophylactics (vaccines, serums, bacteriophages, immunomodulators)
- New methods of diagnostics, drug discovery, detection, and decontamination
- Developing aerosols especially as anatoxins and vaccines in emergency situations, e.g. to fight avian flu.
- Finding standard methods for disinfecting against anthrax and dangerous infections.
- Developing a set of programs for training medical personnel, administrators and governmental bodies on how to act in emergencies

This cooperation could be handled within the ISTC as well as other frameworks, including multilateral and bilateral approaches. Priority should be given to a simple agreement or memorandum of understanding (MOU) with a streamlined implementation process.

9. While most literature on the subject relates to humans, for future projects the Group recommends paying specific attention also to the research on issues related to plants and animals, specifically as potential subjects of bioterrorism. The Group recommends sharing methods of inspection and sanitary control of the food and water supply. Quality and safety are paramount in these areas. The Group recommends the creation of a working group consisting of scientists specializing in dangerous pathogens and diagnostics that would monitor the latest developments in the scientific field and commend these to the responsible authorities.
10. The Group recommends several activities to be undertaken concerning the improvement and standardization of detection and diagnostics:

- To develop a first draft of standards for testing and evaluating an environmental detection system as a cooperative project among a few laboratories in Russia and other European countries engaged in detection work. A list of laboratories will be elaborated upon request.

- To develop a concrete proposal for the establishment and provisional operation of a joint Russian – European test center for environmental detection systems, including identification of a host institution in Russia and financing arrangements together with industry.

- To subsequently establish common standards among Russia and other European countries for evaluating environmental samples (air, water, etc.) and other detection equipment for pathogens and conducting a comparison of facilities for indoor and outdoor testing.

- To join efforts in developing diagnostic microchips to help provide automatic warning and detection methods. Russia already has special equipment for making such microchips. Together, Russia and other European countries should develop specialized chips for disease and toxin detection.

The Group further recommends that different methods of detection and diagnosis in Russia and various European countries be compared to find the most suitable technology for bioterrorism events. Sharing of facilities for indoor and outdoor testing could be an important component of such cooperation.

11. The Group recommends creating a school to train scientists in the practical application of international standards in quality assurance such as Good Laboratory Practice (GLP), Good Manufacturing Practice (GMP), biosafety and biosecurity. This school could be located at the Enterprise for Science Research Center for Toxicology and Hygienic Regulation of Biopreparations at the Federal Medico-Biological Agency in Serpukhov, Russia. The school should also offer courses in intellectual property rights and business training for managers.

12. The Group recommends that an international meeting be arranged for Russian and European scientists and specialists working with scenarios and computer modeling of epidemics and contagious diseases. The aim of such a meeting would be to analyze and compare epidemic modeling systems, pathogen emergence scenarios, and epidemic forecasting experiences. The meeting could also provide guidance on how to develop common research projects in this area.

13. The Group recommends that a workshop or more extended study be conducted to address the psychological, social and economic aspects of a bio attack or bio threats. The
workshop/study should bring together experts in psychology, sociology and economics, as well as government officials and bio experts. The purpose should be to:

- Review basic psychological and social factors influencing the resilience of a society to terror acts.
- Analyze psychological, social and economic consequences of bioattack/threat scenarios.
- Provide guidance on measures to be taken to develop the resilience of societies against bio terror.
- Identify ways and means to improve international cooperation in this area.

14. The participants in the Group recognize that they constitute a unique collaboration among different professional communities and nationalities that do not normally interact on a regular basis. It is the first attempt to conduct substantive discussions in the area among scientists, representatives of industry and policy-makers from Russia and other European countries. This international Group of bio experts has established excellent working relations and a high degree of confidence among its participants. The Group is thus a valuable asset in further promoting trust, confidence and collaboration among scientists and institutions in Russia and Europe in the sensitive area of bio-security. The Group should facilitate and review the implementation of specific activities that are recommended in this Report as a result of the Group’s initial work and therefore suggests that it meet annually to maintain a dialogue on bioterror issues and to review the work on the specific issues identified above. The Group suggests that it continue to meet in the same informal manner, under the auspices of the Swedish Institute of International Affairs (UI), the Center for Strategic and International Studies (CSIS, United States), the Institute of World Economy and International Relations (IMEMO, Russian Federation), and the Committee of Scientists for Global Security (Russian Federation).
One can find on the web how to inject carrier animals, like rats, with pneumonic plague and how to extract microbes from infected blood... and how to dry them so that they can be used with an aerosol delivery system, and thus how to make a biological weapon. If this information is readily available to all, is it possible to keep a determined terrorist from getting his hands on it?

1. Introduction

Let us consider a scenario of an urgent and epidemic spread of a hypothetically new contagious disease, avian flu (H5N1), in European countries. In January 2006, information appeared in the European media that a Turkish journalist traveling from Turkey to Brussels was diagnosed with the symptoms of avian flu. He contacted the doctors one day after arriving in the Belgian capital. If one assumes that the ill patient from Turkey was infected with a mutant strain that could carry the disease from human to human, his arrival could have created an outbreak of this new dangerous disease in Brussels. Within one day, a single perhaps intentionally infected person in Europe could start an uncontrollable avian flu epidemic, which could affect tens of people within 10-15 days. Unless emergency measures are applied, the epidemic will move from the initial phase to the expansion phase: the avian flu will affect hundreds and thousands of people in different European countries.

The estimates made by American epidemiologists show that in the case of an H5N1 epidemic, comparable in scope to the outbreak of the Spanish flu in 1918-1919, up to 1.9 million Americans could die if there was no intervention. An extreme scenario foresees 142.2 million people dying and SUS 4.4 trillion in lost GDP on a global level. By way of comparison, the average number of deaths in recent years in the U.S. caused by complications during the “local” influenza epidemics is up to 36,000 per annum. It has been suggested that avian flu could also be transmitted by scattering powdered dry bird droppings.


\(^3\) HHS Pandemic Influenza Plan, U.S. Department of Health and Human Services, November 2005, p. 18.


\(^4\) www.cdc.gov/flu/keyfacts.htm
While the avian flu would take time to reveal its sinister results, an outbreak of anthrax would not. Such a scenario could involve the dissemination of a spray contaminated by spores of anthrax in the ventilation system of a large building (a theater, a museum or a supermarket). In this case the people on the lower floors would inhale the highest dose and die within 2 -3 days.

Detecting and recognizing something that is invisible, that has no taste or smell and that could pass from person to person or through the air, food or water is a major challenge. The scenarios experts have created are almost like Hollywood nightmares, yet worse because they could come true. Such scenarios can be studied by the experts in different countries using the unique computer models for studies of epidemic development and outbreak of dangerous contagious diseases. These models allow us to analyze the results of unintentional releases of agents from scientific laboratories, unexpected natural disasters or man-made accidents and to propose adequate countermeasures. This is especially valuable if we consider that the incubation period for a biological event could last up to 60 days, depending on the agent.

The unpleasant subject of bioterrorism has received a great deal of attention of late--some people believe too much because it may be diverting resources from other valuable medical research. In spite of the devastating capacity of biological weapons, it should be noted that they have rarely been used. For the terrorist it is problematic to obtain suitable bioagents that can be easily dispersed through, for example, aerosolization. However, a delivery system may be quite primitive and still achieve the intended impact on the public. As Senator Sam Nunn has often stated, “I view the threat of biological terrorism as equal to the nuclear threat and more likely in the years ahead.” Put another way, Interpol’s Secretary-General Ron Noble said, “When you talk about bio-terrorism, that’s one crime we can’t try to solve after it happens because the harm will be too great.”

With the advances in biotechnology, the increased availability of dual-use materials and the ease of transporting biological agents across borders, many view the potential threat as a growing one. “There is currently no international framework for regulating security-related aspects of the biotechnology industry.” There is no technology available that is able on its own to protect the population; thus the provision of vaccines is important.

Worldwide concern has grown over the possibility that biological agents in Russia and elsewhere, as well as the scientists possessing knowledge about them, may not have been adequately controlled and could be used by terrorists. Relatively little has been done to fight this threat compared to the resources spent on nuclear and chemical terrorism. The G8 Global Partnership Against the Spread of Weapons and Materials of Mass Destruction

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5 Reportedly $5 billion annually in the U.S. on civilian biodefense for FY 2004, 05, 06
7 Speech at Inter-Parliamentary Conference in Strasbourg, Nov. 20, 2003
(GP) was launched in June 2002 to expend $20 billion over ten years to reduce the risk that weapons or materials of mass destruction fall into the hands of terrorists or States. Yet Global Partnership countries have spent only 1.5 percent of the $20 billion on bio-related programs.10

This Strategic Study on Bioterrorism was undertaken to increase the awareness of the threat of bioterror and to identify means by which States individually and collectively can prevent and respond to such threats to increase their biosecurity. The Study aimed to identify the strategic and technical issues to be solved. It further intended to establish a dialogue on bioterror among high-level Russian and other European experts to create increased mutual confidence as a basis for sharing knowledge and identifying areas of future cooperation. Although a number of cooperative threat reduction projects have been undertaken on a bilateral basis between the Russian Federation and the United States, very few have been initiated with European countries. Experts believe that trust and confidence would not be difficult to establish among Russia, which has a strong tradition of scientific excellence, and other European countries.

