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Protecting the Health of U.S. Military Forces: A National Obligation

THE GULF WAR in 1991 was the last critical test of military medicine during full scale ground and air combat operations. By nearly all measures, this war was a victory not only for United States combat troops and its allies, but also for the military health care system (26). The Department of Defense (DoD) was able to deploy an extensive clinical care and preventive medicine infrastructure rapidly to a distant, desert environment (2). As a result of these efforts and prevention programs established before the war, the disease and non-battle injury rate among deployed U.S. forces was lower in this war than in previous major conflicts (10,11). Even more importantly, the number of combat deaths was much less than anyone had predicted, mainly because of the quick and decisive defeat of the Iraqi military by superior U.S. and allied forces (39).

Despite the success of military medicine in the Arabian Gulf, the general perception 9 yr later is considerably different because of unresolved questions about the health of Gulf War veterans (31). In particular, veterans have experienced fatigue, joint pain, sleep problems, and other diverse symptoms that have not been definitively explained (15,28,37). Gulf War health questions have resulted in substantial controversy over potentially hazardous exposures during the deployment, the possibility of adverse affects from preventive health measures, and the role of stress in causing chronic illness (23,31).

Although further research is in progress, an optimistic perspective on veterans' health already has been provided by an extensive research effort based on clinical evaluations and medical records (29). Systematic clinical examinations have not identified a unique syndrome or a characteristic organic abnormality among over 100,000 U.S., British, and Canadian Gulf War veterans (7,22,27). Additionally, the mortality rate of Gulf War veterans has been less than half that of the civilian population (adjusted standardized mortality ratio of 0.44), and deaths due to medical causes have not increased (24,25). Only deaths due to accidents have been higher, as similarly observed after previous wars (5). Moreover, there has been no overall increase in hospitalizations among Gulf War veterans or birth defects among their children (8,18).

In response to health questions following the Gulf War and the increasing demands of a series of hazardous deployments, the military health system has undergone a fundamental

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reorientation. A new strategy has been developed and is being implemented to protect U.S. forces against all foreseeable physical and psychological threats. DoD's "Force Health Protection" strategy balances the military's responsibilities to: 1) promote and sustain health and wellness throughout each person's military service; 2) prevent acute and chronic illnesses and injuries; 3) rapidly stabilize, treat, and evacuate casualties; and, 4) perform medical surveillance, longitudinal health studies, and ensure adequate medical records documentation and clinical follow-up for deployed forces.

While U.S. military forces are arguably the healthiest in history – suffering the fewest casualties and living longer than the general population – continued controversy remains over health risks during military service. A review of recent experiences involving the anthrax vaccine will serve to illustrate the challenges facing the military health system and the necessity for a scientific standard and better risk communication strategy in the development and implementation of military health policy.

Anthrax Vaccinations

In December 1997, Secretary of Defense William Cohen made the decision to administer anthrax vaccine to all active duty and Reserve personnel (12). The total force "Anthrax Vaccine Immunization Program" was instituted because several hostile countries had weaponized this biological warfare (BW) threat (21). Additionally, terrorist groups, like the one that bombed U.S. troops in Saudi Arabia, could potentially use anthrax against American forces. The reality of the terrorist threat was clearly demonstrated by a cult in Japan, which produced this biological agent and then tried to use it against the general public (21).

In making the decision for total force immunization, one central fact could not be ignored: anthrax poses the greatest and most immediate threat of all possible BW agents (14,21). Anthrax can be produced and dispersed more readily than other weapons of mass destruction (21). And unlike other possible BW agents, the offensive potential of anthrax has been demonstrated by 68 deaths downwind from an accidental release of anthrax spores in the former Soviet Union (21). In a large American city, an airborne release of anthrax would possibly cause thousands of deaths (21).

Anthrax is a naturally occurring infectious disease of animals caused by the spore-forming bacterium, *Bacillus anthracis*. This bacterial infection can be grown using standard microbiology laboratory techniques. Due to the stability of the non-vegetative spore, large quantities of *B. anthracis* can be easily transported and stored for prolonged periods. The hardy spore makes it possible to aerosolize this agent using crude sprayers and agricultural machinery. Of major concern, microscopic amounts of the 1-5 μ m sized spore can cause fatal disease when inhaled. In short, *Bacillus anthracis* is an ideal agent for biological warfare (21).

