

## **In Pursuit of the Unvaccinated: Whatever Happened to Informed Consent? Draft Only.**

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### *Introduction*

The twentieth century could be said to have been infamous for the ignoring of the rights of patients and research participants alike in the medical treatments and medical research. The first half of the century was witness not only to the practice of eugenics, but also to the atrocities committed by the Nazis in the name of medical research. They were not alone in pursuing medical research without the consent of those on whom the research was being conducted. Nazi Germany medical barbarities were prosecuted in the Nuremberg trials and led to the Helsinki Declaration (1964), which sought to provide guidelines for the conduct of medical research. Other violations of human rights uncovered in the Tuskegee medical experiments that were carried out from 1932 to 1972 in the United States, prompted the Belmont Report (1979) that attempted to end the exploitation of patients by medical practitioners in the conduct of medical research. Since then, many national governments have refined the ethical principles which govern medical research with human participants. In many countries this has resulted in the codification of these principles in a document that guides the work of ethics research committees, established to oversee research involving human participants. One of the key moral principles which guide these documents is informed consent. This principle not only governs informed consent in medical research with human participants, but also informed consent in medical treatment. In this paper, I will briefly outline what is meant by informed consent and argue that in mandating vaccination against Covid-19, governments are violating human dignity and undermining democratic freedom. There are good reasons why individuals should be vaccinated against Covid-19, but these do not licence a government to override individual autonomy by coercing individuals to be vaccinated through prohibiting the unvaccinated from working or engaging in social activity. It will further be argued that informed consent to medical treatment is no different to informed consent to medical research. That is, the same principles govern both. It also points to the importance of education in understanding the principles of democracy and the limits of government interference in individual lives.

### *Informed Consent*

The requirement that researchers seek informed consent from their potential research participants has been an outcome of the medical research community addressing the many scandals in medical research in the twentieth century. Notoriously, it is well known that the Nazis carried out many medical experiments on human subjects without their consent and were prosecuted during the Nuremberg trials for their gross violations of human dignity and human rights. (Spitz, 2005) Less well known is that medical experimentation on patients without their consent has been widely practised in many places. It has not been an aberration restricted exclusively to just the Nazis. Various scandalous experiments, for example, were carried by United States medical researchers on a population of black men in Tuskegee from the 1930s until the 1970s without their consent. United States medical researchers investigated the effects of atomic radiation on unsuspecting victims exposed to it as a result of atomic bomb tests. Japanese medical researchers carried out medical experiments on Chinese individuals during World War II. New Zealand researchers carried out research on women with cancer without their consent in 1966-67. Other examples abound. (Brandt, 1978, Edgar, 1992, LaFleur, 2007, Paul and Brookes, 2015)

The issue of informed consent has arisen once more during the present Covid pandemic, in particular, in relation to the coercion of the unvaccinated by governments in order to increase vaccination rates. While generally informed consent is associated with consent to participate in medical research, it is not restricted to medical research. Researchers in every other discipline in which research is carried out with human participants are expected to seek informed consent from potential research participants. In Education, for example, researchers working with children are expected to not only obtain consent from parents or guardians, but to also elicit the agreement of the children themselves. Many countries, such as Australia, regulate the conduct of research with human participants. (National Health and Medical Research Council, 2007) In addition, medical patients undergoing medical treatment are asked to provide their informed consent for those medical procedures. The guidelines for what is expected of medical doctors are outlined in *Good Medical Practice: Code of Conduct for Doctors in Australia* (Medical Board of Australia, 2020). The document stresses the importance of good, clear, communication by doctors with their patients. Before the Covid pandemic, there was a clear expectation that individuals must be asked to give their consent to medical treatment. Despite climbing vaccination rates in Australia and an expectation that at least 90% of adults will be fully vaccinated, several state jurisdictions are planning to ban unvaccinated individuals from participating in work, normal public, social activities, such as visiting restaurants, pubs, attending sporting events, religious services, theatre and concerts. Staff and students in higher education are expected to be fully vaccinated, otherwise they are prohibited from attending campus, giving or participating in face to face classes. Restrictions on the ability of the unvaccinated to shop for other than groceries and other necessities are also to be introduced. Some politicians have even gone so far as to suggest that unvaccinated people should be refused medical treatment. (Chung, 2021) The inability to work, and so to provide for oneself and one's family is not only heavy-handed, violates a range of basic human rights, but also is ineffectual and unnecessary.

There are several issues that result from the suppression of individual autonomy in relation to the giving of informed consent. Not least of these is the tension between individual liberty and the obligations and responsibilities that are owed by individuals to the society in which they live. In a democracy, it is to be expected that citizens will take an active role in their government at least through the ballot box and through paying their taxes. They are also expected to obey the law. The pandemic, however, is an unusual situation since governments have declared a state of emergency which enables them to impose various emergency measures on the population. These have included lockdowns, restrictions on travel and on normal activities, such as visiting family and friends. It is another matter whether the state of emergency includes the right by governments to compulsorily vaccinate all people. The seeking of informed consent is a recognition that human beings, who are independent, autonomous individuals, need to be asked to give their consent before either participating in research or undergoing any medical treatment. This follows from the respect due to every human being because they are human beings. Bearing in mind the Kantian injunction that we should never treat human beings merely as means, but always as ends in themselves, the following questions arise: 1) Why we need to seek informed consent; 2) What is meant by informed consent; 3) Who needs to give consent and 4) What information should be given to participants.

