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**THE IMPORTANCE OF HEALTH RISK COMMUNICATION  
IN THE CREATION OF THE ANTHRAX VACCINE  
IMMUNIZATION PROGRAM**

**BY**

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THE ANTHRAX VACCINE IMMUNIZATION PROGRAM**

by

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## ABSTRACT

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When Secretary of Defense William Cohen announced that military service members would take the anthrax vaccine, few anticipated the widespread reluctance to accept his directive. Service members have been required to take several vaccinations and this new force protection measure involved a vaccine approved by the FDA in 1970. An extensive information campaign was developed in response to the unanticipated opposition on the Internet and in the press. This paper suggests that a more proactive educational program with a greater utilization of health risk communication techniques would 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 the challenges of trust, credibility and organizational biases, which appeared as the program matured. A greater application of health risk communication in the creation of the Anthrax Vaccine Immunization Program Agency would have generated less controversy. Studying the development and implementation of health risk communication in the anthrax program can be applied to other military vaccines or the discussions on depleted uranium rounds or toxic exposure standards.



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**THE IMPORTANCE OF HEALTH RISK COMMUNICATION  
IN THE CREATION OF THE  
ANTHRAX VACCINE IMMUNIZATION PROGRAM**

"A camel is a horse designed by committee."

—Sir Alec Issigonis, The Guardian

It was not too long ago that a service member's only question to a directive to take an immunization was, "Which arm?" There has been a paradigm shift where society is more questioning, especially in the area of medicine. In today's military, individual concerns about health and environment generate countless questions. When Secretary of Defense William Cohen announced in 1997 that military service members would take the anthrax vaccine, he recognized a need for a communication plan. However, widespread reluctance to accept the vaccine was not anticipated. Service members are required to take several vaccines and this new force protection measure involved a vaccine approved by the Food and Drug Administration (FDA) in 1970.

The Department of Defense (DOD) recognized that an educational campaign was required, but early efforts failed to anticipate the vocal opposition. To meet the communication needs of this multi-service immunization program, a committee of about forty-five representatives was formed. This diverse group of professionals created the first brochures and briefings for the Anthrax Vaccine Immunization Program (AVIP). 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. Although the original committee had individuals trained in risk communication, their voices failed to carry the majority of this large group.

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 and concerns and thus generated less resistance. As the AVIP developed and expanded, risk communication took on a greater role. As a result, 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.

## BACKGROUND OF ANTHRAX

Before discussing the importance of risk communication in the AVIP's development, one must have a basic knowledge of anthrax and the vaccine. A brief discussion on risk communication in other government agencies will follow this background foundation.

## HISTORY AND DEFINITION

Anthrax is a dangerously fatal disease normally associated with plant eating animals. The name anthrax comes from the Greek word for coal, which is associated with the blackened patches of dead skin on the affected areas. Anthrax is a bacterial infection created by *Bacillus anthracis*, which forms a spore. Anthrax spores can survive 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, the animals ingesting enough anthrax spores will die. Although anthrax spores are persistent in the soil and resist environmental degradation, humans rarely get exposed directly from the soil. The spores tend to clump and bind to the soil which reduces the possibility of inhaling anthrax. 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 the 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 60,000 people. In the mid 1800's, 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 were occurring even back in the colonial times. The first recorded human death 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 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 the western countries.<sup>3</sup>

#### HEALTH EFFECTS IN HUMANS

Humans contract anthrax by exposure to a cut on the skin, eating an infected animal or inhalation of the anthrax spores. Inhalation exposure is the most deadly. Initial symptoms include fever, nonproductive cough, malaise, and fatigue similar to a common cold, flu or upper respiratory tract infection.<sup>4</sup> Compounding these vague symptoms is the fact that they do not appear for three to five days after exposure by inhalation.<sup>5</sup> Treatment of inhalation anthrax is only effective 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 24 to 48 hours. Once symptoms develop, mortality rate is near 100 percent as evidenced by several studies.<sup>7</sup>

#### CERTIFICATION, DOSAGE AND SAFETY

Microbiology's founding fathers worked on developing an anthrax vaccine. In 1881, Louis Pasteur had several successful demonstrations of an anthrax vaccine for animals. Anthrax vaccines for humans started in the 1950s in Great Britain and in the 1960s in the United States.<sup>8</sup> The National Institute 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 recertified safe and effective when the responsibility for biomedicine was transferred from the National Institute of Health to the FDA.<sup>9</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 from the first shot. There is a requirement for an annual booster for prolonged protection.

