

**HEALTH RISK COMMUNICATION  
IN THE ANTHRAX VACCINE  
IMMUNIZATION PROGRAM:  
Lessons for the Future**

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**Colonel Bradley D. Freeman  
April 2001**

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## ABSTRACT

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April 2001

When Secretary of Defense William Cohen announced that all military service members would be vaccinated with the anthrax vaccine, few anticipated the widespread reluctance to accept his directive. Service members were already required to take several vaccinations and this new force protection measure involved a vaccine that had been approved by the Food and Drug Administration in 1970. In response to the unanticipated opposition on the Internet and in the press, an extensive information campaign was developed. This paper suggests that a more proactive educational program with a greater utilization of health risk communication techniques could have reduced much of the negative reaction to the anthrax vaccine. Such techniques as early use of focus groups and surveys could have measured the effectiveness and comprehension of the message. Early evaluations could have identified challenges involving trust, credibility, and organizational biases, which appeared as the program matured. More focused application of effective health risk communication techniques in the creation of the Anthrax Vaccine Immunization Program would have reduced the amount of controversy generated by the program. Lessons learned by studying the development and implementation of health risk communication in the anthrax program can be applied to other military programs, including not only those involving vaccines, but also those having to do with controversial issues such as depleted uranium rounds or toxic exposure standards.



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**HEALTH RISK COMMUNICATION  
IN THE ANTHRAX VACCINE IMMUNIZATION  
PROGRAM:  
LESSONS FOR THE FUTURE**

“A camel is a horse designed by committee.”  
—Sir Alec Issigonis, *The Guardian*

## **1. INTRODUCTION**

It was not too long ago that a service member’s only question in response to a directive to be vaccinated was, “Which arm?”

But times have changed. There has been a paradigm shift, and society is more questioning, especially in the area of medicine. In today’s military, individual concerns about health and the environment generate countless questions.

When Secretary of Defense William Cohen announced in 1997 that military service members would be vaccinated with the anthrax vaccine, no one anticipated widespread reluctance to accept the vaccine. Service members were already required to have several vaccinations and this new force protection measure involved a vaccine that had been approved by the Food and Drug Administration (FDA) in 1970.

In his announcement, the Secretary of Defense had called for a communication plan. The Department of Defense (DOD) also recognized that an educational campaign was required. To meet the communication needs of this multi-service immunization program, a committee of about forty-five members was formed. This diverse group of professionals created the first brochures and briefings for the Anthrax Vaccine Immunization Program (AVIP). Committee members included some individuals who had been trained in risk communication, but their voices were in the minority. In order to

reach consensus and quickly produce the products, many compromises were made. Instead of a high-speed horse that could win the information war, the committee designed a camel, which few members liked and which was inadequate for battling the increasingly vocal opposition to the AVIP.

Since the Vietnam War, no other subject has generated as much public debate both within and outside the military. A few hundred service members who refused the vaccine may seem like a small number when compared to close to two million vaccinations administered, but the impact has been large, especially in terms of the negative publicity generated.

This paper suggests that a greater utilization of health risk communication techniques in the creation and implementation of the AVIP would have helped to minimize questions, concerns, and resistance to the program. As the AVIP developed and expanded, risk communication took on a greater role. Consequently, current AVIP informational products and methods are more reflective of the high-speed horse that is running fast to catch up, anticipate, and address all service members' questions.

Before discussing health risk communication lessons learned during development of the AVIP, this paper presents information on anthrax and the anthrax vaccine, the decision to implement the immunization program and its aftermath, and an overview of risk communication.

## 2. ANTHRAX

### 2.1 Definition and History

Anthrax is a fatal disease normally associated with plant-eating animals. The term “anthrax” comes from the Greek word for coal, which is associated with the blackened patches of dead skin that appear on affected organisms.

Anthrax is a bacterial infection caused by *Bacillus anthracis*, which forms a spore. Anthrax spores can survive for decades because they are highly resistant to climatic changes, sunlight, radiation, acids and many disinfectants.<sup>1</sup> Grazing animals normally inhale or swallow the spores while eating. If unvaccinated, animals ingesting enough anthrax spores will die.

Although anthrax spores are persistent in the soil and resist environmental degradation, humans rarely are infected as a result of direct exposure to spores in the soil. This is because the spores tend to clump and bind to the soil, thus reducing the possibility of inhalation of anthrax spores. In humans, infection results from contact with contaminated animals or animal products. There has never been a reported case of human-to-human transmission.<sup>2</sup>

Anthrax is one of the oldest infectious diseases known to man. The earliest reference is in biblical descriptions of great plagues which killed Egyptian cattle. In the seventeenth century, a disease known as the “Black Bane” devastated the livestock of Europe and killed sixty thousand people. Records indicate that, in the mid-1800s, workers who had direct contact with raw animal fibers developed anthrax. It became known as wool sorter’s disease in England and rag picker’s disease in Germany.

In the United States, cattle deaths from anthrax were occurring even back in colonial times. The first recorded human death attributable to anthrax in the United States was in 1824 among ranch hands in Kentucky who were exposed to diseased animals. Since then,

cases have been reported in just about every state. In the early part of the twentieth century, the number of human cases of anthrax was over a hundred a year. Vaccinations of both the animals and the at-risk human population combined with occupational health measures have reduced the occurrence in the United States to one case in the last ten years.

The occurrence of anthrax has been reported in just about every country of the world. Most human cases today occur in Africa and Asia, where preventive measures are not as strictly enforced as in Western countries.<sup>3</sup>

## **2.2 Health Effects in Humans**

Humans contract anthrax by exposure through a cut on the skin, eating an infected animal, or inhalation of anthrax spores. Inhalation exposure is the most deadly. Initial symptoms include fever, nonproductive cough, malaise, and fatigue, all of which are similar to the symptoms of a common cold, flu, or upper respiratory tract infection.<sup>4</sup> Compounding the vagueness of these symptoms is the fact that they do not appear until three to five days after exposure by inhalation.<sup>5</sup> Treatment of inhalation anthrax is effective only when administered *before* symptoms appear. Treatment consists of large quantities of antibiotics given intravenously several times a day for at least six weeks.<sup>6</sup> Upon onset of symptoms, death from hemorrhage, respiratory failure, and toxic shock follows in twenty-four to forty-eight hours. Once symptoms develop, the mortality rate is near 100 percent.<sup>7</sup>

## **2.3 Anthrax as a Weapon**

Issues relating to the ongoing debate on the validity or probability of the threat posed by anthrax as a weapon are outside the scope of this

paper. Nevertheless, it can be assumed that the threat of biological warfare is real and warrants force protection measures.

Anthrax is considered the biological weapon of choice for many reasons. As mentioned above, it is close to 100 percent lethal if not treated before the onset of symptoms. Once the flu-like symptoms appear, there is no effective cure. Anthrax has no smell or taste and cannot be seen. One deep breath of anthrax spores can kill a human being.<sup>8</sup> Anthrax is found naturally around the world and, with a basic knowledge of biology, can be produced in large quantities in a laboratory. The equipment used to create anthrax spores can be hidden in legitimate facilities. There are valid public health and zoological justifications for possessing anthrax bacteria or spores. Anthrax spores are resilient and have a shelf life that can be measured in decades. Anthrax can survive the delivery system of a rocket, a missile, or an artillery shell. Sprayers—either industrial or hand-held garden-style units—can be transported by car or plane and can deliver anthrax spores as a dry powder or liquid slush. Small anthrax particles can remain airborne for long distances and cover large areas.

Rear Admiral Lowell Jacoby, Director of Intelligence for Joint Staff, testified before the 106th Congress:

A smaller quantity [of anthrax] is required for the same area of coverage when compared to other weapons of mass destruction...For comparison, for 120 square kilometers of coverage, you would need [a] one-megaton yield of nuclear material, 158 metric tons of a chemical agent, and only 6.5 kilograms of anthrax. Anthrax is 100,000 times more lethal than chemical agents.<sup>9</sup>

In 1979, an outbreak of inhalation anthrax occurred in Sverdlovsk, an industrial city of the old Soviet Union. Sixty-six individuals died as the result of an accidental aerosol leak from a biological weapons research facility.<sup>10</sup> This accident illustrates the very real possibility of anthrax being manufactured and used as a lethal weapon by a potential enemy.

## **2.4 Vaccine: Ideal Force Protection Measure**

In the late 1990s, the military determined that the anthrax vaccine is the most effective risk management option to reduce the threat or hazard of anthrax exposure. Protective masks and clothing offer effective protection, but they cannot be worn for extended periods of time. Advance detection devices lack the sensitivity and response time to protect our forces. As mentioned earlier, treatment for inhalation anthrax is effective only if administered before symptoms appear. Even if early identification of exposure were possible, the treatment of a large number of casualties for several weeks would overwhelm medical resources.