In order to enhance the ability to respond to a deliberately introduced infectious disease, most technical assessments recommend meeting the threat of terrorists using dangerous pathogens with increased surveillance, detection, diagnostics, vaccines and therapies.11 This Study addressed a number of salient issues, including bio-threat and response scenarios, risk assessment, modern diagnostic techniques and methods to strengthen capabilities for early detection, surveillance and response to natural and bio-terror disease outbreaks, and political, social and psychological aspects of bio-terrorism. Participants in the study included 20 high level bio-experts from Russia and Europe who provided their expertise in the discussions upon which the study is based. Experts from international organizations concerned with biosecurity issues, such as WHO, OIE, Interpol and the new European Center for Disease Control, as well as representatives of the pharmaceutical industry, were also invited to participate in relevant sessions. The study was hosted by the Swedish Institute of International Affairs (UI) as part of the CSIS Strengthening the Global Partnership project, with financial support from the Swedish Defence Research Institute (FOI) and the Nuclear Threat Initiative (NTI). Sweden has the largest number of biotech companies per capita worldwide, a well known pharmaceutical industry, a strong collaboration between academic and industrial sectors, cost efficient research and development (50% lower than the U.S.), and it is the host to the newly established EU Center for Disease Prevention and Control.

The participants in the Study include professional communities that do not normally interact on a regular basis and, in addition to the language barriers that commonly occur despite translation, there were obvious differences in background, culture, training and world perspectives, as well as the historical events that led to substantial mutual suspicion during the Cold War. Yet the collaboration among the participants was extremely rich and productive, creating a greater understanding of the societal and global challenges posed by dangerous diseases, both those that occur in nature and those that are man-made. This report and the accompanying papers, which are attached in a CD-Rom, embody the intellectual product and concrete recommendations of this unique venture. The participants expect to be able to influence their governments to undertake the implementation of these recommendations. They agreed that the threat of bioterrorism and emerging infections can be substantially contained with a high level of government commitment and international collaboration when necessary. In addition, industry should be an important partner in that cooperation. The group realized that better coordination among Russia and other European countries could assist and alleviate the burden of finding national solutions to these problems.

A primary goal of the Study is to influence decision makers to move the bio issue high up on the national and international agendas. It should become a priority issue in the Global Partnership Against the Spread of Weapons and Materials of Mass Destruction and should obtain funding corresponding to its importance. As the Russian Federation is the President of the G8 during the year 2006, the participants in this study recommend that the declared priority, fighting against infectious diseases, should receive additional attention and funding within the Global Partnership. A recent opinion poll on “Attitudes in the Russian Federation towards WMD Proliferation and Terrorism” showed that 69 percent of Russians believed Russia should participate more actively in international cooperation with the G8 countries in the field of biosafety and biosecurity, to prevent terrorist acts using biological weapons and fight against infectious diseases. To cope with the bio threat is a demanding challenge; thus it should receive more, not less, attention and support. The Global Partnership Principles to develop measures to account for and secure WMDs and related materials as well as to maintain effective border controls, export and transshipment controls are even more valid today than when they were adopted in Kananaskis, Canada in June 2002. Terror on the subways of Madrid, London, Tokyo, in a theater in Moscow or a school in Beslan, is an international problem wreaking havoc on all aspects of society.

In the event of a bioattack the challenge is to detect and interrupt the insidious spread and results as early as possible. In this study we address the different elements of that chain of events, starting with the threat: how can it be identified and reduced? How can agents be detected before a disease makes contact with a person, and how can it be diagnosed after

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12 See “The G8 Global Partnership: Principles to prevent terrorists, or those that harbour them, from gaining access to weapons or materials of mass destruction,” Statement by the Group of Eight Leaders, Kananaskis, Canada, June 27, 2002, www.state.gov/e/eb/rls/othr/11514.htm. The Principles also call for providing assistance to states lacking sufficient resources to account for, secure, protect and establish border and export controls for these materials.
it has infected a person? The same question can be posed for animals and plants. Early
detection is a most important factor in mitigating the effects of a bioterrorist event. What
can be done to increase the resilience of a society against bioterror events? How can we
improve the treatment of infected people to reduce the dissemination and the casualties?
How can modeling help us be more prepared at different levels in our societies and help
us assess the values of new scientific and medical achievements? In what fields can
Europe and Russia cooperate to address a threat of common concern? These are the
questions we address in this study. The study does not aim to repeat technical findings
that are already available in other studies in abundance, but rather focuses on describing
concrete areas that can be put in the pipeline, identifying the relevant stakeholders, and
pointing the way ahead. It also summarizes the discussion of the Group.

2. Threat assessment

For many years world peace was maintained by the theory of mutually assured
destruction; now we are trying to create peace by mutual dependence. Events such as
bioterror make us dependent on each other, as no state can have adequate intelligence and
early warning of its own. And no state can have enough vaccines and medical supplies to
cope on its own with what might happen as seldom as a bioterror event. Thus building
trust and confidence and studying threat perceptions are essential contributions.

Bio-agents are readily available in the modern world and are relatively inexpensive to
produce, store and transport from one country to another. At the same time, they can be
toxic, transmissible and lethal. Some have a long period of incubation, and many items
involved in biotechnology are dual use, thus difficult to ban. The physical security of
biological agents is very poor in a number of facilities, with dangerous pathogens stored
in unlocked kitchen refrigerators and simple fences without alarm systems surrounding
the facilities. Lax border controls make illicit trafficking of drugs, arms and materials of
weapons of mass destruction a possibility in regions such as Central Asia and the
Caucusus, which is an area also traveled by terrorist groups. This report focuses on bio
agents that may be available to terrorists rather than terrorism in general. How can we
secure, collect or destroy strains that may pose a serious threat and prevent them from
falling into the hands of terrorists? How can we channel the knowledge and experience
of unemployed former Soviet bioscientists into benefits for the international community?

It is almost impossible to detect and deter the movement and/or transfer of a small
quantity of dangerous infectious agents. It is very difficult to forecast consequences of a
bioterrorist attack. For example, in the case of a sudden appearance of an epidemic type
of avian flu H5N1, the epidemic will travel the globe quickly, while the development,
testing and production of the necessary quantities of a vaccine against the avian flu will
take at least 4 to 5 months; this will provide protection for 50% of the world population.
Therefore, the protection of the population from epidemics and pandemics of dangerous
diseases caused by natural outbreaks, man-made accidents or bioterrorist attacks is an
issue of national and international concern. Given their proximity, Russia and other
European countries are well placed to cooperate on improving communications and surveillance systems to reach hospitals and doctors, including in isolated areas.

There is no common definition of bioterrorism. A modified FBI definition refers to it as the “unlawful use of viruses, bacteria, fungi, toxins or other pathogenic material against a government, the civilian population, livestock, crops or any segment thereof, in furtherance of political, social and/or economic objectives.”13 An unofficial Russian definition states, “Bioterrorism is the use of dangerous biological agents for inflicting damage to the life and health of people in order to reach goals of a political and materialistic nature.” The possibilities for bioterrorism exist in water, land, food, air, and the human being itself. Much has been written about possible scenarios of pathogens in the major water reserves, the food supply, animal husbandry, the subway, sport arenas, railway stations, and places where large numbers of people congregate. The sources of water supplies are generally considered protected in the cities, though they are not failsafe. Certain safeguards are in place for food protection, though a number of experts have expressed concern in particular about possible contamination of milk.14

The experts in this Study agreed that the highest risk was that of air contamination, and they recognized that it is close to impossible to protect the population from being contaminated. The method of dissemination of bio agents depends on the kinds of diseases. Non-contagious diseases require complex dissemination equipment such as a spray system or an explosive device to create a large-scale effect. The anthrax letters delivered in the United States Senate Office Building showed that widespread psychological effects could be inflicted via a simple means of delivery and a small number of actual victims.

Various organizations have compiled lists of agents that are based on parameters such as lethality, toxicity, morbidity, and mortality. The United States Centers for Disease Control and Prevention has defined three categories of bioterrorism agents/diseases. Category A comprises high priority agents that “include organisms that pose a risk to national security because they can be easily disseminated or transmitted from person to person; result in high mortality rates and have the potential for major public health impact; might cause public panic and social disruption; and require special action for public health preparedness.” The CDC lists the following under Category A: Anthrax (bacillus anthracis), Botulism (Clostridium botulinum toxin), plague (Yersinia pestis), Smallpox (variola major), Tularemia (Francisella tularensis) and Viral hemorrhagic fevers (filoviruses [e.g. Ebola, Marburg] and arenaviruses [e.g. Lassa, Machupo]).