As a lethal weapon and as a cause of mass terror, anthrax has few equals. A population exposed to airborne anthrax would be unaware that it had inhaled this deadly, odorless and colorless pathogen. Within a few days, flu-like symptoms would begin, followed by massive thoracic hemorrhage and meningitis (21). The sight of infected persons gasping for breath, with increasing cyanosis and then shock, would have a terrifying effect. Adding to the terror, any self-perceived symptom would be cause for alarm because once symptoms begin, nearly all patients have died of inhalation anthrax despite medical intervention (14,21). In the immediate aftermath of a biological attack, everyone would have to overcome fears of becoming the next victim of an unsuspected exposure. Although a successful, widespread BW

attack by a terrorist group is unlikely, the consequences of large numbers of anthrax casualties would be so devastating that this threat has to be countered with every effective health measure.

In an operational setting, American troops are vulnerable to both the acts of terrorists and a surprise military attack with artillery shells, aerial bombs, or missiles loaded with anthrax spores. Anthrax casualties would destroy combat capabilities and overwhelm health care resources. Neither gas masks nor protracted antibiotic therapy is sufficient to counter this threat because it has not been possible to devise detection equipment that can reliably warn troops of lethal exposure (12). After an undetected exposure to anthrax spores, troops could begin dying after it was too late to provide effective medical care or even to identify the perpetrators of an attack. Protection provided by the anthrax vaccine is, therefore, essential before a biological attack occurs.

Anthrax vaccines were first developed and demonstrated to provide protective immunity in animals more than 100 yr ago (34). The human vaccine, which is made from a non-infectious and sterile bacterial filtrate, was licensed in 1970. The anthrax vaccine has been shown to be protective against cutaneous anthrax, and there is substantial experimental data that the vaccine is effective against inhalation anthrax (3,12). In recent studies, 98% of 45 vaccinated, non-human primates have survived an aerosol challenge compared with none of 14 unvaccinated controls (12). These animal studies have been essential in assessing the vaccine's efficacy because inhalation anthrax is too lethal for ethical human trials. In addition, naturally occurring cases of inhalation anthrax are now very rare (none reported in the U.S. since 1978), so meaningful epidemiological studies are not possible (21).

The anthrax vaccine has been used by laboratory personnel, livestock handlers, veterinarians, and goat hair and woolen mill workers for over 30 yr without indications of long-term health effects. Notably, this vaccine has been administered with many other licensed and investigational vaccines to protect laboratory personnel in the Special Immunization Program at the U.S. Army Medical Research Institute of Infectious Diseases, Fort Detrick, MD. No unexpected incidence of adverse events or patterns of illness have been observed in this group immunized with multiple vaccines, including the anthrax vaccine (38).

Although the anthrax vaccine has been shown to be effective and safe (3,12), several arguments have been made against the systematic vaccination of U.S. military forces (36). For one, there is speculation that anthrax strains could be developed that would cause disease despite vaccination (30). However, the U.S. Food and Drug Administration (FDA) licensed vaccine is directed at the primary virulence factor of anthrax, which would be difficult to alter and still maintain the characteristic pathogenicity of this infectious agent (30,33).

Another argument against force-wide vaccination is that a rogue government or terrorist organization could simply choose another BW agent to attack American forces. In actuality, forcing our enemies to use a different BW agent may be preferable – none of the other potential BW agents is as lethal or readily produced and disseminated as anthrax (12,14).

A final argument put forward is that there are no long-term studies of the safety of the FDA-licensed anthrax vaccine (36). This claim, however, ignores the fact that few long-term studies of any non-living vaccines have been conducted, although these vaccines have been administered for generations. Aside from rare short-term reactions and their sequelae, inactivated vaccines have not been shown to be associated with the later development of

autoimmune, neoplastic, or reproductive health problems. What is being hypothesized – a chronic vaccine-induced syndrome – is a side effect that has not been demonstrated following the kinds of non-living vaccinations everyone receives. Although vaccines and numerous other exposures during the Gulf War have been considered as possible causes of long-term health problems, there is no objective data linking wartime vaccinations with organic disease (31).

Without demonstrable evidence of harm, any long-term health risk of anthrax vaccination remains speculative. Furthermore, in vaccine development it is not feasible to first evaluate long-term health effects over decades and only then license the vaccine. Much of the effort to link anthrax vaccine with long-term adverse health effects has not been driven by modern concepts of medicine and science but rather by unfounded conjecture and anecdotal experience (17).

As in every health policy determination, the decision to vaccinate U.S. troops against anthrax had to balance benefits and risks. A large body of research data had demonstrated that troops would benefit from immunization prior to exposure. A long history of vaccine use had shown that the risk was limited mainly to local and short-term systemic reactions such as erythema and slight tenderness and subcutaneous nodules at the injection site which may persist for several weeks in a few persons. After carefully weighing benefits and risk, the Secretary of Defense and the Joint Chiefs of Staff concluded that they had an obligation to provide troops with as much protection as possible against this deadly weapon (6).