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

Secretary of Defense, the Service Secretaries, each of the Joint Chiefs of Staffs, and the military Surgeons General all stated that the vaccine is safe and were among the first to take the immunization. The AVIP Agency compiled a list of 13 independent human safety studies spanning over 50 years and 366,000 vaccine recipients.<sup>10</sup> These studies demonstrate that the anthrax vaccine is safe. As with most vaccines, there is pain and swelling after the injection. Like 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 1 to 3 days. Significant events beyond the injection site occur in less than one percent of the recipients. These rates are the same as or lower than mandatory childhood vaccinations and the same as or lower than other vaccines administered to military personnel.<sup>11</sup>

As part of its safety surveillance program, the FDA uses the Vaccine Adverse Event Reporting System (VAERS) to identify problems with licensed vaccines. The system was initiated in 1990 and is jointly managed by the Centers for Disease Control and Prevention (CDC) and FDA. The VAERS is a passive system that relies on voluntary reports from physicians, patients or parents. The voluntary nature and lack of monitoring of reporting practices implies that not all adverse reactions are reported. Conversely, not all reports received are related to a vaccine.<sup>12</sup> All Department of Defense 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 24 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>13</sup> At DOD's request, the Department of Health and Human Services created the Anthrax Vaccine Expert Committee. The committee was formed in October 1998 to review VAERS reports. Table 1 shows, as of 23 January 2001, that of the 1,439 reports submitted only 756 reports were attributed to the vaccine. Of the 756 reports caused by the vaccine, only eleven resulted in hospitalization for allergic reactions. This group of independent civilian experts meets every 4 to 6 weeks to look for clinically significant patterns. This type of review does not occur for any other licensed vaccine.<sup>14</sup> This unique independent review demonstrates DOD's commitment to continue to monitor the safety of the vaccine.

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>

Source: As of 1 February 2001, 500,270 people had been vaccinated with 2,005,357 doses of anthrax vaccine; 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.

#### ANTHRAX AS A WEAPON

This paper makes no attempt to add to the debate on the validity or probability of the threat. It is 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. 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.<sup>15</sup> It is found naturally around the world and can be produced in large quantities with a basic knowledge of biology. The equipment used to create anthrax spores can be hidden in legitimate facilities. There is also a valid public health and zoological justification to possess anthrax bacteria or spores. Anthrax spores are resilient and have a shelf life that can be measured in decades. It can survive the delivery system of a rocket, missile or artillery shell. Sprayers can deliver anthrax spores as a dry powder or liquid slush. The spray can be delivered by plane or car using industrial sprayers or a hand-held garden style apparatus. 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 106<sup>th</sup> Congress:

A smaller quantity [anthrax] is required for the same area of coverage when compared to other weapons of mass destruction means. For comparison, for 120 square kilometers of coverage, you would need 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>16</sup>

In 1979, an outbreak of inhalation anthrax occurred in Sverdlovsk, an industrial city of the old Soviet Union. Sixty-six individuals died from an accidental aerosol leak from a biological weapons research facility.<sup>17</sup> This accident illustrates the threat of anthrax as a lethal weapon being manufactured by a potential enemy.

#### VACCINE: IDEAL FORCE PROTECTION MEASURE

The military has determined that the vaccine is the most effective risk management option to reduce the threat or hazard of anthrax exposure. The protective mask and clothing offer an 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 only marginally successful before symptoms appear. Even if early identification of exposure was possible, the treatment of 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 an October 1999 testimony before the Military Personnel Subcommittee of the House Armed Service Committee, Deputy Defense Secretary John J. Hamre testified 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>18</sup> At the same session, General John Keane, Army Vice Chief of Staff testified, "we have a moral obligation to do everything in our power to protect our troops from the anthrax threat."<sup>19</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 that [anthrax], I would be derelict in my duties sending you out in an environment in which you weren't properly protected."<sup>20</sup>