Category B diseases/agents are defined as those that “are moderately easy to disseminate; result in moderate morbidity rates and low mortality rates; and require specific

14 See Lawrence Wein and Yifan Liu “Analyzing a Bioterror Attack on the Food Supply: The Case of Botulinum Toxin in Milk,” Proceedings of the National Academy of Sciences (PNAS), July 12, 2005. This article drew considerable attention and a government official requested that it not be published due to concerns that terrorists might use it as a model (see “The Bioterrorist Cookbook,” The Bulletin of the Atomic Scientists, November/December 2005).
enhancements of CDC’s diagnostic capacity and enhanced disease surveillance.”
Category B includes: Brucellosis (Brucella species); Epsilon toxin of Clostridium perfringens; Food safety threats (e.g. Salmonella species, Escherichia coli 0157:H7, Shigella); Glanders (Burkholderia mallei); Melioidosis (Burkholderia pseudomallei); Psittacosis (Chlamydia psittaci); Q fever (Coxiella burnetii); Ricin toxin from Ricinus communis (castor beans); Staphylococcal enterotoxin B; Typhus fever (Rickettsia prowazekii); Viral encephalitis (alphaviruses [e.g. Venezuelan equine encephalitis, eastern equine encephalitis, western equine encephalitis]); Water safety threats (e.g. Vibrio cholerae, Cryptosporidium parvum).

The third highest priority agents, Category C, are defined as “emerging pathogens that could be engineered for mass dissemination in the future because of availability; ease of production and dissemination; and potential for high morbidity and mortality rates and major health impact.” The CDC list mentions emerging infectious diseases such as Nipah virus and hanta virus.15

Similar lists of pathogens exist for plants and animals.

Recent examples of diseases that have caused economic as well as psychological distress include foot and mouth disease in the United Kingdom in 2001, which cost an estimated $12 billion, SARS, which cost Canadian tourism almost $1 billion in lost revenue,16 and avian flu. Even the process of finding a disease capable of causing bioterrorism costs a great deal in research and development, money that could be spent on other activities such as treating tuberculosis, dengue fever or other severe diseases.

During the Soviet era the country had very strong scientific and engineering capabilities, with a high level of university training. President Yeltsin acknowledged in 1992 that the Soviet Union had violated the Biological Weapons Convention, which entered into force in 1975. The legacy of suspicion and mistrust between the former Soviet Union and the United States that persisted during the cold war has continued to this day. The economic decline that set in after the Soviet era resulted in poor physical security systems in facilities housing large collections of dangerous pathogens and a drop in salaries for an estimated 10,000 former Soviet biological scientists possessing relevant bioweapons expertise.17 Many either changed careers or sought work in other countries, causing concern over the possibility of terrorists acquiring knowledge from them. Many Russian officials now talk about the “lost generation” of scientists: at the Russian Academy of Medical Sciences, for example, more than half the researchers are older than 45, and only 15 percent are between the age of 30 and 45.18

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16 www.ctv.ca
Apprehensions have also been expressed over whether some of the biodefense research of the United States might violate the Biological Weapons Convention as well as over the letters delivered to the Senate Office Buildings in 2001 that contained a well developed form of anthrax believed to be from a military defense facility. It also demonstrated that anthrax can be a handy weapon for bioterrorists. This is compounded by the fact that it is possible to produce resistant strains. On the territory of the former Soviet Union thousands of burial grounds of cattle with anthrax infection can be found.

The mistrust of the Russian Federation and the United States about each other’s possible illicit activities has had some degree of negative affect on the cooperative projects between the two countries, although work is being done. Strains of pathogens today reside at a number of laboratories and other bio-facilities in many places around the world. Many of those are vulnerable where security protection is insufficient or lacking. The common challenge is to identify and secure those strains or to collect them and move them to a secure facility. The Group recommends that Russia and other European countries continue to cooperate on securing and consolidating vulnerable stocks in certified facilities or destroy them, either through the G8 Global Partnership against the Spread of Weapons and Materials of Mass Destruction or through bilateral arrangements. It also would be beneficial to have the former Soviet anti-plague institutes participate in the Global Partnership. The G8 and other international efforts could supply basic items of security such as fences, alarm systems, video cameras, secure refrigerators, ventilation systems, guards, etc.

Recent emerging diseases such as severe acute respiratory syndrome (SARS), West Nile encephalitis, monkey pox and avian influenza, have set off alarms about the need to strengthen early warning and response systems. A multilateral effort is essential to fight diseases—whether naturally occurring or intentionally introduced—as well as to maintain public health systems, food supplies, economies and psychological well-being of the populations. The Group realizes that disease surveillance can be a cornerstone in mitigating the effects of a bio-terrorist attack and recommends strengthening national and international capabilities for disease surveillance of intentional releases of pathogens and toxins as well as natural outbreaks. The global surveillance capability is far from even and could benefit from strengthened activities of the World Health Organization in Russia and other areas. In addition, Russia could develop a system such as phage detection to differentiate between a terrorist event and a natural outbreak. In this connection, the U.S. National Academies, in cooperation with the Russian Academy of Science, suggested establishing two model State Sanitary Epidemiological Surveillance Centers for surveillance, diagnosis, analysis and communication of information concerning episodes of infectious diseases. These model centers would establish standards that would assist in enhancing the other 2,300 centers and would be

electronically linked to each other as well as to the WHO and other international entities involved in disease surveillance.20

The bio-threat is not limited to humans, but also animals and crops are exposed, with possible severe social and economic consequences for society. Early examples of bioterror against animals range from the book of Exodus to World War I. Research and development in the area of protection against bio agents is primarily driven by military needs and focuses on microorganisms in the air. While the food and water consumed by the military are generally considered safe, there is far less focus on detection tools to monitor the civilian food chain. The Group agreed that this priority should be changed, because the population, as the main target of terrorism, is unprotected. Measures to be included should be both pro-active (prophylaxis and protection) and reactive (detection, identification, diagnosis, treatment, decontamination).

No production of agricultural bioterror weapons is needed, as they exist in abundance in nature. Plant illnesses caused by various live organisms and pathogens can result in high losses of agricultural crops. For example, the world loss of crops caused by illnesses and insects for a number of years of the 20th Century averaged around 40%, without any acts of bioterrorism. One should keep in mind that nature nourishes the transmission of viruses, bacteria and fungi via wind, insects and birds. Fungi spores are stable and they can infect crops in different environments, at different stages of the plants’ development. The fungi produce toxins and even a light infection can poison crops. Further, it is easy to produce and use for terror purposes fungal plant pathogens that cause smut, mold, scab or rust. Thus, in addition to natural losses that could be minimized using specific measures, losses due to potential terrorist activities could reach catastrophic proportions.

The majority of farms and fields are not at all protected from bioterrorists, and the planning of large-scale attacks is facilitated by long incubation periods. An agro-terrorist could easily go into hiding or leave the attacked facility and the country long before the appearance of dangerous symptoms in the fields of agriculture. A bioterror attack against an agricultural facility is not only a psychological and ecological attack; it also produces a long-term destabilization of a system of food security in an entire region, causing rapid price increases for food before the expression of infection/intoxication symptoms.

Therefore, it is advisable to focus on the development of new detection and identification methods that would allow us to quickly and reliably identify pathogens/toxins used against living things and to take the necessary countermeasures. This system should be coordinated on the national or broader level since a number of dangerous pathogens are carried by winds, bugs and birds, which are not aware of national borders.

For the future, the Group believes it is important to analyze large-scale damage made to crops in the past (e.g. an almost complete destruction of the tobacco plantations in Cuba in the 1960s), in order to analyze this data for possible elements analogous to bioterror. Possible measures to mitigate damages and threats from bioterrorists include: development and funding of a federal research program, “AntiAgroBioTerrorism;”

20 See “Biological Science and Biotechnology in Russia,” p. 4.
research and development of attack prevention technologies; educational programs for experts in plant pathology; creation of an “agricultural pathogenic plant police;” development of a new generation of fungicides and insecticides; development of pathogen-resistant plants through selection and genetic engineering; abandonment of single culture farming and rotation of crops within large facilities for quick containment of the infection; and the development of quick and efficient methods of identification. It should be noted that the enormous ecological and climatic diversity in Russia provides a unique environment for bio-research.

While most literature on the subject relates to humans, for future projects the Group recommends paying specific attention to the research on issues related to plants and animals, specifically as potential subjects of bioterrorism. The Group recommends sharing methods of inspection and sanitary control of the food and water supply. Quality and safety are paramount in these areas. The Group recommends the creation of a working group consisting of scientists specializing in dangerous pathogens and diagnostics that would monitor the latest developments in the scientific field and commend these to the responsible authorities.

