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The Bioethics of Forced Flu Vaccination

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Abstract

The topic of government sanctioned vaccination has become an increasingly discussed issue since the start of the COVID-19 pandemic, and the ethics regarding forced vaccination have become relevant to virtually every nation on the globe. Prior to the onset of concerns regarding the spread of COVID-19, the United States was engaged in the aggressive advocacy of mandatory vaccination against the influenza virus. Although encouraged in the entire populous, vaccines became mandatory for those employed in professions considered "high risk" for contracting, and subsequently transmitting, the influenza virus to others. The push to vaccinate every health care worker, every year, against influenza has been controversial since its inception, and legislative efforts have been met with pushback from those who believe in their right to autonomy with regard to all healthcare decisions. This article approaches the issue of mandatory vaccination, its roots in society, and the ethical questions that come into play when medical treatment becomes legislated by governmental agencies or employers. Although focused on the influenza vaccine, concepts discussed have direct application to the current COVID-19 pandemic. The bioethics of forced vaccination presented in this article can be applied to the current governmental push toward mandatory vaccination against the corona virus responsible for the COVID-19 pandemic.

Keywords: Bioethics, Vaccine, Virus, Influenza, Immunity, Immunization

1918 marked an important year in healthcare as it was the beginning of an influenza pandemic that infected twenty percent of the world's population and brought with it a mortality rate so significant that the life expectancy in the United States was decreased by 10 years. In fact, it is estimated that between 1918 and 1920, 675,000 Americans succumbed to the deadly virus. Alarmingly, in contrast to previous epidemics this virus caused the greatest mortality in those between fifteen and thirty-four years of age rather than in the usually susceptible very young or very old. Also alarming was the fact that death sometimes occurred rapidly, even within hours of the onset of symptoms and often before the individual could seek treatment. Taxed to their limits by returning World War I soldiers as well as by as a decrease in workforce due to physician and nurse deaths from the flu, hospitals lacked the resources needed to combat the deadly virus. In addition, because infection rates were high throughout the globe (twenty five percent of the United States and twenty percent of the world's population were infected with the virus), individuals were unable to fully escape possible infection and this contributed to a sense of widespread panic. To help combat the epidemic the government put into place public health ordinances that restricted personal liberty by limiting an individual's right to travel through requiring a signed certificate to enter some towns or travel by railroad, requiring the wearing of gauze masks in public and by restricting group gatherings through the use of tactics that included confining funerals to fifteen minutes and prohibiting stores from holding sales; those who did not comply were fined heavily. It must be considered that in post-World War I America there was a pervasive belief in Nationalism (defined as "an ideology based on the premise that the individual's loyalty and devotion to the nation-state surpass other individual or group interests"), and due to advances in medical science including the newly described Germ Theory, there was strong public support for new scientific breakthroughs and new technology [1,2]. In addition to the concept of Nationalism, America at that time subscribed to the notion of utilitarianism. As defined by John Stewart Mill, a leading philosopher of the time, the utilitarian standpoint can be described as "Actions are right to the degree that they tend to promote the greatest good for the greatest number" [3]. The concepts of utilitarianism and nationalism dominated thinking and attitudes prior to World War II and it was the combination of these philosophical beliefs that enabled the government to put restrictive public health policies in place without opposition.

The ideals of nationalism and utilitarianism continued to pervade thinking until the conclusion of World War II, and in Nazi Germany utilitarianism was used to justify many inhumane acts, including medical experimentation on human prisoners. Despite their claim during the Doctors trial at Nuremberg that the knowledge gained from their experiments would benefit society, the idea that it is acceptable to sacrifice or abuse an individual in order to benefit the group was rejected, and in fact it was due the atrocities perpetrated upon humanity by the Nazi government during World War II that bioethics became a consideration. Following the 1948 Doctors trial at Nuremberg the Nuremberg Code was written, effectively leading to the emerging and now well studied field of bioethics. As was stated by Dr. Arthur Caplan, a noted medical ethicist, "The whole discipline of biomedical ethics rises from the ashes of the Holocost" [4]. One important ethical issue that arose from post-World War II human rights violations and one that is widely followed in modern day healthcare is that of Informed Consent. As opposed to the utilitarianism view that the good of the group supersedes the rights of the individual, informed consent provides for the right of the individual to be provided with the risks and benefits of a proposed medical treatment (or experiment) in order to make an informed decision to either participate or to decline the proposed treatment. The right to decline treatment without repercussion is an essential component of informed consent, because if there is a perceived risk for retaliation for either decision there is not true informed consent, and the right to informed consent is one liberty that is in jeopardy for health care workers in America today.