The senior leadership strongly believes the vaccination is imperative to protect the troops. In testimony before the Military Personnel Subcommittee of the House Armed Service Committee in October 1999, Deputy Defense Secretary John J. Hamre noted that the anthrax vaccine is as necessary for force protection as a flak jacket or helmet. “If you don’t get inoculated, you’re going to die.”<sup>11</sup> At the same session, General John Keane, Army Vice Chief of Staff, testified that “we have a moral obligation to do everything in our power to protect our troops from the anthrax threat.”<sup>12</sup> While addressing the troops at Al Jaber Air Base, Kuwait, on 9 March 1999, Secretary of Defense William S. Cohen stated: “If you were not properly protected against [anthrax], I would be derelict in my duties sending you out in an environment in which you weren’t properly protected.”<sup>13</sup>

## **2.5 Vaccine: Certification, Dosage, Safety, and Surveillance**

During the nineteenth century microbiology’s founding fathers worked on developing an anthrax vaccine. In 1881, Louis Pasteur successfully demonstrated the effectiveness of an anthrax vaccine for animals. Work on producing an anthrax vaccine for humans dates

back to the 1950s in Great Britain and the 1960s in the United States.<sup>14</sup> The National Institutes of Health's Division of Biologics Standards awarded the Michigan Department of Public Health a license for the U.S. vaccine on 4 November 1970. In 1980, the vaccine was re-certified safe and effective when responsibility for biomedicine was transferred from the National Institutes of Health to the FDA.<sup>15</sup>

The policy of the Department of Defense is to administer the vaccine in accordance with the FDA schedule of six shots over eighteen months. The first three shots are given two weeks apart and the next three shots are given five or six months apart. For prolonged protection, an annual booster is required.

This paper does not attempt to add to the volumes of material and heated discussions on the safety and efficacy of the anthrax vaccine. As with any vaccine or medicine, there is always a risk of side effects, long-term effects, and combined effects.

The Secretary of Defense, the Service Secretaries, each of the Joint Chiefs of Staff, and the military Surgeons General have all stated that the anthrax vaccine is safe and were among the first to take the immunization. The AVIP Agency compiled a list of thirteen independent human safety studies spanning over fifty years and 366,000 vaccine recipients.<sup>16</sup> These studies demonstrate that the anthrax vaccine is safe.

As with most vaccines, there is pain and swelling after the injection and, as with all vaccines, there may be some flu-like side effects and occasional adverse reactions. Approximately 30 percent of men and 60 percent of women will experience soreness and redness at the injection site. These injection-site reactions go away in one to three days. Significant events beyond the injection site occur in less than 1 percent of the recipients. These rates are the same as or lower than the rates for mandatory childhood vaccinations and the same as or lower than the rates for other vaccines administered to military personnel.<sup>17</sup>

As part of its safety surveillance program, the FDA uses the Vaccine Adverse Event Reporting System (VAERS) to identify problems with licensed vaccines. This system was initiated in 1990



and is jointly managed by the Centers for Disease Control and Prevention (CDC) and the FDA. The VAERS is a passive system that relies on voluntary reports from physicians, patients, or parents. Because of the voluntary nature and the lack of monitoring of reporting practices, it is likely that not all adverse reactions are reported. Conversely, not all the adverse reactions reported are necessarily related to a vaccine.<sup>18</sup>

All DOD physicians are required to submit a VAERS report when an anthrax immunization causes an adverse reaction that results in a loss of duty time greater than twenty-four hours or when a service member is hospitalized. Any potential contamination of vaccine vials must also be reported. The healthcare provider (or the service member) can report any other vaccine-associated event.<sup>19</sup>

At DOD's request, the Department of Health and Human Services created the Anthrax Vaccine Expert Committee in October 1998 to review VAERS reports. The independent civilian experts who make up the committee meet every four to six weeks to look for clinically significant patterns. This type of review, which is not conducted for any other licensed vaccine,<sup>20</sup> demonstrates DOD's commitment to continue to monitor the safety of the anthrax vaccine.

Table 1 shows that, as of 23 January 2001, of the 1,439 reports submitted, only 756 reports were attributable to the vaccine. Of the 756 reports related to the vaccine, only 11 involved hospitalization for allergic reactions.

**TABLE 1. REPORTS REVIEWED BY THE ANTHRAX VACCINE EXPERT COMMITTEE**

	Total Unique Form VAERS-1 Reviewed Through 23 Jan 01 <sup>a</sup>	Reports Other Than Serious (no loss of duty >24 hrs nor hospitalized)	Loss of Duty >24 hours (not hospitalized)	Hospitalized
Total Reports	1439 <sup>b</sup>	1200	186	53
Certainly or probably caused by anthrax vaccine	756	621	124 <sup>c</sup>	11 <sup>d</sup>

As of 1 February 2001, 500,270 people had been vaccinated with 2,005,357 doses of anthrax vaccine. Source: available from <<http://www.anthrax.osd.mil>>; Internet; accessed 13 February 2001

<sup>a</sup> VAERS-1 forms record events that happen after vaccination. Some events are caused by the vaccine, some are not.

<sup>b</sup> Excludes 19 duplicate reports for a total of 1458 VAERS-1 forms reviewed; represents VAERS-1 forms for 1390 individuals.

<sup>c</sup> Includes injection-site reactions (76), rash (17), acute allergic reaction (10), flu-like symptoms (9), pruritus (4), gastroenteritis (2), angioedema (1), bronchiolitis obliterans (1), myalgia (1), paresthesia (1), photophobia (1), swollen lymph node (1)

<sup>d</sup> All eleven were allergic, inflammation reactions at injection site.

### **3. IMPLEMENTING THE ANTHRAX VACCINE IMMUNIZATION PROGRAM**

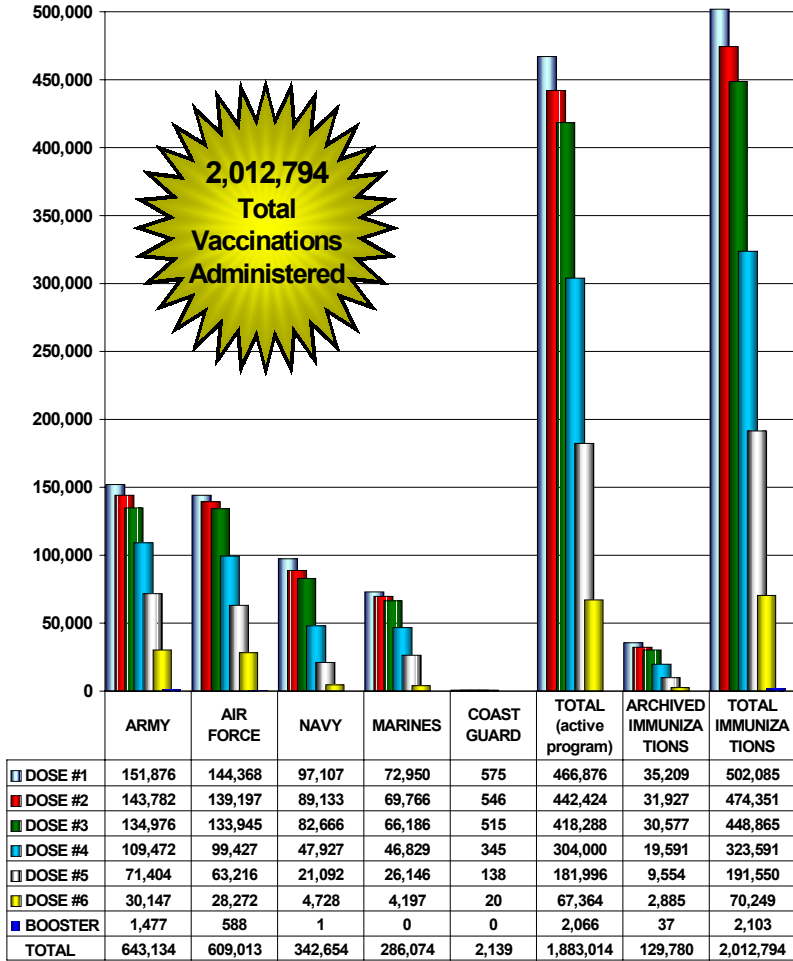
#### **3.1 Decision to Implement**

On 15 December 1997, Secretary of Defense William S. Cohen announced plans to vaccinate all 2.4 million military personnel against the biological warfare agent anthrax. Calling the program a force protection issue, he stated that vaccinations would start only after four conditions had been met:

- Supplemental testing, consistent with Food and Drug Administration standards, to assure sterility, safety, potency and purity of the vaccine
- Implementation of a system for fully tracking personnel who receive the anthrax vaccinations
- Approval of appropriate operational plans to administer the immunizations and communications plan to inform military personnel of the overall program
- Review of health and medical issues of the program by an independent expert<sup>21</sup>

To immunize the total force (including the Reserve components) of 2.4 million would cost \$130 million and take over six years.<sup>22</sup> The services were tasked to develop a three-phase implementation plan beginning with troops stationed in high-threat areas (Southwest Asia, Korea). The second phase was immunization of early deploying forces. The third phase was immunization of the remaining service members and new accessions. Table 2 depicts the total force anthrax immunization status as of 7 February 2001.

