Innovative Approaches for Training Clinicians for Bioterrorist Attacks

Final Report

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EXECUTIVE SUMMARY

OVERVIEW

RTI International, together with the University of North Carolina at Chapel Hill and The MayaTech Corporation, developed and evaluated two educational tools to train clinicians for bioterrorist attacks. The principal goals of this project were to develop prototype approaches for training clinicians to recognize and respond appropriately to a possible bioterrorist attack; develop one simulation-based approach that might be suitable for evaluating the effectiveness of web-based or other educational materials; disseminate the prototype educational materials; and evaluate these prototype educational materials in clinical, knowledge acquisition, and usability terms.

During the first year of the project, bioterrorism acts were considered rare in this country. This attitude, held by most clinicians at that time, was reflected in the opinions and advice of our Technical Advisory Committee (TAC). Early in the project, we convened a two-day workshop with the TAC to discuss the bioterrorism threat and develop approaches for training clinicians for bioterrorism events. At that time, the TAC considered use of biologic agents as a bioterrorist attack an unlikely, not even a rare, event. They suggested that the learning material content should be a concise, quick read; they also advised that the learning content should include information on emerging diseases in addition to bioterrorism agents. Furthermore, the TAC endorsed our notion that virtual simulated patients were a feasible innovation for both training clinicians to respond to bioterrorism attacks and evaluating the effectiveness of such training.

The events of the Fall of 2001 markedly changed the nation's views, and the health community's opinions, about bioterrorism preparedness. New information about bioterrorism disease recognition, treatment, and precautionary measures have evolved with each new patient and event. Moreover, much new information, some of it conflicting, became immediately available to the public and health care professionals. Interest has grown among medical professionals outside major medical centers in becoming better prepared for bioterrorism. By designing educational materials and a delivery system that is aligned with the work style of busy clinicians in primary care, we expect that our approach will help meet their preparedness training needs.

We developed two prototype approaches for training clinicians to recognize and respond appropriately to a possible bioterrorism attack. The first approach is a website (http//:bt.rti.org) that has four main segments: the home page, bioterrorism agents, emerging infectious agents, and notifications and key web links. The primary educational content comprises four modules that constitute two pairs of information: one for bioterrorist agents (history and clinical information) and the other for emerging infectious diseases (history and clinical information). The information on emerging diseases was included to broaden the appeal of the website and thereby draw in a larger clinical audience. We incorporated historical information to let clinicians know that the possibility of bioterrorism attack was real, based on historical evidence. Unfortunately, the likelihood of a bioterrorism attack soon became a real and present danger.

The second approach involved creating simulated bioterrorism patients using virtual reality (VR) technologies previously developed by RTI. We modified the VR software to create a "VirtualClinic" software program for this project; with it, we created unique patients in the clinic (essentially, a physician's office, rather than an emergency room or hospital) who are affected with biologic agents or infectious diseases. The underlying medical databases for the virtual simulated patients included cases of cutaneous anthrax, inhalation anthrax, and Rocky Mountain spotted fever; the test case programmed for all the preliminary assessments and usability testing is an adult white male with cutaneous anthrax.

VirtualClinic follows a Subjective, Objective, Assessment, and Plan model for primary care. Initially it provides vital signs, social information, and chief complaint. Clinicians can make inquiries regarding medical history and physical condition, order diagnostic tests (e.g., chest x-ray), order laboratory tests (e.g., Gram stains), obtain results from these tests, enter differential diagnoses, and plan treatment and patient management.

This virtual simulated patient software provides both a second prototype approach for training clinicians and simulations for evaluating training effectiveness. We envision the software as a mechanism to test clinicians' knowledge, using an interactive approach that allows them to query patient-specific information, including information on exposure, symptoms, disease progression, and clinical management.

Both the web-based learning materials and the simulation-based learning and evaluation materials were assessed by practicing clinicians (in primary care or infectious disease). In general, the clinicians endorsed the broad approach taken by the website in providing both historical and clinical information for emerging infections as well as bioterrorism diseases. In contrast to the TAC recommendations, however, the reviewers would have liked more detailed information on diagnosis and patient management. Developing such clinical practice guidelines was not part of our charge and at this time might better be left to other groups or agencies, such as the Centers for Disease Control and Prevention (CDC), especially given the continuing changing nature of the post-anthrax data. Consequently, we provided rapid web links on our website to such information on the CDC website.

As stated in our proposal, we believed that the virtual simulated patient program would present development challenges, even though the prototype would extend prior RTI simulation software development. Consequently, given the available resources, we concluded that we should place our primary effort on the development phase, because any subsequent evaluation could not be effective without quality software development. We therefore restricted the evaluation to a prototype usability test, using a small number of clinical evaluators, and focused on issues regarding software use, clinical functionality, and user satisfaction rather than formally evaluating training efficacy. This methodology is consistent with our other work in training systems development, where multiple iterations on the simulation implementation and testing are completed before training software is release for formal evaluations.

In our usability evaluation, users testing the software ranked it *moderately high to very high*, with the caveat that improvements would be made. The VirtualClinic simulator fulfilled the TAC recommendations for an accurate, engaging simulation that mimics clinical practice. It provides a unique capability for observing rashes and lesions, such as cutaneous anthrax, with concomitant 3-D characteristics, in a responsive, virtual patient. We completed major revisions to the prototype based on reviewers' suggestions from the usability testing; this included a tutorial for using the software that was made available to AHRQ staff before the end of the project. We will expand and refine the software in various steps; the most immediate will be to

add in the patients with inhalation anthrax and Rocky Mountain spotted fever to join the patient with cutaneous anthrax.

FUTURE TECHNICAL AND CONTENT UPGRADES

Based on the usability test results, we developed plans ("recommendations") for revisions to make the program more responsive to user needs. Recommendations also included software enhancements, medical scenarios, additional patient interactions, and new simulation features. We set priorities for critical recommendations (i.e., errors and omissions) and implemented changes in the last months of the project.

Less critical issues and new features were deferred for future work. The upgrades and enhancements considered most noteworthy include the following:

- Expand the virtual patients to include young, adult, and elderly persons of various racial and ethnic backgrounds;
- Extend the simulator for a larger number of Category A and B biological agents;
- Extend the patient interaction from a single encounter to a set of multiple encounters (over two to three days) over the natural course of a disease;
- Provide for a mouse rollover method to conduct a physical examination of the virtual patient, together with pop-up images of actual rashes and lesions to provide photographic quality for visual examination of lesions;
- Revamp several elements of the diagnosis portion of the program;
- Add voice recognition and natural language processing for verbal interaction with the patient;
- Provide a mentoring system with a natural language interface to request help on diseases, diagnostic pearls, and patient information;
- Link simulation after-action reviews to remedial multi-media training materials; and
- Provide training and action components for infection precautions and patient isolation.

Apart from these steps within the virtual simulated patient software, RTI plans to continue to extend both the website and the VirtualClinic application using funding from numerous sources. A key technical challenge on our road map for this program is the fusion of the VirtualClinic functionality and the web materials into one web-delivered application.

FUTURE RESEARCH ISSUES

Beyond these numerous technical improvements and a broad array of expansions noted above, we identified several questions might be considered for future research and development. Three are directed more at education and training issues than at software development or applications per se; the fourth considers the broader uses to which such technologies might be put. Briefly, they are

- First, what is the efficacy of individual and combined modes of training involving didactic materials, lectures, video presentations, and case-based simulated patients?
- Second, can virtual simulated patients be used to evaluate competency for diagnoses of rare and emerging diseases, and if necessary, provide corresponding remedial training, for primary care physicians?
- Third, considering the relatively low cost and potential variety of virtual simulated patients compared to live standardized patients, what are the limits to the virtual patient simulation that may preclude their acceptance as an alternative to standardized patient in medical education?
- Fourth, can case-based patient simulation be used in a broader sense to test and evaluate emerging systems for disease surveillance, public health notification, and large-scale bioterrorism, chemical terrorism, or other response preparedness training and evaluation exercises?

CONCLUDING THOUGHTS

We believe that the outcomes of this project should be viewed in a context that now takes into account the known history of terrorist events in this country and elsewhere but also the tragedy of September 11, 2001. As noted at the outset of the report, our plans for this project were set in motion nearly a year before the September 11 catastrophe; after some consideration of how best to proceed, we concluded that continuing on the same track was preferable (and indeed more feasible, given time and resources constraints) than trying to reorganize or revamp the project. At the close of the project, we drew the following broader conclusions about this work and the environment in which its outcomes need to be considered.

First, training and education may be our best national defense against bioterrorism. In large measure, the purpose of terrorism is terror. The best defense, then, is knowledge regarding what to expect and what to do to as many people as possible before such events occur.

In addition, we see the results of the final evaluation of our prototype as a vital component of improving the knowledge base by which AHRQ and others can assist physicians in their daily practice of patient care. Lessons learned here, and corollary expansions of the products, may be applied to training and education materials not only for physicians, but also for nurses and emergency medical services technicians, police, fire and rescue personnel, and even citizens outside these professions.

Moreover, no other educational medium offers the flexibility, consistency, deployability, effectiveness, and ability to safely portray unsafe or rare situations as cost effectively as virtual patient simulation (that is, interactive three-dimensional 3-D programs). When the clinical issue involves rare conditions, specifically including those related to potential or real terrorist acts, the advantages of interactive 3-D technologies can be profound. Given that no similar body of work on simulated patients in the bioterrorism realm exists, our work has elucidated numerous points for which, heretofore, no consensus existed about the correct approach. In that regard, AHRQ's investment in this work would clearly permit us or others to leapfrog some development activities and move more briskly into expanded clinical content, fuller testing with more potential user audiences, and broader dissemination. In short, we have the ability to use the research

conducted so far to create a training program that will prepare clinicians to do an uncommon job better, when they are called upon to do it right the first time.

Finally, this approach (the website, the virtual simulated patient software, and a web-based version of the simulated patient) has the potential for defusing a large part of the damage that will be caused by the next bioterrorist attack. Assuming that such attacks materialize is, of course, an unhappy prospect, but doubtless a prudent one. Insofar as the potential for this type of training medium is realized, there is no American who might not benefit directly or indirectly.

Acknowledgments

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We also thank the members of the Technical Advisory Committee for their advice and critique in developing and evaluating both the website and VirtualClinic patient simulator.

Chapter 1. Introduction

OBJECTIVES

In 2000, the Agency for Healthcare Research and Quality (AHRQ) established a set of task order contracts under its newly developed umbrella program, the *Bioterrorism Initiative.* Shortly thereafter, the Agency awarded a project on "Innovative Approaches to Training Clinicians for Bioterrorist Attacks" to RTI. RTI and its partners, the University of North Carolina at Chapel Hill (UNC) and The MayaTech Corporation, were tasked to develop two educational tools to train clinicians for bioterrorist attacks and to devise creative methods for evaluating their effectiveness. The approaches were to be applicable on a broad scale, provide knowledge in a format that could be widely and inexpensively disseminated, and be adaptable to the information needs and current challenges confronting busy clinicians.

The first educational tool is a web-based series (a form of "multimedia courseware") detailing historical perspectives on and providing clinical descriptions for bioterrorism agents and emerging infectious diseases. The second is a virtual-reality (VR) software program intended for clinicians to "interact" with patients exhibiting symptoms associated with bioterrorism agents, infectious diseases, and other diseases. It was expected to provide accurate physiological signs and symptoms and emotional responsiveness that could complement existing clinical experience. The VR approach is particularly useful for presenting situations and phenomena (e.g., bioterrorist agents and infectious diseases) that clinicians rarely encounter but would require critical knowledge and skills.

In summary, the objectives of this project were to

- Develop two prototype approaches for training clinicians to recognize and respond appropriately to a possible bioterrorist attack;
- Develop one simulation-based approach that might be suitable for evaluating the effectiveness of web-based or other educational materials;
- Disseminate the two educational tools (as appropriate to their underlying platforms, on the web and on laptop computers); and
- Evaluate the prototype educational materials in clinical and other terms.

The remainder of this chapter provides a brief background to the project and outlines the structure of this final report.

BACKGROUND

During the first year of the project, bioterrorism acts were considered rare in this country. Then the tragic events of September 11, 2001, occurred, followed by the anthrax infections in October and November 2001, and the nation's views about its preparedness for a bioterrorist

event swung to the opposite side of the pendulum. Suddenly, bioterrorism became a high-priority issue. New information about biowarfare, recognition, treatment, and precautionary measures became a daily event, and much new information, some of it conflicting, became immediately available to the public and health care professionals. Moreover, for many in the clinical or public health community, the biological agents that bioterrorists are likely to use were rarely, if ever, encountered in typical medical training or careers. At this juncture, however, the new situation confronted clinicians, policymakers, and the public with a quite new clinical reality.

Before the events of fall 2001, training clinicians to respond to extremely rare events was not viewed as a cost-effective use of their already overtaxed time. Nonetheless, interest was growing among some medical professionals in becoming better prepared for responding to a bioterrorist event. AHRQ itself led in attempting to meet this need, not only with this project but also by supporting a sister project from the University of Alabama at Birmingham and commissioning a systematic evidence review on the topic of training clinicians for rare events.

We knew that, to be accepted, a system designed to provide training to a target population must be engaging, accurate, and efficient. Our solution was to develop a computer-based and a simulation-based training tool that would offer a wide range of possibilities for a trainee to learn at a personally convenient time and in a self-paced manner. These media might complement or enhance the usual continuing education courses for bioterrorism topics, which generally use text and slides, occasionally supplemented with case-based table-top or patient/actor exercises. This latter format is costly, often requiring travel to a central facility to achieve economies of scale. Such courses can effectively deliver didactic information, but knowledge without practice can neither effectively establish nor maintain critical skills. Case-based simulation training provides an opportunity to apply lessons learned, evaluate understanding, and experience bioterrorism patients in a controlled setting.

TECHNICAL ADVISORY COMMITTEE

At the start of the project, we established an expert advisory panel — Technical Advisory Committee, or TAC — comprising experts in the fields of infectious disease, medical education, medical informatics, emergency preparedness, and education evaluation. TAC members are listed in Appendix A. Specifically, they provided expertise in (1) infectious disease relevant to bioterrorism; (2) emergency response training; (3) psychological aspects of mass casualties; (4) continuing clinical education (e.g., medicine and nursing); (5) medical informatics relevant to medical education and training; (6) bioterrorism medical readiness analysis and modeling; (7) public health at the local level; and (8) evaluation and evaluation research. Two individuals also represented key professional associations and provided insight on those organizations' processes for potential dissemination of products in the future.

The TAC members' main assignment was to furnish guidance in the identification of a target population, development of training materials and methods, and dissemination approaches. Specifically, the TAC participated in the project in four main ways. First, we convened a 2-day planning meeting early in the project to come to agreement on the focus and direction that the plans for educational materials and the strategy for evaluating both the materials and the dissemination strategies should take. Second, several members provided materials, reference articles, and consultation that either were incorporated into the training and simulation products or influenced the development of these products. Third, depending on their expertise and ability to be available at the appropriate time in the project's schedule, several

members participated in the interim reviews of the training and simulation materials. Finally, other members participated in the evaluation of the two products.

ORGANIZATION OF THIS REPORT

The remainder of this chapter documents the work done in this project. Chapter 2 describes both the web-based educational tool (http://bt.rti.org) and the virtual-reality simulated patient software. Chapter 3 provides extensive technical documentation of the development of these two learning tools. Chapter 4 briefly notes the efforts undertaken to alert potential users to these products. In Chapter 5, we describe the work to evaluate both these products in terms of content, usability, and other factors. Finally, Chapter 6 provides our main conclusions and recommendations.

Appendix A lists the members and affiliations of our Technical Advisory Committee. A bibliography (publications and websites) used at various times in development of these materials can be found in Appendix B. Finally, Appendix C reproduces four questionnaires or interviewer guidelines used for pre- or posttest evaluations of both the website and the simulated patient.

Chapter 2. Development of the Two Learning Tools

INTRODUCTION

As noted in Chapter 1, we focused on two different educational strategies, one a web-based information and training site and the other a simulated bioterrorism patient based on RTI's prior software technology called virtual reality for medical training. We briefly describe here our early planning and development work, with the assistance of the TAC, and then describe the two educational tools in turn. Several tables and exhibits illustrate the content and appearance of the two products (especially the website); they are not a comprehensive set of all pages, however. Chapter 3 discusses the technical issues relating to development of the patient simulator in more detail.

TECHNICAL ADVISORY COMMITTEE

WORKSHOP PLANNING AND OUTPUTS

We began the development of the two learning tools with a workshop for the Technical Advisory Committee (TAC) staff from RTI, the University of North Carolina at Chapel Hill, the MayaTech Corporation, and other guests. The four aims of the TAC meeting were to (1) identify training requirements; (2) tap the biological-exposure and patient-care knowledge base of experienced clinicians, researchers, and trainers; (3) establish the scope of training; and (4) set realistic and effective design goals for the training and evaluation methods.

Before this workshop, we had examined the civilian and military literature (e.g., that from the US Army Medical Research Institute of Infectious Diseases) for information on exposure to and treatment of biological agents (see bibliography in Appendix B) and classified the agents according to their physiological effects. From these, we had selected a subset to nominate to the TAC based on feasibility of implementation. As part of this information package, our UNC subcontractors reviewed information about casualty signs and symptoms, medical protocols, casualty behavior, potential caregiver-casualty interactions, and current teaching practices. The medical experts assisted in determining how much visual realism would be required to convey the essential information for evaluating a patient exposed to a biological agent, especially considering the psychological impact of exposure.

At the workshop, RTI presented prior work, capabilities, and concepts for web- and desktop-based training technologies as examples of what could be incorporated into the eventual educational materials. Each advanced training technology, such as desktop virtual reality (VR), simulated patients, and medical modeling, has a spectrum of advantages, disadvantages, tradeoffs, and costs that must be examined in the context of the goals, objectives, and budget of the program. TAC participants provided guidance on which technologies should be employed and set forth their expectations for use in the developed

systems. Other elements of the meeting included a review of experience and insights from other industries regarding detection and response to rare events.

TAC members suggested that anthrax, smallpox, or plague would all be good candidates for a prototype simulator, but they were concerned that comprehensive case data would not be readily available for such diseases. They left it to us (RTI and UNC) to select one or more bioterrorism agents for the prototype simulator, depending on whether we could identify suitable case data to build the patient database. TAC members suggested that a single infectious agent (i.e., Rocky Mountain spotted fever) could serve as our example of an agent that is not generally a high-visibility topic in routine medical education but for which clinical case data would be available. After the unexpected availability of anthrax data, we were able to simulate patients with cutaneous anthrax, inhalation anthrax, and Rocky Mountain spotted fever.

The TAC also discussed and agreed on a single target audience for the project (i.e., primary care physicians) based on their perspective as to which health care provider group should receive priority training and taking into consideration other efforts under way across the nation (including other AHRQ projects). The experts also addressed several issues relating to educational materials and methods of delivery.

POST-SEPTEMBER 11 CONSIDERATIONS

At the time the TAC made these recommendations, experts considered use of biologic agents as a bioterrorist attack an unlikely, not rare, event. Thus, the TAC discussions focused on creating an approach that would entice this group of busy clinicians to take the time to go through the learning materials. They wanted learning materials that were concise, modular, and could be reviewed in less than 15 minutes. Until fall 2001, the challenge was to find a convincing answer to the following question: With their time already precious, managed care affecting their practice, and more than enough new medical knowledge to learn for more prevalent events, why should primary care physicians bother with training for a rare bioterrorism event? A principal recommendation was that the educational materials should include information on emerging diseases, not just expected bioterrorism agents.

Events in late 2001 changed the environment for these educational materials and our assumptions about how best to proceed. With anthrax-tainted envelopes contaminating mail at diverse locations in the eastern United States, the interest in helping clinicians prepare to respond to a bioterrorist event increased dramatically. For example, following the September 11 attack, the federal government set up a new office of the Department of Homeland Security, and Congress mandated that millions of dollars be distributed to state public health department readiness training. RTI itself was faced with heavily increased demand in the fall and winter of 2001 for quick-turnaround products using some of the technologies (web and VR programming, for example) required for this project.

Despite this heightened interest and rapid implementation of new educational efforts, however, some clinicians still consider bioterrorism a rare event. In some quarters, clinicians or others may believe that federal dollars directed at infectious diseases might be better spent on preventing influenza deaths in the elderly, reducing the numbers of new cases of human immunodeficiency virus infections, or developing and testing new vaccines. In short, they may still see training for a rare event as not worth their while, and the barriers to acceptance of any such training, on this topic, remains an issue.

That being said, the anthrax exposures of 2001 opened the minds of many clinicians to receive remedial training on bioterrorism diseases; hence, the audience for such training is doubtless larger that when the Agency for Healthcare Research and Quality (AHRQ) began these projects. Moreover, recent initiatives by the Department of Health and Human Services (DHHS), through the Centers for Disease Control and Prevention (CDC) and the Health Resources and Services Administration (HRSA), provide for assessing clinical readiness and remedial education state by state across the United States. Thus, the clinical environment is more attuned to these issues and clinicians are probably more willing and able to devote some time to learning about bioterrorism through these types of technologies. Nonetheless, because time and resources for busy clinicians remain constrained, we concluded that our "before September 11" strategies about the media and the content for these learning materials were still on point and that our original plans for developing the web- and VR-based educational components remain in concert with this national need. For those reasons, we did not materially revamp our approach in the post-September 11 period.

WEB-BASED LEARNING MATERIALS

BACKGROUND

Web-based interactive courseware allows for rapid dissemination of information 24 hours a day, 7 days a week. This methodology is especially attuned to the needs of busy professionals who do not always have the luxury of attending classes in fixed locations or at set times. Such educational materials are, of course, distributed primarily via the Internet. For non-Internet users, they can also be downloaded to a CD or printed as hard-copy materials. For this project, we focused on electronic access to the learning materials, that is, use via the Internet, and computer (desktop) applications of the simulated patient (discussed below).

The project website (http://bt.rti.org) remains freely open to the public (as of June 2002). It has four main segments: the home page (Exhibit 2.1), bioterrorism agents, emerging infectious agents, and notifications and key web links. Table 2.1 lists the main elements of the two key segments: bioterrorism agents and emerging infectious agents. RTI has decided to keep the website online for 1 year beyond the end of this project, however, specific plans and budgets for updating the website during this period have not yet been established

RTI and staff from the UNC School of Public Health developed a modular approach for the web-based method for training primary care providers in handling atypical patient cases, such as those that might arise from a bioterrorist attack or an emerging infectious disease. Our UNC partners developed the content for the educational materials for the website; RTI's graphic designers created the website. During a series of pretests in 2001, we invited the project team and other RTI staff (including one physician) to review the emerging website and to provide input on its usability.

In all, we created five modules for the website. Four provide educational content (Table 2.1), and the fifth provides information on VR-based patient simulation (discussed below). The four content modules each focus on a different area of expertise and together constitute two pairs of information: one for bioterrorist agents (history; clinical information) and the other for emerging infectious diseases (history; clinical information).

