



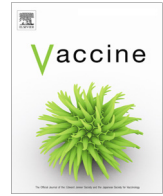
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A historical analysis of vaccine mandates in the United States military and its application to the COVID-19 vaccine mandate

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ABSTRACT

The Department of Defense has implemented a mandate that all military personnel be vaccinated against COVID-19. This article reviews the historical precedent of vaccine mandates for United States military personnel dating back to the formation of the continental army, as well as previous controversies about vaccine mandates such as the first influenza vaccine mandate and the Anthrax Vaccine Immunization Program. The historical review discusses precedent for the current COVID-19 vaccine mandate and the reception of these vaccine mandates by military personnel. The review then discusses how these historical lessons can inform the present COVID-19 vaccine mandate.

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1. Background

After the Food and Drug Administration approved Pfizer's mRNA COVID-19 vaccine, it only took days for the Department of Defense to swiftly mandate that all military personnel be vaccinated against COVID-19[1]. The mandate is controversial due to significant vaccine hesitancy, even among military and healthcare personnel[2–4]. The controversy begs the question of precedent. When and how have previous vaccine mandates impacted military personnel? If so, what lessons from the past can help contextualize the controversy at hand? We evaluated these questions with desk research by analyzing archived historical documents, secondary sources, and policy statements regarding the inception of military vaccine mandates and two other historically prominent mandates.

2. The birth of the United States military and mandatory inoculation

The United States Army was founded in June of 1775 amidst the turmoil of the revolutionary war[5]. Even at this inception of the United States military, as the newly founded Continental Army pushed its first major military advance targeting the British-owned province of Quebec, immunizations became a central

debate in military operations. Smallpox was killing American soldiers and crippling the offensive[6]. General Benedict Arnold, under the command of Major General Schuyler, led the conquest toward Quebec. While the British troops were formidable, perhaps an even greater threat to Arnold's conquest was smallpox. George Washington wrote, "I have been particularly attentive to the least Symptoms of the smallpox. . . we shall continue the utmost Vigilance against this most dangerous Enemy." [7] Smallpox would ultimately wipe out a third of General Benedict Arnold's troops as he marched toward Quebec[8]. Dr. Lewis Beebe, a physician to the soldiers of General Arnold, wrote, "If ever I had a compassionate feeling for my fellow creatures, who were objects in distress, I think it was this day, to see large barns filled with men in the very height of the smallpox." [9]

Not only was the disease spreading within the camps, but the British were likely using smallpox as a biological weapon. George Washington wrote to congress about his suspicion of this, stating that he heard British forces were deliberately sending infected people into cities where American soldiers were residing with the intention of crippling their forces[10].

While the world was a couple decades away from Edward Jenner's invention of vaccination, there was a similar immunologic tool to fight smallpox called inoculation. For centuries people had known that prior infection with smallpox conferred immunity. In the early 18th century, it also became known that taking pus from someone with smallpox and introducing it into a small cut would confer immunity while usually only causing mild symptoms. This procedure of inoculation had been widely disseminated

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by Lady Montague, who was passionate about preventing the effects of smallpox[11].

Inoculation was not without risks. The recipient could also develop severe infection and possibly death[12]. Among military personnel, there was fear that recipients could spread it to other troops and inoculating many troops at the same time could weaken defenses. Yet, as General Arnold watched his troops continue to fall to the scourge, he pushed for this risky measure and ordered that troops be able to perform inoculations in May of 1776[13].

That same month, General Thomas arrived at camp and subsequently retracted the order, forbidding the inoculation of troops. It was only a matter of days before General Thomas would himself be stricken with smallpox. He would die from the disease within two weeks[13]. Then troops again began to perform inoculations by themselves without organization or quarantining those that could potentially infect others.

The Continental Army would be forced to retreat from Quebec and not necessarily due to British forces. John Adams would write, "The smallpox is ten times more terrible than Britons, Canadians and Indians together. This was the cause of our precipitate retreat from Quebec." [14] As the losses from smallpox continued, it became apparent that to win the war against the British would require the Continental Army to win the war against infection.

In 1777, George Washington wrote to the Chief Physician of the Continental Army, William Shippen Jr., "Finding the smallpox to be spreading much and fearing that no precaution can prevent it from running through the whole of our Army, I have determined that the troops shall be inoculated. This expedient may be attended with some inconveniences and some disadvantages, but yet I trust in its consequences will have the most happy effects. Necessity not only authorizes but seems to require the measure, for should the disorder infect the Army in the natural way and rage with its usual virulence we should have more to dread from it than from the Sword of the Enemy." [15] After mandating inoculation, there was no recorded resistance from troops against Washington's inoculation mandate[16]. The rates of smallpox within the army were reduced to a trickle, cutting the percentage of soldiers reporting illness by approximately two-thirds[13].