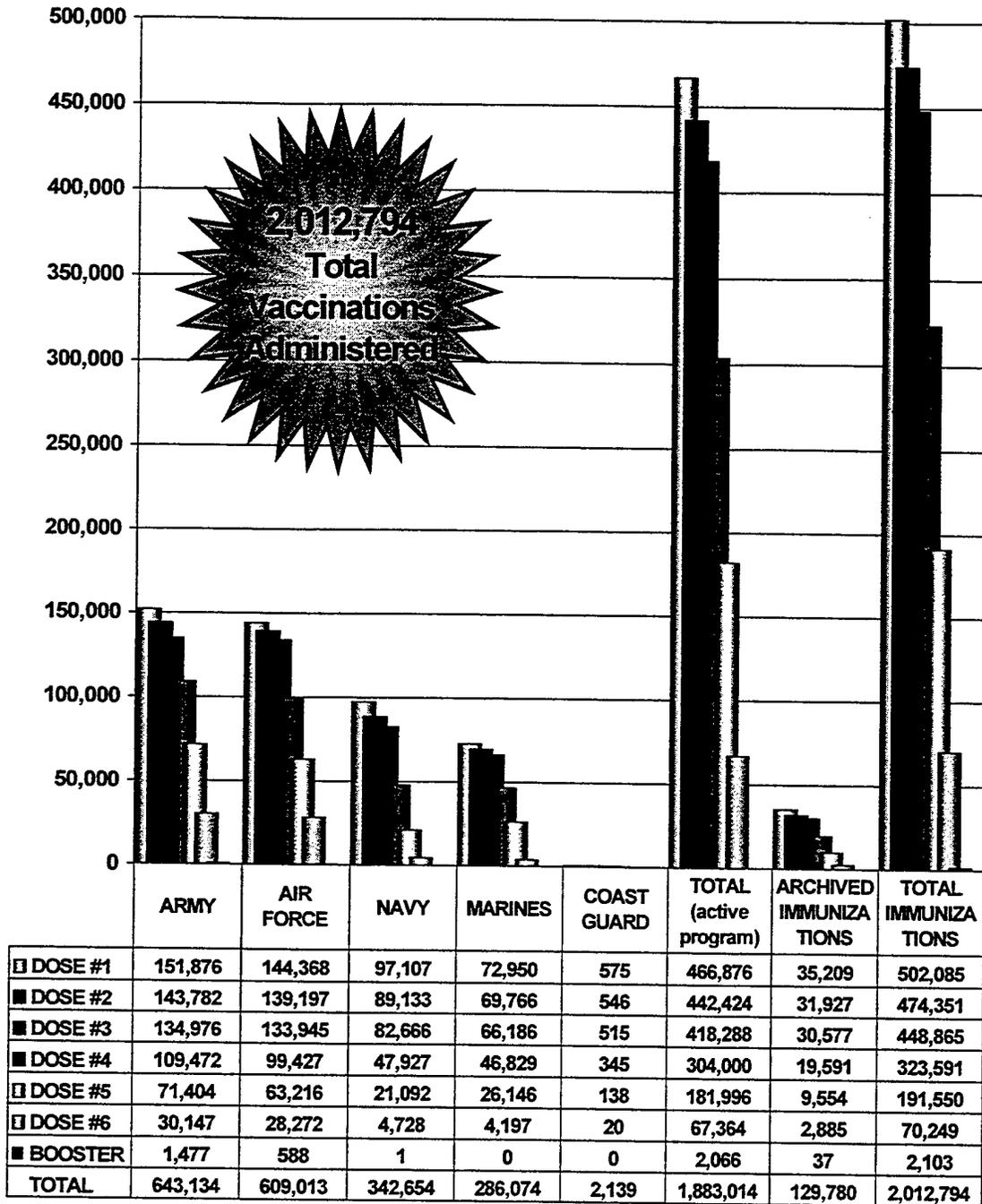
## DECISION TO IMPLEMENT

The concept of having an education program to communicate the risks and risk management was initially a major concern of the senior leadership. 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. The communication plan was a key component of the program. Calling the program a force protection issue, he stated that vaccinations would start only after four conditions were 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, it would cost \$130 million and take over six years.<sup>22</sup> The services were tasked to develop a three-phased implementation plan beginning with troops stationed in high threat areas (Southwest Asia, Korea). The second phase was early deploying forces. The third phase was the remaining service members and new accessions. Table 2 provides 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

## CREATING THE COMMUNICATION PLAN

When the Secretary of Defense approved the program on 15 December 1997, the communication plan and materials were merely concepts to be developed as indicated by one of his preconditions. The original communication materials were 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 to distribute during the briefings. Emphasis was placed on ensuring that vaccine recipients were provided information on the threat, the vaccine, its safety, and its benefits prior to their first vaccination.<sup>23</sup> If a service member was not serving or scheduled to serve in a high-threat area, then they did not receive the briefing.

## PROGRAM STAFFING

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

## EXPERT REVIEW: THE NEED FOR FOCUS GROUPS

One of the Secretary of Defense's preconditions 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 the review and submitted his report on 19 February 1998. Dr. Burrow commented about service members having a heightened concern 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 U.S. Army Center for Health Promotion and Preventive Medicine to travel to Fort Bragg, North Carolina on 23 February 1998.<sup>25</sup> On 28 April 1998, the Assistant Secretary of Defense for Health Affairs sent a memorandum to the Secretary of Defense indicating the four preconditions have been met. He also stated the recommendation to use focus groups had been

implemented.<sup>26</sup> Although originally scheduled to begin shots in the summer of 1998, the program started 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 was obtained from the deployed soldiers on the tri-fold brochure and briefings.