Exhibit 2.1. Home Page for Website (bt.rti.org)

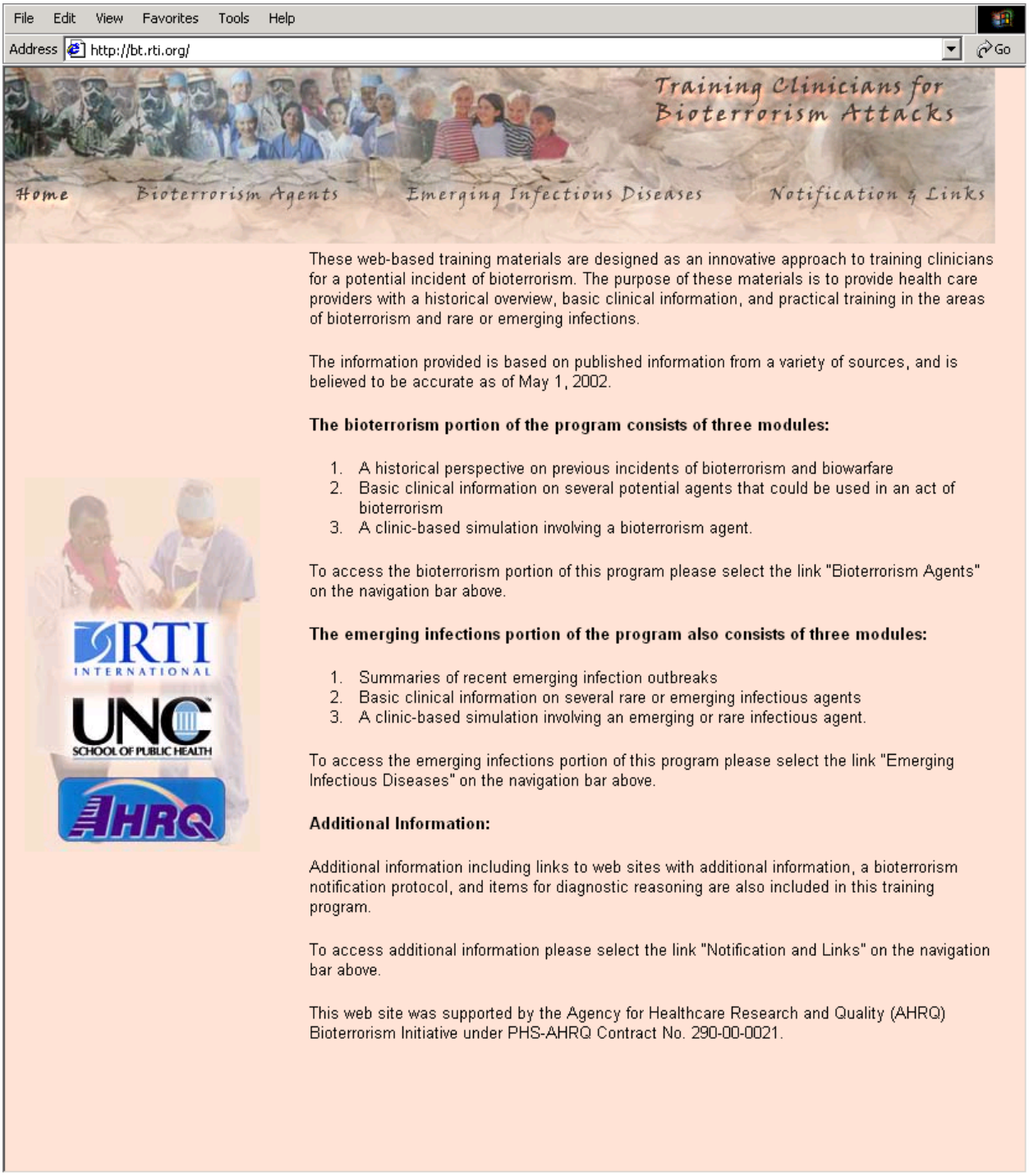


Table 2.1. Outline of the Bioterrorism Website (bt.rti.org)

Historical perspective on biowarfare

1346 – Use of plague-infested corpses in the medieval siege of Kaffa
1763 – Use of smallpox during the French and Indian War
1916 – German use of biological agents during World War I
1942 – Japanese use of biological agents during World War II
1972 – Terrorist attempts to culture bioterrorism agents
1979 – Accidental anthrax release in Soviet Union
1984 – Salmonella contamination of salad bars in Oregon
1990 – Aum Shinrikyo Japanese cult efforts to acquire bioterrorism agents
1991 – American anti-government group acquisition of ricin
1996 – Intentional food contamination at a Texas medical center
2001 – Anthrax outbreaks in the United States

Clinical information on potential bioterrorist agents

Anthrax
Botulinium toxin
Brucellosis
Plague
Q fever
Smallpox
Staphylococcal enterotoxin B
Tularemia

Recent outbreaks of rare and emerging diseases

1975 – Initial recognition of Lyme arthritis
1976 – Legionaire's disease in Philadelphia
1981 – Recognition of acquired immune deficiency syndrome in the United States
1992 – Bloody diarrhea and hemolytic uremic syndrome associated with E. coli
1993 – Hantavirus pulmonary syndrome
1993 – Cryptosporidiosis in Milwaukee
1995 – Ebola Hemorrhagic Fever
1995 – Variant Creutzfeldt-Jacob Disease (CJD) in the United Kingdom
1996 – Human monkeypox in the Republic of Congo (Zaire)
1997 – Vancomycin-intermediate resistant staphylococci in the United States
1999 – West Nile encephalitis in New York

Clinical information on rare emerging diseases

Hantavirus
Human ehrlichiosis
Lyme disease
Rocky Mountain spotted fever
West Nile encephalitis

The four learning modules are self-contained, but we also provide links to content on several other Internet sites (e.g., the CDC). Clinicians can complete the modules either individually or as a series, depending on their interest or need. Users can move quickly within or between segments through clicks on graphic features and specific words. The TAC advised that the learning materials should be brief and concise and that they should inform the clinician about bioterrorism but not necessarily be used as a clinical reference. For definitive information, TAC members were clear that they still would prefer to use a peer-reviewed article. Details about the modules in the website educational materials are given below.

We had developed essentially all these materials before the September 11 attacks. Given the outpouring of information after that point, we immediately began to update the anthrax content with information taken from major peer-reviewed publications; this includes, for example, articles appearing since September 2001 in the *Mortality and Morbidity Weekly Review*, the *Journal of the American Medical Association*, the *New England Journal of Medicine*, and *Emerging Infectious Diseases*. Full citations can be found in the bibliography in Appendix B.

We incorporated the current clinical knowledge on the bioterrorist agents included in the website through April 2002, but we note that knowledge continues to mount on these and other infectious agents. Because continuous updating of the website was not feasible within this development and evaluation project, we did not continue to update information after April 2002.

MODULE-SPECIFIC INFORMATION

We briefly describe the four modules here and note the "learning objectives" intended for each one. We append to this chapter selected exhibits and tables to illustrate the types of information provided.

Module 1. Historical Perspective on Bioterrorism (and Biowarfare)

The purpose of this module was to provide clinicians who will be using the modules with a context in which biological agents have been previously utilized as weapons (both military and terrorist). UNC provided written descriptions (including scientific journal references) with suggestions for graphical displays for each of the bioterrorism or biowarfare events in the following list (first panel of Table 2.1):

- 1346 – Use of plague-infested corpses in the medieval siege of Kaffa
- 1763 – Use of smallpox during the French and Indian War
- 1916 – German use of biological agents during World War I
- 1942 – Japanese use of biological agents during World War II
- 1972 – Terrorist attempts to culture bioterrorism agents
- 1979 – Accidental anthrax release in Soviet Union
- 1984 – Salmonella contamination of salad bars in Oregon
- 1990 – Aum Shinrikyo Japanese cult efforts to acquire bioterrorism agents

- 1991 – American anti-government group acquisition of ricin
- 1996 – Intentional food contamination at a Texas medical center
- 2001 – Anthrax outbreaks in the United States.

RTI formatted the information provided by UNC into graphic depictions for the website. We created an interactive timeline that displays icons corresponding to dates when significant bioterrorist and biowarfare events have occurred. This graphic display allows the provider to click on a date and obtain detailed information about the indicated event For example, Table 2.2 provides a brief description of the first "modern" bioterrorism event – use of corpses infected with plague during the 1346 siege of the Genoese city of Kaffa – and Exhibit 2.2 depicts the actual page.

After completing this first module, clinicians should be able to meet the following five learning objectives:

1. Describe biological agents involved in bioterrorism and biowarfare;
2. Describe when and where bioterrorism and biowarfare events have occurred;
3. Describe who was involved in the bioterrorism and biowarfare events (victims and terrorists);
4. Describe methods of delivery of selected agents; and
5. Identify the outcomes of these events.

Module 2. Clinical Description of Potential Bioterrorism Agents

This module briefly addresses the clinical features of bioterrorism agents considered highly likely to be employed in future attacks. It provides clinicians with a brief background on

1. Clinical features, including symptoms and disease progression;
2. Morphological features, including size, shape, chemical, and physical stability;
3. Epidemiological features, including exposure and transmission;
4. Diagnosis and clinical management;
5. Prevention of a selected bioterrorism agent; and
6. References.

Included in the module are visual aids that address the biological and clinical aspects of the following diseases (second panel of Table 2.1):

- Bacillus anthracis (anthrax)
- Clostridium botulinum (botulism)

Exhibit 2.2. Timeline for Website (Module 1)

File Edit View Favorites Tools Help

Address http://bt.rti.org/FrameBioAgeHistory.html Go

1346 **Use of plague-infected corpses in the Midieval siege of Kaffa**

Location: Crimean Peninsula (Now Feodosia, Ukraine)

Biological Agent(s) Involved: *Yersinia pestis* (plague)

Cases: Unknown

Fatalities: Unknown

Incident Summary: During an attempt to siege the Genoese city of Kaffa in 1346, the Mongol/Tartar attacking army was engulfed with an epidemic of plague that had spread down the Silk Road of China. Since the conventional siege strategy was initially unsuccessful, the attackers deliberately attempted to initiate a plague epidemic within the city by propelling plague-stricken corpses over the walls of the city by use of a trebuchet (a massive catapult). A plague epidemic subsequently ensued throughout the city and the Genoese fled Kaffa for Constantinople, the Italian peninsula, and Sicily. The Genoese retreat back to Mediterranean ports is thought to have contributed to the second plague pandemic in Europe. The last recorded episode of casting plague-infected corpses over walls during a city siege was in 1710 in Estonia.

Clinical Notes: Since plague has a complex ecology and epidemiology, there is general consensus that plague-infected corpses were not the sole cause of the plague epidemic in Kaffa. In fact, since infected fleas are known to leave corpses to parasitize living hosts, it is plausible that the corpses propelled into the city did not contain sufficient plague vectors to transmit disease. Plague may have been imported into Kaffa via a natural flea-rodent cycle and the population inside the city may have been particularly vulnerable to an epidemic due to deteriorating sanitation and hygiene.

References:

Robertson AG. From Asps to allegations: biological warfare in history. Military Medicine 1995;160(8):369-373.
Christopher GW, Cieslak TJ, Pavlin JA, Eitzen EM Jr. Biological warfare – a historical perspective. JAMA 1997;278(5):412-417.

Table 2.2. Information on an Historical Bioterrorist Event: Use of Plague-infected Corpses in the Medieval Siege of Kaffa, 1346

Location: Crimean Peninsula (Now Feodosia, Ukraine)

Biological Agent(s) Involved: *Yersinia pestis* (plague)

Cases: Unknown

Fatalities: Unknown

Incident Summary: During an attempt to siege the Genoese city of Kaffa in 1346, the Mongol/Tartar attacking army was engulfed with an epidemic of plague that had spread down the Silk Road of China. Since the conventional siege strategy was initially unsuccessful, the attackers deliberately attempted to initiate a plague epidemic within the city by propelling plague-stricken corpses over the walls of the city by use of a trebuchet (a massive catapult). A plague epidemic subsequently ensued throughout the city and the Genoese fled Kaffa for Constantinople, the Italian peninsula, and Sicily. The Genoese retreat back to Mediterranean ports is thought to have contributed to the second plague pandemic in Europe. The last recorded episode of casting plague-infected corpses over walls during a city siege was in 1710 in Estonia.

Clinical Notes: Since plague has a complex ecology and epidemiology, there is general consensus that plague-infected corpses were not the sole cause of the plague epidemic in Kaffa. In fact, since infected fleas are known to leave corpses to parasitize living hosts, it is plausible that the corpses propelled into the city did not contain sufficient plague vectors to transmit disease. Plague may have been imported into Kaffa via a natural flea-rodent cycle, and the population inside the city may have been particularly vulnerable to an epidemic due to deteriorating sanitation and hygiene.

- Brucellosis (*Brucella* species)
- Plague (Yersinia pestis)
- Q Fever (Coxiella burnetti)
- Smallpox (Variola) virus
- Staphylococcal enterotoxin B
- Tularemia.

Table 2.3 illustrates the types of information assembled for tularemia. By contrast, Exhibit 2.3 depicts a portion of the page devoted to inhalation anthrax. Within the anthrax submodule (not shown), we provided a link to the key federal website maintained by the CDC:

> Additional Information: US Centers for Disease Control and Prevention (CDC) Bioterrorism Preparedness and Response Cite http//:www.bt.cdc.gov/.

Module 3. Recent Outbreaks of Emerging Infections

The purpose of this module was to provide clinicians with a context of outbreaks of emerging infections that have occurred in the past 25 years. UNC provided the textual information for the following emerging infection outbreaks (see Table 2.1, third panel):

- 1975 – Initial recognition of Lyme arthritis
- 1976 – Legionnaire's disease in Philadelphia
- 1981 – Recognition of acquired immune deficiency syndrome in the United States
- 1992 – Bloody diarrhea and hemolytic uremic syndrome associated with E. coli
- 1993 – Hantavirus pulmonary syndrome
- 1993 – Cryptosporidiosis in Milwaukee
- 1995 – Ebola Hemorrhagic Fever
- 1995 – Variant Creutzfeldt-Jacob Disease (CJD) in the United Kingdom
- 1996 – Human monkeypox in the Republic of Congo (Zaire)
- 1997 – Vancomycin-intermediate resistant staphylococci in the United States
- 1999 – West Nile encephalitis in New York

To illustrate the types of information provided within these pages, Table 2.4 reproduces the facts shown for the most recent of the outbreaks included in the website: the 1999 appearance of West Nile encephalitis in New York City.

The five learning objectives for this module paralleled those for Module 1:

1. Describe the group of persons involved in the outbreak;
2. Describe the agents involved in disease transmission in each outbreak;
3. Describe where and when each outbreak occurred;

Exhibit 2.3. Clinical Information Page for Inhalation Anthrax

File Edit View Favorites Tools Help

Address http://bt.rti.org/FrameClinicalHis.html Go

Training Clinicians for Bioterrorism Attacks

Bioterrorism Agents

Home History Clinical Information Simulation Emerging Infections

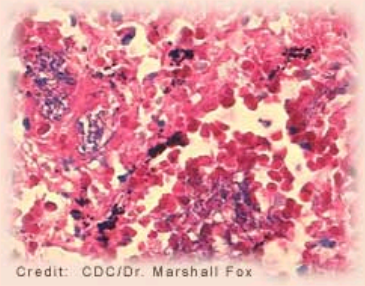
Anthrax-------Botulinium Toxin-------Brucellosis-------Plague-------Q Fever

Smallpox----------Staphylococcal enterotoxin B----------Tularemia

Anthrax (Inhalation)

Agent: *Bacillus anthracis*, a gram-positive spore-forming, bacterium

Incubation Period: 1-6 days (range, up to 6 weeks)



Credit: CDC/Dr. Marshall Fox

For the latest information on Anthrax, see the Bioterrorism Website of the Centers for Disease Control and Prevention

Clinical Presentation and Course: Insidious onset of nonspecific "flu-like" symptoms (duration 1-4 days) including fever, nonproductive cough, fatigue or malaise, shortness of breath, sweats, nausea or vomiting, and chest discomfort or pleuritic pain. Followed by increased fever and increased shortness of breath, often with hypotension, confusion, and meningeal signs.

Mortality: Inhalational cases are usually fatal (>90%) if left untreated..
Recent data indicate approximately 50% fatalities when antibiotic therapy begins before onset of fulminant disease.

Person-To-Person Transmission: None (rarely direct person-to-person transmission occurs with skin lesions).

Likely Method Of Dissemination: Aerosol, contaminated letters/packages.

Pre-Exposure Prophylaxis: Vaccine (not commercially available).

Recommended pre- and post exposure prophylaxis and therapy may change. Always check definitive source for information (e.g., CDC). When providing therapy also check manufacturer's instructions regarding dosing, route, duration, monitoring, precautions, and contraindications.

Diagnostic Samples (Biosafety Level/BSL): BSL2 (BSL 3 for production quantities or concentrations of culture, and for activities with high potential for aerosol production).

Diagnostic Tests: Gram strain of blood (CSF if patient has meningitis, pleural fluid if patient has empyema), blood cultures x 2.

If disease is suspected follow recommendations of laboratory for diagnostic testing.

Patient Isolation Precautions: Standard (Use Contact Precautions if skin lesions present). (CDC)

Decontamination of fomites (e.g., cloths) recommended: Yes.

Post exposure Prophylaxis: Doxycycline, Ciprofloxacin.

Table 2.3. Clinical Information on Tularemia

Agent: *Francisella tularensis*, a gram-negative coccobaccillus

Infective Dose: 10-50 organisms

Incubation Period: 3-5 days (range, 1-14 days)

Clinical Presentation and Course: Acute onset of nonspecific febrile illness progressing in some patients to pharyngitis, bronchiolitis, pneumonitis, pleuritis, and hilar lymphadenitis. Untreated infection may lead to overwhelming sepsis.

Mortality: 30-60% for untreated pneumonia (10-15% for all types of infection). Case-fatality rate in treated tularemia ~2%.

Person-To-Person Transmission: No.

Likely Method Of Dissemination: Aerosol.

Pre-Exposure Prophylaxis: Vaccine (investigational in U.S.).
Recommended pre- and post exposure prophylaxis and therapy may change. Always check definitive source for information (e.g., CDC). When providing therapy also check manufacturer's instructions regarding dosing, route, duration, monitoring, precautions, and contraindications.

Diagnostic Samples (Biosafety Level/BSL): BSL 2 for activities with clinical material (BSL 3 for manipulation of cultures).

Diagnostic Tests: Culture of sputum, tracheo-bronchial secretions, and blood using cysteine-enriched medium. DFA available in some laboratories for rapid diagnosis (also PCR and antigen detection).

If disease is suspected follow recommendations of laboratory for diagnostic testing.

Patient Isolation Precautions: Standard Precautions. (CDC)

Decontamination of fomites (e.g., cloths) recommended: Yes.

Post exposure Prophylaxis: Doxycycline or Ciprofloxacin for 14 days.

Therapy: Gentamicin. Alternatives include Doxycycline or Ciprofloxacin.

Additional Notes: Diagnosis likely to be difficult initially due to nonspecific nature of symptoms.

References:
U.S. Department of Health and Human Services. Biosafety in Microbiology and Biomedical Laboratories. Fourth Edition. Washington, U.S. Government Printing Office, 1999.
Dennis DT, Inglesby TV, Henderson DA, et al. Tularemia as a biologic weapon: medical and public health management. JAMA 2001; 285:2763-2773.
Gill V, Cunha BA. Tularemia pneumonia. Seminars in Respiratory Infections 1997; 12:61-67.

Additional Information: US Centers for Disease Control and Prevention (CDC) Bioterrorism Preparedness and Response Site: http://www.bt.cdc.gov/

Table 2.4. Selected Information on Emerging Infectious Agents: Outbreak of West Nile Encephalitis, 1999

Outbreak Location: New York Metropolitan area.

Agent: West Nile virus (a flavovirus of the Japanese encephalitis group)

Cases: 59 hospitalized

Fatalities: 7

Outbreak Summary: In August 1999, the New York City Department of Health was contacted concerning two patients suffering from encephalitis in a hospital in the borough of Queens. Subsequent investigation revealed 6 additional encephalitis cases in nearby hospitals and testing of cerebrospinal fluid suggested viral infection, potentially from an arthropod-borne virus (arbovirus). Case specimens tested positive for St. Louis encephalitis virus, and mosquito control measures were quickly enacted in the New York City area. During the same time period another group of investigators noted that a substantial number of bird deaths had occurred. Since St. Louis encephalitis infection in bird species does not normally result in death, extensive veterinary examinations of birds were conducted. A month after recognition of the human cases, West Nile virus was isolated from the tissues of both deceased crows in nearby Westchester County and a flamingo that had died in a New York zoo. West Nile virus was then demonstrated as the agent causing a common outbreak of humans and bird species in the New York City area. This outbreak was the first recorded outbreak of West Nile virus in the Western Hemisphere. West Nile virus was isolated from overwintering mosquitoes during the winter following the outbreak, and additional bird and human cases were reported during the following summer, indicating endemic presence of West Nile virus in the United States.

Outbreak Reservoir: Mosquitoes. Antigenic mapping of outbreak isolates with previous West Nile isolates from around the world indicated the most resemblance with virus found from a dead goose in Israel in 1998.

Incubation Period: Unknown

Case Demographics: Median age of 59 patients was 71 years and cases ranged from 5 to 90 years of age. 88% were at least 50 years old. Thirty-one of 59 were male and 28 were female and 41 of 59 were white race. Thirty-two of 59 lived in the borough of Queens.

Additional Clinical Notes: The overall attack rate in the outbreak was determined to be at least 6.5 per million persons and increased sharply with age (attack rate was 19.6 times higher in persons >50 years of age compared with persons younger than 50 years of age. The mean duration of symptoms before hospitalization was approximately 5 days. One reported unusual clinical aspect observed in the New York West Nile outbreak was profound muscle weakness in patients with encephalitis. West Nile infection in birds was more geographically widespread than the human cases.

4. Describe the factors that influenced disease transmission in each outbreak; and
5. Describe the outcome of each outbreak.

Module 4. Clinical Description of Emerging Infectious Diseases

This module is similar in scope and design to Module 3, but it focuses on infectious agents whose appearance to most clinicians would be out of the ordinary. We incorporated information on hantavirus, human ehrlichiosis, Lyme disease, Rocky Mountain spotted fever (see Table 2.5 as an example of material provided on this page), and West Nile encephalitis as emerging or rare emerging infectious diseases.

After completing this module, clinicians should be able to

1. Understand the mechanisms of exposure of the selected diseases;
2. Describe the clinical features (signs, symptoms, and disease progression), morphological features (size, shape, and chemical/physical stability), and epidemiological features (exposure and transmission) of the selected diseases;
3. Describe the diagnosis, clinical management, and prevention of selected diseases; and
4. Describe the stage of infections and corresponding morbidity and mortality.

ADDITIONAL INFORMATION

The final button on the website home page is Notifications and Links. It essentially provides CDC recommendations on outbreak notification and direct URL links to other relevant websites (Table 2.6 and Exhibit 2.4). Exhibit 2.5 is a printout of a Bioterrorism Wall Chart from the North Carolina Statewide Program for Infection Control and Epidemiology link presented in this page of the website. Finally, the website also describes the prototype VR-simulated patient project (see Table 2.7 and Exhibit 2.6 for extracts of the data on this page).

VIRTUAL SIMULATED PATIENT

BACKGROUND

As implied above, the “fifth” learning module involves virtual simulated patients for clinical training and validation (VSP). VSP development provides both a second prototype approach for training clinicians and simulations for evaluating training effectiveness. We envisioned this module as a possible mechanism for testing clinicians’ knowledge, using an interactive approach that allows them to query patient-specific information, including information on exposure, symptoms, disease progression, and clinical management. The remainder of this section of Chapter 2 describes the development of this software program (and see Table 2.7 and Exhibit 2.6).

Exhibit 2.4. Depiction of the Notification and Links Page

Exhibit 2.5. Printout of the Bioterrorism Wall Chart from the North Carolina Statewide Program for Infection Control and Epidemiology

BIOTERRORIST AGENTS

WATCH FOR THESE SYMPTOMS

Disease	Signs & Symptoms	Incubation Time (Range)	Person-to-Person Transmission	Isolation	Diagnosis	Postexposure Prophylaxis for Non-Pregnant Adults	Treatment for Non-Pregnant Adults
Anthrax *Bacillus anthracis* A. Inhalation	Flu-like symptoms (fever, fatigue, muscle aches, dyspnea, nonproductive cough, headache), chest pain; possible 1-2 day improvement then rapid respiratory failure and shock. Meningitis may develop.	1 to 6 days (up to 6 wks)	None	Standard Precautions	Chest x-ray evidence of widening mediastinum; obtain sputum and blood culture. Sensitivity and specificity of nasal swabs unknown - do not rely on for diagnosis.	Prophylaxis for 60 days: Doxycycline 100 mg PO q 12h Or Amoxicillin* 500 mg PO q 8h Or Ciprofloxacin 500 mg PO q 12h Alternative: Ofloxacin 400 mg PO q 12h Or Levofloxacin 500 mg PO q 24h Or Gatifloxacin 400 mg PO q 24h *if strains are susceptible	Penicillin G* 2 to 4 MU IV q 4 to 6h Or Amoxicillin* 500 mg IV q 8h Or Ciprofloxacin 400 mg IV q 12h Or Doxycycline 200 mg IV load, then Doxycycline 100 mg IV q 12h Alternative: Ofloxacin 400 mg IV q 12h Or Levofloxacin 500 mg IV q 24h Or Gatifloxacin 400 mg IV q 24h * if strains are susceptible
B. Cutaneous	Intense itching followed by painless papular lesions, then vesicular lesions, developing into eschar surrounded by edema.	1 to 12 days	Direct contact with skin lesions may result in cutaneous infection.	Contact Precautions	Peripheral blood smear may demonstrate gram positive bacilli on unspun smear with sepsis.		
C. Gastrointestinal (GI)	Abdominal pain, nausea and vomiting, severe diarrhea, GI bleeding, and fever.	1 to 7 days	None	Standard Precautions	Culture blood and stool.		
Botulism botulinum toxin	Afebrile, excess mucus in throat, dysphagia, dry mouth and throat, dizziness, then difficulty moving eyes, mild pupillary dilation and nystagmus, intermittent ptosis, indistinct speech, unsteady gait, extreme symmetric descending weakness, flaccid paralysis; generally normal mental status.	Inhalation: 12-80 hours Foodborne: 12-72 hours (2-8 days)	None	Standard Precautions	Laboratory tests available from CDC or Public Health Dept; obtain serum, stool, gastric aspirate and suspect foods prior to administering antitoxin. Differential diagnosis includes polio, Guillain Barre, myasthenia, tick paralysis, CVA, meningococcal meningitis.	Pentavalent toxoid (types A, B, C, D, E) 0.5 ml SQ may be available as investigational product from USAMRIID.	Botulism antitoxins from public health authorities. Supportive care and ventilatory support. Avoid clindamycin and aminoglycosides.
Pneumonic Plague *Yersinia pestis*	High fever, cough, hemoptysis, chest pain, nausea and vomiting, headache. Advanced disease: purpuric skin lesions, copious watery or purulent sputum production; respiratory failure in 1 to 6 days.	2-3 days (2-6 days)	Yes, droplet aerosols	Droplet Precautions until 48 hrs of effective antibiotic therapy	A presumptive diagnosis may be made by Gram, Wayson or Wright stain of lymph node aspirates, sputum, or cerebrospinal fluid with gram negative bacilli with bipolar (safety pin) staining.	Doxycycline 100 mg PO q 12h Or Ciprofloxacin 500 mg PO q 12h	Streptomycin 1 gm IM q 12h: Or Gentamicin 2 mg/kg, then 1.0 to 1.7 mg/kg IV q 8h Alternatives: Doxycycline 200 mg PO load, then 100 PO mg q 12h Or Ciprofloxacin 400 mg IV q 12h
Smallpox variola virus	Prodromal period: malaise, fever, rigors, vomiting, headache, and backache. After 2-4 days, skin lesions appear and progress uniformly from macules to papules to vesicles and pustules, mostly on face, neck, palms, soles, and subsequently progress to trunk.	12-14 days (7-17 days)	Yes, airborne droplet nuclei or direct contact with skin lesions or secretions until all scabs separate and fall off (3 to 4 weeks)	Airborne (includes N95 mask) and Contact Precautions	Swab culture of vesicular fluid or scab, send to BL-4 laboratory. All lesions similar in appearance and develop synchronously as opposed to chickenpox. Electron microscopy can differentiate *variola virus* from varicella.	Early vaccine critical (in less than 4 days). Call CDC for vaccinia. Vaccinia immune globulin in special cases - call USAMRIID 301-619-2833.	Supportive care. Previous vaccination against smallpox does not confer lifelong immunity. Potential role for Cidofovir.