**TABLE 2. TOTAL FORCE ANTHRAX IMMUNIZATION STATUS**



Source: DEERS, 7 February, 2001; available from <<http://www.anthrax.osd.mil>>; Internet; accessed 13 February 2001

## **3.2 Creating the Communication Plan**

It is clear that, from the beginning, a communication plan was a key component of the AVIP. Senior leadership recognized the importance of an education program to communicate information regarding anthrax-related risks and risk management.

Nevertheless, when the Secretary of Defense approved the AVIP program on 15 December 1997, the communication plan and informational materials were merely preconditions; they had not yet been developed.

The first set of communication materials was developed at an Anthrax Risk Communication Off-Site Conference on 10–12 February 1998. The initial communication plan consisted of a coordinated series of press releases and articles in military publications and installation newspapers. Separate standardized PowerPoint briefings with text were prepared for the leaders, troops, and healthcare workers. A tri-fold brochure was created for distribution during briefings. Emphasis was placed on ensuring that, prior to their first vaccination, vaccine recipients were provided with information on the threat, the vaccine, its safety, and its benefits.<sup>23</sup> If a service member was not serving or scheduled to serve in a high-threat area, then that individual was not briefed.

## **3.3 Program Staffing**

The initial AVIP program was designed and run by a tri-service committee. This committee met weekly until 18 May 1998 when the Secretary of Defense tasked the Army to serve as lead agent. Staffing of the program grew over time. What had begun in late 1997 as an additional duty assigned to one officer was by the fall of 1999 a full-time agency of thirty personnel with three supporting contracts.

### **3.4 Expert Review: The Need for Focus Groups**

One of the preconditions listed by the Secretary of Defense was a review of health and medical issues of the program by an independent expert. Dr. Gerald Burrow of Yale University School of Medicine conducted this review and submitted his report on 19 February 1998. Dr. Burrow commented on the heightened concern among service members regarding the anthrax vaccination: “Focus groups composed of military personnel might be helpful in ensuring that the proper message is being conveyed to the individuals receiving the vaccine.”<sup>24</sup>

In order to comply with the suggestion to use focus groups, DOD tasked the risk communication office of the U.S. Army Center for Health Promotion and Preventive Medicine to travel to Fort Bragg, North Carolina on 23 February 1998 to conduct a series of focus groups with soldiers and their families.<sup>25</sup>

On 28 April 1998, the Assistant Secretary of Defense for Health Affairs sent a memorandum to the Secretary of Defense indicating that the four preconditions had been met. He also stated that the recommendation to use focus groups had been implemented.<sup>26</sup>

Although vaccinations were originally scheduled to start in the summer of 1998, the program actually began on 10 March 1998 at the request of the Commander of Central Command.<sup>27</sup> The training materials were immediately sent to Southwest Asia for the start of immunizations. Informal anecdotal feedback on the tri-fold brochure and briefings was obtained from the deployed soldiers.

### **3.5 Vocal Opposition and Refusers**

In April 1998, the first large-scale opposition began when ten sailors on the USS Independence refused to take the vaccine. Grassroot efforts questioning vaccination policy, safety, and effectiveness began to appear on a number of Internet websites. Several Air National

Guard pilots resigned or transferred to avoid taking the vaccine. Active duty troops who refused to be vaccinated were court-martialed and discharged from the service. Congressional hearings publicized several sensational cases of service members who had become ill and who blamed the vaccine for their ailments. Congressional bills were introduced to halt the program or to make it voluntary.<sup>28</sup>

The anthrax threat assessment had warranted a mandatory force protection program of inoculations. This was not the first time the military had required mandatory vaccinations.<sup>29</sup> The concept of placing the mission of protecting the force over the need to obtain informed consent was not new to the military. So why was there so much opposition from service members refusing to take shots? What was the reason for the congressional inquiries and unfavorable reports in the media?

During congressional testimony, Deputy Defense Secretary John J. Hamre said that the initial education program had been directed at the deployed members of Central Command. He testified, "I would admit we have not done a good enough job explaining to all of the people at home."<sup>30</sup> Dr. Sue Bailey, the Assistant Secretary of Defense for Health Affairs, commented in October 1999 that it is particularly difficult to communicate with Reservists. "We are not with them frequently enough to provide as much in terms of the intense communication that I think assures the success of a program like this."<sup>31</sup> Deputy Secretary of Defense Rudy de Leon testified before Congress on 13 April 2000 that improvements were needed in education and communication.<sup>32</sup>

## **4. RISK COMMUNICATION**

Before discussing ways in which risk communication techniques could have improved the anthrax communication plan, an overview of risk communication is provided. This emerging field has many applications in designing, implementing, and delivering a desired message.

### **4.1 Communicating Information about Risk**

There are many hazards in modern life. Our environment, food, occupations, and leisure activities all have potential hazards and risks. Government, science, and industry communicate messages about those risks. Historically, the messages have tended to flow in only one direction, from experts to non-experts.<sup>33</sup>

In 1989 the National Research Council altered this one-way approach by describing risk communication as “an interactive process of exchange of information and opinion among individuals, groups and institutions.”<sup>34</sup> DOD went even further. In 1998 it proposed a tri-service definition describing risk communication as “the early and ongoing process of building and maintaining relationships based on mutual trust and credibility through meaningful dialogue about complex and sensitive issues.”<sup>35</sup>

### **4.2 Risk Analysis and Management**

When there is a potential threat to health, the environment, or even national security, a risk analysis is performed. Then, to reduce the risk, a course of action or risk management is selected. Managing the risk usually involves changing peoples’ behavior, which is attempted through risk communication.



There are three types of risk communication that can be used to help manage risk. First, risk communication can simply be advocacy to persuade or convince people to take the desired course of action. Next, risk communication can provide education so that people can have the information they need to make their own decisions. The third method of risk communication (which is viewed as the most successful) is to promote a partnership early in the process of risk analysis and selection of the risk management solution.<sup>36</sup>

### **4.3 Health Risk Communication**

Traditionally, risk communication has been used in environmental health decision-making with community involvement on issues like lead-based paint, indoor radon, air or water pollution, pesticides, or hazardous waste. Health Risk Communication (HRC) is one of the most common applications of risk communication. In HRC, the message is designed to change people's behavior so as to improve health and well-being (e.g., eating more vegetables, quitting smoking).

### **4.4 Vaccine Risk Communication**

Although HRC has existed for decades, vaccine risk communication is a relatively new field. There are some unique challenges in the area of vaccine risk communication because, with vaccines, healthy individuals are given a medication for some presumed future benefit. All vaccines, like all medicines, have the potential for side effects. In fact, no vaccine is 100 percent safe or 100 percent effective. Sick patients are often more willing than healthy patients to accept treatment involving the small risk of a potentially adverse reaction in order to improve their health. Cancer patients, for example, are willing to accept painful and life-threatening treatments to extend their life expectancy.

Compounding the issue of “invading” a healthy body with a vaccine is the fact that the occurrence of some vaccine-preventable diseases is rare in industrialized Western societies. This can make it a challenge to convince a parent who has never seen the devastation of a vaccine-preventable disease. In the case of polio, for example, a parent may perceive the risk of the vaccine’s side effects as greater than the risk of the disease.

Even though vaccines are credited with saving more lives than antibiotics, there has always been a vocal minority opposed to vaccinations. In England during the 1800s there was an anti-vaccination political party and there were demonstrations against a mandatory smallpox vaccine.<sup>37</sup> Even today there are people opposed to the concept of giving a healthy person a shot with a low risk of side effects for the sake of a future possible benefit. The arguments used by most objectors are that the disease is uncommon or not serious (treatable) and that the vaccine is ineffective or unsafe.