3. Detection and Diagnostics

Early detection of an attack or outbreak of a disease is crucial in order to confine the spread and to deploy the most effective response mechanisms, including medical countermeasures. In this context, the Group discussed rapid detection of biological agents, effective laboratory analysis to determine the exact nature of the agent and diagnosis of the infectious agent present in the human or the animal.

In the case of a bio-terror event, the first step involves the first responders. The first to arrive at the scene may be the fire brigade. They are likely to contaminate themselves before finding out what happened. Bomb experts, on the other hand, would know how to take samples, and might call scientific and medical experts for advice. Then the patients would be transported to hospitals, where doctors would probably be the first to see victims of a biological attack. Thus accurate diagnosis, which may be supported by detection tools, is essential, yet few hospitals have the ability to conduct diagnostics for anthrax or smallpox, for example. Anthrax can live longer than smallpox, and it is essential to determine the place where it was disseminated in order to disinfect it. An efficient alarm system that could provide warning could save time for decontamination and assist in judging whether the attack was an intentional or an unintentional outbreak. Unfortunately, technical limitations have constrained the development of an alarm system that would provide sufficient warning before a pathogen might be ingested.

Detection systems should be sensitive, specific and rapid. However, the limitations of available technology have thus far enabled the development of detection instruments that are either small, quick and unspecific or large, slow and more specific in their response to different agents. Because numerous reports have been written about detection research and available instruments, this study group did not attempt to duplicate those efforts. Yet
most planning includes parallel use of a trigger and a more qualified detector. It is widely believed that a biodefence strategy should have several layers of activities aiming at prompt detection. The first layer of protection comprises standoff detectors, the next one uses point detectors, and the third layer includes the collection of epidemiological data that can complement biosensors.

Several research groups in academia, national research establishments, as well as industry in Russia and within the European Union are involved in research on bio-detection. A small portion of these activities are funded within the EU framework. Russia is developing equipment based on the laser and optic technique, which is still under development. The final product and its broad implementation are still a number of years away. Russia is also working on microchips that can detect a number of diseases simultaneously. A new hand-held system is able to detect a number of microorganisms related, among others, to anthrax and smallpox. An ISTC project is financing the construction of a sampler for the U.S. army.21 It was built to weigh no more than 300 grams to be attached to a belt. International cooperation is needed to test and evaluate the existing detection systems. The Group recommends that different methods of detection and diagnosis in Russia and various European countries be compared to find the most suitable technology for bioterrorism events. Sharing of facilities for indoor and outdoor testing could be an important component of such cooperation.

Analytical instruments benefit from recent achievements in nanotechnology and biotechnology. The instruments have become more powerful, more sensitive and more sophisticated at the same time as they are becoming smaller. Thus more techniques and instruments that were developed primarily for the laboratory have become of interest for use in the field.

Diagnosis of an exposed or infected individual is suggested or confirmed following the analysis of blood, plasma or urine.22 Analytical techniques traditionally used are: culturing and isolation, morphological assessment by light or electron microscopy, immuno techniques for marker proteins or various PCR techniques. The developments incorporate faster techniques for identification and techniques that allow for a better resolution of various sub-strains.

The Group discussed developments in the creation of miniaturized lab-on-chip biosensors that could be used in the field by first responders. These sensors combine immunoassays (detectors based on antigens and antibodies that imitate the immune system of the human body) or DNA-based assays, with signal transduction on a chip to provide a direct quantitative electronic readout. Such sensors would be inexpensive, quick, and easy to use, and they would integrate several functions in one device. They hold the potential of detecting a number of diseases simultaneously.

21 Roman Borovik, “Sampler for Detection and Express Identification of Airborne Microorganisms,” ISTC Project #1487p. The sampler takes 60 liters of air per minute and will work for 30 minutes per cartridge.
22 There are different methods: microscope; enzyme properties; anti-serum reactions; electrophoretic mobility of macrophages (EMM); mouse injection. Detection methods: conventional PCR; real time PCR; virus isolation and electron microscopy (results within 2 hours).
Matrix Assisted Laser Desorption /Ionization- Time of Flight (MALDI-TOF) mass spectrometry was also noted as a technique of great potential for large molecule analyses. The need for a common database comparing MALDITOFF with mass spectrometry was noted. The Group also examined diagnostic methods such as pyrosequencing (a DNA sequencing technique), DNA microarray and other methods of detecting the presence of antibodies against a pathogen.

The Group believed that sensor development should seek a new focus, to protect the general public. While large research efforts are spent among the members of the European Community, Russia is currently behind in fast developing hi-tech areas. This could eventually jeopardize the development of a common understanding of important preventive measures to protect against bioterrorism. It is essential that the knowledge available in Europe and Russia in the fields relevant for advanced sensor development be used in a coordinated way. The Group recommends that Russia and the EU explore the potential for cooperation on emerging technologies and initiate such cooperation where possible.

**Surveillance systems**

Given that reliable environmental detection systems might be many years away, health care professionals can add to the layers of detection by providing observations, collecting and analysing statistical data on symptoms reported by people entering health care facilities. Such syndromic surveillance is being developed in a number of countries to focus on symptoms instead of confirmed diagnoses, and can include statistics on work and school absenteeism, numbers of admissions to emergency rooms, or physicians reports of particular symptoms in patients. It is thought that Syndromic Surveillance could detect bioterror events earlier than traditional disease surveillance systems, though it remains relatively untested. Therefore it is essential to develop reporting procedures and systems based on observations of patients in hospitals. Various national surveillance systems, such as BioSense in the United States and the Eurosurveillance system of the European Centre for Disease Control, have been developed in order to monitor epidemiological situations and sound an alert over suspicious observations. The possibility of communicating such information across borders between the Russian Federation and other European countries was highlighted by the Group.

The Group recommends that the standards and procedures for rapid reporting on symptoms and diagnoses in Russia and other European countries be studied and eventually harmonized. Health providers should be trained and syndromic surveillance methods developed to detect changes in the patterns of reported symptoms and diagnoses that might indicate an outbreak.

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23 Published applications include nucleic acid and protein sequence, post-translational modification, cleavage, purity, structure and heterogeneity of samples among other uses. The combination of Maldi-tof and immunochips can be impressive.
The Group recommends several activities to be undertaken concerning the improvement and standardization of detection and diagnostics:

- To develop a first draft of standards for testing and evaluating an environmental detection system as a cooperative project among a few laboratories in Russia and other European countries engaged in detection work. A list of laboratories will be elaborated upon request.

- To develop a concrete proposal for the establishment and provisional operation of a joint Russian – European test center for environmental detection systems, including identification of a host institution in Russia and financing arrangements together with industry.

- To subsequently establish common standards among Russia and other European countries for evaluating environmental samples (air, water, etc.) and other detection equipment for pathogens and conducting a comparison of facilities for indoor and outdoor testing.

- To join efforts in developing diagnostic microchips to help provide automatic warning and detection methods. Russia already has special equipment for making such microchips. Together, Russia and other European countries should develop specialized chips for disease and toxin detection.

4. Countermeasures and Treatment

Treatment can be considered in two time frames: as prophylaxis prior to an exposure to increase the resistance of population to particular diseases; and as treatment of patients who have been infected. Vaccines have traditionally been used to make populations immune or less vulnerable to certain diseases, be it smallpox or flu. However, vaccines do not guarantee that a population is protected, in part because it is not possible to vaccinate every person, particularly the sick and elderly. Some 20 percent of the population cannot be vaccinated because of their immunodeficiency. It takes about two or three weeks for a vaccine to become effective. Since vaccinating against smallpox ceased 35 years ago, 85 percent of the world has no such immunity, which is why it is considered an ideal weapon in terrorist scenarios. Such scenarios are unlikely in reality, however, because only two strains exist in well-guarded facilities in the United States and the Russian Federation.

Variation in scientific methods and medications reflect cultural and historical differences among countries. For example, in the Russian Federation a single live dry vaccine is provided for anthrax, whereas the United States uses a chemical vaccine. Third generation vaccines are being developed in Russia. These include DNA and genetically engineered vaccines, not yet used in medicine, and “cocktails” of vaccines for possible use against 10-12 agents. The Russian Federation plans to establish a lab in 2006 to develop DNA vaccines. It is working with the United States on developing a vaccine
against hanta virus. Could a DNA vaccine be developed against avian flu? This disease is perceived to be a large threat, while there are only a few drugs available to fight avian flu (e.g. Tamiflu and Relenza) and it is not known if they will be effective. Russia has been working on the possibility of using aerosols to vaccinate a large group of people at the same time in an aerosol chamber, although getting the dose right will pose a challenge. Some members of the Group believe that small stockpiles of at least a few vaccines should be available for local populations in the case of an event.