In response to the human rights violations perpetrated by the Nazis during World War II as well as other irresponsible studies including the Tuskegee Syphilis Study in which impoverished African Americans were denied treatment for known syphilis despite knowledge that it was treatable with penicillin, in 1978 the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research created the Belmont Report in order to protect individuals through the identification and definition ethical principles which must be respected by those who perform research or provide treatments for human beings. The report first defined the difference between "practice" and "research" stating:

"The purpose of medical or behavioral practice is to provide diagnosis, preventive treatment or therapy to particular individuals. By contrast, the term "research' designates an activity designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships). Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective" [5].

In addition to providing definitions as to the concepts of practice and research, the report identified the three bioethical principles that are in use today: respect for persons, beneficience and justice. Respect for persons includes providing autonomy and protection. According to the report. "To respect autonomy is to give weight to autonomous persons' considered opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others. To show lack of respect for an autonomous agent is to repudiate that person's considered judgments, to deny an individual the freedom to act on those considered judgments, or to withhold information necessary to make a considered judgment, when there are no compelling reasons to do so." [6].

The report goes on to state that those who lack the capacity to make autonomous and informed decisions must be protected from the risk of loss of liberty associated with being coerced into participation. The second principle described in the report is that of beneficence which was defined in the document as the importance of respecting the decisions of individuals while protecting them from harm and ensuring their well-being. Thirdly the Commissioners defined justice as an important ethical consideration for all researchers using human subjects. The principle of justice ensures that no one is denied a benefit without appropriate reason and that no group is unfairly burdened. In addition to the three main principles, the concept of informed consent was explored in the document. Informed consent, according to the report, can only occur when certain criteria are met, and in fact the authors believed that informed consent requires: "… that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them" (HHS, n.d., para. 25). This can only occur when individuals are provided with education that they understand as well as "conditions free of coercion and undue influence" (para. 34) with "coercion" defined as occurring when an individual is presented with a threat of harm for non-compliance. Finally, for research using human subjects to be ethical there must be a clear benefit that overrides the risks and subjects must be selected fairly with respect to the principle of justice. It is these basic principles that come into question when considering the current issues related to vaccination against the influenza virus.

1984 marked the first year that the Centers for Disease Control and Prevention (CDC) recommended vaccination against the influenza virus for all healthcare workers (HCW) with direct patient contact and in 1993 it was advised that all HCW should accept influenza vaccination. Despite aggressive attempts to increase rates, vaccination rates in HCW remain below anticipated benchmarks and in the 2013-14 flu season only 75.2% of HCW received the vaccination [7]. The CDC's recommendation for universal HCW immunization was based upon the belief that those who are at high risk for flu related mortality (the very young, the very old, those who are immunocompromised and those with chronic illness) would be protected if healthcare workers were vaccinated because it was believed that a reduction in the incidence of flu in those caring for high risk individuals would result in a reduced rate of infection in the at risk population [8]. The concern of the CDC is based upon the belief that without vaccination there is the risk of another influenza pandemic, just as was experienced as recently as 2009 when the H1N1 influenza virus infected people in 74 countries, impacting 18,000 known Americans. The estimated incidence of the H1N1 infection between 2009 and 2010 was 43 to 89 million people and the epidemic resulted in the deaths of an estimated 8,870 to 18,300 individuals worldwide [9]. Similar to the virus from 1918, the H1N1 virus was unusual in that it sickened those considered to be at low risk for flu related morbidity and mortality rather than those with high risk factors. Although there are some known risks related to morbidity and mortality from infection with the influenza virus, it is not surprising to note that viral action differs from year to year. According to Dolin (2014) Influenza A, the type of virus known to cause serious illness, is well known for its ability to mutate and remain potent [10]. In his article for Up to Date, Dolin states: "Influenza A viruses, in particular, have a remarkable ability to undergo periodic changes in the antigenic characteristics of their envelope glycoproteins, the hemagglutinin and the neuraminidase." (para. 1). "Influenza hemagglutinin is a surface glycoprotein that binds to sialic acid residues on respiratory epithelial cell surface glycoproteins. This interaction is necessary for the initiation of infection" (para.2). Major changes in the envelope glycoproteins, the hemagglutinin and the neuraminidase, are referred to as antigenic shifts, and minor changes are called antigenic drifts. Antigenic shifts are associated with epidemics and pandemics of influenza A, whereas antigenic drifts are associated with more localized outbreaks of varying extent (para 5).