#### VOCAL OPPOSITION AND REFUSERS

The vaccination program has been the subject of increasing controversy. 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 appear small when compared to close to 2 million vaccinations administered, but the impact is large. Refusing the mandatory vaccinations jeopardizes military careers and liberty at a time when the services are struggling to meet their recruiting goals. In April 1998, the first large-scale opposition began when ten sailors on the USS Independence refused to take the vaccine. Grassroot efforts questioning the policy, safety, and effectiveness began to appear on several Internet websites. Several Air National Guard pilots resigned or transferred to avoid taking the vaccine. Active duty troops were courts-martialed and discharged from the service. Congressional hearings publicized several sensational cases of ill service members who blamed the vaccine for their ailments. Congressional bills were introduced to halt the program or make it voluntary.<sup>28</sup>

The anthrax threat assessment warranted a mandatory force protection program of inoculations. The military had a precedent for requiring mandatory vaccinations.<sup>29</sup> The concept of placing the mission of protecting the force over informed consent was not new to the military. So why was there so much opposition from service members refusing to take shots, congressional inquiries, and unfavorable reports in the media? During congressional testimony, Deputy Defense Secretary John J. Hamre said that the initial education program was 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 more 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>

## **RISK COMMUNICATION**

Before presenting how risk communication techniques could have improved the communication plan, a brief discussion on risk communication is provided. The techniques of risk communication are often used to deliver health messages and vaccine education. The application of risk communication strategies will serve as the foundation for this paper's suggested improvements.

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 on those risks. Historically, these messages tend to flow one way, from experts to nonexperts, in an attempt to create a behavioral change.<sup>33</sup> The National Research Council expanded this one-way communication by describing risk communication as "an interactive process of exchange of information and opinion among individuals, groups and institutions."<sup>34</sup> In 1998 DOD created a tri-service definition that states risk communication is "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> When there is a potential threat to ones health, the environment or even national security, a risk analysis is performed. To deal with the hazard, a course of action or risk management is selected to reduce the risk. Managing the risk usually involves changing peoples' behavior, which is attempted through risk communication. There are three ways risk communication can help manage risk. First, risk communication can merely involve advocacy to persuade or convince people to take the desired course of action. Next, risk communication can provide education for people to have the information 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>

## **HEALTH RISK COMMUNICATION**

Traditionally, risk communication is 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 one's behavior to improve health and well being (e.g., eating more vegetables, quit smoking).

## VACCINE RISK COMMUNICATION

Although HRC has been actively researched for decades, vaccine risk communication is a relatively new field. There are some unique challenges in the area of vaccine risk communication because 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 more willing to accept treatment involving a small risk of a potentially adverse reaction to improve their health. For example, cancer patients are willing to accept painful and life-threatening treatments to extend their life expectancy. Compounding this concept of "invading" a healthy body with a vaccine is the rare occurrence of some vaccine-preventable diseases 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. The parent may perceive the risk of vaccine side effects greater than the risk of a disease like polio.

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

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

Most physicians use vaccine risk communication to educate the patient or parent on the risks and benefits to enable them to make the decision. Vaccine risk communication attempts to convey the science and probability, weighing the benefits against the risks. But effective vaccine risk communication is more than understanding risk versus reward; it involves transmitting and receiving the information so that the patient can voluntarily make a decision. The acceptance or consent by a patient to

assume the risk of a vaccination in exchange for the benefits is called informed consent. In an extreme example, informed consent is the difference between surgery and assault with a deadly weapon.<sup>38</sup>

There are situations where the government, in the interest of public safety or national defense, has the right to override individual rights. An historical example of a government overriding individual rights occurred with 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, 14,000 British soldiers took the shot. During the war, 58,000 troops contracted typhoid fever and 9,000 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.

## **STRATEGIES FOR IMPROVEMENT**

The emerging field of risk communication has many applications in designing, implementing and delivering a desired message. The remaining part of this paper focuses on a few risk communication techniques, which could have improved the anthrax program. Principles of risk communication recognize that evaluating the plan, establishing trust, and identifying stakeholders are critical components to any communication program. Applying these principles in the creation of the AVIP would have produced a more effective implementation. Since the AVIP has learned from their early omissions, this discussion serves as a strategy for improvement of future programs. The value of this retrospective analysis is when DOD creates a similar communication program for a new vaccine or technology with health concerns. The analysis begins with an evaluation plan because early evaluation identifies and reinforces the need to apply the other principles.

## **VALUE OF EVALUATION**

In 1993, the Public Health Service conducted an analysis of their HRC programs. The analysis determined that lack of evaluation was the greatest weakness of the HRC programs. Once a message is designed for a communication plan, it should be evaluated for comprehension and acceptance. Goals and objectives must be established and evaluated. The Public Health Service study found that most programs

used a collecting process (i.e., number of pamphlets printed) and anecdotal information in lieu of evaluating the outcome or impact.<sup>40</sup> In the AVIP, the initial communication plan failed to address the concept of testing the message or evaluating the success of the plan. Creating an evaluation plan 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) are critical to insure identification of stakeholders and their perceptions. Identification of the stakeholder's values, priorities, and sources of information can determine the success of the HRC. Pre-testing and pilot studies can determine the effectiveness of an HRC program and provide feedback on the HRC materials. The evaluation plan should also measure success. Reporting on the number of immunizations administered or briefings conducted reflects implementation rather than message acceptance.