Although antibiotics are widely used against various diseases, they are not a panacea because they have been over-used over the years and new strains of pathogens are already resistant or are beginning to resist many of them. Research in Russia has focused on immunomodulators and bacteriophages as an alternative to antibiotics. Also Russia and Europe could further explore bacteriocins, which are natural proteins produced by competing non-pathogenic bacteria that might provide an alternative to antibiotics in the veterinary and medical fields. Immunomodulators, used to amplify or suppress the immune system, have been widely used and are considered promising in Russia. The Russian experience shows that the use of immunomodulators could substantially lower, up to a factor of 4, the effective dosage of vaccine, and that they might be able to replace or support vaccines in the future.

Bacteriophages were widely used for gastrointestinal diseases in the 1950s and 60s, and are thought to work well against plague, anthrax, cholera and other dangerous diseases. They can be held in a dry form for up to 18 years and are less expensive than antibiotics. However, they can also produce side effects such as allergies. Some experts believe that there is a need to look deeper into the use of phages for the prevention of particularly dangerous infections and for use in decontamination in case of a terrorist event.

In order to promote a regeneration of the sciences following the economic decline in Russia, the Group recommends that there be an increase in the exchange of researchers among scientific institutions in Russia and other European countries as part of a long-term cooperative project. Such exchange represents an important confidence building and transparency measure. It helps to multiply and rationalize efforts aimed at solving existing problems and stimulates general development of science. The Group recommends promoting scientific exchange and collaboration in the following areas:

- Developing and improving drugs and other prophylactics (vaccines, serums, bacteriophages, immunomodulators)
- New methods of diagnostics, drug discovery, detection, and decontamination
- Developing aerosols especially as anatoxins and vaccines in emergency situations, e.g. to fight avian flu.
- Finding standard methods for disinfecting against anthrax and dangerous infections.

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24 “Biological Science and Biotechnology in Russia: Controlling Diseases and Enhancing Security,” p. 65, sourcing U.S. Department of Agriculture, December 2004. Experts from the State Research Center for Applied Microbiology in Obolensk, Russia and the U.S. Agricultural Research Service have already produced patent developments and a cooperative agreement with Cargill, Inc.
• Developing a set of programs for training medical personnel, administrators and governmental bodies on how to act in emergencies

This cooperation could be handled within the ISTC as well as other frameworks, including multilateral and bilateral approaches. Priority should be given to a simple agreement or memorandum of understanding (MOU) with a streamlined implementation process.

Developing a vaccine may cost up to 600 million euros and can take 10-12 years from the beginning (research and development) to the end (marketing) of the pipeline. For each new product a validated and standardized efficacy study needs to be conducted. While it takes one month for a virus epidemic to move around the world, a vaccine will take a minimum of 4, but usually 9-22 months to produce, with quality control required after each step. Thus in trying to fight bioterror, it is difficult to develop a vaccine for which there is no disease and impossible to involve the larger population in the experimental stage. It is then more complex to prove the efficacy of the product and to obtain approval from the regulation authorities. Moreover, the pharmaceutical industry focuses on marketable products, whereas products geared to fight terrorism might never be used. While scientists have a hard time keeping up with the mutations of strains and determining what kinds will occur in the next year, governments must understand that industry will not wish to make major investments in a disease that might not occur.

In addition, in the pharmaceutical industry strict adherence to international standards and quality assurance in developing countermeasures is essential: Good Laboratory Practice (GLP), Good Clinical Practice (GCP) and Good Manufacturing Practice (GMP). In France, for example, a laboratory notebook (based on the Belgian model) is used to ensure that the scientist “writes what I have done and how I did it.” The aim is to be able to trace chemical and biological materials, lab work, people involved in the lab work, and results, according to three international standards: GLP, ISO 17025 and ISO 9001. Information documented in the notebook includes the title and date of the experiments, specific descriptions of each stage of the experiment, protocols, measurements taken, observations, etc. Quality assurance is also useful for patenting, as a proof of the identity of the inventor and the date of the invention.

The Group recognized that while concepts of GLP and quality assurance are widespread in the West, there is little money available for implementing them in the Russian Federation, which is thus hindered from participating in the market with the EU or elsewhere. There are four institutes that have been approved in Russia, including the branch of the Institute for Bioorganic Chemistry in Puschino, and the Institute for Toxicology and Hygienic Regulation of Biopreparations in Serpukhov. A new law requires all production facilities in Russia to comply with GMP regulations, and data used to produce new products must originate in laboratories that comply with GLP standards.25

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25 “Biological Science and Biotechnology in Russia,” p. 47.
The Group agreed that European countries should cooperate in training and putting into practice international standards, procedures for licensing facilities, approving products and obtaining funding for new business and biotechnology in Russia. Russia holds a comparative advantage in a number of areas such as diagnostic kits, new antibiotic products, and vaccines, and these products should receive greater investment in order to be developed and marketed on a par with others in the international arena. As of 2002, only two of the 20 largest drug-producing companies were owned by Russians and many of the herbicides, insecticides and active ingredients used in Russia are imported from foreign countries. Most of the cooperative efforts have supported scientific work rather than commercial endeavors and thus cooperation is needed in this area as well for Russia to develop its potential biotechnology capability. Russia has the expertise and needs the resources to develop its pharmaceutical and biomarketing sector to join the global effort in fighting infectious diseases.

5. Psychological and social aspects

Fear is the main weapon of the terrorists. The aim of the terrorist is not just to make someone sick but to cause mass psychological, social and economic disruption. It is therefore essential that societies prepare themselves to handle such events. There is a need for a greater understanding of how to create societies resilient enough to absorb a terror event and recover swiftly to normal conditions. Panic or social unrest created by a terror event in one country could easily have severe consequences for neighboring countries. It is thus essential to develop cooperation also on this issue.

The population, as a general matter, is not psychologically prepared for a bioterror event. The first results of an outbreak are infection and stress, and thus preventive activities to counter infection and stress relief are first priorities. People in the area of the attack will manifest symptoms of emotional distress: their behavior changes, as does the cardiovascular system; breathing and biological disorders occur more readily, as do phobias and mental diseases. A certain part of the population will start counteracting the epidemic by leaving the contaminated area, thereby spreading the infection. For those in the area of an event, fear persists long after the event takes place, long after the source of infection is removed, and long after the patients are cured from their physical illness.

Other factors that would enter the equation in a bioterror event include social upheavals that would result from evacuation, isolation, quarantine, and delicate decisions regarding the distribution of prophylactic medications and administration of vaccines. Who would decide which patients would be offered hospital beds in the case of a shortage?

Relatively small epidemics, such as SARS and avian flu, and occasional events of deliberate release such as the anthrax letters in the United States, have shown that a limited number of casualties can produce a substantial global social and economic impact. Relatively small acts of terror and even small numbers of casualties can create panic and large psychological effects. To inject ricin in a few bottles in the supermarket would be enough to disrupt a society and cause widespread fear as well as social and
economic effects. People in an area of a terrorist act manifest severe symptoms of emotional distress. Bioterror is a weapon of mass disruption because it will disrupt government and society. The panic that resulted from the anthrax incidents in the United States in 2001 led to a large number of people taking antibiotics, some unnecessarily, and purchasing protective equipment that would not be available on a mass scale if needed for a large event.

The mass media have a large role in spreading—or controlling the spread of—panic. The degree of freedom of the press and the method of managing information given to the public vary considerably in different countries. For example, in the Russian Federation the population is more accustomed to state control of the media than in western countries. In order to quell the psychological terror that can result from reporting in the media about an event or information about biological diseases or the ease of producing microorganisms, some members of the Group believe that the media should be regulated and should be liable for what they say. Other members disagreed with that view. In addition, there is a delicate line between the thirst for scientific and medical knowledge versus the need for non-proliferation. The problem of bioterror is a wide one, spanning from lists of pathogens, availability and production to delivery and propagation and other possibilities of application. Should knowledge of the horrific things that can be perpetrated on mankind in the biological field be spread in the media and over the web?

Computer modeling has been used in Russia to forecast the scope and intensity of the development of mass panic among the population caused by a large-scale epidemic of dangerous infections.

The Group recommended that a workshop or more extended study be conducted to address the psychological, social, and economic aspects of a bioterrorist attack or bio threats. The workshop/study should bring together experts in psychology, sociology and economics, as well as government officials and bio experts. The purpose should be to:

- Review basic psychological and social factors influencing the resilience of a society to terror acts.
- Analyze psychological, social and economic consequences of bioattack/threat scenarios.
- Provide guidance on measures to be taken to develop the resilience of societies against bio terror
- Identify ways and means to improve international cooperation in this area.