Exhibit 2.5. Printout of the Bioterrorism Wall Chart from the North Carolina Statewide Program for Infection Control and Epidemiology (continued)

Photo Credits: Anthrax A and C - JAMA 1999;281:1737-8 ; Anthrax B - CDC; Botulism - JAMA 2001;285:1062 Copyrighted 2001 American Medical Association; Plague - JAMA 2000;283:2283; Smallpox - CDC

References:

- Arnon SS, Schechter R, Inglesby TV, et al. for the Working Group on Civilian Biodefense. Botulinum toxin as a biological weapon: medical and public health management. JAMA 2001;285:1059-1070.
- Centers for Disease Control and Prevention. Chemical/Biological Survival Cards for Civilians. 2000.
- Chin J, ed. Control of Communicable Diseases Manual. 17th edition. Washington, DC: American Public Health Association. 2000.
- Henderson DA, Inglesby TV, Bartlett JG, et al. for the Working Group on Civilian Biodefense. Smallpox as a biological weapon; medical and public health management. JAMA 1999;281:2127-2137.
- Inglesby TV, Henderson DA, Bartlett JG, et al. for the Working Group on Civilian Biodefense. Anthrax as a biological weapon: medical and public health management. JAMA 1999;281:1735-1745.
- Inglesby TV, Dennis DT, Henderson DA, et al. for the Working Group on Civilian Biodefense. Plague as a biological weapon: medical and public health management. JAMA 2000;283:2281-2290.
- U.S. Army Medical Research Institute of Infectious Diseases. USAMRIID's Medical Management of Biological Casualties Handbook. 4th ed. Fort Detrick, Frederick, Maryland. 2001.

NOTIFICATION PROCEDURES IN THE EVENT OF A BIOTERRORIST INCIDENT

1. **First call the Public Health Officer at your local health department; after hours contact local Health Director via 911.**
2. **If no answer at local health department, call the North Carolina Communicable Diseases Branch 919-733-3419.**
3. **If criminal activity is suspected, call your local law enforcement and the NC FBI 704-377-9200.**

FOR MORE INFORMATION ON BIOTERRORISM:

CDC - Centers for Disease Control and Prevention
www.bt.cdc.gov/

APIC - Association for Professionals in Infection Control & Epidemiology
www.apic.org/bioterror/

SPICE - North Carolina Statewide Program for Infection Control and Epidemiology
www.unc.edu/depts/spice/
919-966-3242

USAMRIID's Medical Management of Biological Casualties Handbook
www.usamriid.army.mil/education/bluebook.html

DECONTAMINATION FOR ALL OF THESE AGENTS

1. Place clothing from suspected victims in airtight impervious (e.g., plastic) bags and save for law authorities (e.g., FBI, SBI).
2. Use soap and water for washing victim.
3. For environmental disinfection for all of the above, use bleach (standard 6.0% - 6.15% sodium hypochlorite) in a 0.6% concentration (1 part bleach to 9 parts water). For botulism, plague and smallpox an alternative is to use an EPA-approved germicidal detergent.
4. For smallpox, all bedding and clothing must be autoclaved or laundered in hot water and bleach.
5. Healthcare worker should wear PPE (gowns, gloves and mask) during decontamination of anthrax, plague, and smallpox.

DETECTION OF OUTBREAKS

Epidemiologic Strategies

- A rapidly increasing disease incidence
- An unusual increase in the number of people seeking care, especially with fever, respiratory, or gastrointestinal symptoms
- An endemic disease rapidly emerging at an uncharacteristic time or in an unusual pattern
- Lower attack rate among persons who had been indoors
- Clusters of patients arriving from a single locale
- Large numbers of rapidly fatal cases
- Any patient presenting with a disease that is relatively uncommon and has bioterrorism potential

Chart developed by:
North Carolina Statewide Program for Infection Control and Epidemiology (SPICE) email: spice@unc.edu
KK Hoffmann, DJ Weber, EP Clontz, WA Rutala

Support provided by:
The North Carolina Institute for Public Health and The North Carolina Center for Public Health Preparedness, in the School of Public Health at The University of North Carolina at Chapel Hill

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Allegiance Healthcare, a Cardinal Health company
Bayer Corporation
Bristol Myers Squibb
Clorox
Becton, Dickinson and Company
Ortho-McNeil Pharmaceutical
Kendall

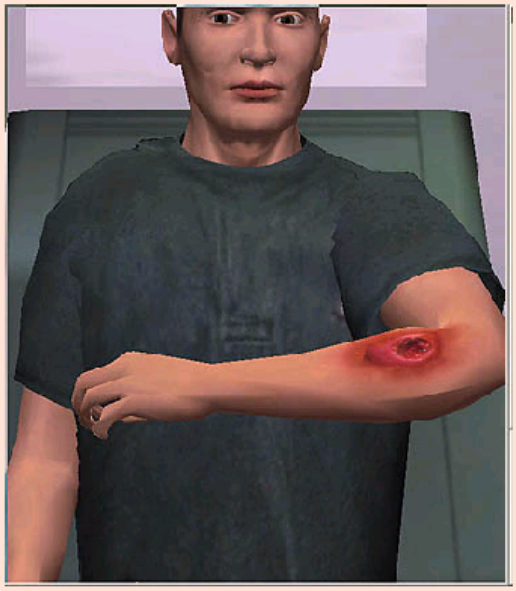
Exhibit 2.6. Explanation of Virtual Simulated Patient Software

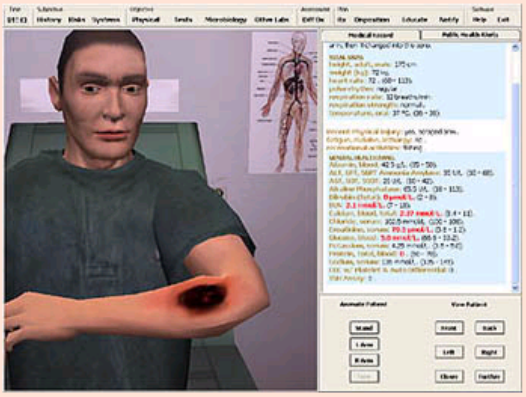
File Edit View Favorites Tools Help

Address http://bt.rti.org/FrameBioAgeHistory.html Go

RTI International has developed prototype virtual patient simulations for practice in handling rare patient cases, such as those that might arise from a bioterrorism attack or an emerging infectious disease.

RTI's VirtualClinic simulator provides virtual simulated patients for training clinicians in bioterrorism disease recognition. VirtualClinic follows the Subjective, Objective, Assessment, and Plan protocol for primary care. Each patient may present at different stages of disease with a chief complaint, vital signs, and animated clues such as coughing, hyperventilation, and sneezing. The clinician makes inquiries regarding medical history and physical condition, orders diagnostic (chest x-ray, CT scan) and lab (Gram stains, CBCs) tests, enters differential diagnoses, and plans treatment and patient management. The patient's medical record is updated as new findings become available. Public health alerts are also available for the physician's reference. Clinical findings are taken from published data, case reports, and hospital medical records.





Click here for a full-size version of the above image.

Case-based simulations have been developed for cutaneous anthrax, inhalation anthrax, and Rocky Mountain spotted fever. Other diseases may be developed later to broaden the training spectrum and provide practice in differential diagnosis. The simulations familiarize and refresh the clinician in clinical characteristics, including symptoms and disease progression; morphological features, size and shape or lesions, differential diagnosis, and management.

The UNC School of Public Health at Chapel Hill provided advice and clinical content. On a scale of 1 to 5, a small group of users gave the VirtualClinic software a 4.0 rating, and rated it's applicability as a training tool at 4.2.

For information on software content and availability please contact Paul Kizakevich at kiz@rti.org or Jerry Henegan at JerryH@rti.org.

Table 2.5. Information on Rocky Mountain Spotted Fever

Clinical Presentation and Course: Moderate to high fever that persists for 2-3 weeks, significant malaise, deep muscle pain, severe headache, chills, conjunctival infection. A macopapular rash appears on the extremities on the third to fifth day that soon includes the palms and soles and spreads rapidly to much of the body. A petechial exanthem occurs in 40-60% of patients on or after the sixth day of illness.

Occurrence: Throughout the United States, primarily from April to September. Nearly half of cases are reported from South Atlantic USA and relatively few cases are reported from the Rocky Mountain region. In the Western United States, adult males are most frequently infected but in the Eastern US children have the highest incidence.

Reservoir: Maintained in nature by ticks.

Mortality: 13-25% if untreated. In recent years 3-5% of cases in the US have been fatal.

Mode of Transmission: Tick bite. At least 4-6 hours of tick attachment are required for human infection. *Dermacentor variabilis* (American dog tick) and *Dermacentor andersoni* (Rocky Mountain wood tick) are the common vectors in the United States.

Person-to-Person Transmission: No.

Diagnostic Test: PCR (blood), PCR/Immunostain (skin biopsies)
If disease is suspected follow recommendations of laboratory for diagnostic testing.

Pre-exposure Prophlyaxis: No.
Recommended pre- and post exposure prophylaxis and therapy may change. Always check definitive source for information (e.g., CDC). When providing therapy also check manufacturer's instructions regarding dosing, route, duration, monitoring, precautions, and contraindications.

Additional Notes: None.

References:
Chin J (ed.). Control of communicable diseases manual – 17th addition. Washington, DC: American Public Health Association, 2000.

Additional Information:
US Centers for Disease Control and Prevention (CDC) Website: www.cdc.gov
Emerging Infectious Diseases Journal Online: www.cdc.gov/eid

Table 2.6. Links Provided on the Notifications and Links Page

www.unc.edu/depts/spice/bioterrorism.html
CDC web page - US Centers for Disease Control and Prevention (CDC) Bioterrorism Preparedness and Response Site:
www.bt.cdc.gov/
USAMRIID's Medical Management of Biologicial Casualties Handbook, 4th edition (February 2001), Fort Detrick, Maryland:
www.usamriid.army.mil/education/bluebook.html
Johns Hopkins University Center for Civilian Biodefense Studies:
www.hopkins-biodefense.org/
New York City Department of Health:
www.ci.nyc.ny.us/html/doh/html/cd/wtc8.html
CDC Guideline for Isolation Precautions in Hospitals:
http://www.cdc.gov/ncidod/hip/isolat/isolat.htm

Table 2.7. Illustrative Description of the Virtual-Reality Based Simulation as Presented on the Website

The case-based simulations use an interactive approach that allows the clinician to query patient-specific information in a 3-D "virtual clinic." Information on exposure, symptoms, disease progression, and clinical management can be determined via interaction with a responsive virtual patient. Lab tests, other diagnostics, and consults can be ordered and reviewed. Special emphasis has been placed on bioterrorism case identification and management.
The simulations will familiarize and refresh the clinician in clinical features, including symptoms and disease progression; morphological features, including size and shape or lesions; and diagnosis and clinical management.

For developing this simulation program to train and evaluate practitioners' skills in bioterrorism case identification and management, we created an interactive "Doctor's Office" on their computer screen, which offers a choice of virtual patients at different stages of the disease. For the initial work and for simplicity here, we assume clinicians to be physicians in primary care (e.g., general internal medicine or family practice). This work was not done with pediatric patients in mind, so the simulated patients are all adults.

The patients created for this project are simulated examples of patients (all male, all adult) infected by either biowarfare agents or, for contrast, emerging (uncommon) infectious diseases. Patients "exist" first in clinical databases that hold considerable amounts of clinical information; from these databases are coded the three-dimensional simulated patients who can then appear in the "Doctor's Office" (i.e., on the screen). In this case, we compiled the clinical databases for cases who could exhibit signs and symptoms associated with various infectious diseases (i.e., cutaneous anthrax, inhalation anthrax, and Rocky Mountain spotted fever). The cutaneous anthrax patients illustrate three levels of severity for this disease; the inhalation anthrax database has two types of cases; and the Rocky Mountain spotted fever databases reflects four different days in the progression of this disease. Details of these steps are documented later in this chapter.

For purposes of testing the prototype, we coded the "VirtualClinic" software (Exhibit 2.6) only for any of the three levels of severity of cutaneous anthrax, which was the best choice for enabling us to take the most advantage of the graphics capabilities of this software.

The advantage of the simulated-patient approach is that clinicians can gain experience with diseases they are unlikely to encounter in real life. The simulation initially provides physicians with vital signs and a brief description of each patient and his (or eventually, her) chief complaint. The clinicians can make inquiries regarding medical history and physical condition, order diagnostic tests (e.g., chest x-ray, computed tomography scan), order laboratory tests (e.g., Gram stains, complete blood counts), obtain results from these tests (provided the procedure has a rapid turn-around time), enter differential diagnoses, and plan treatment and patient management.

The patient's online medical record is updated as new findings become available. The software also makes "public health alerts" available for the physicians' reference. These alerts can be used to inform the clinician of current outbreaks, and to illustrate the subsequent public health consequences of a misdiagnosis. Thus, at the end of the simulation, the clinician student should be able to do the following: recognize cutaneous anthrax, inhalation anthrax, or Rocky Mountain spotted fever; carry out special diagnostic procedures and laboratory tests; invoke disease-appropriate treatment procedures, and notify public health and law enforcement authorities.

DETAILED INFORMATION

For each patient, we started with a base set of medical and social history information and expected normal findings for physical examination parameters and clinical laboratory results. We then augmented these patient data using published data for cutaneous anthrax and inhalation anthrax, and we extracted information for Rocky Mountain spotted fever directly from medical records.

Table 2.8. Case Data Coded in the Database for Constructing Simulated Patients

Disease	Designation	Description	Data Source
None	Normal	Normal	Constructed
Cutaneous anthrax	Mild	Reddening of skin	Constructed
Cutaneous anthrax	Moderate	Infection, pus, inflammation	Constructed
Cutaneous anthrax	Severe	Formation of eschar	Constructed
Inhalation anthrax	Case 1	First case	Publications
Inhalation anthrax	Case 6-a	Sixth case, early data	Publications
Inhalation anthrax	Case 6-b	Sixth case, mid data	Publications
Inhalation anthrax	Case 6-c	Sixth case, final data	Publications
RMSF	Case 1-Day 4	Rash on hands	Medical record
RMSF	Case 1-Day 5	Rash on hands	Medical record
RMSF	Case 1-Day 6	Rash on hands, & arms	Medical record
RMSF	Case 1-Day 7	Rash on hands, arms, & trunk	Medical record

Table 2.8 displays the twelve sets of clinical data contained in the database for creating patient scenarios. The disease column refers to the four patient conditions that were created under this project: a normal person and three infectious diseases (i.e., cutaneous anthrax, inhalation anthrax, and Rocky Mountain Spotted Fever). The normal patient serves a dual purpose, first as a baseline for testing the database and validating the VirtualClinic simulation software, and secondly, as a baseline patient that can be modified to create an infinite number of other scenarios using various cases of patient diseases or conditions.

The designation column shows the different cases that were created for each condition. For cutaneous anthrax, three sets were created representing one patient with mild, moderate, and severe stages of infection. Two cases were created for inhalation anthrax representing one visit for the first case and three visits for the second case (the change in the condition over time). For RMSF, only 1 case was developed but there were four different time points of the condition depicted.

The data source column details where we retrieved the information to create each patient scenario. Constructed data were taken from narrative values (i.e., expected lab values) or estimated from published descriptions. For cutaneous anthrax, visual representations of the skin lesion were created for the 3-D virtual model based on representative images published on the Internet. Clinical data were constructed ad hoc after reviewing the open literature (e.g., Inglesby et al, 1999). Gram stains for the lesion and venous blood on buffy coat were taken from representative images published on the Internet (Jernigan et al., 2001).

For inhalation anthrax, the first case was based on published data for the first reported inhalation anthrax case (Jernigan et al., 2001). The next three cases were based on published data for the sixth reported inhalation anthrax case; with the three cases representing early, mid, and final clinical data during the course of the disease (Jernigan et al., 2001). Gram stains for the lesion and venous blood on buffy coat, chest x-rays, and chest CT scans were taken from representative published images (Jernigan et al., 2001).

For RMSF, UNC provided clinical data extracted from UNC hospital medical records for seven patients. The first case was representative of the data that were available. Visual representations of the skin lesion were created for the 3-D virtual model based on representative images published on the Internet.

Bioterrorist Agent

Because of the rarity of cutaneous anthrax cases in the United States before the Fall of 2001, we were unable to obtain actual medical records. After the new cases became publicized, we incorporated what data were available into the medical databases supporting the virtual patient simulator and then developed a set of patients presenting with different stages and symptoms of cutaneous and inhalation anthrax. RTI obtained approval from its Institutional Review Board to use patient medical records as the basis for the medical database for the simulator; in the end, however, we used only published data..

Rare Infectious Disease

As noted earlier, our TAC had strongly advised that the educational materials include both an actual bioterrorism agent and a nonbioterrorism infection that is only rarely encountered in general primary care practice. Thus, the TAC selected Rocky Mountain spotted fever as the rare infectious disease to be represented by the patient simulator. UNC staff reviewed charts from cases of Rocky Mountain spotted fever, abstracted data, and provided extracted data to RTI. Information obtained from the medical records related to the following key clinical questions: standard history and physical examination items, diagnostic tests (labs), Gram-stained smear of organism, chest radiographs, and pictures of persons infected by agent showing clinical signs (i.e., skin lesions).

The Simulated Patient

During this initial project, we were able to move from the supportive medical databases to fully coded and tested simulated patient(s) for only one of these conditions. Thus, we opted to concentrate on cutaneous rather than inhalation anthrax. This focus enabled us both to use a potential bioterrorism agent and to take advantage of the visual capabilities of the patient simulation and its graphics.

As described in more detail in Chapter 3, we subjected the simulated patient software, for cutaneous anthrax only, to substantial review by our TAC physicians. On the basis of their critiques and suggestions, we undertook a great deal of structural changes and reprogramming. For instance, we moved options concerning differential diagnosis earlier in the process, so that the software options would map better to the order in which physicians think about patient problems and go through an iterative decisionmaking process. These modifications were made for the cutaneous anthrax patient but are, of course, completely relevant for coding the inhalation and Rocky Mountain spotted fever cases as well.

Chapter 3. Simulator Development

The "VirtualClinic" bioterrorism simulator is an extension of RTI's Virtual Reality for Medical Training software architecture for patient simulation (called VMET) (Kizakevich et al., 1998). The simulator architecture integrates case-based patient scenarios, three-dimensional (3-D) patient visualization, static and dynamic patient models, multimedia patient information, situational and/or scenario information, learning modules, student activity monitoring, and after-action review. Initially developed for simulating trauma patients, we expanded the simulator architecture in the present study to support medical patient simulations, especially patients presenting with an infectious disease in a primary care setting. For example, in a concurrent project for the National Science Institute, VirtualClinic is being refurbished as a pediatric clinic with children as patients.

Thinking ahead to other terrorism (or epidemic) situations, we invested significant effort in expanding the base architecture; doing so meant that the developed software could more easily be adapted for other applications of patient simulation (e.g., chemical agent, asthma, or anxiety), not only bioterrorism patients. In terms of the investment that the Agency for Healthcare Research and Quality (AHRQ) has made in this educational tool and technology, we believe this was a prudent and efficient focus.

This chapter discusses the development of VirtualClinic, with particular regard to four major elements: (1) concept of operations, (2) the primary care model, (3) the virtual simulated patient, and (4) patient scenario learning management. Features of each element, aspects of the development process, and the limitations of the approach taken are discussed. Citations in text can be found in the bibliography in Appendix B.

CONCEPT OF OPERATIONS

During the workshop of the Technical Advisory Committee (TAC) described in Chapter 2, participants suggested various options for presentation of simulated bioterrorism patients. These included simple case studies (such as journal articles), guided multimedia-based case studies, and fully interactive virtual-reality-based simulated patients. The advantages and disadvantages of these approaches are discussed below. For perspective, workshop attendees also discussed current use of live standardized patients in medical training but did not consider writing standardized patient scripts as a project objective. We also discussed the time that clinicians may spend doing such simulations, considering their relatively busy schedules and the perceived benefit of taking bioterrorism training.

TEXT-BASED CLINICAL CASES

This model presents patient information primarily through a textual user interface. Generally, the chief complaint, the medical history, and physical examination information are presented as summary findings. Various tests can be requested. Diagnosis is made via a menu selection.

The American College of Physicians-American Society of Internal Medicine (ACP-ASIM) uses this model for an on-line course called Clinical Problem-Solving Cases (ACP-ASIM, 2002). For each patient, the model presents an initial screen with patient history information, then allows the physician to choose diagnostic tests, determine a differential diagnosis, order treatments, respond to outcomes, and manage complications. Various diagnostic images, charts, laboratory values, test utility ratings, clinical calculators, references, and other data are available upon request. The method is highly linear, with prompting along the way. For example, for diagnostic testing, a short list of possible tests is given, whereas in real life a physician may order from a large list of tests and must know what to request. Furthermore, at least in the sample case, no visual representation of the patient is provided.

A similar but less effective example is the Virtual Internet Patient Simulation (VIPS) program available on-line (VIPS, 2002). The VIPS system presents an initial screen with a chief complaint, then allows the clinician to conduct a history via a text-based natural language query system. The clinician can conduct a physical examination and request diagnostic tests via a menu system. Again, the system offers no visual representation of the patient.

2-D INTERACTIVE MULTIMEDIA PATIENTS

This model builds on the text-based clinical cases by providing a more graphical user interface (GUI), including a photographic or hand-drawn two-dimensional patient. The 2-D patient is generally used for interrogation of body regions to conduct the physical examination or for presentation of data on regional body systems. In preparing for our software development, we identified one main system: ClinicSoft, a CD-ROM-based patient simulation program.

ClinicSoft broadens the model to include a low-resolution representation of the patient and a GUI representing a physician's office. The graphical patient offers a view of body habitus (e.g., in one case an overweight, middle-aged male is presented) and a point-and-click method for the physical examination. The graphical office allows for point-and-click of various major functions (i.e., see the patient, order laboratory tests, request consults, and prescribe drugs). To some extent, ClinicSoft is more office centric than patient centric, because the user has to return to the office to order tests and so forth, thus taking the user away from the patient view. ClinicSoft does support the use of ancillary multimedia, such as chest x-rays, for an accurate portrayal of diagnostic information.

3-D INTERACTIVE VIRTUAL SIMULATED PATIENTS

This model offers the most potential for representing a realistic infectious disease patient. Using responsive virtual human technology, virtual simulated patients can be fully interactive, with body movements, dialogue, behavior, and a visual representation that more fully communicates signs and symptoms to the clinician. For example, a patient who does not feel well may have a slouching posture or be holding her head up, even though she expresses a more positive outlook. Behavioral animations such as sneezing may help differentiate an allergy from respiratory disease. Facial expressions and holding her stomach could indicate pain and gastric distress. Alternative "skin textures" can be used to represent pallor or regional lesions such as cutaneous anthrax, including the 3-D nature of the lesion. Furthermore, sequential skin textures can be used to illustrate progression in the course of a disease.

At the TAC kick-off workshop, the simulation subcommittee recommended that we use the virtual simulated patient model. Ultimately, the goal is to present such patients in a 3-D model of a primary care clinic with multiple examining rooms. Each examining room would present a 3-D patient, with a personal medical and social history, and with signs and symptoms of a particular disease. The physician could move among multiple patients and perhaps be presented with the rapid introduction of additional patients to experience the challenge of a disease outbreak. Patients might have the same disease or other confounding diseases, which would permit the physician to practice differential diagnoses with regard to a specific biological agent.

The multiple-patient concept may well be a valid simulation of the complexity and potential chaos of patient care in the midst of a rapidly expanding bioterrorism event. Nonetheless, the first step is to simulate an individual patient in an individual examining room, with full resources available for patient examination, diagnostic hypothesis testing, and patient management. Within the resources available to the project, we could take only that first step, so we limited the representation to the single-patient model. As noted earlier, however, we provided for multiple-patient scenarios in the database structure; this would facilitate future expansion to a multiple-patient mode.

PRIMARY CARE MODEL

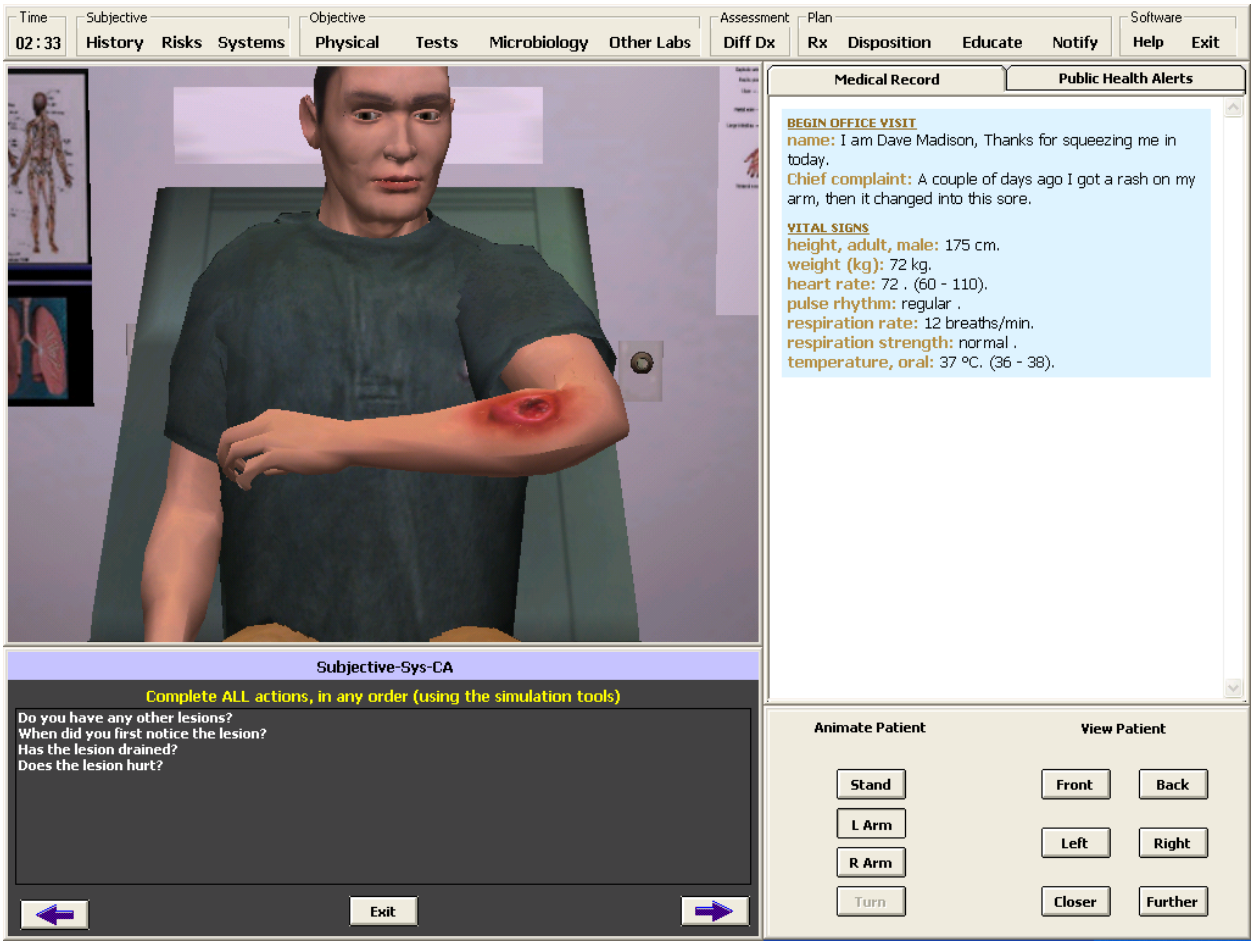
VirtualClinic follows a Subjective, Objective, Assessment, and Plan (SOAP) model for primary care (Naval Hospital, 2001; Auburn, 2002). In contrast, no other clinical simulator we could find mentioned a specific model of primary care that formed the basis of its design.