Vaccinations can be painful. When we become ill, the human tendency is to look for explanations as to how and why we got sick. This is especially true for disorders for which there are no known causes, like Sudden Infant Death Syndrome, autism, or illnesses among Gulf War veterans. Any illness following a shot may be erroneously attributed to the vaccine.

Most physicians use vaccine risk communication to educate patients or parents on the risks and benefits, thus enabling them to make appropriate decisions. Vaccine risk communication attempts to convey the science and probabilities, information regarding benefits and risks. But effective vaccine risk communication is more than a presentation of facts on risk versus reward; it involves transmitting the information in such a way that the patient can voluntarily make a decision. A patient’s willingness to assume the risk of a vaccination in exchange for the benefits is called informed consent. In an extreme example, informed consent is what differentiates surgery from assault with a deadly weapon.<sup>38</sup>

There are situations in which the government, in the interest of public safety or national defense, has the right to override individual rights. A historical example of the consequences of not doing this

occurred during England's involvement in the 1898 Boer war. The senior British leadership wanted to inoculate all deploying troops with the new typhoid vaccine. Opposition was so strong that Parliament made the vaccine voluntary. Ultimately, fourteen thousand British soldiers took the shot. During the war, fifty-eight thousand troops contracted typhoid fever and nine thousand of them died. In contrast, during World War I, mandatory typhoid shots protected millions of British and U.S. service members.<sup>39</sup>

In today's forces, a partially protected force could impact the mission and easily overwhelm the medical evacuation system and field hospitals.

## 5. STRATEGIES FOR IMPROVEMENT

The remaining part of this paper focuses on several risk communication techniques that could have been used to improve the anthrax program. Principles of risk communication recognize that evaluating the plan, identifying stakeholders, delivering the message, and establishing trust are critical components in any communication program. Utilizing these components in the creation of the AVIP would have resulted in more effective implementation.

Since the AVIP has learned from its early omissions, this discussion serves as a strategy for improving future programs. Lessons learned through this retrospective analysis can be applied when DOD needs to create a communication plan for a new vaccine or technology with health concerns.

The analysis begins with evaluation because early evaluation gives shape to the plan and reinforces the need to apply the other components.

### 5.1 Importance of Evaluation

In 1993, the Public Health Service conducted an analysis of its HRC programs. The analysis determined that lack of evaluation was the greatest weakness of these programs.

In designing a communication plan for a message, goals and objectives must be established and a method of evaluation must be incorporated. The Public Health Service study found that most programs used a collecting process (e.g., number of pamphlets printed) and anecdotal information in lieu of evaluating the outcome or impact of the plan.<sup>40</sup>

The initial AVIP communication plan failed to address the concept of testing the message or evaluating the success of the plan. Creating a system of evaluation prior to the start of the program

could have reduced the learning curve and produced a more effective communication plan.

Evaluation techniques (focus groups, questionnaires, surveys) can be used to identify stakeholders and their perceptions. Identification of the stakeholders' values, priorities, and sources of information are critical to the success of an HRC. Pre-testing and pilot studies can determine the effectiveness of a proposed HRC program and provide early feedback on the HRC materials. The evaluation plan should also measure the success of the plan. Reporting on the number of immunizations administered or briefings conducted reflects implementation rather than message acceptance.

### ***5.1.1 AVIP Evaluation Plan: Missing in Action***

If evaluation is so critical, why is it so often omitted? The traditional reasons for lack of evaluation in HRC are probably not applicable to the AVIP. Funding was not a limiting factor, nor were the program administrators fearful that evaluations might identify serious problems. Limited staffing, the rush to implement, and vague goals interfered with the creation of an early and extensive evaluation plan.

### ***5.1.2 Limited Personnel and Time***

Less than ninety days after the Secretary of Defense announced the need for a communication plan, soldiers were receiving the anthrax vaccine. The short time allotted for creating a plan did not permit the planning committee sufficient time to effectively evaluate the plan.

As mentioned earlier, there was one focus-group test conducted at Fort Bragg. This one and only instance of pre-implementation testing occurred with only a three-day notice. A small team met with fourteen groups of ten soldiers and two groups of family members. Some groups were interviewed before receiving the anthrax training and others groups met following the training. The training itself was conducted after only a couple of days of preparation time.

The focus groups raised several important issues and generated useful comments. The results were immediately telephoned back to Washington D.C. for consideration. Personnel in Washington were standing by the phones at 8:30 P.M. to get the results of the evening discussions with family members. The reason for this immediate feedback was not to satisfy curiosity but to meet the deadline for producing the briefing materials and educational brochures. The speed with which this was all done is best illustrated by the fact that the risk communicators were told they did not have to submit written reports on the focus groups because the results had already been received and incorporated. Even though this focus-group testing identified several new concepts and potential barriers, use of focus groups was not continued.<sup>41</sup>

Feedback from the Fort Bragg focus groups as well as informal comments from the first troops to get the vaccine in Southwest Asia were unquestionably useful. However, this small sample of one installation and one set of deployed troops did not reflect the entire force. More extensive data collection from professional facilitators would have provided critical information on the perceptions of such groups as Reservists and aviators. Having a full-time staff working on the anthrax program could have made possible the design and implementation of an effective evaluation plan even within tight time constraints.

When creating future communication programs, DOD needs to recognize that resources of staff and time must be available to accomplish critical tasks like designing and implementing an evaluation plan.

### ***5.1.3 Measurable Objectives***

As noted above, without evaluation there is no way to determine the effectiveness of an HRC effort. The Public Health Service review of HRC programs found that a clearly defined outcome is critical to an evaluation program.<sup>42</sup> In order to conduct an evaluation, one must have a clearly defined objective that is measurable.

In the Army's May 1999 implementation plan, the communication objective was to "Ensure full understanding and acceptance of the Anthrax Vaccine Immunization Program by all stakeholders..."<sup>43</sup> How does one evaluate achievement of this objective? Does one use the number of briefings conducted, shots or doses administered, or service members refusing the vaccine? When the program was initiated, DOD did not have a method to define and measure acceptance.

The ultimate goal of the AVIP is to immunize the 2.4 million members of the DOD, although normal turnover makes this a process rather than an end point. The number of doses administered has often been briefed as an indicator of the program's success.

Acceptance could be defined as someone who does not refuse the vaccination. If service members refuse the immunization, then they receive individual counseling from their chain of command and healthcare professionals. If they continue to refuse, they are subject to disciplinary action that may result in separation from the service. Is lack of acceptance measured by counting the number of personnel counseled or just those disciplined? What about the service members who declined reenlistment or retired to avoid the vaccination? It is difficult to assess departures as solely attributable to lack of acceptance of the AVIP. Service members leave the service or transfer from Reserve units for a variety of reasons and sometimes multiple reasons.

The U.S. General Accounting Office (GAO) reported that DOD collected anecdotal data on refusals until January 1999. At that time, according to GAO, AVIP program managers felt that the small number of refusers was not worth the labor-intensive data-collection effort.<sup>44</sup> The relatively low number of refusers is even offered by DOD leadership in support of the program.<sup>45</sup> In contrast to this view, however, the number of refusers is one of the most often asked questions at official news conferences and during congressional testimony.

To determine the success of any vaccine HRC plan, DOD must measure message comprehension and message acceptance. To measure acceptance, DOD needs to quantify and analyze all service members who express a reluctance to receive the vaccination. In re-

sponse to the above-mentioned GAO report, DOD indicated that it planned to expand survey collection and study methods to collect refuser data. The challenge of collecting refuser numbers is being met jointly by the services, which are striving for consensus on how to define and measure refusers.

Identifying measurable outcomes for use in evaluating communication is a key component in determining the success of any future communication plan.

## **5.2 Stakeholders: Identify and Involve Early**

Identifying the stakeholders who are impacted by the risk management action is also a key step in designing an effective message. Involving the stakeholders early in the process will assist in message creation as well as message acceptance.

The Public Health Service has noted that, for effective HRC, stakeholders must be clearly specified.<sup>46</sup> The message as well as the HRC methods should be tailored to meet the needs of each subgroup.

The military is far from a homogeneous group representing similar values, perceptions, education, gender, and duty status. Although leaders and policy makers generally use science to make decisions, some troops may use emotion to make decisions. One group is influenced by statistics and another is moved by stories. There are many stakeholders outside the military, such as Congress, parents, veterans' organizations, and the media. Using the same message for all groups merely creates visibility for the program. A tailored message with varying levels of detail for each stakeholder group is required to meet the wide assortment of informational needs.