It is the ability of the virus to change surface glycoproteins that enable the microorganism to foil the body's defenses and infect individuals every year and it is also this ability that renders the efficacy of the vaccine inconsistent. According to the CDC "How well the flu vaccine works (or its ability to prevent flu illness) can range widely from season to season" [11]. The vaccine components are a "best guess" derived from information gathered from 141 influenza centers located in 111 countries. Data is gathered throughout the year and viral samples are sent to "World Health Organization (WHO) Collaborating Centers for Reference and Research on Influenza located in Atlanta, Georgia, USA (Centers for Disease Con-

trol and Prevention, CDC); London, United Kingdom (National Institute for Medical Research); Melbourne, Australia (Victoria Infectious Diseases Reference Laboratory); Tokyo, Japan (National Institute for Infectious Diseases); and Beijing, China (National Institute for Viral Disease Control and Prevention) for additional analyses" [12]. Despite best efforts, as occurred in 2007 with the H1N1 pandemic, the vaccine may not protect those who receive it from serious or life threatening infection. Statistics regarding efficacy are difficult to compile due to unknown data including the number of those who are vaccinated who would not have become infected without the vaccine. Although CDC data indicates some reduction in flu associated hospitalizations, the information gathered is primarily based upon high risk populations including pediatric patients (with a purported 74% decrease), patients 50 years of age or older (77% decrease) and those with chronic underlying illness (70% reduction in those with diabetes and 52% in those with chronic lung disease) (CDC, 2013) these statistics are evidence of the aforementioned ability of the virus to change in order to protect itself from eventual extinction and they indicate that a significant number of vaccinated individuals were hospitalized for flu related illnesses [11]. Additionally, the uncertainties regarding the year to year efficacy of the vaccine and the information gathering and trial and error nature of its development indicate that the use of the vaccine is an ongoing research study rather part of a known and proven medical practice and therefore individuals who are involved in vaccination development must be held to the same standards as those who are conducting other medical studies and those who receive the injection must be provided with the same rights afforded to all human subjects including respect for persons, beneficence, and informed consent, all of which are currently under threat of being withheld from HCW by the federal government.

Fearing another outbreak of influenza such as the H1N1 pandemic, in 2012 the members of the National Vaccine Advisory Committee voted 12-2 to recommend that all healthcare facilities with fewer than 90% of employees voluntarily receiving vaccination "strongly consider" adopting a mandatory vaccination policy [13]. This recommendation was based upon evidence that when employees face the threat of sanctioning or termination the vaccination rates increase. Babcock, Gemeinhart, Jones, Claiborne Duangan and Woeltjel (2010) found that when annual flu vaccination was made a mandatory condition of employment in a large Midwestern hospital the immunization rate climbed to 98.4% with 0.3% exempted for religious reasons and 1.2% exempted for medical reasons [14]. Although clearly effective, threatening loss of employment for immunization violates multiple ethical principles. According to the ethical tenents described in the Belmont Report, any use of coercion constitutes a violation of informed consent and it is clear that threatening loss of one's livelihood constitutes a threat related to non-compliance with a hospital policy. Although it can be argued that employment is considered "at will", and therefore there is not true coercion because employees can choose to accept the policies of the institution or move on, because the federal government has put pressure on all hospitals in the nation to force employees to accept immunization the ability for unvaccinated individuals to find work within the industry has been greatly restricted. In addition to violating an individual's right to informed consent, threatening individuals with sanctions based upon a healthcare decision is in violation of their right to autonomy since it denies persons the freedom to act based upon their own considered judgment.