The VirtualClinic user interface comprises a menu bar across the top of the screen, a 3-D interactive window frame for presentation of the virtual patient, tabbed window frames for accumulation of medical records and presentation of public health alerts, and a command and navigational window frame to direct patient behaviors and provide alternative patient views.

A menu system is employed for the majority of interactions. Menus are discrete and can be mapped directly to the relevant response in the patient database. Furthermore, menus can be generated dynamically from database content; thus, menu lists can be developed and revised by changing database entries rather than program code. In a previous work (Hubal et al., 2000), we employed a speech-based system with natural language processing to carry on a spoken dialogue with a virtual asthma patient. Although that system is more natural than using hierarchical menus, it occasionally had errors in speech understanding; developing a context-based speech understanding system was not feasible given project constraints. (In the various steps of testing our system, however, several reviewers expressed a desire for a spoken language interface for patient queries. This would probably be a desirable next step to consider.)

In the **Subjective** section of the menus, the clinician can query the patient about present illness, past medical history, social and family history, lifestyle and medical risks, and symptoms according to body systems (Exhibit 3.1). The patient verbalizes his response (using a text-to-speech processor) and might show a related expressive behavior. A definitive textual response is then recorded (and displayed) in the medical record (window). Subjective patient inquiries were derived from Nagelkerk (2001).

Exhibit 3.1. Subjective Segment: History and Patient Response



In the **Objective** section, the clinician can conduct a physical examination according to body systems, order diagnostic tests (e.g., ECG, chest x-ray, CT scan) and clinical laboratory tests (e.g., Gram stains, urinalysis, blood chemistries). Test results, such as Gram stains, radiograms, and electrocardiograms, are presented via a pop-up window frame. For each objective query, a definitive textual response is also recorded in the medical record (e.g., chest x-ray: pulmonary effusions). Laboratory results are presented along with the expected normal range for the measurement (Exhibit 3.2), and results that are outside normal limits are highlighted.

In the **Assessment** section, the clinician can make differential diagnostic hypotheses from a set of more than 1,550 diseases. The disease table comprises a set of 1,500 expected diseases in primary care, augmented with additional bioterrorism and emerging diseases. To make a diagnostic hypothesis (Exhibit 3.3), the clinician types a word fragment (e.g., “anth”) and receives a subset list of diseases containing that fragment (e.g., anthrax, cutaneous; anthrax, inhalation). If multiple fragments or multiple words are entered, the subset list contains all diseases that match variations of the entry. At the present time, the clinician cannot specify a disease that the database does not already contain. Multiple disease hypotheses can be specified, and each is recorded in the medical record. Whenever a definitive diagnosis is available, the clinician can reenter the differential diagnosis form and remove incorrect diagnoses from the list.

In the **Plan** section, the clinician prescribes medications, provides patient education, schedules follow-up visits, makes referrals, and ultimately disposes of the patient. A set of 1,210 medications is available based on a hospital formulary found on the Internet. To order a prescription (Exhibit 3.4), the clinician types a word fragment (e.g., “cipr”) and receives a subset list of medications containing that fragment (e.g., Ciprofloxacin IV, Cipro oral). After selecting a medication from this subset, the prescribed medication instructions (dose, route, and frequency) are entered. The clinician can prescribe multiple medications, and each is recorded in the medical record. Referrals can be ordered to any of 16 medical specialists.

The **medical record** window frame begins with patient demographic information, the chief complaint, and a panel of vital signs (presumably taken by a nurse). As mentioned above, all inquiries, patient interactions, diagnostic tests, disease hypotheses, prescriptions, and other plans are automatically accumulated in the medical record as the clinician performs each task. Clinical laboratory results are presented along with their expected normal ranges; such results are highlighted whenever the clinical data are outside normal limits. Laboratory test panels (e.g., lipid panel) are highlighted to indicate that all data came from the same sample.

The **public health alerts** window frame contains public health information in the form of a “Blast Fax” alert associated with the current scenario. This frame is provided to remind clinicians to read their public health alerts, because they may contain clues to patient diagnosis. This public health alert frame shares screen space with the medical record window frame. The clinician uses a tab metaphor to switch between the two frames.

Exhibit 3.2. Objective Segment: Report of Laboratory Test Results

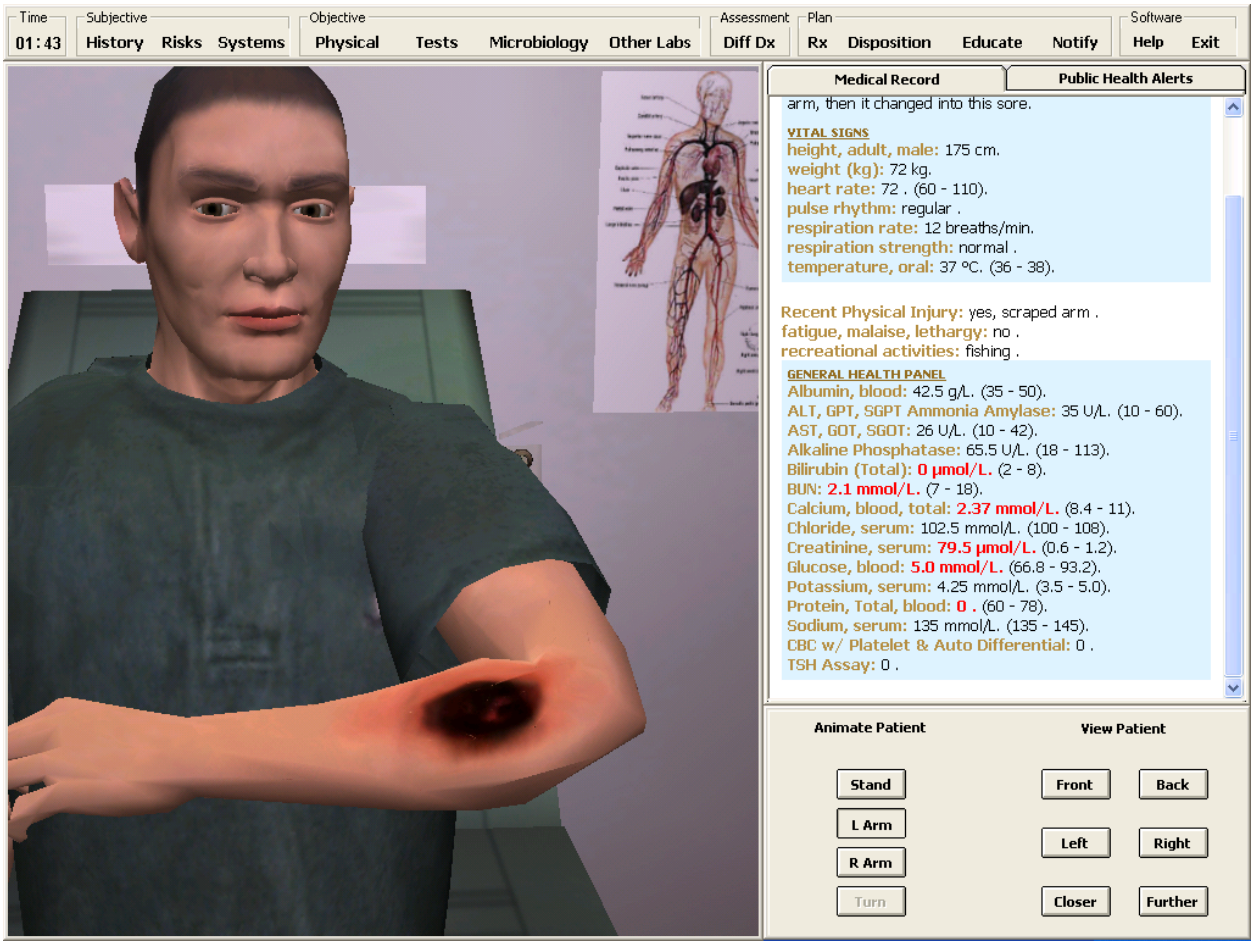


Exhibit 3.3. Assessment Segment: Diagnostic Hypothesis

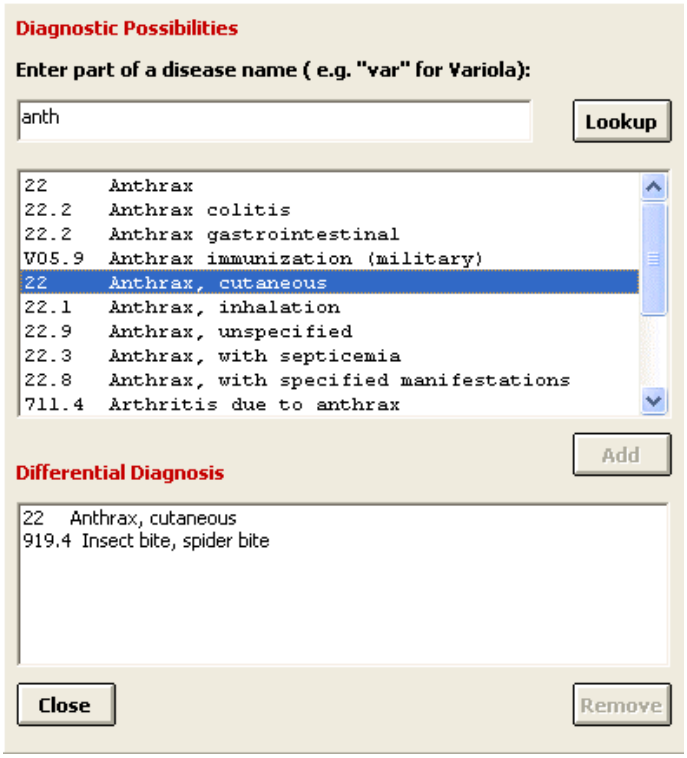
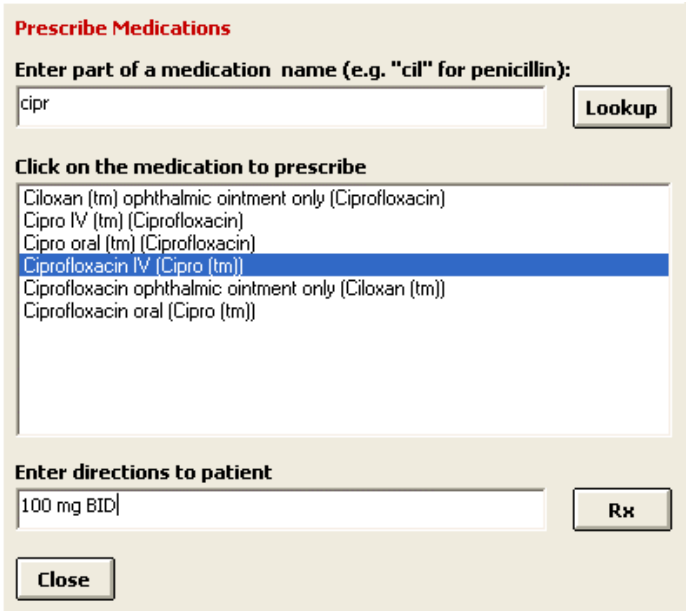


Exhibit 3.4. Plan Segment: Medication Prescription



VIRTUAL SIMULATED PATIENT

PATIENT VISUALIZATION

In real life, patients may present at different stages of disease with a chief complaint, vital signs, and behavioral clues such as coughing, hyperventilation, and sneezing. Patients may also present with lesions, rashes, skin color, and regional skin features that are characteristic of a particular disease or stage in the progression of a disease. For example, smallpox presents with lesions on the trunk that spread outward over the head and extremities. In contrast, the characteristic rash of Rocky Mountain spotted fever starts on the extremities and migrates centrally.

In previous work, RTI developed unanimated trauma patients with visual characteristics of various injuries (Kizakevich et al., 1998; Bauer et al., 1999) and animated medical patients with facial expression, speech-related lip movements, and a few gestures (Hubal et al., 2000). To enhance the realism of the simulation and provide additional diagnostic cues, we integrated these technologies and developed a new technology for visualization of animated 3-D characters as virtual patients.

This new technology, called responsive virtual human technology (RVHT), was developed using the combined resources of this project, related projects on chemical casualty simulation, trauma patient simulation, human simulation, and several RTI internal research and development projects. By combining resources and considering a range of issues in virtual human simulation broader than would arise in individual projects and their specific requirements, we were able to achieve a generalized solution that will support virtual patients with a variety of medical, trauma, and behavioral characteristics.

The principal human simulation technologies and their application to the simulated bioterrorism patient are described below.

Swappable Heads and Skin Textures

Using new technology for human modeling from the entertainment industry, RTI is constructing a library of virtual humans to include men and women of various ages, ranging from children to geriatric adults. Facial features and skin tone characteristics of various ethnic and racial groups can be readily incorporated to mimic the diversity of humanity. Once a 3-D body model is constructed, a “skin texture” is applied and a “head” is attached. For people of various ethnicities with similar skin tones, a new head with appropriate facial features may be applied to an existing body, saving weeks of development over constructing a model from scratch.

Texture-swapping technology can replace skin images with alternate skin images depicting lesions, rashes, burns, abrasions, and cyanosis in extremities. Skin textures are applied to a body model at the start of each case presentation, so progression of a disease (e.g., a rash) across the body surface is easily demonstrated by applying a different set of

textures for each patient encounter. Dynamic skin textures can be used to represent real-time visual phenomena such as bleeding and muscle fasciculation.

For the present study, we constructed an adult male with textures representing three levels of cutaneous anthrax lesions and three levels of Rocky Mountain spotted fever. We attempted to represent smallpox as well, but we could not effectively represent the bumpy characteristics of the pox with suitable quality using texture graphics alone. We identified a method to produce realistic smallpox lesions but deferred development because of the necessary level of effort and insufficient resources to implement the method in the present project.

Toward the end of the project we adapted one of our child models (i.e., a 12-year old Hispanic boy) for use in the VirtualClinic and gave him a case of cutaneous anthrax as well. We did this simply as a test of database structures and simulator presentation for alternative patient models. The test was successful in that we demonstrated our capability to provide multiple patient representations in the VirtualClinic simulator; however, because no clinical data on these particular diseases were available for a patient with these age or other characteristics, we subsequently removed him from the database.

Body Animation

RTI's virtual humans are animated to depict various lifelike gestures and behaviors related to disease and injury. These animations add a more real-life personality to the virtual patient, enabling a more engaging clinical simulation. These animations also give users a sense of the medically relevant body language; this in term permits clinicians to assess the level of consciousness (in trauma cases) and to determine visually if the patient is vomiting, convulsing, shaking, or exhibiting other generalized body reactions. The user can also quickly see if a conscious character demonstrates guarding behavior, such as holding his head or abdomen.

To prevent animation "collisions," the body is partitioned into regional segments including the head, upper body (trunk and arms), and lower body (pelvic floor and legs). Each section can be independently animated, yet animation can occur at the same time across segments. For example, a patient can sit on a bed, tilt his head back, raise his hand to cover his face, move his head forward, and sneeze as an integrated, smooth motion.

The virtual humans can display chest motion associated with breathing. The virtual breathing can show normal, slow, and labored breathing rates. We did not employ this particular feature in the current project because the bioterrorism patient development was "frozen" for usability testing before we had chest motion fully available; however, breathing can readily be incorporated in future versions.

Animations are intended to be medically relevant, not simply gratuitous. Merely animating a virtual character can impart the wrong message. For example, in our testing, several reviewers observing a virtual patient that had been animated to display an idle motion thought that the patient had a nervous tic or Huntington's chorea. We have learned to be careful with this feature.

Facial Animation

Facial motions include expression and speaking. Through the use of 3-D morph technology, we can now display a wider range of facial expressions than had been possible with our earlier virtual patients. Like general body motions, facial expressions can help depict level of consciousness, but they can also depict pain and emotion (e.g., fright, anger). Eye animation includes blink rate, pupil size and response, and eyeball rotation. Lip shape changes dynamically as the character speaks and corresponds to the appropriate phoneme. In this project, we employed only the speech-related lip shape animations.

PATIENT SIMULATION ARCHITECTURE

Databases

RTI's simulation architecture comprises nine databases, each with a set of data tables holding various aspects of the visual, physiological, educational, and administrative information necessary for virtual patient simulation, medical setting simulation, and learning management. The nine databases and their functional content are as follows:

- ***Administration:*** Record-keeping functions, including all clinician-patient interactions;
- ***Behavior:*** Available verbal and animated patient behaviors, including verbal responses to medical history queries;
- ***Body:*** Patient properties, including 3-D virtual models, physiological data, etc.;
- ***Clothing:*** Available clothing, and clothing relationships to underlying 3-D models;
- ***Language:*** Not used in bioterrorism simulator;
- ***Learning:*** Learning management, including lessons, knowledge domains, and skill domains;
- ***Reference:*** Tables of stable information, such as sex (male or female), ethnicity, and age groups, and data source citations;
- ***Simulation:*** Scenario definitions, including 3-D models, patient assignments, and similar factors; and
- ***Viewer:*** Not used in bioterrorism simulator.

Patient simulations can represent both static and dynamic patient conditions – that is, patient information that is relatively stable or unstable during a given patient encounter. Static patient data, such as history of present illness or blood type, are held in a database comprising a set of patient objects (e.g., social history, blood, lungs) and object properties (occupation, blood type, lung sound) that represent the complete patient state at a specific instant in time. Dynamic patient data, generated via a set of real-time physiological and pharmacokinetic models, can change rapidly based on the present injury (e.g., gun shot), pathological events (e.g., airway obstruction), and interventions (e.g., intravenous fluid administration) (Kizakevich et al., 1988).

Whenever an analytical model is unavailable for changing patient data, we can use the static database component to capture multiple patient states over a period of time. This approach provides an illusion of a dynamic analytical data model. For this project, we assumed that the bioterrorism patient simulations were static during the time frame of the primary care office visit; for that reason, we depended largely on the static database component of the simulator.

Data Tables

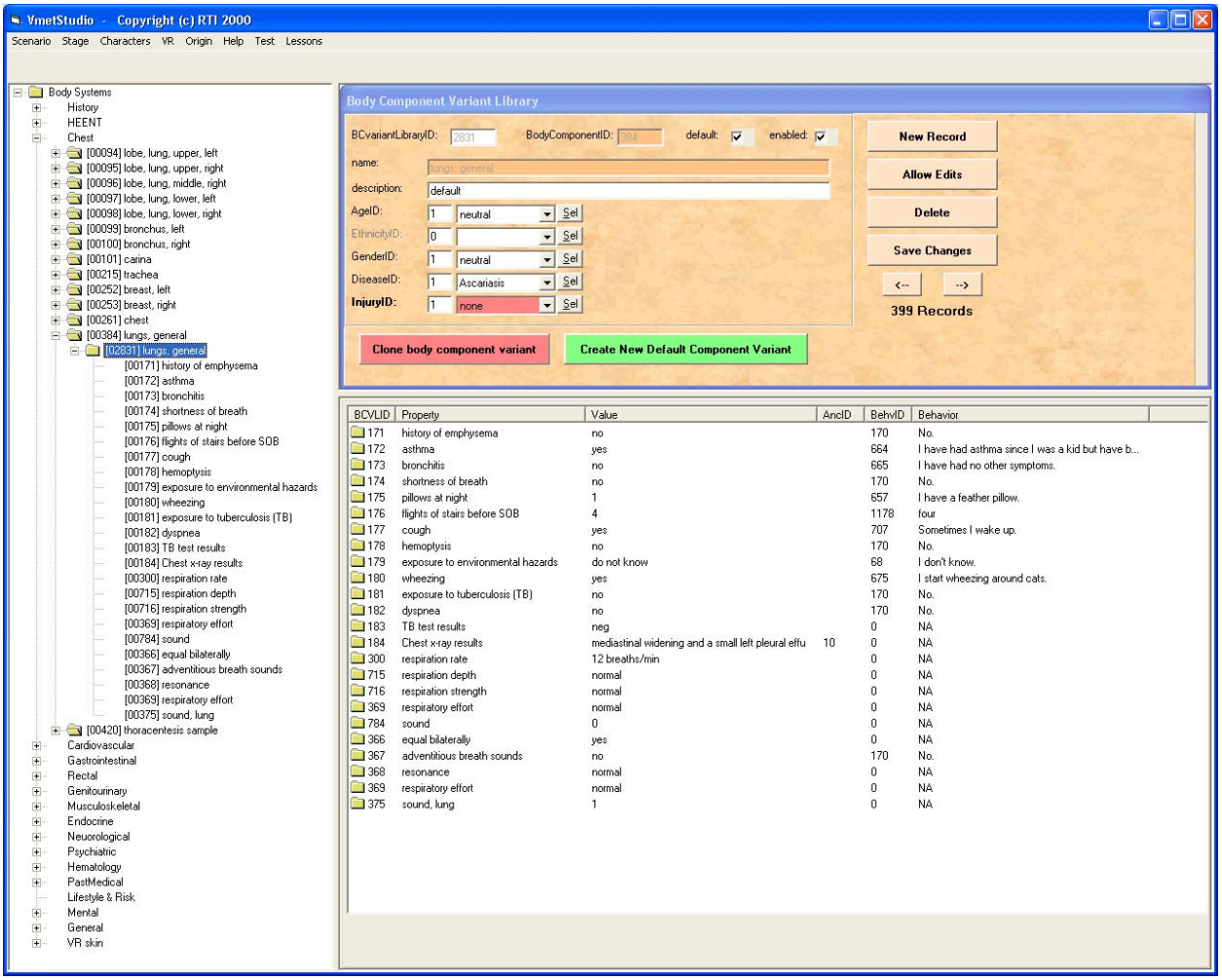
The principal data tables that define patient state information for virtual simulated patients are the Body System, Body Component (BC), and Body Component Properties (BCP). These tables provide structure and organization for physiological systems (e.g., chest) and medical and social histories (e.g., childhood diseases). Data for a given patient in a given scenario are saved in an associated table. For example, Exhibit 3.5 illustrates the properties of the lung for a simulated patient with inhalation anthrax.

The aggregate set of Body Component Property Values (BCPV) represents a snapshot of the patient's medical state at a certain time. Developers of simulated patients can assume property values by using published normal data, calculating values from published mean data and expected variances or ranges, estimating values based on descriptive published data (i.e., elevated body temperature), or transferring them from actual patient medical records. Our database currently includes 842 data elements that together constitute each simulated patient case.

To ease the development of simulated patients and database entry of BCPV information, we devised a layering mechanism for building simulated patients. This building mechanism involves four layers, as follows:

- ***BC Property Template:*** Default responses for all patient queries and diagnostic data. For example, alcohol use = "unknown"; blood type = "undetermined." This layer provides a definitive response during patient simulation for data that are truly unknown or for property values that were missed during patient case development.
- ***BC Property Normal:*** Default responses for all patient queries and diagnostic data that represent a healthy patient. In particular, this layer ensures that normative laboratory values are available for all clinical laboratory tests.
- ***BC Property Social:*** Stock responses for social questions for a patient. A large fraction of the social history data does not affect the differential diagnosis of a given disease. By developing a series of stock responses for a variety of men, women, and children, we have a starting point for building complete histories. This feature saves time in building new patient histories and minimizes errors that might occur in reentering information.
- ***BC Property Pathology:*** New information for all patient queries and diagnostic data. Using published data or medical records for the BC Property Pathology layer, we can specify patient information for a particular state in the progression of a disease.

Exhibit 3.5. Hierarchical Data Structure of Body Systems, Components, and Component Properties



To build a new patient case, the developer starts with template data and overlays normal data for the patient's age and sex. Next, the developer selects an appropriate social data set and layers that over the base information. At that point, the developer constructs a pathological data table, and these pathological data are layered over the normal and social data to form a complete patient case. Each table has the same set of component properties fields, but higher layers do not necessarily have entries for all properties; many are left blank. The layering process simply replaces the appropriate data for those component properties where definitive data are available.

The result is a complete new instance of a patient case that can be printed and reviewed before using it as a patient case scenario. The layering method ensures that a valid, reasonable response is available for all patient queries and diagnostic data.