The only alternative to force-wide immunization was to base health policy on the hope that America's enemies would not use anthrax against U.S. troops. Waiting for further research and second generation vaccines was not an option. U.S. troops would be left unprotected for years to a known health threat – a threat that is expected to increase, not decrease, if U.S. troops were perceived to be vulnerable.

DoD has listened carefully and responded to the questions expressed by military members about the anthrax vaccine program. The Department launched an unprecedented outreach and risk communication effort and instituted a multi-faceted surveillance program to monitor vaccinated personnel (32,33). The safeguards of the DoD Anthrax Vaccine Immunization Program meet or exceed every standard for vaccine administration in the civilian population (16). In more than 1 million military immunizations given to date, the anthrax vaccine has proved to be extremely safe with few serious reactions (16).

An additional important policy consideration pertaining to anthrax vaccine as a military force health protection measure concerns the mandatory vs. the voluntary nature of the preventive measure. Although "health" is a key component, this type of policy is really a "line" or "command" issue. Our national obligation extends beyond just a requirement to protect the health of the individual service member. We have a national obligation and an operational necessity to protect the health of the total force. As the Secretary of Defense and the Chairman of the Joint Chiefs of Staff have said, "Soldiers, sailors, airmen and marines fight in teams, and they need to know that all team members are protected from anthrax" (6). Commanders cannot compromise the success of a mission and the lives of their troops because a member of their command is at risk of becoming a casualty of biologic warfare.

Health Policy Development

As demonstrated by the decision to immunize troops against anthrax, the development of

sound health policy for Force Health Protection has to rely on a rigorous standard of scientific proof to improve clinical care and preventive medicine practices. This standard has to be based on the use of objective research data. When health policy changes are considered, independently verified scientific proof is required. Preferably, such proof should be based on peer-reviewed science published in leading medical journals, because the limitations of individual research studies require expert review and confirmation before a study's conclusions are adopted.

The enormous challenges for policy formulation in the military health system have to be understood and must not be underestimated. Myriad of hypotheses and suggested changes are continually being advanced by clinicians, scientists, advocates, and concerned citizens, both in and out of the military and federal government. These ideas are just as often implausible as plausible, and are just as likely to originate from unauthoritative sources as experts. For instance, to explain chronic symptoms among Gulf War veterans, speculation has ranged all the way from scientifically possible explanations (toxic exposures to smoke from oil well fires) to unlikely causes, such as beef allergy and reactions to artificial sweeteners in soft drinks (20,40).

Even restricting acceptance of ideas to those that are plausible and popularly believed would lead to chaos in health care because most untested hypotheses are wrong, as scientists know from painful experience. Peer review and independent confirmation are necessary because there is no other unbiased mechanism to distinguish good science. Objective standards, not individual opinion and non-scientific influences, need to guide health care and preventive medicine policy.

In developing health policy, reliable information is indispensable because benefits and risks have to be balanced. An effective medical intervention, whether a preventive measure like a vaccine, a therapeutic drug, or a surgical procedure, reflects a trade-off between benefits and risks. For health policy development, the decision never depends on the unattainable goals of perfect safety and absolute benefit. In the evaluation of the benefits, risks, and safety of anthrax vaccination, policy makers made an informed decision based on an extensive body of research data (12).

When balancing benefits and risks, the findings of research studies are of primary importance. And when science has yet to provide evidence-based answers, further research has to be supported. For Gulf War health questions, over 130 million dollars has been allocated for a wide-ranging research program because of gaps in our current medical knowledge (29). The DoD also has established a comprehensive biological and chemical defense research program to counter the mounting threat from unconventional weapons.

Community experience and medical standards also have a place in the decision making process, although these factors are not as decisive as independently verified, research findings. For example, in the decision to vaccinate U.S. troops against anthrax, the decades-long use of the anthrax vaccine provided evidence of safety, as did the excellent safety record of the national childhood vaccination program. In contrast to a long track record of vaccine safety, unfounded speculation did not provide an adequate basis for making an informed decision.

The federal judiciary provides a contemporary example of how conflicting health care claims have had to be managed (1). With the Daubert decision in 1993, the Supreme Court directed

federal judges to determine whether expert testimony was grounded in "the methods and procedures of science" and not simply subjective belief or unsupported speculative opinion (9). The courts were to consider whether a hypothesis is testable, whether a theory or technique had been subjected to peer review and publication, and whether a theory had gained general acceptance. Like the federal judiciary, the Department of Defense has to adhere to objective scientific standards in order to develop sound health policy and deal with controversial issues of medicine and science.