3. Influenza and anthrax vaccine mandates

Over the centuries following George Washington's mandate, a multitude of vaccines that could safely and effectively prevent illness among troops were developed. As the list piled, a list of vaccines mandated for military personnel grew. As of 2020, mandatory vaccinations for North American military personnel included hepatitis B, MMR (measles, mumps, and rubella), tdap (tetanus, diphtheria, and pertussis), polio, meningococcal, and influenza[17]. Two vaccine mandates, influenza and anthrax, exemplify historical lessons that apply to current controversy with the COVID-19 vaccine mandate.

The influenza vaccine mandate is an important consideration because, like COVID-19, it represents a naturally occurring respiratory infection capable of spreading at pandemic proportions. The context of the influenza vaccine for military personnel is rooted in World War I. The pandemic of 1918 was tremendously devastating to troops, with 20–40 % of U.S. Army and Navy personnel getting ill, leading to about 8,743,102 lost duty days[18]. The toll would amount to over 26,000 deaths among American soldiers [19].

This devastation would inspire a mission to combat influenza. The U.S. Army Surgeon General commissioned research to develop influenza vaccines during the following decades[20]. By the 1940's, a clinical trial among troops demonstrated excellent efficacy[21].

The discovery was just in time for the tail end of World War II, when a multitude of factors pushed toward rapid implementation of the influenza vaccine. One reason being the fresh memory of devastation that influenza had caused in the first world war. Another reason being the threat of biological warfare use by rival nations. This threat would later prove to be real, as Japan conducted extensive research on biological weapons throughout World War II[22]. Both influenza's historic damage and threat as a bioweapon culminated in the first influenza vaccine mandate for military personnel in 1945, leading to the rapid vaccination of seven million people[23].

The reaction to the mandate is difficult to determine. There was little to no research conducted on vaccine hesitancy during the era, and little to no recorded resistance against the mandate. The absence of recorded resistance does not mean millions of military personnel unanimously accepted it. A study on civilian vaccine hesitancy during the era, specifically on over 76,000 industrial employees in the mid 1950's, demonstrated 22.6 % refusing influenza vaccination for reasons such as, "I was doubtful of its value," "allergic to inoculations," "allergic to eggs," "advised not to," or "don't believe in any shots[24]." These findings would suggest that the lack of recorded resistance reflects a lack of recording rather than absence of resistance, though this comparison is a substantial extrapolation forced by the absence of specific data.

After the implementation of the influenza vaccine mandate, researchers quickly noticed the effectiveness of the vaccine fading, leading to the withdrawal of the influenza vaccine mandate in 1949[23]. Antigenic shifting of the influenza virus would later explain the quick downtrend. Once the antigenic changes became clearer and combatable, the influenza vaccine became mandated again in the early 1950's and remains mandated today. Contemporary vaccinations are effective for military personnel but still subject to unpredictable antigenic changes[25]. Compliance by military personnel remains much higher than civilian vaccination rates, over 95 % versus less than 75 %[26].

The anthrax vaccine mandate is another historical context to consider because it was the most controversial. In the 1990's, the United States became entrenched in the Gulf War. Saddam Hussein had a history of implementing bioweapons, which contributed to the United States seeking protection against potential anthrax attacks[27]. In 1997, it formed the Anthrax Vaccine Immunization Program (AVIP), which mandated vaccination of troops[28].

The anthrax vaccine was developed in the 1950's[29]. Early studies showed it to be safe, leading to side effects in less than 3 % of individuals[30]. Nearly all side effects were local injection site reactions that resolved within a couple days. It was also very effective with an efficacy rate of 92.5 %[31]. One crucial caveat to this efficacy is that most of the data evaluated people exposed to cutaneous anthrax rather than inhalational (the latter being the primary exposure in biological warfare). Thus, while the vaccine had been licensed, the military's implementation for the prevention of inhalational anthrax would become widely debated as an off-label use[32]. Demonstrated effectiveness from inhalation exposure relies on the Animal Rule, meaning that since exposing humans to anthrax is obviously unethical, extrapolation from well-conducted animal studies is permitted to demonstrate effectiveness[31].

A public-relations and legal backlash would ensue against the AVIP[32]. There were large concerns about the efficacy and safety of the vaccine against inhalation anthrax, and some critics even attributed Gulf War syndrome as a vaccine side effect[33]. A minority of service members adamantly refused the vaccine, leading to other-than-honorable discharges or in some cases court-martial action[32]. The entire program was forced to cease multiple times over the next decade due to various injunctions and court rulings[32]. A crucial step in this process was the Food and Drug

Administration (FDA) revoking previous precedent and declaring informed consent is required from military personnel for any intervention that is considered investigational[34]. Subsequently, another cessation of the AVIP occurred after six service members filed a class-action lawsuit alleging experimentation without informed consent[32]. Despite the controversial saga, the anthrax vaccine was ultimately permitted under emergency use authorization to allow military use when there is significant risk of biological warfare[35].