The AVIP has developed many state-of-the-art HRC methods to address a wide group of stakeholders. The early planning committee identified twenty groups as potential stakeholders. Additional key groups were discovered after the program's implementation. Military aviators were among the most vocal opponents to the program.<sup>47</sup> This highly educated subgroup is required to have an in-



creased sensitivity to health concerns. Merely taking over-the-counter antihistamines can impact an aviator's flight status. Another group of stakeholders identified after program implementation was civilian anti-vaccine organizations. Reservists are yet another group that poses a communication challenge. Reservists have infrequent contact with their units and may receive most of their information and healthcare advice from sources outside military channels.

The early use of survey groups and pre-testing would have identified some key groups early in the program's implementation. A proactive HRC program designed by flight surgeons and the Federal Aviation Administration could have reduced opposition from the vocal and influential aviators. An early assessment of the concerns and methods of the civilian anti-vaccine groups may have resulted in the creation of better HRC materials. Survey groups could have highlighted the challenges of designing a tailored communication plan for Reservists.

Once all the stakeholders are identified, it is important to involve them early in the process. The unanticipated reluctance to accept the anthrax vaccine may have been avoided or reduced by involving service members in the design of the communication plan.

The Environmental Protection Agency attempts to get stakeholder involvement before the risk management decision is completed.<sup>48</sup> In vaccine risk communication, the goal is to ensure full comprehension of the message so that people can be self-sufficient in making decisions and arriving at informed consent. Conventional wisdom and recent research indicate that effective risk communication requires early stakeholder involvement. How can this apply when the government retains decision-making authority and the risk management method is mandatory?

When stakeholders cannot be involved in the risk analysis or the selection of the risk management, then stakeholder involvement in the risk communication takes on even greater importance. Stakeholders can be given an early and active role in identifying the most influential sources, determining which third-party experts are most credible, selecting the most important aspects of the message,

and highlighting the barriers or obstacles. The risk communication plan itself must be carefully designed and thoroughly tested.

### **5.3 Delivering the Message**

Risk communication techniques provide ways of delivering a message through public presentations. The chain of command has the primary mission to educate troops by using its HRC materials prior to initiation of the program. The challenge is that the message may be delivered through means other than the training conducted by commanders. The media and the Internet are primary sources of information and sometimes send a message counter to DOD's goal. Incorrect perceptions can be instilled in service members exposed to oppositional coverage prior to receiving DOD's HRC message.

#### ***5.3.1 First Impressions Are Sometimes Lasting Impressions***

The reason the literature advocates early stakeholder involvement and extensive pre-implementation testing is to enable the risk communication program to get out in front of the opposition. If one's first exposure to an issue is a skeptical questioning article or conspiracy-style website, the result may be a negative first impression. This, combined with ambiguous outcomes and uncertainty within science, may lead to a cognitive bias that favors the initial impression even as new evidence disputes the early perception.<sup>49</sup> Subsequent presentation of more complete and accurate information may be unable to overcome the initial impression that has, over time, become embedded. Later attempts by the government to explain its motivations and decisions can be viewed as defensive or heavy handed.

In the case of the AVIP, the initial approach was to provide "just-in-time" education that intensively briefed members of a unit a few months prior to their inoculations. The expectation was that, by presenting the information concurrently with the announcement of a shot date, the attention of the audience would be ensured. The prob-

lem was that other units (even on the same installation) without a projected inoculation date were not receiving any education. One could only hope that they were reading the official news releases in the installation newspaper or service magazines, not oppositional news articles. One can only wonder what the results would have been if AVIP initial efforts had been directed at the total force rather than focusing on an early immunization of Central Command.

Delivering a timely message remains a challenge for the AVIP. The military bureaucracy necessitates a lengthy and complex process to arrive at a policy decision. This is best illustrated by the anthrax video. Early on, the decision was made to create a professional 15-minute educational video that utilized risk communication techniques. This video was to be viewed by every service member in DOD. The video was produced in three weeks but took nine months to staff. In order to accommodate all services, every comment was incorporated, which meant making over 150 changes and going through countless staffings. The result was a 23-minute video, which hardly anybody liked. The worst part was that the video entered the information war almost a year after it had been requested. The AVIP Agency has learned from this experience and is attempting to streamline the consensus process to seek a more expeditious approval procedure for future products.<sup>50</sup>

### ***5.3.2 The Media Is Not Always an Ally***

The media is one of the largest and most influential sources of information in any risk communication campaign. Congress is extremely sensitive to how the media portrays an issue. The media influences the stakeholders and, in the case of the AVIP, has been the primary source of information for parents and Reservists. Coverage of the Army's anthrax program has not always been favorable. Articles, editorials, and letters to the editor have frequently presented distorted coverage of the program.

In 1988, the U.S. Environmental Protection Agency commissioned some of the most renowned researchers in risk communica-

tion to create the “Seven Cardinal Rules of Risk Communication.” Rule number six is “Meet the needs of the media.”<sup>51</sup> The AVIP Agency has done a good job with rule number six by preparing numerous press releases and arranging for spokespersons to appear on television shows like “60 Minutes,” “Talkback Live,” “Nightline,” and “20/20.”

Working effectively with the media means more than having an effective Public Affairs staff. It is important to remember that the media may be more focused on entertainment than on education. In addition, the media has certain limitations and concerns that must be kept in mind.

The media usually attempts to present a balanced story that reflects both sides of an issue without judging one side over the other. Some reporters do not seek the truth, but rather accurately report what others believe to be true.<sup>52</sup> This appearance of balance hardly seems fair in the case of something like the anthrax vaccine, which is supported by the preponderance of scientific data and the judgment of medical professionals. Emotional and sometimes sensational counter-arguments based on isolated cases may not deserve the weight they are given in a particular news story. Stories that depict the government making a mistake, being reckless, or seemingly harming a helpless citizen create sensational headlines and sound bites. The challenge to HRC is to publicize the overwhelming weight of evidence that produces credibility. It is not an easy task to overcome skepticism about the government.

History provides examples of cases in which inaccurate or misleading reports have reduced participation in vaccination programs, thus resulting in outbreaks of preventable disease. In the mid-seventies, the pertussis (whooping cough) vaccine was reported as being suspected of causing serious side effects. Immunization rates fell in several countries (e.g., United Kingdom, Japan) and, consequently, hundreds of unvaccinated children died. Several later studies concluded that the vaccine’s side effects were temporal coincidences.<sup>53</sup>

One unfavorable news report will not derail an effective HRC program. The challenge arises from the momentum created by a

news story being investigated by other reporters. This is especially true when a media leader covers a story. Even when the news story presents something as a rumor, it can be perceived as a fact if it is reported frequently enough.

The AVIP Agency has recognized this synergistic effect and has attempted to respond to all unfavorable coverage through the *Washington Post*. What if the AVIP Agency had had a Public Affairs staff dedicated to this effort back in 1997 when the anthrax decision was announced? Could a more timely and proactive response have prevented the sensational and frequently inaccurate media coverage?

### **5.3.3 Dominant Internet Presence Is Required**

The Internet is a relatively new media form that has had a tremendous impact on the anthrax campaign. This private in-home source of information has proven to be one of the most important influences for many stakeholders.

The challenge posed by the Internet is that there are no journalistic standards or even attempts at balanced coverage. Unlike newspapers and television stations, which exercise self-imposed disciplines, the Internet has no requirement to validate sources or facts. There are no attempts to make retractions when errors are made. Websites can highlight the extremes without discussing the probabilities. They can appeal to the emotions and display rare shocking photos. Anyone with an opinion can create a website and offer official-sounding perceptions as absolute facts. Dubious scientific research or “junk science” can be presented as having the same credibility as information in a peer-reviewed journal.

Prior to the establishment of the AVIP Agency, an ad hoc committee designed the initial communication plan. Someone suggested that DOD create a website to assist in delivering the HRC message. This idea was rejected because a senior committee member expressed the view that service members do not use the Internet.<sup>54</sup>

By early fall of 1998, it became apparent that the anthrax “information war” had begun and that DOD was losing the Internet battle. In November 1998, DOD quickly posted some anthrax

information papers on the Defense Link website. At a modest cost of \$12,000, an Internet presence was established. The site experienced about 5,000 visits per week.<sup>55</sup> In the summer of 1999, DOD invested almost \$500,000 to create a much more sophisticated website dedicated to the AVIP. At present, the AVIP's third-generation, state-of-the-art interactive website has become one of its most effective ways of interacting with stakeholders.