The choice to visually separate those who have refused immunization against the influenza virus from those who have received the flu shot is likely to result in groupthink and the accompanying ostracization of individuals. The development of groupthink involves specific and well described processes beginning with strong interpersonal pressure. During this phase the pressure to conform in order to form a group consensus becomes so strong that dissenting individuals succumb to the stress and non-conformists must self-censor and go along with the group to avoid being left out. Those who choose to remain independent thinkers often find themselves as outsiders, perceived as evil or weak by the group. The result of the groupthink process in addition to the shunning of individuals leads to lack of verbalized dissention and due to a lack of disagreement the group begins to make decisions that are poorly informed and often based upon an attachment to alternatives that are not representative of the big picture [15]. This is an important concept when considering mandatory vaccination because according to Sleek, Michel and Mikulak (2014) a recent Canadian study of U.S. workers showed that ostracizing was "more likely to douse an individuals' sense of belonging and their organizational commitment and engagement compared with harassment" (para. 8) [16]. Thus, the threat of exclusion from the group is also a form of coercion making the use of colored stickers or badges to identify the vaccinated from the unvaccinated in violation of informed consent.

Additionally, hospitals who choose to identify those who have been vaccinated from those who have opted to refuse immunization are in direct violation of employee rights to privacy under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Under the HIPAA law health care institutions have the responsibility to protect patient information including all "protected health information" or PHI. According to the Department of Health and Human Services (n.d.a) PHI includes any "information that relates to the individual's past, present or future physical or mental health or condition (or) the provision of health care to the individual…" (para. 6). By "marking" those who have received the vaccination as well as those who have not, hospitals are violating employee rights to federally protected health care privacy. Under HIPAA it is only legal to transfer personal medical information if the information is needed in order to provide patient care and it is clear that patients, visitors and co-workers do not have the right to know anything about a HCW's personal medical information. It is important to also consider the long term ramifications related to this violation of privacy rights. Once it becomes required that a HCW wear a sticker or badge denoting their "flu shot status" it opens the door to other requirements for disclosure including, for example, infection with the human immunodeficiency virus (HIV) or Hepatitis C (HCV).

The aforementioned violations of employee rights by healthcare facilities has resulted directly from pressure put upon them by Centers for Medicare and Medicaid Services (CMS). Since 2013 hospitals have been required to report vaccination rates among employees or pay a fine. Beginning in fiscal year 2015, under the Value Based Purchasing section of the Affordable Care Act, CMS will begin withholding monies owed to hospitals who participate in Centers for Medicare & Medicaid Services (CMS) Inpatient Prospective Payment System (IPPS) Hospital Inpatient Quality Reporting Program and who have not reached a 90% employee immunization rate. Employee rates of immunization will also eventually appear on the Hospital Compare website for patient scrutiny. This withholding of funding by CMS brings into play the ethical principle of justice. Throughout the United States there are 5,724 hospitals, 35% of which serve rural (and often poor) communities. 1,325 of the rural hospitals are considered critical access facilities meaning that they care for a low volume of patients, have fewer than 25 beds and are located at least 35 miles from another healthcare facility. Because of the low number of billable patients, these hospitals are reimbursed by CMS for operating costs rather than through direct patient billing. Another category of rural facilities is the safety-net hospital, so designated because they provide care for a larger than average number of patients insured by Medicare or Medicaid as well as those who are uninsured and for which the facility receives no compensation. These facilities are also compensated differently by CMS (they receive Disproportionate Share Payments (DSP) to offset the cost of caring for patients who bring lower reimbursement for services than privately insured patients), however the Affordable Care Act calls for a decrease in these payments over the next few years [17]. Financial sanctions against those facilities who fall below benchmark in employee vaccination rates will clearly have a greater