6. Modeling, scenarios

Computer modeling and forecasting of epidemics can serve to provide politicians and decision makers with information on possible threat situations. Although not all scientists are convinced of the accuracy or applicability of computer modeling, it can provide an input for planning in the areas of prevention, preparedness and mitigating the consequences of an event in order to prevent global consequences and mass casualties.
among the population. Modeling can also be used to estimate the consequences of introducing new drugs or improving early detection and imposing quarantines to prevent the spreading of a disease. For example, the Gamalaya Institute of Epidemiology and Microbiology created a computer software, epidynamics, based on epidemiological studies and how disease develops in humans. It can forecast the spread of avian flu, smallpox and anthrax in a country, group of countries, or the world as a whole.

The institute has used data on the routes and volumes of passengers traveling across the territory of a large country (e.g. flight patterns), together with the data on influenza epidemiology, to create a computer model of a large-scale influenza epidemic and make a simultaneous forecast of the progress of the epidemic for the following 3 – 4 months for several cities.

Computer models of epidemics and outbreaks can also be used to assess the scope of social and economic consequences of a bioterrorist attack and the efficiency of the application of new diagnostic, prophylactic and therapeutic measures against dangerous diseases. A computer technology for modeling and forecasting of epidemics, EPID MOD, was developed in Russia in the end of the 1990’s based on the synthesis of modern epidemiology and theoretical physics. This method developed a new model of epidemics and pandemics that provides forecasting qualities as well as possibilities of studying the proliferation of viral and bacterial infections among populations of humans and domestic animals.

The computer modeling of a hypothetical epidemic H5N1 development scenario shows that if the avian flu agent arrives in Moscow (population 10 million) during the cold period of the year, e.g. winter 2006, then one can expect a difficult epidemic: the number of infected will be between 2.5 and 3 million people and the number of deaths caused by complications will be several hundred thousand people. On the other hand, if the dangerous infection is detected in time (within 2 weeks from the appearance of the infection) and if a rational strategy of countermeasures is applied, the epidemic can be suppressed quickly and efficiently. In this case the medical losses among the population of Moscow will be several thousand infected people, including no more than 300-400 casualties.

A computer modeling and forecasting of an avian flu pandemic occurring simultaneously in the 52 largest cities of the world shows that the avian flu pandemic will last for more than 8.5 months, the peak number of infected people can amount to 1 billion people and the number of casualties will amount to several million people.

Thus the relevant demographic and other input data for modeling and forecasting of dangerous epidemics, along with scenarios for emergence of pathogens (natural disaster, man-made accident or an act of bioterror) and computer modeling, can serve as a

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26 See Dr. Boris Boev’s presentations in the CD-rom attached to this report: “The role of computer modelling in studies of countermeasures against epidemics of dangerous disease”, “The forecast of the global influenza (H2N2) epidemic caused by the mailing of the agent in December 2004”, “Avian flu” April 5, June 14, October 14, 2005.
valuable scientific tool for consequence analysis and development of pathogen countermeasure strategies. The Group of experts suggested carrying out an exchange of data for computer modeling and forecasting of avian flu epidemics for each of the countries in the Strategic Study. This will provide the possibility of comparing the quality and validity of computer modeling results. The Group suggests that social, economic and cultural differences among the countries participating in the Study should be taken into account when conducting such modeling.

While a number of authorities and scientific institutions in the EU possess similar computer systems and epidemic models, different infectious disease models can suggest different counterstrategies. The main purpose of computer models is to develop recommendations to the leaders of Governments and relevant authorities on how to structure an effective policy of protecting the population from infectious diseases. The analysis and comparison of different epidemic modeling systems, as well as the results of their application by the experts in Russia and other European countries, could have value for reaching conclusions on their utility and practical capacity. The comparison would also serve to estimate the limitations of the application of these models in practice. Some members of the Group believe that, because computer modeling can also be used by terrorists and the software for modeling epidemics can be used by terrorists to find the “soft spots” in the counter-terrorist systems, the availability of software to the general public should be restricted.

The Group recommends that an international meeting be arranged for Russian and European scientists and specialists working with scenarios and computer modeling of epidemics and contagious diseases. The aim of such a meeting would be to analyse and compare epidemic modeling systems, pathogen emergence scenarios, and epidemic forecasting experiences. The meeting could also provide guidance on how to develop common research projects in this area.

7. **Biosafety, Biosecurity and International Agreements**

The WHO has been working for some time with other international organizations on developing guidelines for biosafety and biosecurity. Laboratory biosafety includes containment principles, technologies and work practices to prevent unintentional exposure to pathogens and toxins and to prevent their accidental release into the environment. Biosafety is basically a preventive set of practices and efforts to reduce the unintentional exposure of workers and the environment to biological hazards.

Laboratory biosecurity refers to administrative, managerial and technical measures designed to prevent the loss, theft or misuse of relevant biological materials. Laboratory biosecurity is achieved basically through “administrative and procedural requirements that clearly identify the threats to be addressed, the materials to be protected, the responsibilities of workers, and the measures that restrict access to these materials by
authorized individuals.” It thus provides a culture of responsibility and accountability among those who work with pathogens and other biological materials.

Both laboratory biosafety and laboratory biosecurity are required for GLP. Universal application of international standards is important to enhance biosecurity and biosafety, especially since a global code of conduct is not available and there are no international regulations for controlling the material.

When it comes to international arrangements, are the Biological Weapons Convention (BWC), which does not have an implementation organization like the Chemical Weapons Convention Organization (OPCW), the Organization for Economic Cooperation and Development (OECD), the Euro-Atlantic Partnership Council and the WHO biosecurity guidelines enough, or could we benefit from additional international agreements? At the Fifth Review Conference of the BWC, States agreed to hold three annual meetings between 2003 and 2006 to promote: national measures to implement the prohibitions set forth in the Convention, including penal legislation; national mechanisms to establish and maintain security and oversight of pathogenic microorganisms and toxins; enhanced international capabilities for responding to alleged use of biological weapons or suspicious outbreaks of disease; strengthened efforts for surveillance, detection, diagnosis and combating of infectious diseases affecting humans, animals and plants; and codes of conduct for scientists. It is understood that many nations have regulations on biosafety and biosecurity, although they vary widely and there is clearly room for improvement.

Model legislation has been proposed as a way forward on some of these issues, and this may be further considered at the Sixth Review Conference of the BWC in November-December 2006. In addition, United Nations Security Council Resolution 1540 (2004) decided that “all States shall take and enforce effective measures to establish domestic controls to prevent the proliferation of” and to account for and secure biological (nuclear and chemical) weapons and their means of delivery. While it is widely agreed that law enforcement should play an increasing role in preventing a bioterrorist attack, different agencies share very little information, except on individual cases, according to Interpol. An international data base of exercises conducted, incidents, model programs and legislation would be most useful in this regard. In the absence of collective provisions, there will always be a possibility for proliferation activities. As one expert said, “Proliferators will only be truly hindered if uniform, robust regulations are applied in thousands of culture collections and laboratories worldwide.”

In the event of a biological attack, law enforcement and public health officials would need to coordinate roles on epidemiological and criminal investigations, collection and handling of evidence, protective equipment, disclosure of information, patient privacy, etc.


Although Russia is not a member of the Australia Group, it follows voluntarily the export control restrictions imposed by the Group. Russia has a criminal code and customs code that includes criminal punishment for violations of export control laws. The procedures for obtaining an export license are different in each country, and thus could be a subject for international review, as there may be discrepancies in the application of export control measures.

The WHO is not a treaty implementing body, but rather a consulting and advisory body. It focuses on response to outbreaks and has a Global Outbreak Alert and Response Network composed of 110 networks that are linked to provide real-time alerts of outbreaks and assistance to Member States with response activities. It is not allowed to distribute the information received, in case it is incorrect, but WHO immediately contacts the Ministry of Health of the country to alert the authorities of possible infections. It is up to the government of each country to determine if an act is natural or a deliberate act of terrorism. WHO has a number of infectious disease collaborating centers in Russia.

The Food and Agricultural Organization (FAO) and the World Organization of Animal Health/Office International des Epizooties (OIE) focus on plants and animals. The OIE was created in 1924 to promote transparency in animal health and to report diseases quickly. It is also mandated to provide a better guarantee of the safety of food of animal origin and to promote animal welfare. FAO provides technical assistance and information exchange among 175 Member States to improve detection, reporting and response to plant and livestock diseases. The Emerging Prevention System for epidemic animal diseases and the International Plant Protection Convention focus on preventing, responding and communicating the incidence of infectious animal and plant diseases.

The new EU Center for Disease Control (ECDC) was established in Stockholm in 2005 to advise the European Commission on issues surrounding communicable diseases. It carries out surveillance, risk identification and assessment, preparedness planning, response to health threats and events when they affect more than one member state. Its four priority areas are influenza, antimicrobial resistance, HIV/AIDS and zoonoses. The ECDC is cooperating with the U.S. and intends to do so with the Russian Federation as well. However, there is still reluctance to share information even among countries of the EU, and initiating new activities in the EU can be time-consuming and cumbersome.