Ease of access to the site is critical in reaching the intended audience. In early 1999, when someone typed "anthrax" on a search engine, the top ten hits would be the anti-anthrax groups and the Anthrax Rock Band website. The official DOD information site did not even appear. In stark contrast, a search today finds AVIP several times in the top ten with the opposition ranked far back in the third set of ten choices.<sup>56</sup> One can only wonder what impact a strong Internet presence and domination would have had back in 1998.

#### **5.4 Trust and Credibility**

It does not take an extensive survey of stakeholders to determine that one of the greatest challenges facing the AVIP is to establish trust and credibility. Questioning of big government by a democratic society has been fundamental in the development of the United States. During the last decades of the twentieth century the practice of questioning governmental health decisions became increasingly prevalent in both civilian and military settings. It is evident that the exposure of military personnel to risks from radiation testing and Agent Orange has had a lasting impact. More recently, issues relating to the undefined causes of health problems experienced by veterans of the Gulf War continue to degrade trust and the credibility of senior leadership.

Some of the many theories concerning Gulf War illnesses are directly related to the anthrax vaccine. In response to the chemical/biological threat, deploying troops received a variety of prophylactics and immunizations, including some investigational drugs. Dur-

ing the Gulf War approximately 150,000 out of the 700,000 deployed troops received the FDA-licensed anthrax vaccine.<sup>57</sup> Exact figures are not known due to the haste of wartime preparations and the unreliability of paper records (many troops received shots without updating their individual managed yellow shot-records; medical records were not always presented for concurrent documentation). Investigations by the National Institutes of Health, the Presidential Advisory Committee, the Institute of Medicine, the Defense Science Board, and three studies published in the *New England Journal of Medicine* have consistently failed to find a correlation between the anthrax vaccine and Gulf War illnesses.<sup>58</sup> Nevertheless, even without scientific evidence, the perception of doubt continues when DOD policy makers discuss anthrax vaccine health risks.

A greater emphasis on effective HRC techniques could have enhanced the credibility of the initial AVIP message. Following is a discussion of several principles of risk communication that can be applied in order to increase trust and enhance credibility.

#### **5.4.1 Hiding Advocacy within Education Creates Distrust**

If a company presents a seminar on financial planning and the same company sells life insurance, do you wonder whether they are presenting all the options? What about politicians running for election and claiming that they just want to educate you on the issues? Do you believe you'll get a balanced report on all the facts? With mandatory vaccinations in the military, is the goal of the communication plan education or persuasion?

To a certain extent, the answer lies somewhere between education and persuasion. To educate means to present a full picture, to strive for a full understanding of risks and benefits. To persuade means to advocate a certain position and to reduce opposition to it. In the case of mandatory military vaccinations, information is not provided to enable service members to make informed-consent decisions. On the other hand, refusers are not restrained and forcibly vaccinated (which is permitted by Army regulations). Consequently, a compromise goal of "persuasive education" is at-

tempted. Confusion can arise when the message is designed to persuade but presented under the guise of informing or educating. This could create feelings of manipulation, distrust, and resentment in the audience.

DOD has made great efforts not to distort the truth, but the techniques used to inform can be viewed as attempts to deceive. The AVIP Agency cannot include all details known to science in its messages and still have them read or understood. It must highlight some information and omit other information for the sake of clarity and brevity. Even when presenting a purely informational briefing, one will highlight certain facts with visual aids, voice emphasis, or order of placement. Other techniques used in presenting information may include selection of outside experts, emotional appeals, and risk comparisons. Whatever techniques it uses, DOD as a government agency is expected to follow standards of behavior to uphold the public trust.

The AVIP goal is to foster understanding and encourage acceptance of the vaccine program. To achieve this goal, it must provide information, and do so in a manner that balances education with persuasion. Most important, it must ensure that the persuasion never degenerates into deception or manipulation.

#### ***5.4.2 Discussing Uncertainty Up Front Improves Credibility***

The early AVIP communication materials stated that the potential for a reaction at the site of injection is 30 percent and the incidence of systemic reactions is 0.2 percent.<sup>59</sup> This is a true statement supported by the original study used for FDA approval.<sup>60</sup> Other scientific studies have varied the sample size, measurement techniques, or other design aspects and have produced different results. In voicing their objections to the program, the opponents of anthrax vaccine would sometimes cite a study with a higher rate than that mentioned in the HRC material. They would then declare this to be evidence that the government was lying and could not be trusted.

Risk analysis has few absolutes. There is usually some variation in assessment of the severity, frequency, and probability of the



hazard. There is uncertainty that the method of risk management will be effective in reducing the risk. In the case of vaccines, one must consider the potential for side effects or adverse reactions. Effective vaccine risk communication must include the full range of potential risks. Even if an allergic reaction is only remotely possible, it should be discussed. Presenting a restricted range of possibilities based upon consensus among experts could be viewed as misleading. Failure to mention a possible outcome may jeopardize the risk communication process, as the audience may become disillusioned when they discover the rest of the story.

In addition to conflicting studies or conflicting opinions of the same study, there are usually conflicting opinions within an organization. The reason for doing a risk analysis is to consider the pros and cons of a situation so that a possible course of action can be evaluated. It is necessary to have a complete analysis of the negative possibilities in order to reach the appropriate risk management decision. However, any discussion of the negative aspects could be used at a later date by the opposition as evidence of a cover-up or conspiracy.

For example, anthrax vaccine refusers used quotes from a U.S. Army Medical Research Institute of Infectious Disease 1994 briefing. They did not bother to explain that, at this briefing, participants had outlined the problems with the anthrax vaccine in an attempt to justify new vaccine funding.<sup>61</sup> This example underscores the need to fully acknowledge all potential negative aspects considered in the risk analysis.

A key concept of risk communication is that the messenger must be trusted and credible. Low trust creates a scenario for denial of the issue and greater possibility of an emotional response. To establish trust, the HRC message must discuss uncertainties up front.<sup>62</sup> It must disclose both sides of issues as well as what is known and what is unknown. This is a difficult challenge, because science is never finished and most studies recommend further research. Vaccine risk communication presents an even bigger challenge, because the risks fall into a wide range and have considerable deviations.

### **5.4.3 Minimizing the Risk Weakens Credibility**

Not only does one have to discuss potential risk and uncertainty up front, one has to be careful not to minimize the severity or frequency of a risk. Minimizing the risk can create a perception that could reduce the credibility of both the messenger and the message.

When people don't like the message being communicated, they attack the assessment and assumptions. If they find one thing wrong, one stretched truth, or one omitted fact, this serves as a basis for questioning the entire message. The opposition can use the smallest mistake, exaggeration, or omission as proof that the government is lying about an entire program.

A simple statement used by the AVIP shows how overconfidence or embellishment can degrade credibility. Early press briefings and the literature stated that the anthrax vaccine had been "safely and routinely administered in the United States to veterinarians, laboratory workers, and livestock handlers for more than twenty-five years."<sup>63</sup> Opposition groups surveyed local veterinarians and veterinary schools and could not find anyone who had been vaccinated with the anthrax vaccine. They reported that they could not even find a veterinarian who knew a veterinarian who had been vaccinated. Although this was not a scientific study, it was used to question the credibility of the entire AVIP.

Did DOD lie? Veterinarians had taken the vaccine, but only those working with large grazing animals in high-threat areas. As the prevalence of natural anthrax has diminished and the use of animal vaccines has increased, fewer large-animal veterinarians are at risk for exposure and fewer now undergo the inoculations. The opposition pointed out that the DOD statement listing veterinarians first in a group of three (veterinarians, laboratory workers, livestock handlers) implied that they were the largest group to receive the vaccine.

It is common to suspect organizations of shading the truth to justify their message. The best way to avoid such accusations is to recognize the uncertainties and discuss the full range of possibilities supported by most of the published research. Acknowledging a range

of risks and the fact that the absolute true risk is unknown may seem to detract from providing a convincing and persuasive argument. It does not. In fact, failure to communicate the full possibilities may be perceived as a betrayal of trust when overconfidence about risk estimates is later shown to have been incorrect.

Although creating the perfect message is an unattainable goal, improvements are always possible and it is worth the effort to make them. One can reduce the incidence of small but damaging mistakes by pre-testing and conducting extensive focus-group research with different groups of stakeholders. The National Research Council advises that the best way to regain credibility is “through a sustained effort to be responsive to audience concerns and to be accurate, open, and honest in disclosing essential information.”<sup>64</sup>

#### **5.4.4 Organizational Biases Impact Credibility**

Organizational bias is yet another factor that impacts trust and credibility. When a manufacturer claims that its products are the best on the market, one may view the statement as prejudiced. The impartiality of an expert may be questioned when that individual has an affiliation with the organization. Even commanders and military healthcare professionals presenting the standard anthrax information briefing may be perceived as having a conflict of interest in the vaccine risk communication.