#### **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 was the program administrators fearful of the evaluations identifying serious problems. Limited staffing, rush to implement and vague goals interfered with the creation of an early and extensive evaluation plan.

#### **Personal And Time**

Less than ninety days after the Secretary of Defense announced the need for a communication plan, soldiers were receiving the anthrax vaccine. This short time period to create 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 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 chain of command conducted the training with only a couple of days of preparation time. The focus groups generated several issues and useful comments. The results were immediately telephoned back to Washington D.C. for consideration. Personnel were standing by at 8:30 p.m. to receive the results of the evening discussions with family members. This immediate feedback was not based

upon curiosity as much as the speed to produce the briefing materials and educational brochures. This quick pace is best illustrated by the fact that the risk communicators were told that they did not have to create a written report of the focus groups because the results were already incorporated. Even though this focus group testing identified several new concepts and potential barriers, the focus groups were 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 useful. This small sample of one installation and deployed troops does not reflect the entire force. More extensive data collection from professional facilitators would have provided critical information such as the perception of Reservists and aviators. Having a full time staff to administer the anthrax program could have provided the personnel resources to design and implement an effective evaluation plan even with time constraints. When creating future communication programs, DOD must recognize that resources of staff and time must be available to accomplish critical tasks like designing and implementing an evaluation plan.

### **Measurable Objectives**

In order to have an evaluation, one must have a clearly defined objective that is measurable. How does one evaluate the anthrax program's HRC? Is it the number of briefings conducted, shots or doses administered, or service members refusing? 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>42</sup> Without evaluation, there is no way to determine if the HRC activities are achieving the objective. When the program was implemented, DOD did not have a method to define and measure acceptance. The Public Health Service review of HRC programs found that a clearly defined outcome is critical to an evaluation program.<sup>43</sup> Simply stated, how do you determine success?

The ultimate goal is to immunize the 2.4 million members of DOD, but normal turnover makes this a process rather than an end point. The number of doses administered is often briefed as an indicator of the program's success. With a mandatory program, one does not need HRC to increase the statistics. Acceptance could be defined as someone who does not refuse the vaccination. If a service member refuses the immunization, then they receive individual counseling from their chain of command and healthcare professionals. If they continue to refuse, they receive disciplinary action that may result in separation from the service. Do you measure

acceptance by counting the personnel counseled or just the disciplinary action? What about the service members who decline reenlistment or retire to avoid the vaccination? It is difficult to assess departures solely attributed to the lack of acceptance of the AVIP. Service members leave the service or transfer from a Reserve unit for a variety of reasons and sometimes several reasons. The U. S. General Accounting Office (GAO) reported that DOD collected anecdotal data on refusals until January 1999. GAO reported that AVIP program managers felt the small number was not worth the labor-intensive effort.<sup>44</sup> In contrast, the number of refusers is one of the most often asked questions at official news conferences and congressional testimony. The relative low number of refusers is even offered by DOD leadership in support of the program.<sup>45</sup>

To determine the success of the AVIP's communication plan, DOD must measure message comprehension and message acceptance. To measure the acceptance, DOD should quantify and analyze all service members who express a reluctance to receive the vaccination. In response to the GAO report, DOD indicated their plans to expand survey collection and study methods to collect refuser data. The challenge of collecting refuser numbers is getting a consensus among all the services on how you define and measure a refuser. Identifying measurable outcomes to evaluate the communication is a key component in determining the success of any future communication plan.

#### STAKEHOLDERS: IDENTIFY AND INVOLVE EARLY

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

The Public Health Service workshop on HRC concluded that stakeholders must be clearly specified.<sup>46</sup> Identifying all the stakeholders early in the process is important to any campaign. 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 of similar values, perceptions, education, gender, and duty status. Leaders and policy makers use science to make decisions; but some troops use emotion to make decisions. One group is influenced by statistics and another is moved by stories. There are many stakeholders outside the military like Congress, parents, veteran organizations, and the media. Using the same message for all groups merely creates visibility of the program.

A tailored message of 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 became one of the most vocal opponents to the program. This highly educated subgroup is required to have an increased sensitivity over health concerns. For aviators, merely taking over-the-counter antihistamines can impact their flight status or impact Reserve pilot's civilian occupation.<sup>47</sup> Another group of stakeholders identified after program implementation were the civilian anti-vaccine organizations. Reservists are another group that have a communication challenge. Reservists have infrequent contact with their unit and may receive most of their information and healthcare advice outside the military channels.

The early use of survey groups and pretesting 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 created better HRC materials. The survey groups would 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 the 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 create full comprehension to be self-sufficient in making decisions and achieve informed consent. The conventional wisdom and recent research state that to have an effective risk communication program, one must have early stakeholder involvement. How can these principles apply when the government retains the decision 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 the risk communication takes on a greater importance. Without early stakeholder partnership and informed consent, vaccine risk communication must

be well planned and thoroughly tested. Stakeholders can be given an active and early role in identifying the most influential sources, determining which third-party source is most credible, selecting the most important aspect of the message and highlighting the barriers or obstacles.