International cooperation could make a large difference in the area of quality control, which varies in different countries. Given that the speed of response and detection are the most important factors in a bioterrorist incident, the stakeholders should come together to see if the pace of product development and production are optimal. If physicists from different countries can cooperate on projects at CERN, shouldn’t bioscientists be able to do the same? There are hundreds of biotech companies in Baltimore, San Diego and Sweden. Could they cooperate in the face of bioterrorism? The Group realized that it would be beneficial to establish opportunities for Russian scientists to be invited to Sweden and other European countries, and vice versa, in order to cooperate on developing medicines.
In addition to existing standards and rules is it possible to establish some kind of safeguard agreement on bio agents similar to what exists in the nuclear field under the IAEA? Could we start to develop such agreements gradually among laboratories in Russia and other European countries? Clearly it is easier to control fissile material (few places, few processes) than bio agents (many types, many places, many processes). In addition, bio equipment is more dual use than nuclear equipment. It might be problematic to establish the terms of an international bio-agency, but it is a topic that merits consideration.

8. Concluding Observations

This Group is constituted of a unique composition of Europeans and Russians who offer far-reaching expertise that can be utilized for future collaboration on issues of mutual concern. Following a number of meetings conducted over the past year and a half, the members have established a sense of confidence and share a number of concluding observations and concrete recommendations that they plan to implement in the near future to help reduce the risk of bioterrorism and increase the level of public health.

- There is an urgent need to increase actions to prevent bio-terrorism and enhance biosecurity. This issue should be moved up the political agenda and additional resources must be allocated. The 2006 Russian G8 presidency offers an opportunity for initiatives in this area. An increased cooperation between Russia and Europe is one clear way to assist in this endeavor. Such cooperation should cover a broad spectrum of areas, including government agencies, research organizations and industry.
- Bio-terrorism is a trans-national threat and we are thus mutually dependent. To enhance security in such a situation requires the development and maintenance of mutual trust and confidence among all actors involved.
- Lacking a verification regime to the Biological Weapons Convention, it may not be possible at this time to exchange information on inventories in all facilities involved in microbiological activities. Yet, to prevent dangerous microorganisms from falling into the hands of terrorists, it is essential to establish that strains posing serious threats are not handled outside secure and certified facilities. Important measures would be to collect, secure and consolidate those strains in certified facilities or destroy them.
- There is no silver bullet that would resolve the bio threat issue. Increased capabilities for surveillance, detection, diagnostics, vaccines and therapies will enhance the ability to respond to a deliberately introduced infectious disease. What is needed is to find a cost-efficient combination of these activities in order to achieve the amount of security we are looking for or are prepared to pay for. Accordingly, we should increase our efforts at the systemic level to gain a common understanding of what such a balance could look like.
- Scenario building and computer modeling might be valuable tools to enlighten politicians and decision makers in the transnational character of the bio threat and
on the effects of possible countermeasures to be taken nationally or internationally.

- The first alarm of a bio-attack will most likely be sick patients in a hospital. There is an urgent need to improve our ability for early detection of microorganisms in the environment and for the rapid diagnosis of patients. An increased interaction among Russian and European scientists in these areas should be promoted and financially supported.

- Likewise, vaccines, immunomodulators or efficient drugs to treat specific diseases are essential to increase the resistance of the community against diseases or to cope with actual outbreaks. The scientific basis for the development of new drugs is strong in many institutions in Russia and Europe and a number of interesting development projects are being conducted. However, increased cooperation would make better use of existing facilities and knowledge and should therefore be promoted. In 2006 five or six new projects on the above-mentioned problems will be proposed.

- International standards need to be applied in order to compare and address the capabilities of early detection systems. An epidemiological network and global alert system under WHO, OIE and FAO, and harmonization of national and international response plans in cooperation with international organizations would assist in this effort.

- To handle a situation of mutual dependence on drugs it is essential that they be developed and manufactured using established international norms. The full implementation of such norms is also a prerequisite for increased international industrial cooperation.

- Despite best efforts, governments cannot expect to detect and prevent all acts of terror. Societies must become resilient enough to absorb the shock of a terror event and recover swiftly to normal conditions. Planning international cooperative efforts is an essential element in increasing the resilience of societies against bio attacks.

9. Possible cooperation Russia – Europe

Biosafety and Biosecurity in Europe and Russia

Europe and Russia have a common interest to reduce the threat of bio-terror and to increase the ability to cope with such events, should they occur. The Group recognizes that Europe and Russia are mutually dependent because bio agents and the effects of an event cross borders, and thus increased cooperation in a number of areas below would benefit all concerned. European countries should increase their coordination in the threat reduction efforts and take a leading role in policy making for biological non-proliferation.

It is urgent to identify and secure vulnerable sources of biological agents that could be used in a bioterror attack. In view of the lack of a verification regime to the BWC, it is likely that better results will be reached by trying to remove dangerous materials from facilities that are not safe and consolidate them in a secure site, or simply destroy the
agents not needed. European countries (such as France, Germany, Switzerland, Sweden and the United Kingdom) that have substantial biotechnology industries and experience working on biodefense and with infectious diseases could work with the Russian Federation to increase security and accounting of pathogen collections, and to strengthen export control restrictions.  

As interdependent neighbors, European countries are ideally placed to conduct a survey together with Russian experts in order to identify which facilities work with or store dangerous pathogens and toxins. Due to the differences of views on standards of biosafety and biosecurity, the Group recommends working towards a common understanding of biosafety and biosecurity as a critical element of the confidence building process. Comparing national regulations on biosafety and biosecurity could be a first step in this direction. Enforcing adequate laws would help to prevent, disrupt and carry out an investigation of a bioterror attack. The Group also recommended addressing at the intergovernmental level the possibilities of exchanging national inventories of dangerous pathogens. The European Commission could address in its Seventh Framework Programme the issues of biosafety and biosecurity, as well as monitoring of the environment and food supply.

Further, in order to ensure security of biological materials, institutes in Russia and Europe could agree on safeguard arrangements with regard to these materials. Lessons could be learned from the nuclear field, where the nuclear non-proliferation treaty requires all non-nuclear weapon states parties to conclude comprehensive safeguard agreements with the IAEA. Under these safeguards agreements, IAEA inspectors regularly visit nuclear facilities to verify the accuracy of the records that are kept by state authorities regarding the location of nuclear material under their control. The inspectors also examine their IAEA instruments and surveillance equipment, and substantiate the inventories of nuclear material. Similar requirements could be implemented for biological materials and technology. This would also support the effort to control exports of dangerous biological pathogens. The Group recognizes that this is a difficult issue and suggests that it be approached in a step-by-step process that might lead to a broad international agreement. The Group suggests that the first step be an arrangement among a number of institutions in Europe and Russia to establish and test procedures for tracking, verifying and securing substances and for conducting mutual inspections.

Transnational systemic studies of Biodefence

An analysis of the sub-components of the biodefence system should be conducted in order to identify the relative effect, cost-efficiency and interaction of various steps that could be taken. This would assist in aligning priorities and spending scarce resources in a smart fashion. It would help strengthen and coordinate bilateral and multilateral non-

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proliferation and counter-terrorism policies and disease surveillance, detection, containment and response measures. The Group recommends that a team of international experts conduct a comprehensive study on how to counter the most significant deficiencies in the area of biosafety and biosecurity. The study would provide a roadmap and overall strategy of where resources should be allocated to counter the threats and risks. It should consider the whole chain from prevention, protection and crisis management to consequence management.

**European and Russian Governmental Industry Interaction and Biodefence**

The Group agreed that governments have a special responsibility for the protection of their citizens, including against bio terrorism, and that nations can not rely on the pharmaceutical industry to prepare for potential bio threats. The industry will not invest unless someone will pay; thus governments must realize that they need to pay for products that they want.

This Study should be a foundation on which different levels of cooperation in different fields can be built. The Group recommends that various regulations and legal systems regarding licensing, first responders, protection of the population, etc. be adapted to each other, with the goal of being prepared to cope with a bioterror event as rapidly as possible. Russia and other European countries should collaborate further in the areas of prevention, crisis management and recovery.

The Group recommends that contacts be established among the life science research, development and industrial institutions in Russia and other European countries on specific projects. It recommends convening meetings of government officials, expert communities, agencies and industry from different countries in order to initiate specific co-operative projects on medical countermeasures based on biotechnology against bio-terrorist attacks and welcomes business investments in that field. For example, centres of excellence could be established in Moscow and Puschino for storing strains and mastering the technology of hybridomas and monoclonal antibody production. These centres would support other European countries and provide cultures, expertise, advice and training. The Group recommends that Russia and the EU explore the potential for cooperation on emerging technologies and initiate such cooperation where possible.