PATIENT SCENARIOS AND LEARNING MANAGEMENT

PATIENT SCENARIOS

Patient scenarios are organized in a two-way matrix: diseases and patients having each disease. When multiple scenarios are available for a given disease, each scenario may either be associated with a different patient or represent a progression of the disease in a single patient. In this project, for instance, cutaneous anthrax has three patient scenarios representing early, middle, and late stages of the disease in the same patient.

Each patient has an association with a specific disease; that is, we know the correct diagnosis for that patient and can assign him or her to the right disease group. Each scenario also has an association with a specific disease and a recommended diagnostic procedure for that disease. We call these procedures "diagnostic pearls." For example, the diagnostic pearls for cutaneous anthrax include asking the patient if he sustained a recent physical injury and whether the lesion is painful. Cutaneous anthrax is thought to be introduced at the site of a cut or abrasion and to produce a painless lesion (Swartz, 2001). Hence, these diagnostic pearls are helpful in the differential diagnosis of that disease.

LEARNING MANAGEMENT

VirtualClinic has three modes of operation: learning mode, practice mode, and challenge mode. In learning mode and practice mode, a disease of interest is selected, and then a patient case is selected from a list of available cases for that disease. In learning and practice modes, the user knows what the disease is before seeing the patient and is focusing on the clinical presentation to learn more about the disease. By contrast, in challenge mode, the *program* selects a patient case randomly from the set of available simulated patients. The clinician does not know who the patient is or what disease he or she may have. Because only a few 3-D human models are available, the same "person" may be presented at different times with different diseases, adding to the challenge of performing the diagnosis.

As mentioned above, each case scenario is associated with a specific disease and a recommended diagnostic procedure for that disease. In learning mode, the user is guided step by step through the SOAP protocol and is presented with diagnostic pearls for the associated disease. These remind the clinician of medical and social history, physical examination, and diagnostic tests that would aid in forming a correct diagnosis for that disease. The diagnostic pearls also remind the clinician of differential diagnoses and plans for treatment, follow-up, patient education, and notification of public health and law enforcement officials.

We organize the diagnostic pearls as a list of tasks according to the SOAP methodology. Each task has a set of actions to be concluded via the user interface (e.g., inquire whether the lesion is painful). By following the sequence of tasks and task actions, the clinician can complete a patient encounter and correctly diagnose the disease (or at least make a reasonable hypothesis based on differential diagnoses). For example, one step in the process is prescribing a medication. In learning mode, the user is prompted with actions to be performed (Exhibit 3.6).

For the practice modes, we developed a methodology that provides in-progress and after-action reviews to reinforce the diagnostic pearls and provide feedback. The diagnostic pearls are presented in a hierarchical structure listing tasks and task actions in a tree structure. Initially, all tasks and task actions are shown in red text. As tasks and task actions are completed, they are individually redrawn in green text (Exhibit 3.7). During a patient encounter, the clinician may select the EXIT button, then select the IN PROGRESS REVIEW button to display the task tree and observe progress toward completing all interactions. In challenge mode, the in-progress option is unavailable.

In all three operational modes (i.e., learning, practice, and challenge), an after-action review form is available to show completed interactions as compared with the diagnostic pearl standard for the patient's assigned disease. The after-action review is displayed using the red/green format described above.

Exhibit 3.6. Learning Mode Presentation of Pharmacotherapy Actions for Cutaneous Anthrax

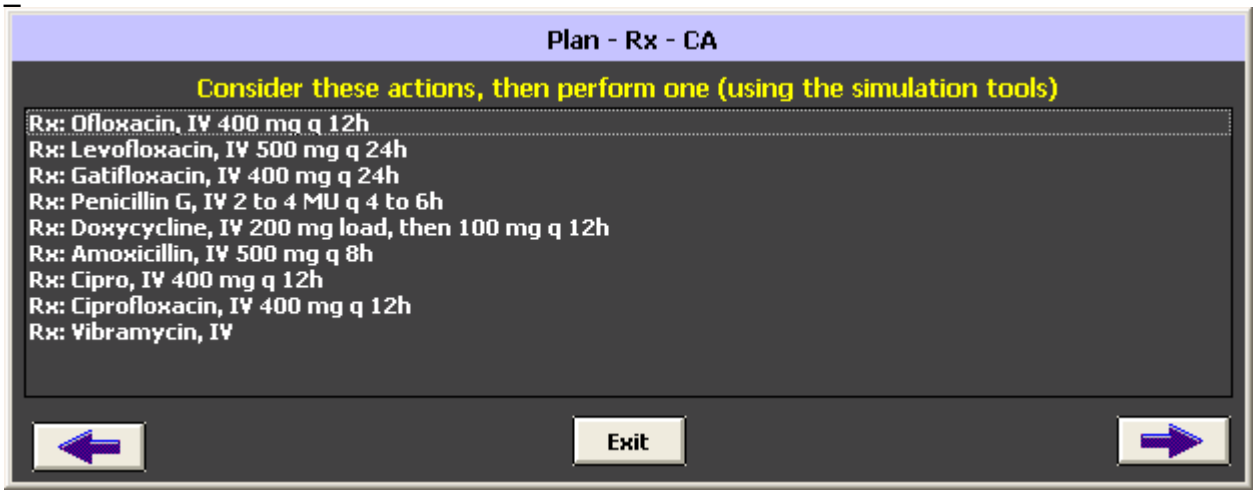
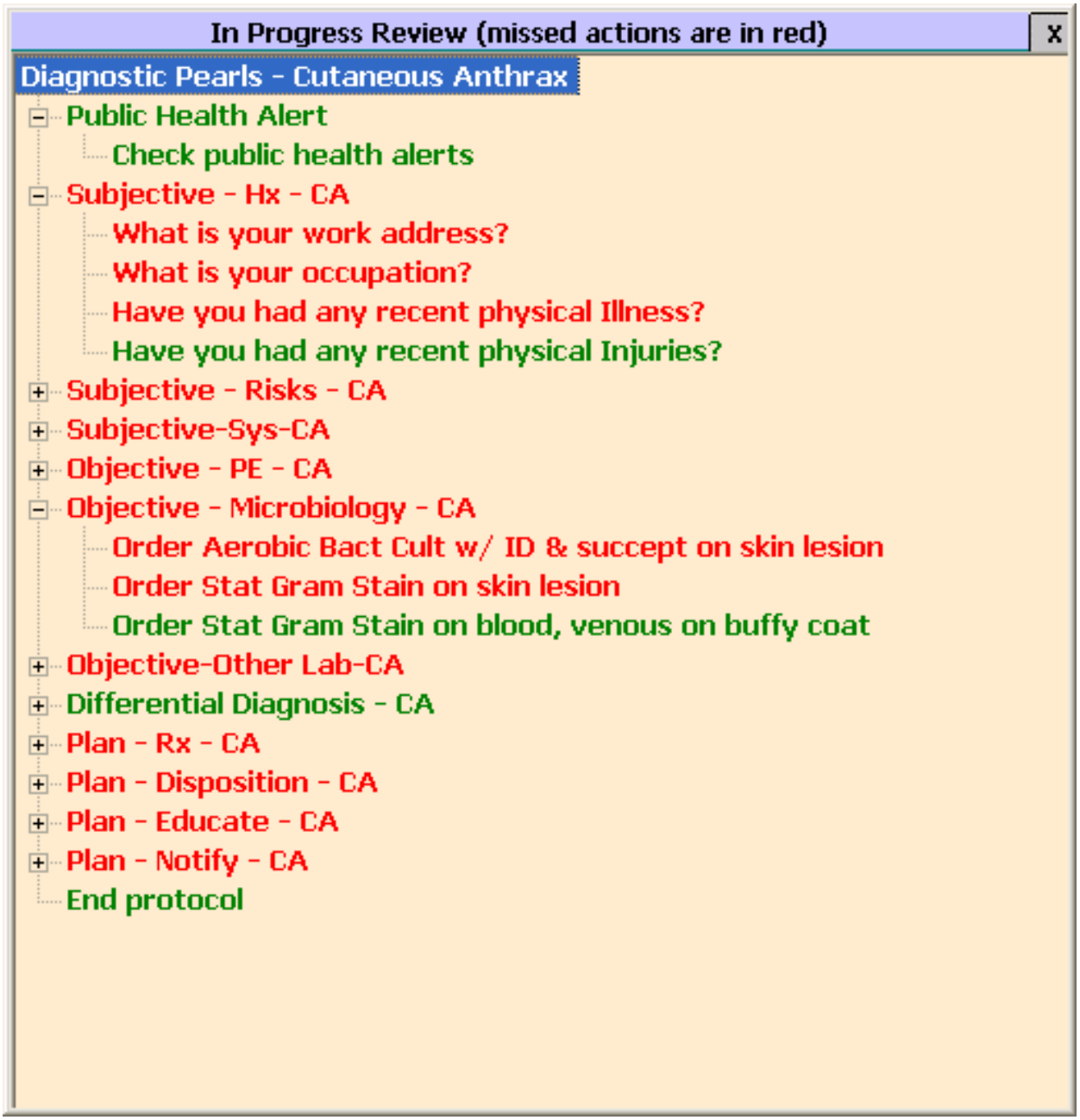


Exhibit 3.7. In Progress Review for Diagnostic Pearls for Cutaneous Anthrax



Chapter 4. Dissemination Plan

INTRODUCTION

As discussed in Chapter 2, we developed two prototype approaches for training clinicians to recognize and respond appropriately to a possible bioterrorism attack. One approach involved developing and placing learning materials on a website that is publicly accessible (http//:bt.rti.org). The second involved creating simulated patients building on technologies previously developed by RTI (see Chapter 3 for additional technical details). We modified the simulation software to create a "VirtualClinic" software program for this project; the goal is to create unique patients in the clinic who are affected with biologic agents or infectious diseases or who have psychologically manifested symptoms. As noted earlier, the simulator might also be seen as a mechanism by which to evaluate the effectiveness of educational materials on the website or within the simulator itself (or, possibly, materials available through other sources).

One activity in this project was to disseminate these materials in ways that would provide us feedback and suggestions about how to improve or update them. Of particular interest, of course, was dissemination to representatives of our target audience, primary care clinicians (here with special emphasis on family practice physicians). We briefly describe these efforts below, first for the web-based educational tool and then for the simulated patient software. Rounds of usability assessment of these materials are more fully documented in Chapter 5 on evaluation.

WEB-BASED LEARNING MATERIALS

We originally planned several ways to test dissemination of the web-based learning materials, essentially through traditional means (letter, email) and through a website link to/from a professional society's website. These steps were additional to simply placing the website on RTI's main website, alerting selected RTI staff and inviting detailed clinical review from an RTI physician, alerting and inviting comments from the Technical Advisory Committee [TAC]), alerting staff of the Agency of Healthcare Research and Quality (AHRQ) to its existence, and similar steps, which we did not regard as any "formal" test of dissemination.

To put the more external dissemination effort into effect, we explored the idea of purchasing the mailing lists (both US Postal Service addresses and e-mail addresses) from professional medical societies, specifically with the North Carolina Academy of Family Physicians (NCAFP) as a regional test and, potentially, for a subsample of members of the American Medical Association (AMA). Unfortunately, several factors precluded us from carrying out this element of dissemination: delays in updating the website, a lapse in acquiring the lists on the part of the evaluation subcontractor, and the time it would have taken to obtain approvals from the NCAFP Board. We had also intended to have the NCAFP include a link on its web page to our website. The NCAFP was willing to place a link on its website for its members to

view, although doing so required an Executive Committee review of our materials. In the end, the timing was such that this proved impossible, and we did not create the linkage on the NCAFP website. Exhibit 4.1 displays the announcement that the research team developed to announce the website to the various professional societies and organizations (e.g., American Academy of Family Physicians, American College of Physicians/American Society of Internal Medicine, Society of General Internal Medicine, American Academy of Environmental Medicine, etc.)

Exhibit 4.1. Web Announcement

To meet the needs of primary care clinicians for concise information on bioterrorism agents and emerging diseases, RTI International* has created an online training and reference resource at http://bt.rti.org/. Clinicians can review the history of biologic warfare and the clinical characteristics of agents such as anthrax, smallpox, and tularemia.

Created with funding from the Agency for Healthcare Research and Quality of the US Department of Health and Human Services, and in collaboration with the UNC School of Public Health, the website will be maintained to ensure that it serves as a valuable resource for busy health care practitioners. RTI invites you to visit the website and welcomes your feedback on the layout and usability of the learning materials. For questions or comments, contact kiz@rti.org.

RTI International is an independent organization dedicated to conducting innovative, multidisciplinary research that improves the human condition. RTI is active in health and pharmaceuticals, environmental research, surveys and statistics, advanced technology, education and training, and economic and social development. Universities in North Carolina founded RTI in 1958 as the first scientific organization in and centerpiece of the Research Triangle Park.

**RTI International is a trade name of the Research Triangle Institute*

The website had been designed to incorporate a short survey to test customer satisfaction with the website and learning materials presented. However, requirements by the executive Office of Management and Budget for websites and dissemination of information sponsored by government agencies stipulated that before the survey could be placed on the web and used to evaluate dissemination practices, an extensive review process had to be done by the Agency. Because of the timeliness issues given these more restrictive OMB requirements, we abandoned the idea of the satisfaction survey and removed the user satisfaction form from the website. Rather, we decided to rely on the usability test results using a small sample of clinicians.

VIRTUAL SIMULATED PATIENT

Because of the logistics of a computer-based software program, widespread "dissemination" of the simulation program is not feasible until formal software testing is completed using a variety of computers, operating systems, and 3-D video graphics adapters.

Nonetheless, for evaluation and testing purposes, we needed to make it available to physicians outside RTI, the TAC, and the University of North Carolina at Chapel Hill (UNC). Several TAC members suggested that a good way to do that might be a "demonstration" at a professional meeting to investigate the level of the interest in our learning materials *per se* (both the website and the simulated patient software) and the possible interest in having such educational tools available on laptops.

To pursue this idea, we took advantage of a professional conference sponsored by the Public Health Leadership Institute (School of Public Health) in the spring of 2002. This timing was dictated largely by the final completion of the updating of the relevant databases for the simulated patient and extensive revising of the software; these steps were done pursuant to TAC reviews earlier in the winter of 2002.

The topic of the UNC conference was preparing for, responding to, and recovering from a bioterrorist disaster. On the one hand, we thought that this group might be more interested (than the average attendee at a professional conference) in these educational materials and their electronic availability; on the other hand, we were concerned that this was such a knowledgeable group that they would be less interested. Unfortunately, the one-day conference was not well attended, and those who did attend were primarily public health professionals, not clinicians.

Exhibitors were located in a conference room near where the seminars and lectures were being held. The conference schedule was very full, so little time was available for looking at the information at the exhibit room. Also, attendance was down by more than 25 percent because of a state budget shortfall. Six people viewed the cutaneous anthrax case on the virtual patient simulator (a doctoral candidate in epidemiology, a National Health and Nutrition Examination Survey [NHANES] manager, a state public health official, the Dean of the School of Public Health, a public health researcher, and a practicing physician). In short, the simulator was observed by only a handful of physicians at this event, and those encounters were too informal to draw firm conclusions.

Nevertheless, reactions from these users were informative about elements of the program that were relatively successful (or not). In particular, they immediately zoomed in on the wound on the patient's left arm for closer inspection as their first action. Then they wandered through the different drop-down boxes to see what was there. No one went through a thorough diagnosis of the patient, although each person expressed enthusiasm about the possibilities of this technology for public health training in the future.

Generally, we thought that the attendees and users at the conference were interested in the program but not overwhelmingly so. In our judgment, this reaction suggested that these types of materials might be of greater interest among less-knowledgeable physicians (that is, physicians who are not so involved directly with bioterrorism issues that they would take a day to attend a special bioterrorism conference). We also concluded that any further testing ought indeed to be done among physicians who are in private (or academic, faculty) practice and not otherwise deeply engaged in bioterrorism matters.

For further dissemination of the VirtualClinic to a wide audience, we recommend the following steps and options:

- Implement the technical recommendations listed in Chapter 6.

- Perform software function testing to assure a commercial-grade quality software product.
- Provide a partially functional web-based version (without animation) for free access over the Internet.
- Provide a fully-functional PC-based version (with animation and spoken-language dialogue) for purchase or free distribution (i.e., user or government-sponsored technical support).

Chapter 5. Evaluation

INTRODUCTION

This chapter describes the set of evaluation activities we undertook for the two educational tools as they evolved during the project. Various tasks were conducted by RTI staff or by staff of our subcontractors, the University of North Carolina at Chapel Hill (UNC) and The MayaTech Corporation. We focus chiefly on components of either the website or the virtual simulated patient software relating to content, logic, navigation, timeliness, overall usability, and potential effectiveness as an educational tool.

Evaluation is a well understood concept with decades of conceptual and empirical history. The state of the art of evaluating *training for rare events,* however, is not well developed. When we started this project, what other researchers engaged in various bioterrorism training activities were doing with respect to either process or outcome evaluation has not been refined or documented sufficiently to inform this evaluation of clinical training, with one exception relating to evaluation of dissemination of training materials. Similarly, evaluations of other potentially relevant areas (e.g., training for detecting or responding to rare or unexpected disasters or terrorist events, and clarifying the impacts of these on health care systems) were insufficiently documented to be directly useful or, indeed, did not exist at all. We did not, however, perceive this gap in useful models to be a major problem for this beginning effort for the Agency for Healthcare Research and Quality (AHRQ). The reason is that, largely, we developed an evaluation strategy that targeted the specific objectives of the plan for creating the two educational tools (website; virtual reality simulation).

As stated in our proposal, we believed that the virtual simulated patient would present development challenges, even though the prototype would be built on prior RTI simulation software development and platforms. Consequently, given the available resources, we felt that the primary effort should be in the development phase; clearly, any subsequent evaluation could not be effective without quality software development. We basically restricted the evaluations to prototype usability tests, using a small number of clinical evaluators, and focused on issues regarding software use, clinical functionality, and user satisfaction rather than formally evaluating training efficacy. This methodology is consistent with our other work in training systems development, where multiple iterations on the simulation implementation and testing must be completed before training software is released for formal evaluation (Weaver et al., 2002).

Generally, information regarding the use of evaluation methods to assess simulations available in the public domain was scarce; what was available proved not to be particularly useful for the purposes of our study. Therefore, we built on the evaluation methods RTI has used to assess the emergency medical services simulation, which provides realistic practice for trauma care providers (Kizakevich et al., 2002). This decision informed the design of the bioterrorism clinical training materials and software, particularly with regard to the simulation aspects, and the development of data collection protocols.

An evaluation report by the UNC School of Public Health was relevant and informative. It concerned the School's inaugural distance-learning-based broadcast entitled "Bioterrorism: Implications for Public Health," which dealt with both dissemination evaluation and web-based distance learning training. The report singled out the following domains as relevant to an evaluation of this type: who was reached, their satisfaction with the program, the success of objectives regarding knowledge attainment, confidence in learning, behavioral intentions, perceived efficacy and usefulness, perceived qualifications of presenters or trainers, and confidence in being able to assist in a bioterrorism disaster after training.

The level of resources and time available for evaluation under this project required a highly efficient and limited approach. Our expectation was that if the prototypes developed and tested under this project showed promise, as evidenced by a limited assessment, then a more extensive evaluation could take place in the future. Such a broader evaluation might yield information to encourage the diffusion and adoption of these training modules nationwide, and it might also afford the opportunity to carry out a more thorough assessment of their capabilities and evaluate a national dissemination plan.

STRATEGY FOR EVALUATION

PRELIMINARY PLANNING

During the workshop held for the Technical Advisory Committee (TAC) in January 2001, we defined provisional evaluation plans (see Chapter 2); these preliminary plans led us to create an evaluation protocol during the system-development phase of the project. We used the evaluative data obtained during development of the educational materials to begin with to inform the design of the general assessment of the educational materials; the longer-range goal was to use the patient simulation as the final cog in the evaluation.

Staff of The MayaTech Corporation were responsible for the planning and implementing of much of the product evaluation. In considering what approaches to evaluation the project would adopt or adapt, MayaTech staff undertook several tasks, starting before the TAC meeting. First, they reviewed evaluation methods used in other industries regarding educational materials and the use of simulations for detection and response to rare events potentially relevant to bioterrorism. By and large, their search did not unearth much useful guidance, as reported at the TAC workshop. Second, late in 2000, one staff member together with RTI project leaders attended a conference of all the organizations conducting projects in the area of bioterrorism with AHRQ funding; several of these projects were directly relevant to clinician training, and all were at least indirectly relevant.

PROJECT EVALUATION PLAN OVERVIEW

We developed a provisional evaluation plan with three components: (1) educational training materials in terms of the *a priori* learning objectives (Chapter 2); (2) modes of training and the virtual simulated patient; and (3) dissemination, with a pilot field test of the two prototypes (web-based and simulator-based). The educational tools came in five modules: the

two on bioterrorism (history of events from the 14th century to the present; clinical facts), the two on emerging infectious diseases (history of outbreaks over the past 25 years, clinical facts), and one constituting the VR-based patient simulation. The ultimate goals of the project dictated, in the end, that we focus on the content and usability of the Internet-based materials and the virtual simulated patients; the remainder of this chapter reports on those evaluations.

Educational Materials for Website

The learning objectives were assessed in terms of four types of variables: knowledge, attitudes, skills, and behavioral intentions, with the emphasis being on knowledge and attitudes measures. As we developed and revised these modules, we obtained evaluative feedback from reviewers and volunteers who "tried them out" at various stages of development. Clinicians and infectious disease specialists were given access to both the web-based training materials and the VR-based simulated patient for practice or assessment; other physicians were given access to web-based training alone.

Virtual Simulated Patient

The evaluation of the modes of training and the simulation involved two components: (1) software validation and (2) user testing. For software validation, we performed exercises on all aspects of the educational materials developed using IMI and desktop-simulated patients. We assessed materials to determine compliance with our previously developed Software Requirements Document, with results going to the lead software developer for corrective action. Part of the software development included recording decisions made by participants as they went through Module 5, a subset of which were identified for electronic extraction and analysis. That is, we assessed whether decisions made and actions taken by the trainee were appropriate or inappropriate.

EARLY PRETESTS

We took several iterative steps to assess the quality and usefulness of both the website and simulated patient developed in this project. These pretests were integral elements of our focus on satisfactory development of these learning tools. In the first two preliminary evaluations of the web-based learning materials and VirtualClinic simulator, we used a small group of medical practitioners for the first round and a group of infectious disease experts for the second round. After each review, we made important modifications to these educational tools; Particularly for the simulated patient tool, we made significant changes to both the patient simulator software and its underlying medical databases; the main issue was to make the product align better with the diagnostic processes of primary care practitioners, especially when confronted with emergency or unfamiliar problems. These pretests were crucial steps in the development of the final versions of the website and patient simulator that were more formally evaluated (discussed later in this chapter).

FIRST PRACTITIONER GROUP

The medical practitioner group consisted of two members of the Technical Advisory Committee and an RTI consultant on issues relating to training clinicians and others about terrorism (especially biological and chemical threats). One was a practicing family physician who has been actively involved in evaluating clinical skills for more than 15 years. He has served on task forces and special committees to assess clinical competencies, developed standardized patient cases and checklists for evaluating clinical skills, and been involved in the development of video presentations on patient simulations. The second physician, with more than 30 years in emergency medical service delivery, has served as a director of disaster medical care in a state health department. The third was a retired U.S. Army physician with more than 10 years experience in developing training materials and presenting courses for diagnosing and treating chemical and biological warfare casualties.

In late 2001, we asked these three experts to comment on the website as it existed at that time and to review the VirtualClinic simulator approach. We placed particular emphasis on relevance to practicing clinicians (i.e., not on technical software or programming matters); especially for the simulated patient, the focus was geared toward making the software appropriate for educational applications and ensuring that it was compatible with the way that clinicians think and practice medicine.

Website Review. This first group of reviewers approved the visual presentation, layout, and color scheme. They recommended that that we keep updating the anthrax information as it appeared in the published literature or on authoritative websites. Because of the amount of new information and the rapidity with which it was being generated late last year and into the present, these experts encouraged us to add the date of most recent revisions or date of certain data and to include the references to specific data, such as incubation period. We endeavored to make all these modifications to the website in the ensuing months. They also suggested that we delete the spore count information, because it is not integral to diagnosing a patient infected with a bioterrorism agent and so was unnecessary given our intent for the website to be concise and easy for a busy practicing doctor to find quickly all necessary but sufficient information.

Virtual Simulated Patient. These experts also contributed many helpful suggestions on how to make the simulated patient more “user friendly” to clinicians, especially in the patient encounter schema (recalling that our approach follows the SOAP [Subjective, Objective, Assessment, and Plan] model for primary care) and the structure of the patient presentation information. For example, we initially placed prescribing medications in the assessment step; they strongly advised moving it to the plan component. They also recommended several technical changes to the structure of the medical database presentation, such as in the patient history and clinical laboratory options. Because of the inhalation and cutaneous anthrax cases occurring at that time, the first group of reviewers recommended that we include in the patient history query section items that provided information pertinent to diagnosing an anthrax case. These questions included, in particular, (a) determining whether the patient had traveled in the past 30 to 90 days, and if so, where the patient traveled to, what prophylaxis measures were undertaken prior to traveling, (b) whether the patient had been on a farm or ranch in the past 30 to 90 days, or (c) whether the patient had received or handled furs in the previous three months. We incorporated all of these questions into the program database. Finally, they pointed us to better sources for some of the medical database content items on which the simulator must rely. For instance, a more complete and more recent listing of antibiotics was available that would also allow the simulator to provide incorrect choices while in the testing mode.