## DELIVERING THE MESSAGE

Risk communication provides detailed techniques on delivering a message through public presentations. The chain of command has the primary mission to educate their troops using the AVIP materials prior to the scheduled immunizations. The challenge is that the message is delivered through other means 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. If the service member receives oppositional coverage prior to the AVIP training then the wrong perceptions may develop.

### **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, a negative first impression may become embedded. With ambiguous outcomes and uncertainty within science, there may be a cognitive bias to favor the initial impression even as new evidence disputes the early perception.<sup>49</sup> More complete and accurate information may be unable to overcome this initial impression that has become anchored. Later attempts by the government to communicate their motivations and decisions can be viewed as defensive or heavy handed. The initial concept was "just-in-time" education that intensively briefs a unit a few months prior to their inoculations. If presented concurrently with the announcement of the shot date this communication would ensure the audience's attention. The problem 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 rather than a questioning oppositional news article. One can only wonder what the results would have been if AVIP initial efforts were directed at the total force rather than the focusing on an early immunization of Central Command.

Delivering a timely message remains a challenge for the AVIP. The military bureaucracy creates a lengthy and complex process to achieve a policy decision. This is best illustrated by the anthrax video. Early on, it was decided to create a professional 15-minute educational video that utilizes risk communication techniques. This video was to be viewed by every service member in DOD. The video was produced in three weeks but it took nine months to staff. In order to accommodate all services, every comment was incorporated which resulted in over 150 changes and 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 was requested. The AVIP Agency has learned from this experience and is attempting to streamline the consensus process to seek a more expeditious approval of future products.<sup>50</sup>

### **Media Is Not Always An Ally.**

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

In 1988, the U.S. Environmental Protection Agency commissioned some of the most renowned researchers in risk communication 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 six by the numerous press releases and television appearances on shows like "60 Minutes," "Talkback Live," "Nightline," and "20/20." The media may be more focused on entertainment than education. Working with the media is more than having an effective Public Affairs staff. There are some limitations and concerns one must remember with the media.

The media usually attempts to present a balanced story reflecting 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 when the preponderance of science and professional organizations are in support of the anthrax vaccine. The emotional and sometimes sensational counter-arguments of isolated cases may not deserve the weight given in a particular news story. Stories that reflect the government making a mistake, being

reckless, or creating harm over a helpless citizen create sensational headlines and sound bites. The challenge to HRC is to establish an overwhelming weight of evidence that produces credibility. It is not an easy task to overcome skepticism about the government.

History is full of examples where inaccurate or misleading reports have reduced participation in vaccination programs that resulted in outbreaks of preventable disease. In the mid-seventies, the pertussis (whooping cough) vaccine was suspected of causing serious side effects. Immunization rates fell in several countries (e.g., United Kingdom, Japan), which resulted in the deaths of hundreds of unvaccinated children. Several later studies disputed the side effects as 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 one of the leaders in the media field covers a story. Even when the news story presents something as a rumor, it can be perceived as a fact if it is frequently reported. The AVIP Agency has recognized this synergy effect and attempts to respond to all unfavorable coverage in the Washington Post. What if the AVIP Agency had the 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 coverage?

#### **Dominant Internet Presence Is Required.**

The Internet is a relatively new form of media that has had a tremendous influence on the anthrax campaign. This private in-home source of information has proven to be very influential to many stakeholders. The challenge that the Internet presents is that there are no journalistic standards or even an attempt to balance the facts. Unlike the self-imposed practices of newspapers and television stations, there is no requirement to validate sources or facts. There is no attempt 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 present official looking perceptions as absolute facts. Dubious scientific research or "junk science" can be perceived with the same credibility as a peer review journal.

Prior to the AVIP Agency, there was an ad hoc committee designing 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> In the fall of 1998, it became apparent that the anthrax "information war" was occurring and 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, they were experiencing 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. The AVIP is on the third generation of a state-of-the art interactive website that has become one of their 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 would not even appear. In stark contrast, a search today places 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 this new Internet presence and domination would have had back in 1998.

#### TRUST AND CREDIBILITY

It does not take an extensive survey of stakeholders to realize that one of the greatest challenges of the AVIP is to establish trust and credibility. The concept of a democratic society questioning big government has been fundamental in the development of the United States. This practice of questioning governmental health decisions was very common in both civilian and the military settings during the last decades of the twentieth century. The exposure of military personnel to risks in radiation testing and Agent Orange has had a lasting impact. More recently, the undefined causes of health problems experienced by veterans of the Gulf War continue to degrade the trust and 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 to include some investigational drugs. During 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 paper records. Many troops received shots without updating their individual managed yellow shot record or the medical record was not

presented for concurrent documentation. The National Institutes of Health, Presidential Advisory Committee, Institute of Medicine, Defense Science Board and three studies published in the New England Journal of Medicine have consistently failed to find a correlation between anthrax vaccine and Gulf War illnesses.<sup>58</sup> Even without scientific evidence, the perception of doubt continues when DOD policy makers discuss anthrax vaccine health risks.