Throughout all of this, safety of the anthrax vaccine remained constant. After nearly 2 million immunizations were given during the AVIP, probable adverse reactions were minimal and only 10 recipients were hospitalized, all due to allergic reactions[36]. The CDC's Anthrax Vaccine Research Program would later report that none of the studies exploring long term effects found higher rates of adverse health effects or chronic diseases after anthrax vaccination[37]. As of 2021, the anthrax vaccine is no longer mandated for all service personnel.

The reason that the AVIP instigated such a backlash compared to other mandatory vaccinations is unclear. There are many possible contributions, including some professions in the military having very low risk of biological warfare attacks, the initial lack of data specific to inhalational exposure, or simply the emotional reaction to the thought of biological warfare. Another possible contributor is the simultaneous traction of the anti-vaccination movement. In fact, the infamous Wakefield paper that erroneously linked the MMR vaccine to autism was published the same year of the AVIP initiation[38]. Another notable characteristic of the backlash is that mission-threatening refusal was exceedingly uncommon. An analysis of active-duty personnel deployed in an area potentially at risk to biological warfare reported just 5 out of 10,000 soldiers refusing the anthrax vaccine[39]. Most of these cases were personnel that did not desire to stay in the military. While official records of total vaccine refusals are not available, it was reported that Pentagon statements estimated 350 service-members had refused the vaccine between 1998 and 2000[40].

4. Discussion and application to the COVID-19 vaccine mandate

Our review of historical vaccine mandates in the United States Military provides several important lessons that contextualize the current COVID-19 vaccine mandate. Since the advent of the United States Military, there have been vaccine (or more specifically inoculation) mandates to preserve military readiness and personnel safety. A full evaluation of the present COVID-19 military vaccine mandate is out of the scope of this article, but the analyzed historical precedents provide both pro and con points on the issue.

The most obvious benefit to military vaccine mandates is the potential to save the lives of military personnel. While a main factor associated with non-vaccination among military personnel is the feeling of "not being a risk group" because of young and healthy demographics of active-duty personnel[41], history shows that military personnel are inherently a risk group. The devastation caused by the 1918 influenza pandemic is just one example of respiratory contagion leading to deaths and substantial time away from duty.

The drawbacks to mandatory military vaccination for COVID-19 largely relate to the potential response by military personnel, for which the backlash from the AVIP program provides a precedent historical context. Over 96 % of service members have received at least one COVID-19 vaccine as of October 2021[42], but precedent suggests it should be no surprise if over the proceeding months to years military members become administratively punished or even court-martialed for refusals. Early reports show that recruits are already being dismissed for vaccine refusals, and active-duty per-

sonnel will be subject to administrative action or court-martial charges at their commander's discretion[42]. Despite these policies, nearly 12,000 Air Force personnel will not comply with the vaccine mandate deadline[43]. The story of the AVIP suggests that current refusals will likely lead to legal action and possibly other-than-honorable discharges. Although, the AVIP history also suggests that this group of refusers will likely remain a decreasingly small minority.

A notable difference of the COVID-19 vaccines is a tremendously stronger evidence base for safety and efficacy compared to the anthrax vaccine at the time of AVIP initiation[41–46]. This fact may suggest that factors other than scientific disagreements are driving COVID-19 vaccine refusals.

Furthermore, some COVID-19 vaccinations have obtained full FDA approval. Thus, while the FDA's policy that informed consent is required for investigational therapies applied to the AVIP, full FDA approval of COVID-19 vaccination moots the application of this FDA policy today. These factors make any legal claim against mandatory COVID-19 vaccination extremely difficult.

Another drawback pointed out by the withdrawal of the influenza vaccine mandate in 1949 is waning efficacy. COVID-19 continues to undergo mutations that may impact the efficacy of vaccination[47]. This precedent highlights the need for continued monitoring and reconsideration by military health personnel.

The United States Military has a unique obligation to balance mission readiness and success with the needs of its people. Vaccine mandates are certainly in line with this obligation when implemented appropriately. The Military Health System continues to study COVID-19 vaccinations and educate military personnel about the safety and efficacy of these vaccines which could help preserve confidence and prevent refusals moving forward. Thus, the current COVID-19 vaccine mandate has both an extensive historical backing and an appropriate balance of mission first, people always.

Data statement

A data statement is not applicable to our manuscript submission.

Disclaimer

The views expressed are those of the authors and do not necessarily reflect the official views of the Wright Patterson Medical Center, United States Air Force, or the Department of Defense. Mention of trade names, commercial products, or organizations does not imply endorsement by the U.S. Government.

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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