financial impact upon facilities who have a low number of patients who are privately insured, potentially impacting the care received by underprivileged, rural patients. In addition, those facilities who are currently receiving DSP are already facing a loss of income and will be hard hit by another loss of funding which not only puts the organization at risk but is also likely to result in greater coercive tactics by administration to force unwanted injections upon workers. This push to immunize can lead to a loss of qualified and expert staff which will ultimately leave the underserved without access to safe care. The undue burden upon facilities (and providers) who care for the underprivileged is a violation of the principle of distributive justice which calls for a fair distribution of resources as well as respect for the rights of the individual and the avoidance of placing an unfair burden on any one group. It is clear from the literature that hospitals receiving reimbursement primarily from private insurance companies will be much less impacted by any financial sanctions threatened by CMS and will have a much lesser need to violate the rights of their employees in order to remain financially solvent.

Vaccinations have been mandated in the United States since 1905 when the case Jacobson v. Massachusetts was decided by the Supreme Court and the right of the Cambridge Massachusetts Board of Health's authority to mandate small pox vaccination was upheld, although even at that time a personal right to liberty was valued and the penalty for refusing vaccination was a fine of five dollars. It is important to consider that in 1905 there were limited interventions available to cure disease and infectious illnesses were a major cause of mortality and as such local and state Boards of Health had a great deal of power. Modern constitutional law considers personal liberty differently due to changes in thought that occurred following the human rights violations of World War II. Today, according to Mariner, Annas and Glantz (2005) "Constitutional limits include protection against unjustified bodily intrusions, such as forcible vaccination of individuals at risk for adverse reactions, and physical restraints and unreasonable penalties for refusal" (p.585) [18]. Additionally, it must be discussed when considering the current movement toward mandating flu vaccines among healthy HCW, that "Public health and constitutional law have evolved to better protect both health and human rights. States' sovereign power to make laws of all kinds has not changed in the past century. What has changed is the Court's recognition of the importance of individual liberty and how it limits that power. Preserving the public's health in the 21st century requires preserving respect for personal liberty" [18].

Thus, the movement to mandate that healthy HCW submit to the flu shot is in violation of current constitutional interpretation and laws such as Florida's "public health emergency law" which mandates vaccination would most likely fail a constitutional litmus test. The common denominator between many constitutional vaccination cases is that of the good of the group versus the desire of the individual. It could be argued that a responsible HCW would, by virtue of their position, voluntarily protect patients from any harm by happily accepting annual immunization. It may be surprising to many individuals that it has been difficult to obtain high voluntary vaccination rates. The reason for hesitance to immunize on the part of providers is based upon the lack of evidence that the vaccination of healthy individuals results in lower infection among at-risk populations. The first issue is that of the uncertainty of vaccine efficacy due to the fact that in essence we know very little about how to prevent the flu and current recommendations are part of ongoing research rather than evidence based medical practice. According to the CDC (2014c) "flu vaccine protects against the three or four viruses that research suggests will be most common" (para.1) [19]. Because the flu shot is composed of a "best guess" mix of viruses there is no guarantee that those who are vaccinated will remain healthy just as there is no guarantee that those who refuse vaccination will be sickened by the influenza virus. In fact the CDC states: "There is still a possibility you could get the flu even if you got vaccinated. The ability of flu vaccine to protect a person depends on various factors, including the age and health status of the person being vaccinated, and also the similarity or "match" between the viruses used to make the vaccine and those circulating in the community. If the viruses in the vaccine and the influenza viruses circulating in the community are closely matched, vaccine effectiveness is higher. If they are not closely matched, vaccine effectiveness can be reduced" [20].