A greater emphasis on HRC techniques could have enhanced the trust and credibility of initial AVIP message. There are several principles of risk communication that can be enhanced to increase trust and credibility. A greater acknowledgement of the following principles would have increased the credibility of the initial message.

### **Hiding Advocacy Within Education Creates Distrust.**

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

To educate implies creating a full understanding of risk analysis and risk versus benefits. To reduce opposition implies creating an advocacy of compelling persuasion. The answer lies somewhere between education and persuasion. Information is not provided to enable the service member to make an informed consent decision. On the other hand, refusers are not restrained and forcibly vaccinated (which is permitted by Army Regulations). A compromise goal of "persuasive education" is attempted. Confusion can arise when the message is designed to persuade but presented under the guise of informing or educating the audience. This could create feelings of manipulation, distrust, and resentment within the audience.

Department of Defense has taken 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. They must highlight some information and omit other information for clarity and brevity. Even when presenting a balanced briefing, one will highlight certain facts with visual aids, voice emphasis or placement in the briefing or brochure. Other techniques involve selection of outside experts, emotional appeals and risk

comparisons. It is possible to achieve the balance between education and persuasion. As government officials, DOD is expected to follow standards of behavior to uphold the public trust.

As previously stated, the program's goal was to create an understanding and acceptance of the vaccine program. The challenge is to find a balance along the continuum that has pure information without any influence on one end and deception and manipulation at the other end.

### **Discussing Uncertainty Upfront Improves Credibility.**

In the early AVIP communication materials, it 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 a different result. The opponents of anthrax vaccine would cite a study with a higher rate than what was mentioned in the HRC material. They would then declare this as evidence that the government was lying and could not be trusted.

There are few absolutes in risk analysis. There is usually variation on the severity, frequency, and probability of the hazard. There is uncertainty that the risk management will be effective in reducing the risk. With vaccines, one must discuss the potential for side effects or adverse reactions during the VRC process. To have effective communication, the message must discuss the full range of possibilities and potential risks. Even if an allergic reaction is remotely possible, it should be discussed. Presenting a restricted range based upon consensus among experts could be viewed as misleading. If you fail to mention a possible outcome during the risk communication process, then the intended audience will be very disillusioned when they discover the rest of the story

In addition to the challenge of conflicting studies or conflicting opinions of the same study, there are usually conflicting opinions within an organization. The reason you do a risk analysis is to evaluate the pros and cons of a situation. You then evaluate a possible course of action. You must have a complete analysis of the negative aspects of risk management to reach the decision. Any discussion of the negative aspects within an organization could be used at a latter date by the opposition as evidence of a cover-up or conspiracy. An example is the refusers quoting the US Army Medical Research

Institute of Infectious Disease 1994 briefing. This briefing outlined the problems with the anthrax vaccine in an attempt to justify new vaccine funding.<sup>61</sup> This illustrates the need to fully acknowledge all potential negative aspects considered in the HRC process.

A key concept of risk communication is that the messenger must be trusted and credible for the messages to be accepted. Low trust creates a denial of the issue and greater possibility of an emotional response. To establish trust, the HRC message must discuss the uncertainty up-front.<sup>62</sup> To prevent this potential loss of credibility and to establish trust, the message 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 a challenge in this area because the risks fall into a range and have considerable deviations.

#### **Minimizing The Risk Weakens Credibility.**

Not only does one have to discuss the 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 message and the messenger's credibility. If a person does not like the message being communicated, then they attack the assessment and assumptions. If they find one thing wrong, one stretched truth, or one omitted fact then the entire program or message is questioned. The opposition will use one small mistake, exaggeration or omission as proof the government is lying about the entire program.

An example in the AVIP of how overconfidence or embellishment degraded credibility occurred from a simple statement. Early press briefings and literature stated that the anthrax vaccine "has 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> The opposition groups surveyed local veterinarians and veterinary schools and could not find anyone who had taken the vaccine. They reported that they could not even find a veterinarian who knew a veterinarian who has taken the anthrax vaccine. Although this was not a scientific study, it was used to question the credibility of the entire AVIP. Did DOD lie? Veterinarians have taken the vaccine, but only those working with large grazing animals in high threat areas. As the prevalence of natural anthrax diminished and the use of animal vaccines 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 the group of three (veterinarians, laboratory workers, livestock handlers) implies that they were the largest users of the three groups.