Although vaccine risk communication should give the stakeholder accurate and unbiased information, the natural tendency is to emphasize the benefits of the vaccine over the risks. To overcome potential bias and possible conflict of interest, standardized briefings must fully address all possible negatives. This full disclosure can increase the credibility of the vaccine risk communication.<sup>65</sup>

The best way to overcome organizational bias and increase trust and credibility is to use outside experts. Third-party verification brings an impartial opinion to the table. The AVIP has been successful in obtaining the support and endorsements of such organizations as the National Institutes of Health, the FDA, the CDC, and many other highly respected organizations and professional groups. Be-

cause trust and credibility are such significant barriers for the AVIP, third-party verification is even more important. Surveys of targeted stakeholders could determine which non-DOD organizations have the most influence. Input from these sources should have a greater role in the HRC process and outside opinion should be part of any potential improvement of HRC materials.

#### ***5.4.5 Comparing Risks Can Create Pitfalls***

Risk communication attempts to deliver a message that conveys information about a way or ways to reduce a risk or threat. If the communication is to be successful, the audience must have an understanding of the risk, including such factors as magnitude, probability, frequency, and duration. This often involves complex scientific evidence.

Risk comparisons enable the audience to understand a new risk in relation to an older and more familiar risk. One example would be comparing the concept of “one in a million” to “one inch in sixteen miles.”

Comparisons must be carefully selected and pre-tested. Comparing unlike risks, such as voluntary and involuntary, natural and man-made, controllable and uncontrollable, can be viewed as a manipulative attempt to minimize or trivialize the risk.<sup>66</sup> The attempt to compare the probability of a severely adverse vaccine reaction to the probability of being struck by lightning is often tempting, but the risks are totally unrelated.

The AVIP has done a good job of avoiding the pitfalls of inappropriate comparisons. In almost all of its HRC messages, it has compared the risks of the anthrax vaccine to the risks of other vaccines, stating that the risks of the anthrax vaccine are no different from the risks of other vaccines that service members receive. It has also pointed out that the anthrax vaccine is as safe as the mandatory vaccines given to our pre-school children. These comparisons are very effective and are not contradicted by the opposition’s lengthy counter-arguments. Maximizing this effective HRC technique could

increase credibility and trust by showing that the risks are within an acceptable range. AVIP presentations could expand upon the comparison of vaccine risks and discuss them in greater detail.

There is one comparison used during briefings by senior officials (rarely mentioned in print material) that may be counterproductive. Senior leaders have stated that the anthrax vaccine is a force protection measure, which protects the troops in battle just like the helmet and flak jacket. Sometimes they add that wearing the helmet and flak jacket is not voluntary; neither should the vaccine be voluntary. The vocal opposition has countered that when a service member retires, he or she can remove the helmet and flak jacket. A retiring soldier cannot remove the twenty-four anthrax vaccinations received during a twenty-year career.

## 6. CONCLUSIONS

The ideal outcome of an effective HRC message is achieved when the stakeholder believes the message source is a better judge of the stakeholder's interest.<sup>67</sup> Most people will acknowledge that a physician knows more about medicine than a lay person, but in today's society most will seek multiple opinions before making significant medical decisions. In today's military, service members are better educated, have access to more information, and display greater autonomy in making many types of decisions. Previous acceptance of mandatory vaccinations has proven to be a poor indicator of future acceptance.

To achieve its goals, DOD has to have an effective communication plan that utilizes HRC techniques. Nevertheless, expectations have to be realistic. Even with a great program, it is a mistake to believe that HRC can always eliminate conflict. Presenting more facts may not necessarily overcome resistance. Even a great risk communication program cannot prevent controversy, but poor risk communication can certainly create problems.

What makes a risk communication program great? Quality evaluation of all materials against a clearly defined objective is a good start. Staffing communication materials through multiple service and DOD agencies can generate helpful comments but does not produce the critical feedback that can be obtained from a professionally run focus group of stakeholders. Focus groups can identify subgroups of stakeholders. Messages can be tailored to address stakeholders' values. Focus groups can identify which trusted sources are most credible to the subgroups of stakeholders. Empirical evaluation conducted by personnel outside the program can provide an unbiased assessment of strengths and weaknesses.

Adjusting the program on the basis of the comments obtained during a gradually phased-in program does not create the clear, consistent, and timely message required to generate the important first impression of a new program. Risk communication should not be a

Public Affairs task added after the risk management decisions have been made.<sup>68</sup> If communication materials are to be effective, they must be timely. Building service-wide consensus may be a time-consuming luxury not advisable when fighting an information war.

It is easy to look back with hindsight and recommend changes based on what was learned during development of the AVIP. The challenge lies in applying the lessons in the future when DOD announces the next mandatory vaccination program. Several new vaccines are currently being developed and tested for FDA licensure by the Biological Vaccine Program and the Joint Vaccine Acquisition Program.

Public skepticism and distrust of government are ingrained in our country. Almost every new technology or product is viewed in terms of both short- and long-range health concerns. The risk communication techniques developed and practiced by the AVIP have a potential utilization beyond vaccines. Health risk communication principles can be applied to discussions on depleted uranium, JP8 fuel, and the environmental impacts of ranges. All of these complex programs involve issues relating to safety and health and require an exchange of information among diverse stakeholders. The lessons learned from DOD's experience with AVIP can have a direct impact upon public acceptance of these important military programs.

## ENDNOTES

<sup>1</sup> Terry C. Dixon, et al., "Anthrax," *The New England Journal of Medicine* 341, no. 11 (9 September 1999): 815-26; available from <<http://www.anthrax.osd.mil>>; Internet; accessed 20 July 2000.

<sup>2</sup> Theodore J. Cieslak and Edward M. Eitzen Jr., "Clinical and Epidemiological Principles of Anthrax," *Emerging Infectious Diseases* 5, no. 4 (July-August n.d.); available from <<http://www.anthrax.osd.mil>>; Internet; accessed 20 July 2000.

<sup>3</sup> Phillip S. Brachman, "Anthrax," *Annals of the New York Academy of Sciences*, 16 (n.d.), 577-82; available from <<http://www.anthrax.osd.mil>>; Internet; accessed 25 June 2000.

<sup>4</sup> Phillip S. Brachman, "Inhalation Anthrax," *Annals of the New York Academy of Sciences*, 353 (1980), 83-93; available from <<http://www.anthrax.osd.mil>>; Internet; accessed 25 June 2000.

<sup>5</sup> James Chin, ed., *Control of Communicable Diseases Manual* (Washington, D.C.: American Public Health Association, 2000), 20.

<sup>6</sup> Dixon.

<sup>7</sup> Anthrax Vaccine Immunization Program Agency (AVIP), "Safety Review of Anthrax Vaccine," 1 September 2000; available from <<http://www.anthrax.osd.mil>>; Internet; accessed 14 September 2000.

<sup>8</sup> DOD Response to the Staff Report of the House Government Reform's Subcommittee on National Security, Veterans Affairs, and International Relations entitled "The DOD Anthrax Vaccine Immunization Program: Unproven Force Protection," 20 February 2000; available from <<http://www.anthrax.osd.mil>>; Internet; accessed 20 July 2000.



<sup>9</sup> Congress, Senate, Armed Services Committee, *Anthrax Biological Warfare Threat*, Statement of Rear Admiral Lowell Jacoby, Director of Intelligence, J-2, 106 Cong., 13 April 2000.

<sup>10</sup> Chin, 21.

<sup>11</sup> Linda D. Kozaryn, "Defense Leaders Stand Firm on Anthrax Shot Program," American Forces Press Service, 7 October 1999; available from <<http://www.af.mil/news/oct1999>>; Internet; accessed 20 July 2000.

<sup>12</sup> Ibid.

<sup>13</sup> Linda D. Kozaryn, "Duty-Bound to Order Anthrax Shots Cohen Says," American Forces Press Service, 10 March 1999; available from <<http://www.defenselink.mil/news/march1999>>; Internet; accessed 18 September 2000.

<sup>14</sup> Peter C. B. Turnbull, "Anthrax Vaccines: Past, Present and Future," *Vaccine* 9 (1991): 533-539; available from <<http://www.anthrax.osd.mil>>; Internet; accessed 14 September 2000. During the same time period, the Soviet Union developed a live spore vaccine. Western countries consider live spore vaccines unsuitable for human use.

<sup>15</sup> DOD Response to Staff Report, "Unproven Force Protection."

<sup>16</sup> AVIP, "Safety Review of Anthrax Vaccine."