Policy Influences

In policy formulation, there has to be an appreciation that the pressures to change health care are increasing and not just from new scientific advances. Strong personal and financial interests are involved in health policy advocacy. Researchers naturally want to see their hypotheses accepted, as demonstrated by policy changes. And advocacy groups make a powerful statement by gaining government acceptance of their ideas. Health care providers and companies that market diagnostic tests, pharmaceuticals, and medical supplies also have financial interests in health policy decisions.

Special interests are a particular challenge for the DoD and Department of Veterans Affairs (VA) health care systems. A single change in the large, national health delivery programs of DoD or VA can affect medical practices throughout the country. Government-run health care systems consequently have become a primary target of advocacy groups because of financial rewards and because DoD and VA policies have a broad impact on the practice of medicine and on social issues when controversial diagnoses and health hazards are concerned. With such high stakes involved in health policy decisions, an objective, evidence-based standard is even more critical for government-run health care programs.

Congress also plays an important dual role in health policy formulation. Often Congress provides an important public forum by which special interest groups as well as private citizens can express concerns and address issues. This is a vital part of the American landscape, but it is a challenge to ensure that sound science-based policy is not overcome by popular, but unproven, principles. It is important to meet this challenge because another role Congress plays in policy formulation – rulemaking and appropriation – govern decisions on final policy determinations and the resources available to implement them.

The other strong influence on health policy is the popular media and the Internet, which is the primary source of medical information for a large proportion of the American public. It must be the responsibility of the government to provide the press with adequate information to prevent misleading and inaccurate stories that frighten rather than inform. The most recent example of misleading reports involved sensational allegations that the U.S. military secretly added squalene, an experimental adjuvant, to the anthrax vaccine (4,17). DoD has confirmed that no vaccines with squalene containing adjuvant were used, supplemental testing of the vaccine found no squalene, and as concluded by the General Accounting Office, there is no evidence that this happened. Independent investigators have not been able to test this idea because the methodology and findings of a purported study have not been published in the peer-reviewed medical literature (35).

The health and well-being of military personnel, veterans, and the general public are clearly hurt by false stories about government deception and lack of concern. The harm caused by unsubstantiated accusations cannot be completely undone after the public has been

misinformed by a mass media or Internet story. In order to ensure accurate reporting, it is critical that government agencies communicate complex health information and health policy changes to the press and to the public in a clear, persuasive and timely fashion.

Conclusions

The U.S. military has incorporated many lessons learned from the Gulf War and subsequent hazardous deployments to Haiti, Rwanda, Somalia, Bosnia, and now Kosovo. The Department of Defense is committed to an aggressive program of Force Health Protection. A comprehensive approach to health care and prevention has been implemented that will coordinate the activities within DoD and among multiple federal agencies (**Table 1**). The health of military personnel will be monitored and promoted from induction training to the end of military service, and then throughout medical care in the Department of Veterans Affairs. New DoD and VA deployment health research centers are being established that will actively investigate potential health risks and medical, psychological, and reproductive outcomes. DoD has recognized the need for proactive health risk communication as an essential part of the force health protection strategy.

Clearly the President and Congress have also heeded the lessons learned from the Gulf War. As early as 1992, Public Law 103-210 provided Gulf War veterans with priority health care in the VA; and, the "Veterans Programs Enhancement Act" of 1998 ensured that all future war veterans have access to health care.

More recently, the Presidential Review Directive 5 established strategies to improve Force Health Protection (13). Protecting the health of U.S. military forces is a national obligation. Americans who defend the vital interests of the nation deserve accurate health information and the finest medical care and preventive measures available to protect their health, wherever they serve.

Table I. Specific "Force Health Protection" Initiatives

1. Documentation of health status, including mental health assessments, blood sample collections, and health threat briefings before deployment.
2. Improvement in medical record keeping, including tracking of immunizations and other preventive countermeasures, during deployment.
3. Improvement in the collection, analysis and documentation of an expanded range of health surveillance data during deployments.
4. Improvement in exposure assessments and record keeping during deployment.
5. Identification of better products for biological and chemical warfare medical countermeasures.

6. Documentation of health assessments at the time of redeployment.
7. Assessment of health status - individual and force - after deployment.
8. Improvement of health risk communication efforts.
9. Improvement in coordination between DoD and VA during and after deployment.
10. Additional support for peer-reviewed research on a wide range of priority health issues.

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