It is common to be skeptical about an organization shading the truth to justify their message. The best way to avoid such accusations is to recognize the uncertainty and discuss the full range of possibilities supported in the majority of published research. Providing a range of risks and acknowledging that the absolute true risk is unknown may sound counter to providing a convincing and persuasive argument. Failure to communicate the full possibilities may be perceived as a betrayal of trust when overconfidence about risk estimates is later shown to be incorrect. Although creating the perfect message is an elusive goal, it is worth the effort to make improvements. One can reduce these small but damaging mistakes by pre-testing and conducting extensive focus groups with the different 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>

#### **Organizational Biases Impact Credibility.**

In addition to minimizing the risks, there is an organizational bias that impacts trust and credibility. When a manufacturer claims that their products are the best on the market, one may view the statement as prejudicial. Impartiality may be questioned anytime an expert is affiliated with the organization. Even Commanders and military healthcare professionals utilizing the standard anthrax information briefing may have a conflict of interest in the vaccine risk communication. The natural tendency is to emphasize the benefits of the vaccine over the risks. At its best, vaccine risk communication should give the stakeholder accurate and unbiased information. To overcome the potential bias and possible conflict of interest, the 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 the organizational biases as well as to increase the trust and credibility of the risk communication 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 Institute of Health, FDA, CDC, and many other distinguished organizations and professional

groups. Because trust and credibility is such a paramount barrier for the AVIP, third party verification should play an even greater role. Surveys of targeted stakeholders could determine which outside DOD organizations have the most influence. The results could indicate a greater role of the outside opinion in the HRC materials. Since trust and credibility are such significant barriers, any potential improvement warrants more resources and exposure in the HRC process.

### **Comparing Risks Can Create Pitfalls.**

Risk communication attempts to deliver a message that conveys a course of action to reduce a risk or threat. For the communication to be successful, the audience must have an understanding of the risk to include the 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. An example is 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 manmade, controllable and uncontrollable can be viewed as a manipulative attempt to minimize or trivialize the health risk.<sup>66</sup> Attempts to convey the probability of a severe 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. The AVIP has focused their HRC message to comparing anthrax vaccine to the risks of other vaccines. Almost every one of AVIP's HRC messages will state that the risks of anthrax vaccine are not different from the other vaccines service members' receive. It is often stated 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 the risks are within an acceptable range. The comparison of vaccine risks should be discussed in greater detail and have a more visible role during the AVIP presentations.

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. They state that wearing the helmet and flak jacket is not voluntary; nor should the vaccine be voluntary. The vocal opposition has countered

that when a service member retires, they can remove the helmet and flak jacket. A retiring soldier cannot remove the 24 anthrax vaccinations received during a twenty-year career.

## CONCLUSIONS

The ideal outcome of an effective HRC message is 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. Some people have unrealistic expectations of HRC. 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 acceptance. To achieve their goals, DOD has to have an effective communication plan that utilizes HRC techniques. Even with a great program, it is a mistake to believe HRC can always eliminate conflict. Resistance may not be overcome by merely presenting more facts. Even a great risk communication program cannot prevent controversy, but poor risk communication can 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 generates comments but does not produce the quality comments 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 subgroup of stakeholders. Empirical evaluation conducted by personnel outside the program can provide an unbiased assessment of strengths and weaknesses.

Adjusting the program from comments obtained during a gradual phased program does not create the clear, consistent, and timely message required to generate the first impression of a new program. Risk Communication is not a Public Affairs task added after the risk management decisions are made.<sup>68</sup> For the communication materials 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 in hindsight and recommend changes learned during the growth and development of the AVIP. The value of these lessons observed is in the

future when DOD announces the next mandatory vaccination program. The Biological Vaccine Program and the Joint Vaccine Acquisition Program are currently developing and testing several new vaccines for FDA licensure. The risk communication techniques developed and practiced by the AVIP have a potential utilization beyond vaccines. Public skepticism and distrust of government is engrained in our country. Almost every new technology or product is viewed with both short and long-range health concerns. Health risk communication principles can also be applied to the discussions on depleted uranium, JP8 fuel, and environmental impact of ranges. All of these complex programs require an exchange of information among diverse stakeholders. The lessons learned from DOD's experience with AVIP can have a direct impact upon the favorable acceptance of these programs.

WORD COUNT = 9962

## ENDNOTES

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<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 on 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, US 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> Anthrax Vaccine Immunization Program Agency, "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> AVIP, SOP.

<sup>43</sup> Public Health Service.

<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), 24-5, 51-2.

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

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

<sup>47</sup> One theory for Reserve Pilots vocal opposition to the AVIP is based in 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 to separate 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.

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

<sup>53</sup> Grabenstein.

<sup>54</sup> Kevin M. Delaney of 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, 30 August 2000.

<sup>57</sup> DOD News Briefing, Army Surgeon General. 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. This 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 Unproven Force Protection.

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

<sup>63</sup> Anthrax Vaccine Immunization Program, "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, et al., 15.

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

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

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



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