**Common Standards for Technologies**

Governments can take a number of measures, unilaterally or in cooperation with other States, to reduce the risk of a bioterror attack or to reduce the consequences if one should occur. Such steps might include the diminution of dangerous biological pathogens and toxins, as called for in the G8 Global Partnership.\(^\text{31}\) It could also include increased capability to achieve early warning by implementing more effective detection and diagnosis methods and increasing precautionary measures.

Early detection and diagnoses is crucial in coping with any bio-terror attack or rapid outbreak of a dangerous disease. Research on new methods and technologies for environmental detection of microorganisms is being conducted in many laboratories around the world, including in Russia and other European countries. New technical systems are also being developed and introduced to the market. To compare and assess the capabilities of different detection systems there is a need to use international standards for the testing and evaluation of such a system.

A further step to enhance the environmental detection cooperation could be to establish a joint test laboratory where such testing and evaluation could be carried out. This laboratory could be established at an existing bio-facility that should be certified to work with a range of relevant microorganisms. It should also draw upon existing expertise in the bio-field. There are several facilities in Russia that will be suitable to host such a test laboratory. It might prove useful to establish such a test center on a provisional basis and gradually develop it.

**Increased scientific cooperation and a Russian-European Bio School**

The Group recommends creating a school to train scientists in the practical application of international standards in quality assurance such as GLP, GMP, biosafety and biosecurity. This school could be located at the Research Center for Toxicology and Hygienic Regulation of Biopreparations at the Federal Medico-Biological Agency in Serpukhov. The school could also offer courses in intellectual property rights and business training for managers.

**Continued dialogue on Bio-terror**

This international Group of bio experts has established excellent working relations and a high degree of confidence among its participants. The Group is thus a valuable asset in further promoting trust, confidence and collaboration among scientists and institutions in Russia and Europe in the sensitive area of bio-security. It could continue to provide a forum for an ongoing dialogue on bioterror and biosecurity issues. The Group should facilitate and review the implementation of specific activities that are recommended in this report as a result of the Group’s initial work. The Group therefore suggests that it meet annually to maintain a dialogue on bioterror issues and to review the work on the specific issues identified above. The Group suggests that it meet in the same informal manner, under the auspices of the Swedish Institute of International Affairs, the Center for Strategic and International Studies (CSIS, United States), the Institute of World Economy and International Relations (IMEMO, Russian Federation) and the Committee of Scientists for Global Security (Russian Federation).
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LIST OF PAPERS AND PRESENTATIONS

First Meeting, 4-8 April 2005

Boris Boev, Alexander Gintsburg, Valentine Yevstignev & Grigory Scherbakov
“The role of computer modelling in studying processes for counteraction of dangerous epidemic infections” (Avian Flu)

Boris Boev
“Scenarios for appearance and development of extremely dangerous infections”

Grigory Scherbakov & Leonid Ryabikhin
“The basic threats to national biological security”

Valentin Yevstignev & Leonid Ryabikhin
“Problems of biological safety”

Valentin Yevstignev & Alexander Pikayev
“Problems of Biosecurity”

Ottorino Cosivi
“Laboratory Biosecurity: WHO Guidance”
“Preparedness for Deliberate Epidemics”

Jan Foghelin
“Scenarios and Missions” (Draft)

Dominique Werner
“Scenarios – Atlantic Storm”

Isabelle Daoust-Maleval, Dominique Masset & Louis Réchaussat
“Quality Assurance System and Biosecurity in drug and vaccine development: A mandatory need for their approval”

Isabelle Daoust-Maleval
“Research and development program framework”

Grigory Scherbakov & Leonid Ryabikhin
“Presentation to the Commission on Biological and Chemical Security in Russia 10-09-2005”

Viktor Popov
“Complex of Actions (scenario) on application of anthrax”

Roman Borovik
“DNA Vaccines a perspective tool to ensure Biosecurity”

Sergey Pchelintsev
“Specific Prophylaxis in cases of bioterrorism events”

**Second Meeting, 13-17 June 2005**

Boris Boev, Alexander Gintsburg, Yevstignev Valentine & Grigory Scherbakov
“The global epidemic flu (H2N2) of Dec 2004”

Boris Boev & Leonid Ryabikhin
“Non medical consequences of dangerous infectious diseases”

Dominique Werner
“Sagbata Project, Consequence management information tools”

Isabelle Daoust-Maleval
“Possible terminology for detection and analysis concepts”
“Research and Development Program Framework”

Jim Pearson
“World Organization for Animal Health (OIE) role in preventing and preparing for bioterrorism”
“OIE Power point presentation”

Leonid Korotkin
“Improvement of national system for export control of biological profile goods and technologies of dual use”

Mats Forsman
“Swedish Defense Research Institute (FOI)”

Mikael Nilsson
“Pox diagnostics”

Martine Polhuijs
“Business Unit Biological and Chemical Protection”

Ali Mohammadi
“International Health Regulations (May 2005) WHO Geneva”
“Laboratory Biosecurity”
“Preparedness for deliberate epidemics: WHO approach”

Roman Borovik
“Sampler for Detection and Express-Identification of Airborne Micro-organisms (ISTC Project #1487)”

Third Meeting, 10-14 October 2005

Peter Wulff
” Development and Manufacture of IMVAMUNE Third Generation Smallpox Vaccine”
“Category A,B & C”

Roman Borovik
”Especially dangerous infectious agents for DNA vaccine studies”
“Design of Experimental Aerosol DNA Vaccine Preparation against Hantavirus Infection (ISTC Project #1813)”
“Who assures GXP Studies? Cooperative Research Partnership for Biodefence”

Dominique Masset
“Pharmaceutical Requirements and Standards for drug and vaccine development and their approval”

Leonid Korotkin
“Realities and myths about sources of biological hazards for the population “

Boris Boev
”A joint Russian-European Scenario (epidemics smallpox)”
”A joint Russian-European Scenario (outbreak of anthrax)”
”A joint Russian-European Scenario (epidemics Avian Flu)”

Marie-Andrée Piedallu
“Laboratory Notebook: A tool of biosecurity and defense of economic interests”

Bernard Meignier
“International Cooperation on Research, Development and Production”

Viktor Popov
“Alternative Research Directions in aspects of Biosafety”

Jan Camber
“Swedish Pharma and Biotech Industry”

Denis Coulombier
“Protecting health in Europe – the new European Centre for Disease Prevention and Control”
“Epidemic Intelligence”

Leonid Ryabikhin & Boris Boev
“Non medical consequences the processes distribution the dangerous diseases”

“Biopreparat – Russian joint-stock company”

Forth Meeting, 6-10 February 2006

Valentin Evstigneev
“International Coalition Program on Biosecurity”

Petra Dickman
“Transparency and Restriction: Biosecurity and the Social Ambivalence of Scientific Knowledge”
“Risk and Crisis Communication: Conceptual Reflections”

Helmut Walerius
“Public Health Threats: Status of the EU and International Cooperation”

Boris Boev & Leonid Ryabikhin
“Forecasting the Masspanic Processes for the Epidemics of Dangerous Infections”

Boris Boev & Alexander Gintsburg
“Computer technics for studying epidemics of Avian Flu A(H5N1) in Europe”

Adrian Baciu
“New Threats from Non-State Actors”

Sergei Zavriev
“AgroBioTerrorism: Targets, Modes, Counteraction possibilities”

Sergey Pchelintsev
“Bioterrorism: Emergency and Specific Preventive Maintainance in system of Protection Against Pathogenic Microorganisms”

Anatoly Ukraintsev
“Problems of remediation of contaminated areas”
Resource papers:

“The expansion (the history) of terrorism in Russia”
Stepan Razin, Ivan Bolotnikov & Yemelyan Pugatchev

“Forecasting the geographical spread of smallpox case by air travel”

“Containing Bioterrorist smallpox”

“Planning for smallpox outbreaks”

“Emergency Response to a smallpox attack: The case for mass vaccination”

“Toward a containment strategy for smallpox bioterror: an individual-based computational approach”

“Modeling potential responses to smallpox as a bioterrorist weapon”
Martin L. Meltzer, Inger Damon, James W. Le Duc & J Donald Miller, Emerging Infectious Diseases, Vol. 7, No. 6, November-December 2001

“Clinical and epidemiologic principles of Anthrax”
Theodore J. Cieslack & Edward M. Eitzen, U.S. Army Medical Research Institute of Infectous Deseases, Ft. Detrick, Maryland, USA

“Analyzing bio terror response logistics: The case of anthrax”

“Special Section: Confronting biological weapons” Donal A. Henderson, Thomas V Inglesby Jr & Tara O’Toole, Clinical Infectious Diseases, 200;31;1409-1413.

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Center for Strategic and International Studies, 2001