<sup>17</sup> Ibid.

<sup>18</sup> Isadora B. Stehlin, "How FDA Works to Ensure Vaccine Safety," U.S. Food and Drug Administration; available from <[http://www.fda.gov/fdac/features/095\\_vacc.html](http://www.fda.gov/fdac/features/095_vacc.html)>; Internet; accessed 20 July 2000.

<sup>19</sup> Ibid.

<sup>20</sup> Arthur M. Friedlander, Phillip R. Pittman, and Gerald W. Parker, “Anthrax Vaccine Evidence for Safety and Efficacy against Inhalation Anthrax,” *JAMA* 282, no. 22 (8 December 1999); available from <<http://jama.ama-assn.org/issues/v282n22>>; Internet; accessed 22 June 2000.

<sup>21</sup> DOD News Release, “Defense Department Plans to Immunize Troops against Anthrax,” Office of Assistant Secretary of Defense (Public Affairs) Washington D.C., 15 December 1977; available from <<http://www.defenselink.mil/news/dec1997>>; Internet; accessed 25 June 2000.

<sup>22</sup> Ibid.

<sup>23</sup> AVIP, “Anthrax Vaccine Immunization Program SOP.” E-1, April 1998.

<sup>24</sup> Gerald N. Burrow, “Review of DOD’s Plan to Immunize the Force against Anthrax,” letter for Undersecretary of Defense for Personnel and Readiness, Yale University, 19 February 1998.

<sup>25</sup> Dale R. Bowlus, Jr. of the U.S. Army Center for Health Promotion & Preventive Medicine (USACHPPM), interviewed by author, 7 November 2000, Aberdeen Proving Ground, Md.

<sup>26</sup> Major General Robert G. Claypool, “Implementation of Anthrax Vaccination Program for the Total Force—ACTION MEMORANDUM,” memorandum for the Secretary of Defense, Washington, D.C., 28 April 1998.

<sup>27</sup> DOD News Briefing, Presenter LTG Ronald R. Blanck, Army Surgeon General, Washington D.C., 3 March 1998; available from <<http://www.definiselink.mil/news/Mar1998>>; Internet; accessed 18 September 2000.

<sup>28</sup> Thomas L. Remphor, *Information Paper for America’s Policy Makers*, (n.d.); available from

<[http://www.dallasnw.quik.com/cyberella/Anthrax/Chron\\_Info.html](http://www.dallasnw.quik.com/cyberella/Anthrax/Chron_Info.html)>; Internet; accessed 14 September 2000.

<sup>29</sup> All recruits are given vaccines for: Diphtheria, Influenza, Measles, Poliovirus, Rubella, Tetanus, and Meningococcal Disease. Additional vaccines are provided by some services and may be required in certain occupations or deployments. See AVIP, "Desk Reference on Vaccine & Immunity," 24 March 2000; available from <<http://www.anthrax.osd.mil>>; Internet; accessed 23 October 2000.

<sup>30</sup> Kozaryn, "Defense Leaders Stand Firm."

<sup>31</sup> Douglas Gilbert, "Anthrax Vaccine Safe, Effective, Top Doctor Says," American Forces Information Services, 9 February 1999; available from <<http://www.defenselink.mil/news/feb99>> Internet; accessed 18 September 2000.

<sup>32</sup> Rudy de Leon, "Prepared Testimony on Anthrax Vaccination Immunization Program, Submitted to Senate Armed Services Committee," 13 April 2000; available from <<http://www.defenselink.mil/speeches/2000>>; Internet; accessed 13 September 2000.

<sup>33</sup> U.S. Public Health Service, "Risk Communication: Working with Individuals and Communities to Weigh the Odds," *Prevention Report* (February/March 1995); available from <<http://www.odphp.osophs.dhhs.gov/pubs/prevept/95fm1.htm>>; Internet; accessed 27 March 2000.

<sup>34</sup> National Research Council, *Improving Risk Communication* (Washington, D.C.: National Academy Press, 1989), 2.

<sup>35</sup> DOD Risk Communication Training Briefing, U.S. Army Center for Health Promotion & Preventive Medicine, 1998; available from <<http://chppm-www.apgea.army.mil/dts/hrc/riskcomm.htm>>; Internet; accessed 19 December 2000.

<sup>36</sup> National Research Council, 1-13.

<sup>37</sup> John D. Grabenstein and James P. Wilson, "Are Vaccines Safe? Risk Communication Applied to Vaccinations," *Hospital Pharmacy* 34, no. 6 (n.d.): 713-29; available from <<http://www.anthrax.osd.mil>>; Internet; accessed 5 July 2000.

<sup>38</sup> Geoffery Evans, et al., eds., *Risk Communication and Vaccination: Summary of a Workshop* (Washington, D.C.: National Academy Press, 1997), 1-4, 13.

<sup>39</sup> AVIP, "DOD Response to Anthrax Program Congressional Request," 16 May 2000; available from <<http://www.anthrax.osd.mil>>; Internet; accessed 17 July 2000.

<sup>40</sup> Tim L. Tinker and Paula G. Silberberg, "An Evaluation Primer on Health Risk Communication Programs and Outcomes," U.S. Public Health Service, May 1997; available from <<http://www.atsdr.cdc.gov/HEC/evalprmr.html>>; Internet; accessed 4 April 2000.

<sup>41</sup> Bowlus.

<sup>42</sup> U.S. Public Health Service.

<sup>43</sup> AVIP, SOP.

<sup>44</sup> General Accounting Office, *DOD Faces Challenges in Implementing Its Anthrax Vaccine Information Program* (Washington, D.C.: U.S. General Accounting Office, October, 1999), 24-25, 51-52.

<sup>45</sup> As of August 2000, DOD was reporting 441 refusers for over 2 million vaccinations.

<sup>46</sup> U.S. Public Health Service.

<sup>47</sup> One theory proposed to explain Reserve pilots' vocal opposition to the AVIP is based on the increased operation tempo of deployments. In the last few years, Reservists have deployed longer and more frequently. Since anthrax shots occur prior to deployment, some Reservists may be refusing as a means of separating from a deploying unit.

<sup>48</sup> Vincent T. Covello and Frederick W. Allen, "Seven Cardinal Rules of Risk Communication," U.S. Environmental Protection Agency, Office of Policy Analysis, Washington, D.C., 1988.

<sup>49</sup> National Research Council, 46.

<sup>50</sup> Butch Wardlaw, Chief, Communications Division of AVIP, interviewed by author, 23 October 2000, Falls Church, Va.

<sup>51</sup> Covello and Allen.

<sup>52</sup> National Research Council, 139.

<sup>53</sup> Grabenstein and Wilson.

<sup>54</sup> Kevin M. Delaney of the U.S. Army Center for Health Promotion & Preventive Medicine (USACHPPM), interviewed by author, 30 August 2000, Aberdeen Proving Ground, Md.

<sup>55</sup> Assistant Secretary of Defense for Public Affairs Kenneth H. Bacon, "Anthrax Web Site," memorandum for the Army Surgeon General, Washington, D.C., 26 February 1999.

<sup>56</sup> Delaney.

<sup>57</sup> DOD News Briefing, Presenter LTG Ronald R. Blanck, Army Surgeon General, Washington D.C., 3 March 1998; available from <<http://www.definiselink.mil/news/Mar1998>>; Internet; accessed 18 September 2000.

<sup>58</sup>The AVIP Agency has compiled a listing (with hot-link Internet access) of several independent expert panels that addressed the possibility of the anthrax vaccine as a cause for Gulf War illnesses. This listing includes three studies published in the *New England Journal of Medicine*. The listing and direct links can be found in "Information About AVIP," 25 January 2000; available from <<http://www.anthrax.osd.mil>>; Internet; accessed 27 June 2000.

<sup>59</sup> AVIP, "Safety Review of Anthrax Vaccine."

<sup>60</sup> Phillip S. Brachman, et al., "Field Evaluation of Human Anthrax Vaccine," 52 (1962), 632-45; available from <<http://www.anthrax.osd.mil>>; Internet; accessed 17 July 2000.

<sup>61</sup> DOD Response to Staff Report, "Unproven Force Protection."

<sup>62</sup> Evans, 3.

<sup>63</sup> AVIP, "What Every Person Needs to Know About the Anthrax Vaccine," tri-fold brochure, 2 December 1998.

<sup>64</sup> National Research Council, 147.

<sup>65</sup> Evans, 15.

<sup>66</sup> National Research Council, 96-100.

<sup>67</sup> *Ibid.*, 95.

<sup>68</sup> *Ibid.*, 148.



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