Based on the recommendations of this first pretest group, we modified the virtual simulated patient software and/or databases to make the changes mentioned above as well as the following expansions:

- Added public health directives, such as a "blast fax" to the current events window, including the location and time of the event;
- Added the identified differential diagnoses to the Medical Record window;
- Replaced the drop-down menu with a text-based search engine for identifying potential differential diagnoses (i.e., enabled users to employ such an engine for diagnostic hypotheses);
- Incorporated more close-up camera angles to visualize 3-D lesions;
- Made it easier for the clinician-user to find the computed tomography scan and x-ray from the clinical laboratory options, especially because these data form one of the determining factors in identifying inhalation anthrax;
- Added the option of sending cultures to either a city or state laboratory; physicians should not send anthrax cultures to a hospital laboratory (although we left this choice as an incorrect option in the teaching component);
- Provided a selection list of clinician specialties for referrals;
- Added text-based search engine to the medication (hospital formulary) lists; and
- Added a way to employ guidelines ("diagnostic pearls") for anthrax cases.

SECOND PRACTITIONER GROUP

The second group comprised two infectious disease experts from the TAC; they met with the project team in early 2002 to review the VirtualClinic simulator and to provide comments on the clinical content in both it and the website. One directs a state public health laboratory (and was a TAC member). She specifically reviewed elements in the clinical laboratory data that are part of each patient data set, identified items to be removed, and recommended items to be added. She also reviewed the organizational structure of the clinical data and the menu systems for requesting laboratory measurements. We also asked a physician with subspecialty training in infectious disease to review our overall approach to patient representation, history and physical examination menus, and the design of clinical laboratory data. This physician, also a TAC member, is a tenured professor at a university medical school and is involved in educating medical students about infectious diseases. He helped identify which laboratory tests would be associated with various fluid and tissue samples, especially for Gram stain assays.

Website Review. By and large, these two specialists had little extra to suggest about the website beyond what our initial group had advised.

Virtual Simulated Patient. As with the first pretest group, these specialists were generally impressed with the capabilities of the virtual simulator and its potential uses in medical training. On the basis of their recommendations for revisions, we made the following key modifications (and several other minor ones):

- Made sure that we do not refer to the condition of inhalation anthrax as pulmonary or respiratory anthrax; the reason is that the latter two designations are misnomers because lymphadenitis does not take place in the lungs;
- Added codes for laboratory findings into the database;
- Allowed for a Gram stain from Buffy Coat to be done by the primary care practitioner;
- Added “pearls of wisdom”; and
- Allow for the term “disposition” to be added to the patient management section.

Summary Reactions

Overall, the reviewers were enthusiastic about the potential of the simulator, for a wide range of medical applications, not just for bioterrorism education and testing. In their view, the obvious advantage to this software, in comparison to other hard-copy clinician education exercises, is the 3-D graphic capability in which physicians or other clinicians can inspect - in very close detail, if desired - the characteristics of the patient’s presenting problem, such as a skin lesion in a case of cutaneous anthrax. Obviously, this cannot be done with standardized patients where actors are used or with text articles with two-dimensional photographs. Moreover, because of the rarity of bioterrorist events, even preparing a video of a patient with cutaneous anthrax that offered the same investigational qualities that the virtual patient simulator does would be difficult.

Post Pretest Steps

Following these two reviews, we concentrated on making all these revisions to the underlying databases and the simulation software itself. For example, we developed "typical" patterns "by day" for databases for temperature, heart rates, blood pressures, respiratory rates (as suggested by the second review group). When the data were published on the first 10 inhalation anthrax cases, we added all of the signs and symptoms as they developed across time to the medical database. Finally, we developed a new 3-D simulated patient with a significantly improved cutaneous anthrax model that featured higher wound resolution.

The next sections of this chapter describe the more formal evaluations of the website and the virtual simulated patient program, respectively. These took place only after we had made most (or all) of the modifications recommended in the pretest assessments. As with the early pretest assessments, we restricted these evaluation steps to nine or fewer individuals, so as not to violate regulations for federal contracts concerning the need to obtain permission from the executive Office of Management and Budget (OMB) to collect the same information from 10 or more individuals.

WEBSITE EVALUATION

Web-based learning and training programs are now being used in a variety of settings as a tool to deliver information to persons who can learn in their own time and space. The purpose of the website materials for this project was to provide primary care providers with a historical

overview on previous incidents of bioterrorism and biowarfare, basic clinical information on several potential agents that could be used in an act of bioterrorism, and practical training in the areas of bioterrorism and rare or emerging infections. The TAC recommended that the site information be presented in a concise, easy-to-read format for busy practicing clinicians.

Evaluation of websites and on-line education and training often uses a variety of methods; these include direct observation, on-line feedback, paper-pencil questionnaires, focus groups, and interviews. Evaluations of virtual and web-based training often concentrate on the content material and user reactions and responses to the site. This report focuses on the content material and users' reactions and recommendations for the site.

METHODS

We asked five primary care physicians, identified from a variety of sources, to complete both a pre- and posttest after thoroughly reviewing the website. All participants could complete the process at their home or office. They were not required to go to a specific site.

We asked all participants to complete a pretest questionnaire that was e-mailed and/or faxed to them. Once they completed the pretest, they were given the website address and additional information to completing the process. They were asked to go through the website and pay special attention to its anthrax and smallpox pages. The posttest was sent to the participants once they had completed the review of the website. Participants had the options of faxing or e-mailing the results of the posttest as well. Five clinicians completed the pretest; four submitted the posttest evaluation.

Pretest Questionnaire

The pretest questionnaire consisted of 25 questions (Appendix C). The questions included rating scales, checklist responses, and open-ended questions. The purpose of the pretest was to collect information about the participants and their experiences with computers and web-based learning methods. It also asked about their clinical experience and skill level with bioterrorism threats, focusing specifically on anthrax and smallpox.

Posttest Questionnaire

The posttest questionnaire consisted of 49 items in a mixed format, including checklists, ratings, and open-ended questions (Appendix C). The questions asked the participants to report on their experiences going through the website, about the usability and benefits of the site as a learning tool, about their feelings about the site, and for specific recommendations on improving the site.

PRETEST RESULTS

Professional Characteristics of the Participants

The five physicians (three men, two women) worked in a variety of settings; all provided direct patient care at some level. Two participants worked primarily as researchers in a federal public health agency; two were in full-time private practice, and one was in a hospital setting. The specialty areas of the participants included internal medicine, obstetrics/gynecology, pediatrics, anesthesiology, and preventive medicine.

Of these five participants, four reported that their preferred method for learning medical or clinical material was in a lecture format; engaging in hands-on activity was the second choice. Other preferences mentioned included reading journal articles, person-to-person interaction, and examining case studies. On-line training or simulation was not mentioned by any participant as a preferred method of learning, even though they all considered on-line training as a viable way to learn.

Computer and Web-based Experience

Their self-reported knowledge and skill with computers were in the average range; one participant reported being above average in both computer knowledge and skills with computers. Most were comfortable using the computer for training purposes (one somewhat uncomfortable; another above average).

Four of the five participants reported having little knowledge about on-line or web-based training. Two (our only reviewers who did not work full time in a primary care setting) had used an on-line or web-based training program.

When asked to describe their feelings about using interactive software for educational and training purposes, the most frequent responses were that it was valuable, innovative, and exciting. They also indicated that with proper training it would be an acceptable way to learn. One reported that it would depend on the topic and another simply did not prefer this method.

The majority of the respondents would be willing to use on-line or web-based training if the subject were one relevant to or of interest to them or if it dealt with an unfamiliar disease or emergency event. Only one respondent indicated a willingness to use this format to assist in clinical diagnosis. The majority of the participants said that three key factors for them to use web-based training were accessibility, content value, and interactivity. The majority also felt that such training was an integral part of clinical training. The two who disagreed with this indicated that it would be an integral part to the extent that it could simulate actual cases and only if it could be accessed in remote areas where resources and supervision are not readily available. In summary, websites are thought to be useful, particularly whenever case-based simulations are presented.

Bioterrorism Experience

All participants believed that a potential bioterrorism incident is of real and/or immediate concern. The range of knowledge about potential bioterrorism threats of these participants was quite broad, the majority reported having little or no knowledge. One reviewer reported having above-average knowledge of bioterrorism threats (because of a personal interest).

Regarding anthrax, everyone reported having some knowledge (with the same individual reporting above average knowledge on anthrax). The majority of participants reported having little skill in diagnosing anthrax.

Overall, the participants reported being knowledgeable about smallpox, with one respondent reported having little knowledge. Two reported having little skill in diagnosing smallpox; two reported average or higher-than-average skills.

POSTTEST RESULTS

The overall reaction to the site was positive: useful, a good tool for education, very informative, easy to read, and interesting. Ease of use, brevity, and accessibility were considered to be the best features of the site. The historical background of the different agents met with approval, as did the ability to “click” on the years to get more information. One participant expressed disappointment with the content of the site (as being too lean); as mentioned earlier, however, his desire for comprehensiveness conflicted with the TAC advice (which we had followed).

The worst feature of the site was reported to be brevity as well, because it made the site incomplete. Others reported that typeface used and the colors were not good features. The lack of real cases was also reported as a negative feature of the sites.

All four respondents reported being very or somewhat comfortable with using the site. The different components of the site were given average and above ratings, with ease of navigation and accessibility rated excellent by all. Comprehensiveness was the one component that the respondents found least favorable. One user commented on the need for a clinical simulation, and another commented on the lack of a stated goal for the website.

Communication

Participants thought that the purposes of the website were to provide quick access to important information on unusual and rare diseases, to permit mass education on bioterrorism threats, and to inform physicians about different threats and how to diagnose and treat resulting diseases. When asked about the goals and objectives of the site, which are stated on the biologic agents and emerging infectious disease pages, one reported that they were confusing but others found them satisfactory and very clear. One participant commented that an overall goal or aim should have been on the home page. The objectives under the section tabs were good, but an overall stated goal would have been more effective.

Participants thought the most apparent element of the website was to inform and, in effect, to serve as an educational tool. The tone was basically factual. The one participant who thought that some features were restrictive, inhibited, or unproductive specifically mentioned inability to apply the information to patient settings and the lack of cases to review. Respondents averaged about one hour to complete the review of the site.

Content

All participants reported that the content of the website flowed in a logical and consistent manner and that the information appeared to be current and up-to-date. They all preferred to view the disease as it would appear to the naked eye as in the smallpox visual rather than the microscopic view that in the anthrax graphic. All thought that the website content could be translated into practice.

One reviewer indicated, however, that some content areas could be discarded or were perhaps not applicable. As to the latter, this physician argued that the statements about smallpox should be revised to indicate that it had been eradicated from the human population. He also reacted to the statement that "smallpox vaccine is not available to the public," believing that it was misleading. He suggested that we should make clear that smallpox has been eradicated from the human population and that, for that reason, public health authorities (the World Health Organization, the US Centers for Disease Control and Prevention [CDC], and similar authorities) have determined that there is no longer a requirement for vaccination.

Accessibility

All participants reported high marks for accessibility. They thought the site and all the pages were easy to access and easy to download. They felt the same way about accessing topics of interest to them and ease of navigating through the screens. Two respondents used the links to access additional information: one accessed CDC pages for software simulations and patient precautions, and one accessed the UNC site. Both were generally satisfied with the extent of information on the subject. Reviewers who did not access any links indicated that they did not feel the need at this time but that being able to do so might be useful in the future.

Applicability and Usability

One participant (a federal agency researcher) was sure that the website was relevant to current work; two others were not sure. We saw similar uncertainty about whether respondents could use what was learned from the site in their daily work; one participant thought that to be the case. Only one felt that the site was adequate preparation for a case presenting in their offices today.

Half of the participants thought that the website can best be utilized as a stand-alone document, but its use as a precautionary tool and a supplemental resource was mentioned as well. Participants reported that the website offered a number of advantages over more traditional training methods. These advantages include good photographs, up-to-date information, immediate access, convenience, accessibility, and availability. They all thought it was compatible or very compatible with both traditional and non-traditional training modules.

As a tool for training and educating physicians, the website was seen as being most effective if used either in medical school or in residency training as well as for continuing medical education (CME) credits.

Knowledge

Interestingly, respondents reported that they learned most from the historical information. The majority indicated that their level of knowledge about potential bioterrorism threats increased somewhat after reviewing the site (more for anthrax than smallpox). Two reported that their diagnostic skills improved somewhat for both anthrax and smallpox.

Reviewer Recommendations

These physicians thought that, beyond other physicians, nurses would be the health professionals who most likely could benefit from this site. They specifically included public health nurses, emergency department nurses, and nurse practitioners. Other clinical fields mentioned as potential targets for the website learning were emergency medial services personnel and emergency medical technicians, laboratory workers, and certain other clinical specialists.

Our reviewers would use the website again because of the accessibility of the site. They mentioned revisiting it if the bioterrorism threat worsened and when clinical simulations were available on it.

Areas needing revisions at this stage included the following: (a) correct the small type face and use a larger font size; (b) modify the color for easier viewing; and (c) add bulleted notes with hyperlink text for more information. One participant recommended that we organize a “quick reference guide,” such as bulleted notes on key features of presentation and diagnosis, and update it regularly, stating that this component would be a positive factor accessing the site again. In addition, several topics, including organic pesticide poisoning, chemicals and toxins, pesticides, radiation, and sabotage of vaccine supplies, were mentioned as other bioterrorism threats that should be included in the clinical information section.

Finally, three participants indicated that they were willing to recommend this site to a colleague. The key factors in their willingness to do this were accessibility, ease of navigation, conciseness of information, regular updates, and (anticipated) availability of the clinical simulation.

Overall Comments and Ratings

Respondents rated the site good overall. They reported that the information as presented was useful especially to clinicians with little practical experience on the subject. One participant thought that it was a good avenue for education on the subject; another thought that it would have been excellent if the site had contained patient presentations such as clinical simulations. One participant indicated that for anyone who has done a bioterrorism course, the website falls short in two ways. First, information on the diagnosis of anthrax is lacking. Second, covering only inhalation anthrax, if the intent is to raise the index of suspicion of

possible events, is inadequate. The concern is that with the same source of exposure, different presentations may occur, and that in and of itself should raise a flag.

VIRTUAL SIMULATED PATIENT EVALUATION

The bioterrorism patient simulator is an innovative approach to provide clinicians with practice and an opportunity to evaluate their performance in diagnosing and treating emerging infections and potential incidences of bioterrorism. It is an interactive, virtual-reality-based simulation program that runs on personal computers and provides a simulation of a patient presenting in a primary care clinic. Although developed for rare events, the simulator may be easily adapted for presentation of more common diseases and injuries, such as asthma, diabetes, and carpal tunnel syndrome. We described the simulated patient and relevant software in Chapters 2 and 3. To reiterate: we developed the "background" medical databases for patients with cutaneous anthrax, inhalation anthrax, and Rocky Mountain spotted fever. Clinical findings are based on a combination of published data and information extracted from medical records. We programmed the full simulated patient with cutaneous anthrax.

This section describes the procedures and measures for usability testing of this software; as with the web-based assessment, this took place following the preliminary pretests described above. It provides results of both components of the formal evaluation, the Task List Script and the Posttest Interview, as well as the informal posttest discussion. We have also included various user recommendations. More detailed information was made available in the "Evaluation Report" submitted separately to AHRQ in April 2002.

METHODS

Usability testing, commonly conducted for commercial software to ensure that it meets the needs of the end user, is vital to creating effective training software employing innovative technologies. Our primary purpose for usability testing was to solicit in-depth qualitative and quantitative feedback from a small group of potential users in their professional role as a primary care provider. The standard usability testing methods we employed included scripted scenarios, data logs, posttest questionnaires, the think-aloud protocol, and test monitor observations. The methods and data collection instruments were adapted from previous usability analyses of virtual reality-based training software.

We considered four main issues in the evaluation: (1) simulated clinical practice, (2) simulated clinician-patient interactions, (3) graphics presentation and performance, and (4) freely expressed preference from the program's anticipated users—primary care practitioners. The testing included observation of users engaged in the simulation and interviews on the users' reaction to the simulation software (Appendix C).

We employed a 'think aloud' methodology that allowed the clinician to follow instructions on using the site and to discuss it or react to it as they proceeded. Five TAC physicians (trained as internal medicine or as infectious disease specialists) served as our main testers. A sixth evaluator was a physician from UNC not otherwise involved in our project. We brought them to the RTI campus in North Carolina and set up a laptop computer with the software program up and running. A large screen projector was available for those users who preferred to view a

large picture on a bigger screen. RTI staff persons served as test monitors; they provided instruction and measured and recorded certain aspects of test participant performance, including observations and comments (e.g., test participant exhibits frustration or satisfaction or offers positive or negative statements).

Testers had the option of choosing which of three simulation modes they would use to start: “Learn” (a tutorial), “Practice,” or “Challenge” modes. Participants were told that the purpose of the software was to brush up on their “diagnostic skills,” specifically with regard to "cutaneous anthrax." They were then guided through the program with specific instructions from the test monitor. We instructed the participants to engage in free play and encouraged them to provide us with a running commentary as they engaged in the process. This allowed an immediate response and reaction to the activity and gave us spontaneous commentary on the activity.

After each usability test, we invited the reviewers to participate in informal discussions with the project team. Contrasting with the usability evaluation, in which the reviewer was cued as to how to navigate the simulated patient software, this discussion focused on the approach the clinician would have taken had he or she been left to explore on his own. This was done to reaffirm prior findings, elucidate additional criticisms and suggestions, and allow for more open commentary outside the bounds of the existing software. It also allowed the software and graphics developers to hear guidance for improvement from any of these physicians first hand.

We used a discussion guideline to prompt the topic of conversation but allowed the clinician to express his or her views (Appendix C). To facilitate the discussion, an investigator would ask “If the patient presented in VirtualClinic came to your office, what would you do first?”… “Now what?” and so on until the patient would be discharged. This technique yielded additional and alternative patient-interactions and clinical processes that may be employed in practice but that we might have missed in the design process and earlier preliminary product reviews.

The objective of usability testing is to evaluate software usability, not content, although we welcomed comments on content and recorded them during testing. Our primary concern was to evaluate the higher-level functionality and organization of the clinician-patient interactions. Thus, we concentrated on:

- the overall primary care model;
- the general “look and feel” of the program;
- the ability to perform clinical interactions effectively via menus, buttons, and data summaries;
- the graphical quality (including the patient, lesions, and clinical images);
- the completeness of menus and tasks; and
- the performance of the software on a typical personal computer.

The tasks performed by the testers were selected and specified to elucidate problems in the aforementioned simulation and user interface elements so that we could refine the software further. The specified tasks, and the scripted order of performing the tasks, would not necessarily be complete or clinically correct for a given simulated patient “sitting in” as the usability test case. If all expected or valid queries had been tested, the test procedure would have taken at least twice the time. Furthermore, at the time of the testing, the clinical content

was known to be incomplete, so certain patient queries would have yielded unexpected, and possibly inconsistent, patient responses or data values. The issues during testing were whether the user could access a desired query and whether a token response appeared. We expected that the database structure might change as a result of the user testing. Therefore, participants were reminded that the usability test would focus on software interactions and that the simulated patient data were not complete and might not be medically accurate.

RESULTS

The following information represents a summation of the attitudes and responses of the physicians who participated in the usability testing of the VirtualClinic software.

Task List

As described previously, the user was given the option of choosing whether to start the testing with the Learn, Practice, or Challenge mode. Our goal was to use the comments on the Practice mode for the evaluation. Interestingly, all five users selected the Learn mode because it was considered to be the instinctive selection as a new user. One user questioned the use of the word Challenge, indicating that it sounded irrelevant and confusing. In the end, we did not change the name of this mode, believing that it was an appropriate label reflecting our intent for this mode to be considered a test of what users could have learned from the Learn and Practice modes.

Users were asked to select one of the presentations of cutaneous anthrax, each a different severity of progression of the disease. The users found the term “presentation” as not intuitively meaning the different level of severities. We prompted each user for better suggestions for this terminology but no clear alternatives emerged.

History and Examination. Users were prompted to look at the lesion on the patient’s arm and to do an intake patient history and a physical examination of the patient. The users were able to access the patient’s medical history by interrogating the appropriate drop-down menus without difficulty. Comments suggested that, in practice, the history would have been done before the physician had seen the patient; thus, these physicians did not want to spend time on this element of the visit. One user remarked that the menus provided for a general medical history, rather than a focused history of the current illness, which is preferred. Another physician indicated a need to know the purpose of the patient’s visit, especially if was a work-related injury or illness, because of the paperwork required for workmen’s compensation and insurance companies. Finally, several reviewers commented that they would prefer to talk to the virtual patient using a microphone.

All users were impressed with the realistic quality of the graphic presentation of the lesion and wanted to immediately explore it in more detail. They expected to click directly on the lesion to see it up close and to zoom in and out as needed rather than go to a separate button to enhance the view. Most of our users wanted a smaller number of mouse clicks to get a closer view (a trade-off in fine versus gross movement); one participant, however, expressed no difficulty in having to use the button to get a closer view.

In conducting the skin examination, most users wanted to click directly on the lesion, rather than to select a query from a menu, to elucidate more information. One user wanted the opportunity to take off the patient's shirt to look for additional lesions or bruising, as he would in a real physical examination.

Diagnostic Tests. After the history and physical examination, users were instructed to request a chest x-ray and additional laboratory work. One participant had a little difficulty locating the x-ray menu item because he did not consider it a test; however, the other physicians found it rather easily. All testers offered a variety of alternatives but no single "consensus" alternative emerged

On the x-ray, some users focused initially on the picture and not the text; others, by contrast, focused on the text, looking for a report or at least impressions from the person reading the x-ray. Users were pleased to have an actual radiograph, but they had different views on the attached reading. The reading merely said "normal"; several physicians desired a more complete report. We were reminded that in a practice setting the test comments are usually limited to "normal" unless abnormalities are present; in academic settings, however, test result reports frequently may contain more information, such as, "no evidence of cardiac or pulmonary disease, size of structures, needs lateral view as well."

Although the previous reviewers, including a state laboratory director, had approved our choice of laboratory tests, this group of users experienced some difficulty requesting the tests. The program's laboratory test option starts with a sample (e.g., blood) or sampling procedure (e.g., thoracentesis), and then the user selects the specific test (e.g., Gram stain). For our users, the process was somewhat unclear and usually required some instruction. Ordering a stat Gram stain is intuitive for clinicians; however, one user expected to see Gram stain of a lesion and not of blood.

After selecting each laboratory test, users were also asked to select a laboratory for the sample analysis. Our users did not know the current CDC recommendations on laboratory use in a potential bioterrorist situation. Thus, they were confused as to whether to select an in-house laboratory, service laboratory, or government laboratory. No matter where the examination takes place - whether a private office, a clinic, or hospital - the CDC recommendations are clear on the process that should be followed. The concept of sending a sample to someplace other that their normal laboratory seemed foreign to our group of physicians, despite the recent anthrax events and all of the information being publicized on how to handle these events.

In the real world, laboratory results are generally not available on the same day, so some testers suggested that we incorporate a delay feature into the program. As a teaching program, they suggested also adding instructions on precautions needed before sending samples out to a laboratory. This would be especially true if it was a suspected anthrax case because special collection procedures are required.

One user wanted the opportunity to *do* a lesion biopsy, not merely select "lesion sample," which is what the software offers. This level of virtual patient interaction, although impossible, was not a design feature of the VirtualClinic software.

Preliminary Diagnosis. Users reported that the process to select preliminary diagnosis was not intuitive, that the instructive note was not clear, and that the form boxes were not obvious to a new user. One user wanted to know if the "Diff Dx" was with or without test results.

He then opted to enter cutaneous anthrax directly into the text box and was frustrated when double clicking the mouse it did not allow him go where he had expected. Users wanted more options, and they wanted to be able to enter a diagnosis in a simpler way. One user intuitively picked the diagnosis and entered the "add" option correctly; however, doing so did not then lead him to the next step that he had anticipated. We easily solved these issues by incorporating the VirtualClinic tutorial.

The users offered us several differential diagnoses for cutaneous anthrax to add to our database. These included cat scratch fever, spider bite, sporotrichosis, abcyst, and factisious.

The diagnoses are presented with the ICD-9 code preceding the text, although one user did not know immediately recognize what the numbers were for until he came across a familiar diagnosis. This doctor would prefer the numbers following the diagnostic name. Another said he has come to think in ICD-9 codes.

Public Health Alert. Users selected "Public Health Alerts" when prompted, although they varied on whom to notify. Some chose to alert only the local authorities, whereas others elected to alert both the local and state health departments. Although each state has a different notification mechanism and our program incorporates that fact, one clinician remarked that how he should do the notification was not apparent to him. Depending on the setting, users should be able to notify other agencies, such as infection control specialists or the police.

Treatment. The majority of our users were able to go directly to "Rx" and enter the information they wanted. They wanted to type in the medication, rather than do a database lookup, and were surprised when the program did not allow for transposing letters or using various names (shortened versus full name) for the same drug. They guessed at the dose because of the lack of information from the history and because, in a real-life setting, they usually look it up. Some testers pondered the choices available for the prescribed medication, and only one prescribed more than one medication.

Follow-up. Users completed this task intuitively. Some thought that the follow-up time choices were too long (default 1 week) given the severity of this lesion. They wanted more options for patient follow-up, such as being able to enter the time in a text box. The users also mentioned a desire for feedback from the software at this point to ensure that the right choices were selected.

Posttest Questionnaire

Following the 'think-aloud' process in the task list evaluation, the test monitor interviewed users. The purpose of this posttest was to get feedback and commentary from the users on specific items of interest to the developers. The section below gives the main elements of the feedback.

Question 1: So, what did you think? The users' overall impression indicated that, for the most part, the VR-based patient and clinical encounter was realistic and somewhat intuitive. We received some comments on the pants that the figure was wearing and requests to make the voice (audio) more realistic (e.g., using recorded rather than computer-generated speech). Users would have liked a more complete medical history provided from the outset and even more history about the lesion, as if taken by a nurse from the presenting complaints. It was

clear that they all wanted to learn more (rather than practice) and that they wanted to see more manifestations of the lesion.

Question 2: On the "Select Simulation" screen, is the screen intuitive? Do you understand what the different buttons are for? Overall, users' response on this point was good: this screen made sense and was intuitive except for one comment that it was "too cryptic." Two participants mentioned they liked the fact that when you held the mouse over the Learn, Practice, and Challenge buttons, text appeared giving a brief explanation of the different modes. Users thought that this screen was reasonably easy to navigate but indicated that, nonetheless, the program needed a tutorial.