In addition to advising the flu shot for all individuals 6 months of age or older, the CDC advises hand washing, avoiding those who are sick and disinfecting contaminated surfaces and objects as additional ways to prevent the transmission of the virus, and in fact the CDC states the flu vaccine can reduce one's risk of illness, and due to the experimental nature of the treatment they stop short of proclaiming the injection as effective in the prevention of influenza related illness. A review of literature related to the efficacy of vaccinating healthy individuals in order to prevent illness in those at risk for flu related morbidity and mortality found that those who support vaccination often cite literature including studies that determine vaccination of HCW reduces death in patients from "all causes" which ostensibly could be interpreted that immunization against flu reduces death from accidents as well all as illness. According to Jefferson as cited in Cassels (2012) a review was undertaken of "four large cluster randomised trials and one cohort trial of nearly 20,000 healthcare workers… the 'flu vaccine showed "no effect on specific outcomes: laboratory-proven influenza, pneumonia, or deaths from pneumonia' (para. 11) [21]. When reviewing data, the Cochrane Library (known as the Gold Standard for evidence based practice) found very limited data gathered from reputable sources and their review of the evidence indicated that much of the "research" that has been published and publicized were funded by pharmaceutical companies and other interested parties rather than by independent researchers. It is interesting to note that when drugs are being trialed the FDA requires pharmaceutical companies to report ALL side effects experienced by those taking the new medication, often leading to a long list of possible adverse effects. The flu vaccine, however, has a very short official list side effects and although the CDC states that illness secondary to the flu shot is not possible, the side effects that are described with the intramuscular injection include low grade fever, aches and soreness at the injection site and those associated with nasal vaccine include runny nose, headache, wheezing, vomiting, muscle aches and fever (all known symptoms of influenza infection). In fact, the pharmaceutical companies who produce immunizations have been safe from litigation related to vaccine injury since October 1, 1988 when the National Vaccine Injury Compensation Program (NVICP) was put into place in order to ensure that pharmaceutical companies would continue to produce vaccinations [22]. The NVICP was established as a "no-fault alternative to the traditional tort system for resolving vaccine injury claims and provides compensation to people found to be injured by certain vaccines. The U. S. Court of Federal Claims decides who will be paid" (HRSA, n.d.,para.1). Because of the suspicion that vaccination was associated with autism, many parents in the 1980's were involved in litigation against the manufacturers of immunizations. Concerned for their fiscal health pharmaceutical companies threatened to halt production of all vaccinations, leaving the United States with no resources. In order to preserve public access to vaccination, Congress created an alternative method by which those injured by vaccinations could seek damages. Funded by a tax on vaccines, those who have vaccine related injuries or deaths receive compensation from the government via the Vaccine Injury Compensation Trust Fund rather than from the manufacturing drug company, giving the Federal Government a vested interest in withholding information related to adverse effects for which an individual may bring suit. It must be stated that any lack of disclosure as to potential adverse effects from the flu (or any) vaccine is a violation of autonomy. Although the formation of the NVICP was successful in maintaining an adequate supply of vaccination, it also removed responsibility and culpability from those who produce vaccines, further bringing into question the safety and lack of known side effects associated with the immunizations [23].

Conclusion

Those who oppose vaccination do so based upon concerns regarding the safety of the vaccine, the uncertain efficacy of immunization, a lack of independently run randomized controlled studies, and the concern that use of immunization may force the savvy influenza virus to mutate into an increasingly aggressive microbe. Despite agreement or disagreement with their point of view, there is no doubt that forcing vaccination upon any individual is a violation of individual liberty as well as a direct violation of informed consent and autonomy. Forcing HCW to identify themselves as "vaccinated" or "unvaccinated" is a violation of patient privacy under HIPAA laws and is a dubious practice from a sociological and psychological standpoint. Perhaps most importantly it must be considered that the rights of many individuals are being violated without strong evidence indicating any benefit to the group. Although the flu of 1918 had an extremely high mortality rate, due to advances in health care even the "deadly" H1N1 pandemic which impacted an estimated 43 to 89 million people worldwide brought with it a mortality rate of only 8,870 to 18,300 individuals, and due to the compilation of flu deaths with pneumonia deaths it is highly likely that the H1N1 accounted for fewer than the estimated number of deaths. It is time for us to realize that liberty is too precious to lose, especially if the loss of freedom nets no absolute gain. In the words of Benjamin Franklin: "Those who would give up essential Liberty, to purchase a little temporary Safety, deserve neither Liberty nor Safety".

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