Question 3: Does the software allow you to manipulate and move around the patient adequately? Users felt that the software allowed them to manipulate the patient adequately. Some thought it would be better if they were able to take off the patient's shirt for further examination. Generally, testers wanted to "do more": move all around the patient, have the patient remove clothing, have the patient "show me the sore," and generally do the types of actions they might normally take in an actual practice setting. One participant specifically mentioned wanting to point and click. Another thought that it would have been nice to move the patient in a 360-degree turn rather than the stepwise 90-degree turns the program currently allows.

Question 4: "Medical Record" or "Public Health Alerts" – which screen should come first? The testing group was split on this issue and we did not achieve consensus on this feature. Three participants mentioned that Public Health Alerts were important and could and should be used to "set up" the scenario. Two suggested putting the Public Health Alerts in a screen before viewing the patient; the other suggested putting it somewhere in the History. By contrast, some users questioned the relevance of the Public Health Alert, as they rarely read them. Only two users reported being familiar with the term "Blast Fax" for Public Health Alerts.

Question 5: Do you have any suggestions on how to improve the acquisition of patient data? Users expected a check list or initial interview information that someone else (e.g., patient, nurse) would have compiled. This would normally be done in a clinic. This information would then be given to the physician, who would have had an opportunity to review it before seeing the patient. The drop-box format was acceptable and efficient, but the multiple layers were confusing.

As a teaching tool they thought the program needed to provide more feedback. Other individual comments included wanting "click and drag capabilities," voice recognition, and free-text questioning.

Question 6: In the "history" function, are all the elements categorized in a logical, intuitive manner? Although users thought the 'history' category was logical and intuitive, they thought it would be better if all the information were in one drop-down box and renamed "medical history." Every participant commented about being able to take the "history of present illness."

They reported that the current structure took a long time to find the questions they wanted to ask. For instance, information under general condition should be "past medical history" because this is the term used by physicians. The "Bates System" of history taking, which is generally used in medical school, was suggested as the structure to be used here.

Another user indicated that the program offered too many choices, implying that a complete medical history is too much.

Question 7: Do you have any suggestions or comments as to how a scenario should end? All participants mentioned two items: expanding the patient follow-up and providing user feedback. Two participants commented they would like to be able to make a final diagnosis. One user suggested a summary of the highlights and critical elements of the case that would be helpful in making the diagnosis. This should then be followed by some indication of the accuracy of their assessment before they then prescribed treatment. Overall, we gained the firm view that feedback at varying stages would have been helpful; users wanted to know whether they had made the correct diagnosis and whether the medications prescribed were appropriate. In addition, some closure was suggested, such as “next patient" or “finished with this patient” and finding out what ultimately happened to the patient days later.

Question 8: Currently there is no “cancel” or “undo” option in the software. Would such an option be helpful? With all the participants, this question almost seemed too obvious. The response seemed to take the tone of “Well, it’s a computer program, of course you are going to be able to cancel or undo…” Some of the computerized training programs used by physicians penalize the user if these undo or cancel options are chosen; for this software and its purposes, that would be an undesirable feature.

One user did want the opportunity to edit and add to the Medical Record, especially for cases that are complex and require a lot of information. Another option might be to hide information that the physician believed was unnecessary. In one instance, the user ordered an antibiotic to which the patient was allergic; he wanted the option to cancel and thus recommended that we add these commands to the program.

Question 9: Other than physicians, what types of clinicians might benefit from using this software? The users suggested that a wide variety of clinicians might benefit from using this software. Among the groups named were emergency physicians, emergency medical technicians (EMTs), pediatricians, dermatologists, occupational medicine personnel, nurse practitioners, nurses, triage nurses, medical assistants, physician assistants, and medical students. One user thought it was too unsophisticated for doctors and dermatologists. By contrast, another thought it was beyond the scope of nurses and EMTs. One user expressed the possible use by social workers.

Question 10: What are the Software’s Best and Second Best Features? The five users had different preferences for the best features. The features reported as best include the animation (one person thought Dave Madison was better than a talking head); the 3-D visual presentation of the lesion; the graphics of the wound, x-ray, and gram stain; access to information about case, and the navigation. One user thought that it was fairly intuitive even though simulation requires more steps than actual practice.

Question 11: What are the Software’s Worst and Second Worst Features? The way the software presently organizes the information made it hard for these physicians to find the steps that they wanted to do; they wanted more queries and information about the presenting complaint. One user said that the software did not flow with the way physicians work; another felt constrained because he did not think the same way that we had set up the software. In addition, users thought that the microbiology menus could be improved. They also reported that limited interaction with the patient was a negative feature, and they noted the lack of any nurse interaction. Although two users had thought that the animations were the best

feature, one user contended that the animations did not add anything to the program. Using still photos or video clips of real people would be more engaging, in his view. Users also thought that the software made them work to get the information they wanted, and a tutorial was needed to become familiar with the menus (RTI has since incorporated this feature).

Ratings of Program Components

As part of the posttest questionnaire, we asked the testers to rate the software on certain variables. Some users provided ratings for the software in its current form; others offered improved ratings for the software assuming that certain improvements would be made. The rating scale was from 1 to 5, with 5 being the best.

Overall. The software was ranked **moderately high to very high** by all *users with the caveat that improvements need to be made.* Also, even though users may not have thought that they would personally utilize the software, they still ranked it on the whole as favorable for use as a training tool (Exhibit 5.1).

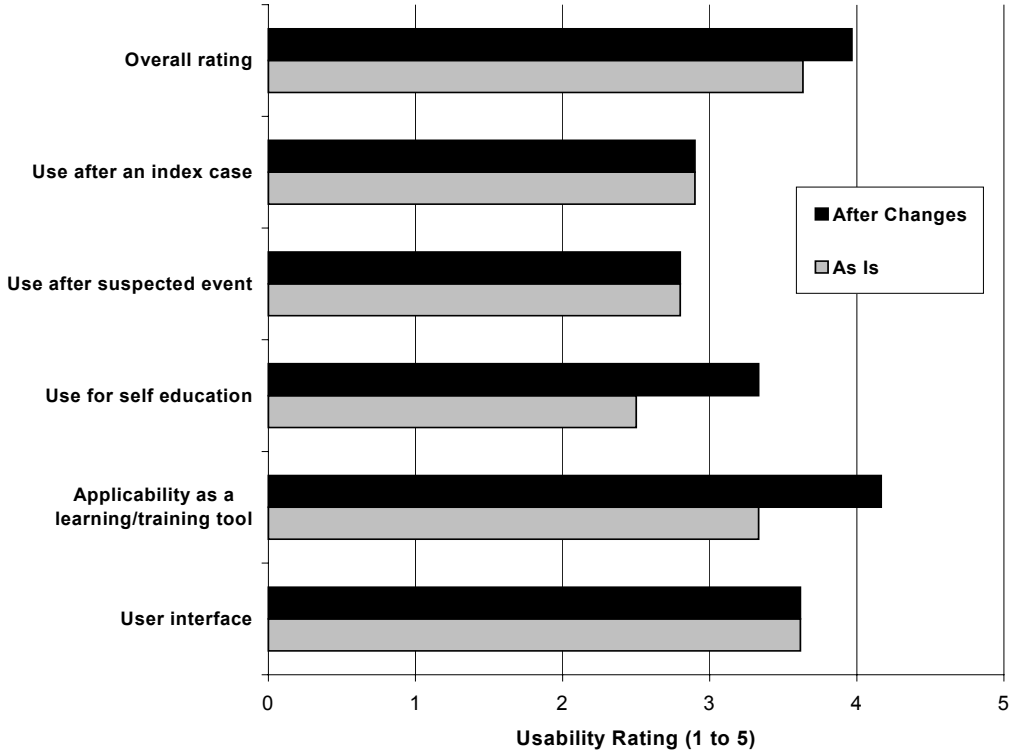
Self Use. The possibility that the program would be modified to incorporate their suggestions strongly influenced their views as to whether physicians might use this simulation program as a learning or training tool. Three reported that they would be highly likely to use the program if (a) we made the indicated improvements and (b) added patients or cases (either different patients with the same disease [although perhaps different severities] or patients with different diseases, or both). One academic physician indicated some bias against use simply because he had already had received "more than enough" training on bioterrorism agents, but we suspect this is an uncommon situation for the typical primary care clinician.

Two reported that, although the program needed improvement, they would likely be more persuaded to use the program in its *current* state if they knew or learned of an actual index case or a suspected release of an agent. However, the majority indicated that hearing of an actual index case or a suspected release of an agent would not increase their use in an emergency. These factors either lessened the chance that a physician would use it during a state of emergency (because of time constraints) or did not have any impact in reversing their decision regarding usability.

Applicability as a Training Tool. The possibility that the program would be improved also strongly influenced their rating of it as a training tool. Assuming that the suggested improvements were to be made, its applicability as a training tool received the highest rating of these subjective measures.

User Interface. Despite the critical comments reported above, which clearly were intended to be constructive, the users gave the user interface a generally favorable rating (one physician even giving it a 5 rating). Implementing the suggested improvements and providing a pre-use tutorial have eliminated virtually all reported problems with the user interface.

Exhibit 5.1. Rating of VirtualClinic Software Components



Posttest Informal Discussion

After each of the usability tests, we invited the reviewers to participate in informal discussions about the software with the project team. We used a discussion guideline to prompt the topic of conversation but allowed the clinician to express his views and lead the way. Contrasting with the usability evaluation, where the reviewer was cued or prompted in how to navigate the simulated patient software, this discussion focused on the approach the clinician would have taken had he left to explore on his own. We present here the interesting findings from these discussions in the order that the physicians said that they would approach the simulated patient software.

Upon presentation of the patient sitting in the room with a wound on his arm, all the physicians went to the arrow cursors and moved the patients arm and zoomed in for a closer look. One reviewer expressed hope that the module would be able to be more three-dimensional in the future because that is where this software is ahead of other graphic learning programs. As stated in the usability evaluation, some reviewers wanted to be able to remove the patient's shirt, one would have preferred to have the wound bandaged so that he would have had to explore further to detect the magnitude of the problem, and there was a lack of consensus as to whether it was important to be able to view the lymph trail and striade. Two reviewers mentioned that the audio did not add to their decisionmaking because statements

also appeared in the progress notes on the right side of the screen. One reviewer missed the vital sign information completely at the far right of the screen because he was so focused in on the graphic of the lesion. Clearly, all users were impressed with the quality of the graphics portion of the software.

All clinicians wanted to review the patient's medical history as the first step. Each physician wanted to know in short, concise terms what the patient's past, current, and family history was before examining or interviewing the patient. Some reviewers did not mind searching through the history menu and clicking on the data that they wanted for developing a working diagnosis, but one researcher/physician was opposed to having to do that much work. He told us that the history portion "was different than I thought it would be; it's a lot of work to get the information that I wanted." He suggested creating a text box where one could enter the questions that needed to be asked and have it programmed so that the response included all of the pertinent details. He said he didn't want to "memorize what he needed to do." For example, if he were to ask whether the patient was experiencing fever or chills and the response was yes, he would prefer that the automated response also include the duration information as well, such as "yes, I've had a fever of 101 for three days."

Basically, the clinicians wanted to interview the patient using the questions noted below. They are generally in keeping with our menu breakdown except that we employed different terms. The items were:

- What is your chief complaint? (Usually from the nurses notes)
- When did the symptoms first appear? (How long have you had it?)
- What happened first? (What are the associated signs and symptoms, such as, pain or fever? What were the precipitating factors?)
- What did the lesion look like? (Does it itch? Have pus? Is it wet or dry? Hot or cold?)
- When did it change? (What was the appearance over time? How rapidly did it change?)
- How did you take care of it? (What did you do for it? What things made it better (palliative factors) or worse (exacerbating factors)?
- What do you think it is?
- Is it job related? (The type of case, e.g., workman's compensation, makes a difference in the whether the visit would be focused or exhaustive.)
- Does anyone else in your family or do any of your coworkers have similar symptoms?
- Did you experience any injuries? Were you exposed to anything unusual?

One practitioner reported that he usually knows what the differential diagnoses are within the first 3 minutes of the visit and that the rest of the visit is spent ruling out or narrowing down the options. We were also told that 80 percent of the differential diagnoses come from the patient's history, so the differential diagnoses menu should move up earlier into the template. All reviewers agreed that the differential diagnoses drop down should be placed just after the history and physical. It should definitely start before tests were ordered and not after. Another remarked that the physical examination (focused system review) is usually conducted simultaneously with the patient interview (questions above); with the simulated patient software,

however, he would have to go back and forth between different menus, which could become confusing. However, no alternative layout was suggested.

Our testers were inconsistent as to what the early differential diagnoses would be for the simulated cutaneous anthrax patient. Burn, spider bite, cat scratch fever; blood poisoning, lymphangitis/ lymphoadenopathy, diabetes ulcer, foreign body, lye or chemical reaction, trauma, or self-inflicted wound were all mentioned by at least one physician. Underlying illnesses or contributing factors that came to mind, when prompted, included substance abuse, being positive for human immunodeficiency virus, or diabetes. Only one practicing physician immediately thought of hypothyroidism because of the appearance of the patient's eyes, but no other reviewer was similarly concerned when asked. One clinician suggested that, if an infectious disease was selected as a possible diagnosis, then a pop-up box ought immediately to appear with a warning "You have chosen a highly infectious disease! Take precautions, use special techniques, as necessary: alert the appropriate organizations or individuals; use appropriate lab; and decontaminate."

There was not much interest in using the Blast Fax, a public health alert component to the program. This feature to the software was set up to add critical current environmental information that would not be available in the patient's record or from the patient interview or physical exam. One physician told us that his office may get 30 alerts every day, of which no more than 5 are relevant to their practice. Several other clinicians reported that they never see any such faxes.

The next step in the physician's evaluation of the patient involves ordering tests to narrow the diagnostic options. One doctor judged that too much information was provided and stated that "the docs see it and know it." He felt that, however, EMTs, nurse practitioners, physician assistants, and medical students will require the full listing. What he meant was, when I see a case, I know what tests to order and do not wait to pull down a list, find the test and select it. I would rather simply type in a test request and have the computer find it.

One practicing physician suggested that we present the tests in reverse order – meaning that he thinks of the test first then the source sample. At present, the software is designed to select the test based on the source, such as skin, blood, or urine. Another reviewer felt that selecting the laboratory tests was problematic, that the blood tests were more complicated than they needed to be, and that individual chemistries were hard to find. One suggestion was to replace the hierarchical menus with a complete laboratory order form where the clinician could quickly locate the tests, e.g., a chest x-ray or blood chemistry, and mark the form.

Reviewers suggested that referrals to specialists, such as a dermatologist or infectious disease doctor, be moved forward and become part of the order (not the disposition). Precautions should also become part of the order menu. As education is ongoing during the visit, it was disconcerting to one doctor to find it as a later option. Another doctor said it should be placed before the disposition. One clinician would prefer a text box where he could type in his education plan.

An interesting aside to this part of the patient evaluation is that doctors varied in who would culture the lesion, what level of a laboratory would be used, and whether public health officials would be alerted. All but one clinician would collect the tissue sample themselves, although there was no discussion about unique requirements of obtaining a cutaneous anthrax tissue sample. One physician reported that if he suspected the lesion was anthrax related, he would not do the culture himself but would walk the patient across the street to the hospital and

have the infection control nurse collect the sample with a special kit and using the special techniques that he is not skilled in.

Regarding what laboratory the tissue sample should be sent to, no one said that they would send it to the special laboratories that have been established for testing potential bioterrorist agents for their geographic regions. Even more surprising was who they felt should be alerted if they did indeed suspect anthrax. One doctor would share it with the private laboratory that would be conducting the test. Two others said there was no need to alarm anyone and would only notify someone once the test results were confirmed in-house and not while the diagnosis was still just a suspicion. Yet another clinician said that he might contact the hospital infectious disease office but not any public health agency. One physician said he would alert public health officials of his suspicion and also immediately refer the patient to a dermatologist or an infectious disease specialist and continue to manage the patient collaboratively with subspecialty colleagues. It is evident that the clinicians need to know what is the right or wrong action to take; what to do when the public health line is busy, or where to send the tissue culture if a biologic warfare agent is suspected.

All reviewers expressed an interest in having a feedback component built into the system, either as immediate feedback or at the end of the simulated patient case. They would also like to have electronic access to a library, such as the CDC site, the Physician's Desk Reference (PDR), or other ready references.

They also expressed interest in creating a multi-day encounter with the patient. For example, the patient presents with the lesion, the clinician would possibly take a tissue sample, dress the wound, prescribe antibiotics, and send the patient home until the laboratory results came back. One clinician said he would want to see the patient back in his office that afternoon because of the severity of the open wound. In the software program, time would pass instantaneously but 1-minute delays should be built in to account for the time lapse for test results. After discharge, the simulation would sequence to the follow-up encounter. Visit 2 of the episode could show the patient's condition worsening or even staying the same. Creating a pop-up box for setting the number of days for a return visit would be useful.

We asked each of the clinicians what would entice physicians to use this product as a learning tool. Their recommendations included:

- Provide CME credits, where the physician can take advantage of doing the work at home or at night;
- Add case scenarios of various diseases;
- Add a feature that reports the consequences of correct/incorrect actions taken;
- Make it harder, with three or four "ringers" for each real case;
- Provide the software free or, for example, for no more than $50 for 20 cases and technical support; charging was definitely seen as a deterrent;
- Make it possible to download upgrades themselves;
- Given hospital bioterrorism lectures mandated for all staff, provide an on-line version that could fulfill the requirement;
- The availability of VirtualClinic;
- Produce an audio-taped version; and

- Produce a Palm Pilot version.

Finally, we sought ideas on the best way to disseminate the eventual product. The consensus of suggestions included the following:

- Announcement in journals and websites;
- Professional organization newsletters, such as that of the American College of Physicians - American Society of Internal Medicine;
- Mailing lists, especially those with e-mail addresses (60 percent of doctors have e-mail) or notification by fax;
- Professional conferences; and
- The Health Alert Network for Public Health, e.g., the Bioterrorism listserv has 120,000 members (about 90 percent are practicing clinicians; most are internal medicine or other primary care specialists; two-thirds are in small private practice).

DISCUSSION AND NEXT STEPS

Chapter 6 discusses selected elements of this project, with special emphasis on the virtual simulated patient, in more detail. We also propose both some next steps with the respect to advancing the technologic aspects of this work and some research questions that we believe will be useful for AHRQ to consider for future projects.

Chapter 6. Conclusions and Future Research

REVIEW OF PROJECT PRODUCTS

A recent systematic review from the Agency for Healthcare Research and Quality (AHRQ) on teaching clinicians to identify rare medical reported that standardized simulated patients are useful and that didactic materials alone do not work (Catlett et al., 2002). The authors also documented that educational interventions generally have been more effective when they have combined techniques, including interactive methods such as case discussion, simulated patients, and hands-on workshops, with didactic methods. In this project, we developed web-based didactic educational materials and virtual patients in a simulated primary care setting for a prototypical, multimodal approach for training clinicians for bioterrorist attacks. The dual-technology approach that we pursued, which focused on rare events (bioterrorism and uncommon infectious disease), begins to fill the gap implied by the findings of the AHRQ evidence report.

The web-based educational materials provide an historical perspective and clinical information for a selected set of potential bioterrorism agents and rare emerging diseases. The website, upgraded and corrected in response to various content and usability assessments, fulfills the recommendations of our Technical Advisory Committee (TAC) for providing concise educational content and key linkages to the Centers for Disease Control and Prevention (CDC) and other prominent sources of more complete and, perhaps, late-breaking clinical or epidemiologic information. RTI plans to keep the website (http://bt.rti.org) operational for at least another year, using internal funds, because of the strong endorsement of it through several rounds of evaluation and our expectation that it will serve a useful social purpose in these uncertain times. We trust it will be useful to many outside audiences, specifically including AHRQ staff; and we request that AHRQ consider referencing (linking) the website from their website and announce the website in the AHRQ Research Activities newsletter.

The computer-based virtual simulated patient program (one prototype of a patient with cutaneous anthrax and the underlying databases for inhalation anthrax and, for contrast, Rocky Mountain spotted fever) provide a means by which primary care physicians, and other clinicians, can acquire or burnish clinical problem-solving skills for bioterrorism and emerging diseases in a primary care setting. In this latter regard, it differs from other web- or computer-based products intended for use by emergency personnel. We believe it is currently the only simulated patient program focused on a victim of (ostensibly) a bioterrorism-related disease seen in primary care, rather than emergency or hospital, settings.

It also offers a technology by which learning and skill acquisition (from whatever sources) by primary care clinicians can be evaluated. Our simulator fulfilled the TAC recommendations for an accurate, engaging simulation that mimics clinical practice and that offers a unique capability for observing rashes and lesions, such as those that would occur in patients with cutaneous anthrax, with concomitant three-dimensional characteristics, in a patient whom they might hope never to see in real life. After refining the virtual simulation software in response to suggestions made in usability testing, we have implemented a prototype simulator that reviewers judge can be beneficial as a learning and training tool.

Virtual patient simulators can familiarize clinicians with diseases, train them to recognize specific signs and symptoms, make them aware of the diagnostic value of public health information, and assess their competence to recognize and treat specific rare and common diseases. By integrating patient simulation, distance learning, and traditional training technologies – combined capabilities clearly called for in the AHRQ report – we believe these prototype training materials can be a model for the nation as it builds and implements training systems for medical homeland security. That is, from the perspective of breaking new ground in clinical education and understanding what information clinicians need to identify, respond to, and manage bioterrorist events affecting their patients, this project and its evaluation provide the Agency with solid accomplishments on which it, other public sector agencies at the national, state, or local level, and professional groups can all build.

Apart from the website and patient simulation software that are main topic of this final report, we note that we delivered five copies on CD-ROM of the patient simulation tutorial (mentioned in Chapter 5) to AHRQ staff in April 2002. The idea was to introduce the virtual patient simulation while the actual software was under final revisions pursuant to the usability assessments already discussed. RTI is, for its own benefit, also planning to take one key next step – namely, to program and incorporate into the prototype software the remaining cases and scenarios (for the same patient, but adding inhalation anthrax and Rocky Mountain spotted fever); as noted in earlier chapters the underlying medical databases needed to do this already exist and the chief task is the programming. Once this is done, which we expect early in the Summer of 2002, we will forward to AHRQ five CD-ROMs containing this expanded software package for staff to examine and test. This material will be a companion piece to the tutorial CD-ROM already made available. Finally, under discussion for several weeks has been a suitable time at which RTI personnel (i.e., the director of the project) to visit AHRQ and provide a briefing and demonstration of the whole package to all interested personnel, with the aim of clarifying and discussing its potential future uses and applications.

SUMMARY OF EVALUATION CONCLUSIONS

WEBSITE ASSESSMENT

Generally, the website presentation was judged to be attractive, easy to navigate and use, informative (especially about the history of bioterrorist events over more than 600 years), up-to-date, and engaging. Some reviewers thought it too sparse, but taking into account the fact that we followed TAC advice to keep the website materials brief and simple to peruse, this was probably an unavoidable criticism. Review comments made clear that clinicians (or indeed interested lay persons) other than physicians would find the website informative, useful, and not beyond their comprehension. Adding the simulated patient capabilities to the website was, of course, seen as a major asset to the utility of the website itself.

VIRTUAL SIMULATED PATIENT SOFTWARE

The chief purpose of the rounds of testing and evaluation for the virtual simulated patient was to solicit qualitative and quantitative feedback from a selected group of representative users

in their professional role as providers of primary care or, in some cases, specialized infectious disease care within ordinary office settings. The chief objective was to evaluate usability of the software for helping clinicians develop or enhance diagnostic and patient management skills in the context of caring for patients with possible bioterrorist diseases. We also recorded all comments and suggestions about content.

The reviewers' tasks were intended to elucidate problems in the simulation and its user interface elements so that we could correct and refine the software before any broader release and improve it in subsequent versions. Of particular concern was whether the menus, order of presentation of information, options for taking clinical actions, ways of moving quickly to differential diagnoses, and similar patient care steps "worked" in the way that busy primary care physicians typically manage diagnostic and treatment activities. Chapter 5 presented results of these evaluations in detail; we note here several steps we took to act on their priority recommendations for refinements and improvements.

Many of the problems that our users encountered with the software menus could be resolved by providing a short tutorial on how to use the software and where information is located. Such a brief tutorial helps familiarize users with simulated patient interactions and ways to acquire needed data for diagnosis and treatment decisions. Despite our attempts to make things as intuitive and natural as possible, the serial nature of computer interactions makes it difficult to portray interactions that naturally occur in parallel (e.g., system-based histories and physicals). We had begun, but not completed, developing a tutorial of this sort before we started the usability testing. We chose not to delay the usability test until the tutorial was done, in part because this gave us an opportunity to determine how well the users would do without the tutorial. The tutorial is now complete. Given the reactions of some users, we concluded that having the tutorial in the program was important, and we have now incorporated it into the software.

The original omission of a "history of present illness" was a clear oversight, yet it had not been noticed in either of the two interim reviews conducted before the usability testing. Those earlier reviews had focused more on the totality and completeness of patient signs, symptoms, and characteristics and less on menu organization. We already had such data in the database to support a focused medical examination in our prehospital "VirtualEMS" simulator, so adding this element to the "VirtualClinic" primary care patient software was a relatively simple change that we have made.

Certain terminology issues and menu problems arose for diagnostic tests, microbiological tests, and other laboratory tests that we had not fully anticipated in the design stage. In designing the menus and choosing menu labels, software and simulation developers must make numerous tradeoffs; these extend even to the number of characters in the labels given limited screen space. For example, we chose "Tests" for electrocardiograms (ECGs), x-rays, and the like, but only one participant understood that intuitively. During the informal discussions, however, no two physicians came up with agreed-upon alternative labels. On this particular point (and some others in which no consensus arose as to the best modifications), we deferred making any revisions pending a more complete design review outside this particular project.

Design of a data collection instrument for usability testing can be as critical as survey design in a research venue. For example, when we asked our reviewers whether they would use the software for learning about bioterrorism, several said no for the simple reason that they already had had training they regarded as sufficient to meet their needs. Even so, they agreed

that the software could be applied in various venues for clinicians (physicians and others) who had had less exposure to bioterrorism-related training.

Overall, users testing the software rated it moderately high to very high, with the caveat that certain improvements would need to be made (as illustrated just above). Even though some users were uncertain that they personally would use the software (if available to them in the future) in a clinical application, they still rated it favorably, on the whole, for use as a training tool.

SUMMARY OF TECHNICAL RECOMMENDATIONS

Based on the usability test results, we developed plans ("recommendations") for revisions to make the program more responsive to user needs. Recommendations also included software enhancements, medical scenarios, additional patient interactions, and new simulation features. We set priorities for critical recommendations (i.e., errors and omissions) and implemented changes in the last months of the project.

Less critical issues and new features were deferred for future work. The upgrades and enhancements considered most noteworthy are presented below.

- Expand the virtual patients to include young, adult, and elderly persons of various racial and ethnic backgrounds. As mentioned in Chapter 3, we have demonstrated the capability with a Hispanic boy; and have a variety of such human models available now from other projects.
- Extend the simulator for a larger number of Category A and B biological agents. These include patients presenting with common diseases (e.g., cat scratch, influenza, asthma) and psychological conditions (e.g., panic, post-traumatic stress disorder) so that clinicians can gain more practice with differential diagnosis and psychological patient management.
- Extend the patient interaction from a single encounter to a set of multiple encounters (over two to three days) over the natural course of a disease. This includes allowing for a minimum two-visit scenario sequence; in this approach, clinicians would make diagnostic hypotheses and request diagnostic tests during the initial visit but would not receive test results until the follow-up visit. This model may well approximate primary care practice (for problems not initially recognized as emergencies or related to a bioterrorism event) better than our initial single-visit approach. In addition, the program should incorporate progression, or remission, of the disease signs and symptoms in the follow-up patient presentation.
- Provide for a mouse rollover method to conduct a physical examination of the virtual patient. Supplementing this should be pop-up images of actual rashes and lesions taken from referenced materials to provide photographic quality for visual examination of lesions.
- Revamp several elements of the diagnosis portion of the program. This includes revising the differential diagnosis form to ease disease lookup for variant forms of the disease name (e.g., cutaneous anthrax = anthrax, cutaneous), allowing the clinician to enter additional diseases, and providing an optional list of differential diagnoses for the case.

- Add voice recognition and natural language processing for verbal interaction with the patient. This would eliminate, or supplant, the menu-based system for conducting the medical history.
- Provide a mentoring system with a natural language interface to request help on diseases, diagnostic pearls, and patient information.
- Link simulation after-action reviews to remedial multi-media training materials.
- Provide training and action components for infection precautions and patient isolation.

RESEARCH RECOMMENDATIONS

Beyond the technical improvements listed above, several questions might be considered for future research and development to improve training of clinicians in responding to a bioterrorist attack or to enhance initial and continuing clinical education in general. We highlight four overarching issues below, which we believe AHRQ and other research agencies can usefully pursue with future funding. Three are directed more at education and training issues than at software development or applications per se; the fourth considers the broader uses to which such technologies might be put.

- First, what is the efficacy of individual and combined modes of training involving didactic materials, lectures, video presentations, and case-based simulated patients? What are the immediate, short-term, and long-term effects of individual and combined modes of training on clinical practice? Does the success of various approaches to training differ according to the number of elements or the intensity and depth of given elements, or both? Does success differ according to the type of clinician (in terms of training, age, clinical experience, or past history of dealing with a potential or actual bioterrorist or rare disease event)?
- Second, can virtual simulated patients be used to evaluate competency for diagnoses of rare and emerging diseases, and if necessary, provide corresponding remedial training, for primary care physicians? Given the inherent privacy of computer-based instruction, would clinicians prefer such training and remedial feedback as a mechanism of continuing education? Is there a role for widespread dissemination of this technology to health systems, facilities, and institutions for broad use by their clinical (physician, nursing, even technical) staffs?
- Third, considering the relatively low cost and potential variety of virtual simulated patients compared to live standardized patients, what are the limits to the virtual patient simulation that may preclude their acceptance as an alternative to standardized patient in medical education? What are the significant features of the visual, behavioral, pathological, and physiological models in patient simulation that convey realism and suspension of disbelief? How can we not only improve these qualities but also measure improvement in them?
- Fourth, can case-based patient simulation be used in a broader sense to test and evaluate emerging systems for disease surveillance, public health notification, and large-scale bioterrorism, chemical terrorism, or other response preparedness training and evaluation exercises?

THE CONTEXT OF BIOTERRORISM THREATS IN THE UNITED STATES

We believe that the outcomes of this project should be viewed in a context that now takes into account the known history of terrorist events in this country and elsewhere but also the tragedy of September 11, 2001. As noted at the outset of this report, our plans for this project were set in motion nearly a year before the September 11 catastrophe; after some consideration of how best to proceed, we concluded that continuing on the same track was preferable (and indeed more feasible, given time and resource constraints) than trying to reorganize or revamp the project. The comments below reflect this perspective and strategy.

To begin with, we note that the most difficult part of any software development effort, and particularly training and education application development, is getting the user community to articulate and reach consensus about what they really want and need. The media we studied simply compounded the challenge, for two reasons. First, the World Wide Web is a relatively new instructional medium, especially for people older than 30, and its capabilities are growing and changing literally monthly. Second, and more important from AHRQ's perspective, RTI's "VirtualClinic" is the first, and only, application of interactive three-dimensional (3-D) technology, coupled with a medically accurate simulation, available on a simple personal computer to train clinicians on how to diagnose bioterrorist events. Where to go with it was nearly wholly unknown before we started.

When dealing with these new media, potential users (such as the members of our TAC), often find it hard even to visualize the final product because, at the time they are commenting on or writing requirements, the product has not really been "invented" yet. Consequently, requirements commonly must be refined, and frequently new requirements emerge, once users have a working prototype in their hands. This is called "cyclical development," wherein a series of small projects is used to evolve from a pen-and-paper vision of what we think will work to a product that actually does work. This approach is, properly, the one we adopted at the outset.

In this AHRQ project, therefore, our final evaluation provided exactly what must be accomplished at this point in new technology evolution: a detailed list of expert opinions as to what needs to be changed and where the product needs to go next. Some findings were obvious: more patients and more diseases. Others were quite subtle and impossible to tease out without a working application: for example, the "SOAP" protocol, although well understood in primary care in theory, proved not to be how some clinicians really think or perform in daily practice.

These points are significant in the context of bioterrorism for several reasons noted below. RTI's bioterrorism work now (and for follow-up projects) more generally reflects this perspective; we believe it is vital for AHRQ's efforts as well.

First, training and education may be our best national defense against bioterrorism. Vaccines and drugs may well be "telegraphed" to our enemies before they are complete and can be rendered ineffective by "inventing around" our defenses. Equipment and infrastructure is easy for an enemy to localize, interdict, or destroy before launching an attack at a given or a substitute target. Training and education, however, cannot be neutralized by the enemy because the assets are carried with every person trained or educated. Knowledge will be our most effective defense against the bioterrorist threat, if we choose to invest in it.

Second, we see the results of the final evaluation of our prototype as a vital component of improving the knowledge base by which AHRQ and others can assist physicians in their daily practice of patient care. Lessons learned here, and corollary expansions of the products, may be applied to training and education materials not only for physicians, but also for nurses and emergency medical services technicians, police, fire and rescue personnel, and even citizens outside these professions. In large measure, the purpose of terrorism is terror. The best defense, then, is knowledge regarding what to expect and what to do to as many people as possible before such events occur.

Third, no other educational medium offers the flexibility, consistency, deployability, effectiveness, and ability to safely portray unsafe or rare situations as cost effectively as interactive 3-D. Video content is limited to what one can film and the availability of actors as subject matter changes. Text and photographic content is good for providing an educational experience in some circumstances, but it cannot offer the opportunity to practice skills that involve changing the work material (in this case a patient) or a psychological components. When the clinical issue involves rare conditions, specifically including those related to potential or real terrorist acts, the advantages of interactive 3-D technologies can be profound.

Fourth, typical interactive 3-D simulations, such as video games, cost between $2 million and $6 million to produce. Although completing an effective VirtualClinic program based on the prototypes developed here would probably not entail costs in those ranges, such figures point to the order of magnitude of investments typically needed for full development efforts, which clearly would include the conceptual development and practical testing steps we took to this point. Given that no similar body of work on simulated patients in the bioterrorism realm exists, our work has elucidated numerous points for which, heretofore, no consensus existed about the correct approach. In that regard, AHRQ's investment in this work would clearly permit us or others to leapfrog some development activities and move more briskly into expanded clinical content, fuller testing with more potential user audiences and broader dissemination.

Fifth, if this program continues, we have the ability to use the research conducted so far to create a training program that will prepare clinicians to do an uncommon job better, when they are called upon to do it right the first time. The follow-on research potential outlined above includes many interesting and novel research avenues to expand the science. RTI welcomes AHRQ and other researchers in further exploring potential applications and limitations of technology to this training and education field.

Sixth, RTI plans to continue maturing and expanding both the website and the VirtualClinic application using funding from numerous sources. A key technical challenge on our road map for this program is the fusion of the VirtualClinic functionality and the web materials into one web-delivered application. The technology to provide interactive 3-D simulations over the web has grown tremendously during this project, and RTI already has several contracts to provide training and education materials using this technology. The next logical step is to apply this technology to this training problem to increase the reach of the training materials in meeting this vital societal need.

Finally, as the number of scenarios and patients available in VirtualClinic expands, and the material available on the website grows, the mass-market potential, whether realized through commercialization or through free distribution underwritten by the government, is also huge. This program has the potential for defusing a large part of the damage that will be caused by the next bioterrorist attack. Assuming that such attacks materialize is, of course, an

unhappy prospect, but doubtless a prudent one. Thus, insofar as that potential for this type of training medium is realized, there is no American who might not benefit directly or indirectly.

Appendix A.

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Appendix B.

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APPENDIX C

QUESTIONNAIRES AND INTERVIEW SCHEDULES

APPENDIX C

QUESTIONNAIRES AND INTERVIEW SCHEDULES

BIOTERRORISM WEBSITE EVALUATION

- Pretest Questionnaire
- Post-test Questionnaire

RTI BIOTERRORISM WEB SITE EVALUATION

Pre-Test Questionnaire

General Information

Name: _____

1. What is your current work setting? *(Please check all that apply)*?

____ Primary Care Setting
____ Specialty Care Setting (*Please identify specialty)* _____
____ Research Setting
____ Academic Setting
____ Other (*Please identify)* _____

2. What would you say is your preferred way to learn medical/clinical material? *(Check the two highest preferences)*

_____ Person-to-person interaction
_____ Listening to lectures
_____ Examining case studies
_____ Engaging in hands-on activities
_____ Reading journal articles
____ On-line training/simulation

3. Do you consider an on-line training program a viable way to learn? _____Yes _____ No

4. If no, why not? _____
_____
_____

Computer Experience

5. How knowledgeable are you about computers? (*Circle the appropriate number)*

Very Knowledgeable	*Somewhat Knowledgeable*	*Knowledgeable*	*Little Knowledge*	*No Knowledge*
5	4	3	2	1

6. How skilled are you in using computers? *(Circle the appropriate number)*

Very Skilled	*Somewhat skilled*	*Skilled*	*Little skills*	*No skills*
5	4	3	2	1

7. How comfortable are you in using the computer for training programs? *(Circle the appropriate number)*

Very Comfortable	*Somewhat Comfortable*	*Comfortable*	*Somewhat Uncomfortable*	*Uncomfortable*
5	4	3	2	1

8. How knowledgeable are you about on-line/web-based training? (*Circle the appropriate number)*

Very Knowledgeable	*Somewhat Knowledgeable*	*Knowledgeable*	*Little Knowledge*	*No Knowledge*
5	4	3	2	1

9. Have you ever utilized an on-line/web-based training program? ___ Yes ___ No

10. If yes, how many times in the last three months? _____

11. Pick the <u>two</u> phrases that best describe your feelings about the utilization of computer interactive software for educational, learning and training purposes. Computer interactive software is _____. *(Check <u>two</u>)*

_____ Too much of an obstacle
_____ Too time consuming
_____ Valuable/preferred
_____ Innovative and exciting
_____ Simply not preferred
_____ Not a problem with proper training
_____ Depends on the topic
_____ Depends on the situation

12. Which subject matter/event would most likely encourage you to on-lin/web-based training? *(Check the <u>two</u> most important)*

_____ Clinical diagnosis
_____ Common diseases
_____ Emergency events
_____ Unfamiliar diseases
_____ Any subject of relevance/interest

13. What are the most important factors for you in utilizing on-line/web-based training? *(Check three)*

_____ Accessibility
_____ Comprehensiveness
_____ Content Value
_____ Urgency
_____ Fun factor/Enjoyment
_____ Interactivity
_____ Challenging
_____ Evaluation and Feedback
_____ Recommending Authority/Source
_____ Colleague referral
_____ Familiarity with material
_____ Unfamiliar material

14. Do you feel on-line training or virtual reality programs are necessary components integral to clinical training? _____ Yes _____ No

15. If no, why not?

_____
_____
_____

Bioterrorism Experience

16. Do you believe the potential incidence of bioterrorism is of real or immediate concern?

_____ Yes _____ No _____ Somewhat

17. How would you rate your level of knowledge about potential bioterrorism threats? (*Circle the appropriate number)*

Very Knowledgeable	*Somewhat Knowledgeable*	*Knowledgeable*	*Little Knowledge*	*No Knowledge*
5	4	3	2	1

18. If you rated the above 5 or 4, what was the primary reason for your gaining knowledge in this area? (*Check one)*

_____ Clinical Experience
_____ Personal desire/Self initiation
_____ Required training
_____ Other *(Please Specify)* _____

19. How would you rate your level of knowledge about anthrax?(*Circle the appropriate number)*

Very Knowledgeable	*Somewhat Knowledgeable*	*Knowledgeable*	*Little Knowledge*	*No Knowledge*
5	4	3	2	1

20. If you rated the above 5 or 4, what was the primary reason for your gaining knowledge in this area? (*Check one)*

_____ Clinical Experience
_____ Personal desire/Self initiation
_____ Required training
_____ Other *(Please Specify)* _____

21. How skilled are you in diagnosing anthrax? *(Circle the appropriate number)*

Very Skilled	*Somewhat skilled*	*Skilled*	*Little skills*	*No skills*
5	4	3	2	1

22. How would you rate your level of knowledge about smallpox? (*Circle the appropriate number)*

Very Knowledgeable	*Somewhat Knowledgeable*	*Knowledgeable*	*Little Knowledge*	*No Knowledge*
5	4	3	2	1

23. If you rated the above 5 or 4, what was the primary reason for your gaining knowledge in this area? (*Check one)*

_____ Clinical Experience
_____ Personal desire/Self initiation
_____ Required training
_____ Other *(Please Specify)* _____

24. How skilled are you in diagnosing smallpox? *(Circle the appropriate number)*

Very Skilled	*Somewhat Skilled*	*Skilled*	*Little skills*	*No skills*
5	4	3	2	1

25. Are there other topical areas related to bioterrorism threats that you would like more information on?

_____
_____

RTI BIOTERRORISM WEB SITE EVALUATION

Post-Test Questionnaire

Name:_____

General Comments

2. What is your overall reaction to the web site?

_____
_____
_____

3. What is the best feature of the web site?

_____
_____
_____

4. What is the worst feature of the web site?

_____
_____
_____

5. How comfortable were you in using this web site? *(Circle the appropriate number)*

Very Comfortable	*Somewhat Comfortable*	*Comfortable*	*Somewhat Uncomfortable*	*Uncomfortable*
5	4	3	2	1

6. Please rate the following components on a scale of 1-5 with 5 being the highest.

Component	Excellent - 5	Good - 4	Average - 3	Fair - 2	Poor - 1
Online instructions					
Links to other web sites					
Layout of screens and pages					
Organization of web site					
Language and terms					
Content					
Time-efficiency					
Ease of navigation					
Accessibility					
Effectiveness of the web site as a training tool					
Usability of the information for your workplace					
Graphics					
Interactivity					
Comprehensiveness					
User friendliness					

Additional Comments: _____
_____
_____

Communication

7. What do you feel was the intent of the web site?

_____

_____

_____

8. How clear were the goals and objectives of the web site? *(Circle appropriate number)*

Very Clear	Satisfactory	Confusing	Never Stated
4	3	2	1

9. What elements do you feel was most apparent in the web site? *(Check <u>two</u>)*

_____ A sense of urgency
_____ A need to inform
_____ Generally informative
_____ Basic
_____ Tool of preparation
_____ Educational

10. What do you feel was the tone of the web site? *(Check one)*

_____ Neutral
_____ Persuasive
_____ Aggressive
_____ Basic factual
_____ Argumentative
_____ Optimistic

11. Were there any features or tasks of the module where you felt restricted, inhibited, or unproductive? _____ Yes_____ No

11a. If yes, please explain.

_____

_____

_____

12. How long did it take for you to complete the review of the web site?_____

Content

13. Did the information flow logically and consistently? _____Yes _____ No

14. Does the information appear current and up-to-date? _____Yes _____ No

15. Did you find it more helpful to view pictures of the disease as it would appear to the naked eye (e.g. small pox) or the microscopic view (e.g. as with anthrax)?

_____ Naked eye_____ Microscopic view

16. Could the web site content be translated into practice?
_____ Yes_____ No_____ Maybe

17. Are there any content area that should be discarded or are not applicable?
_____Yes _____ No

18. (If *yes*, please explain)

_____

_____

_____

Additional Comments: _____

_____

_____

Accessibility

Accessibility	Easy to Access		Reasonable Download Time		Comments
	Yes	No	Yes	No	
19. How accessible was the web site?					
20. How accessible was the anthrax page?					
21. How accessible was the smallpox page?					
22. How easily did you gain access to your topic of interest?					
23. How easy was it to navigate through the screens?					

24. Did you utilize any of the links to access additional information? _____Yes ____ No *(If yes go to question 26)*

25. If no, why not?

_____
_____
_____

26. If yes, which ones?

_____
_____
_____

27. If you accessed additional information, were you satisfied with the extent of the information on the subject? _____Yes _____ No

Additional Comments:_____
_____
_____

APPLICABILITY AND USABILITY

27. Was this web site relevant to your work? _____ Yes_____ No_____ Maybe

27. Can you use what you learned from this web site in your daily work?
_____ Yes_____ No_____ Maybe

28. Does the web site adequately prepare you if a case were to walk in today?
_____ Yes_____ No_____ Maybe

29. In what way do you feel this web site can be best utilized?

_____ As supplemental resource
_____ Stand-alone document
_____ Reference
_____ During bioterrorism attack
_____ As a general precautionary tool
_____ No utility

30. What advantages (if any) did the web site offer over more traditional training methods?

_____
_____
_____

31. How compatible is this on-line program with other training modules including traditional and non-traditional?

_____
_____
_____

32. At what point, would this tool be most effective for training and educating clinicians? *(Check all that apply)*

_____ Medical School
_____ Residency
_____ Re-certification
_____ Fellowship
_____ CME Credits
_____ Other (*please specify)*_____
_____

KNOWLEDGE

33. Did your level of knowledge about potential bioterrorism threats increase as a result of reviewing the web site? *(Circle the appropriate number)*

Increased a lot	*Increased Somewhat*	*No Change*
3	2	1

36. Did your level of knowledge about anthrax increase as a result of reviewing the web site? *(Circle the appropriate number)*

Increased a lot	*Increased Somewhat*	*No Change*
3	2	1

37. Did your skills in diagnosing anthrax improve as a result of reviewing the web site? *(Circle the appropriate number)*

Improved a lot	*Improved Somewhat*	*No Change*
3	2	1

38. Did your level of knowledge about smallpox increase as a result of reviewing the web site?*(Circle the appropriate number)*

Increased a lot	*Increased Somewhat*	*No Change*
3	2	1

39. Did your skills in diagnosing smallpox improve as a result of reviewing the web site?*(Circle the appropriate number)*

Improved a lot	*Improved Somewhat*	*No Change*
3	2	1

40. What else, if anything, did you learn from the web site?

_____
_____
_____

Additional Comments: _____
_____
_____

RECOMMENDATIONS

41. Other than physicians, what type of clinicians might benefit from using this software? (*Please list)*

_____
_____
_____

42. What features would cause you to utilize this web site again?

_____
_____
_____

43. Would you recommend this on-line training course to a colleague?____ Yes
____ No

44. What would be the most important factor, either present in the web site or a modified version of the site, that would influence you in recommending the web site to another user?

_____
_____
_____

45. What aspects of the web site design do you feel need significant modification?

_____
_____
_____

46. Are there other bioterrorism threats that should be included in the clinical information section?

____Yes ____ No

47. If yes, please specify

_____
_____
_____

48. What is your overall rating of this web site?

_____ Excellent
_____ Good
_____ Average
_____ Fair
_____ Poor

49. What final comments or recommendations do you have regarding the web site?

_____
_____
_____

THANK YOU!!! THANK YOU!!! THANK YOU!!!

VIRTUAL SIMULATED PATIENT

- Task List Script
- Post-Test Questionnaire

SCRIPT TO USER:
Please assume the following: that the program is already successfully installed on your computer and is configured for optimal performance. (If tutorial is available, "You've decided to run the tutorial in order to learn how to run the software.) You've decided to use this software to brush up on your *diagnostic skills*, specifically with regards to cutaneous anthrax.

Directions for Test Monitor:
The "Select Simulation Mode" screen will be on the monitor. We will wait to see if the user selects "practice" or "challenge" mode. They *should* select "practice". Once the scenarios are up, cutaneous anthrax (CA) is selected and the choice for 1, 2, or 3 is there, we explain/ask:

SCRIPT TO USER:
This screen allows you to choose a "presentation," meaning you get to select the severity or progression of the disease.

What descriptors/language would work best to identify the different stages of the selected disease?

Is "Presentation" the best word to encompass this concept?

You've now decided to select the intermediate level of CA (#2).

SCRIPT TO USER:

At this point, we are going to ask you to do a series of tasks. These tasks were selected to give us the best feedback on usability and were not selected based on proper medical protocol.

You've decided you want to look at the sore on his arm.

(Animate Patient/L Arm – or – View Patient/Left)

Now you want a closer look.

(Closer)

You want to ask the patient where he works and if he's allergic to and drugs.

(11. History/Demographics/Occupation – 2. History/Allergies)

You want to ask the patient if the sore on his arm is a result of his injury.

(History/General Condition/Any Recent Injuries?)

You want to physically examine his skin.

(Either: Systems/General, Skin – or – Physical/General, Skin)

You decide you want a chest X-ray. (Remind about the "not medically accurate" disclosure)
(Tests/Chest Radiograph)

You want to order a CBC and Platelet.
(Other Labs/Hematology/Order CBC w/ Platelets)

You want to order stat gram stain of the patient's wound.
(Microbiology/Skin /Order stat gram stain)

You are now ready to make a preliminary diagnosis. (Please enter at least two diagnoses.)
(Diff Dx/Enter Information)

At this point, you are pretty sure this is a case of anthrax and you need to alert Public Health Officials.
(Notify/Select your option)

You want to prescribe medication and inform the patient about the medication and possible side effects
(Rx/ Enter Information) (Educate/Medication Side Effects)

At this point, you decide to send the patient home and schedule a follow-up visit.
(Disposition/Schedule Follow-up)

VIRTUAL CLINIC - POST TEST QUESTIONNAIRE

(1. So, what do you think?

(2. On the "Select Simulation" screen, is the screen intuitive? Do you understand what the different buttons are for?

(3. Does the software allow you to manipulate and move around the patient adequately?

(4. "Medical Record" or "Public Health News" – which screen should come first?

(5. Do you have any suggestions on how to improve the acquisition of patient data? *(Currently software uses drop down boxes – other choices are actually talking with the patient, typing a message to the patient, or click and drag – or right click – icons – simulated touch)*

(6. In the "history" function, are all the elements categorized in a logical, intuitive manner?

(7. Do you have any suggestions/recommendations as to how a scenario should end?

(8. Currently there is no "Un-do" or "cancel" option in the software. Would such a command be useful?

(9. Other than physicians, what types of clinicians might benefit from using this software?

(10. What's the software's best feature? Second best?

(11. What's the software's worst feature? Second worst?

(12. On a scale of 1 to 5, rate the software's interface (5 being the best)

(13. On a scale of 1 to 5, rate the software's applicability as a learning/training tool (5 being the best)

(14. On a scale of 1 to 5, how likely would you be to use this software (as-is or with improvements) for:

Self use/general education

After a suspected release of a biological or chemical agent

After diagnosis of an index case

(15. On a scale of 1 to 5, rate the software as a whole (5 being the best)

(16. The "diagnostic Possibilities" screen – do you have any suggestions for improvements.

Discussion Guidelines
for the
Posttest VirtualClinic Interview with Testers

When you first saw the patient:

What did you want to do?

What diagnoses immediately came to mind?

What information did you need?

When did you start to develop the possible differential diagnoses?

Is there anything that you would recommend that we change about the differential diagnoses?

How would you handle taking a tissue sample of the wound?

Where would you send the sample to be analyzed?

What protective measures would you take?

Were you able to find the labs, prescription medications, etc. easily to help you with your patient assessment and plan?

Have you had any experience with a public health alert or blast fax at your medical practice?

After the labs have been ordered, and medication prescribed, what would be your next actions regarding the patient?

Was there anything that you wanted to do that the software did not allow you to, that you consider essential in developing a diagnosis and treatment plan?

Do you think clinicians would be interested in this software as an educational tool for CME's?

Do you have any suggestions for dissemination of the two learning tools?