We seek informed consent because human beings are the kinds of beings who not only have inherent human dignity, but are also rational beings capable of making independent, autonomous decisions about their medical treatment. Respect for the autonomy of human beings is a central concept in modern bioethics and is the reason why we seek informed consent. Given that governments have decided that in the case of vaccination against Covid-19 there are sufficient grounds to compel people to be vaccinated, it can be concluded that the respect for the autonomy of individual human beings is insufficient and dire circumstances justify the overriding of the need for informed consent. This is a somewhat surprising conclusion, given that Western liberal

democracy has been built on the idea of individual freedom and that it is the role of the state to facilitate individual human fulfilment, provided that it does not interfere with or harm the ability of others to pursue their interests.

John Stuart Mill, along with Jeremy Bentham, one of the founders of modern liberalism, says that the struggle between liberty and authority is the most conspicuous feature of history, as can be seen in the civilizations of Greece, Rome and England. (Mill, 2003, 88) In some respects, Mill echoes Hobbes, by describing how liberty is to be conceived as the limiting of the power of rulers to impose their will upon the populace. In the wake of recent legislation in Victoria giving unlimited powers to the government to declare a state of emergency and to rule without proper oversight by parliament, liberty has taken a battering.<sup>1</sup> Opposition to the legislation argues that it gives individuals, namely the Premier and Health Minister not only unlimited power to act, but to avoid independent scrutiny, with oversight of decisions made by both in the hands of a sub-committee controlled by the government. One feature of the legislation is power given to the police or other designated officers, the power to detain people indefinitely without charging them with any offence. Authority has the upper hand over liberty.

Irrespective of whether the legislation is as bad as the Victorian Bar Council and others in Victoria think, it brings into sharp relief the question of where the limits should be drawn between the limits of individual independence and social control. This means that there should be some rules which prescribe the limits of individual freedoms and constrain the tendency of the majority to social control. These rules, however, are not self-evident, nor should it simply be a matter of what people in government think or feel ought to be the rules. Mill observes that where there is an ascendant class, a large portion of the morality of the country emanates from its class interests, and its feelings of class superiority. Mill also notes the tendency of the working or lower classes to accept the values and moral sentiments of the ruling class. He notes that the likes and dislikes of a powerful portion of society often determine the rules by which society regulates itself. (2003, 88-89) Gramsci, for example, writes powerfully of the need to question the hegemonic grip that the ruling class has on the values and beliefs of the rest of society. (Gramsci, 1971) In modern societies this role is carried out by intellectual elites who hold significant power in government administration and corporations. There is no doubt that the Victorian Labor government believes that it has the support of these elites and the majority of citizens in the state and so can use its parliamentary majority (after doing a deal with three independents in the Upper House) to impose legislation which extends its control over the state. The tyranny of the majority, says Mill, is one of the worst problems in democracies. (Mill, 2003, 90-91)

Significantly, Mill asserts that the only rightful purpose for which power can be rightfully exercised over another member of the community against his will is to prevent harm to others. It cannot just be because it might be better for the person to do something or refrain from doing something. It can only be if the intended action leads directly to harming others. Mill says that over himself, over his own body and mind, the individual is sovereign. Of course, adds Mill, this is only to apply to individuals who are mature and possess their minds. (2003, 94-95) Nevertheless, Mill's point is significant in that he affirms that over their own bodies, crucially, individuals are the ones who are the decision-makers. In compelling vaccination, governments are usurping the sovereignty that human beings have over their bodies.

Yet there may be a case to be made that in the situation of the pandemic the usual sovereignty that human beings have over their bodies must be waived and that individuals can be compelled to be vaccinated. Thus far, governments have not resorted to physical force, rather they have resorted to

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<sup>1</sup> For a relatively favourable article, which nevertheless mentions the opposition to the legislation of the Ombudsman and the Victorian Bar Council, see Kinsella, Elise and Dunstan, Joseph (2021).

excluding unvaccinated people from most normal human pursuits. There is more to be said about what is meant by mandating vaccination, compelling vaccination and coercing vaccination. It is obvious that using physical force to vaccinate people is not what is meant, as it is obvious that there are methods of compelling or coercing people to be vaccinated that do not involve physical force. There is, for instance, social pressure that a consensus about the need vaccination brings to bear on unvaccinated persons. One of the general arguments for vaccination, apart from its benefit to the individual through providing a high level of immunity to the virus, is that the more people vaccinated, the greater the chances of “herd” immunity developing. Though it is not possible to state with certainty what vaccination and recovery from infection percentages are required for the development of “herd” immunity in relation to Covid-19, there is some agreement that this is possible once the number of people vaccinated rises above 70%. Clearly, the more people vaccinated, the greater the possibility of the development of “herd” immunity. Since Covid-19 is particularly virulent, the higher the number of individuals vaccinated, the more confident jurisdictions can be of controlling outbreaks of the virus. Hence, vaccination provides a benefit not only for the individual, but to the whole community. Hence, since “herd” immunity requires at least 70% vaccination, if not more, there are good reasons to encourage vaccination. The question, however, is whether the reasons are good enough to compel individuals to be vaccinated, as opposed to persuading them that vaccination is in their own best interests.

In order to respond to this question, we need to establish conditions under which it would be possible to justify the waiving of the requirement of asking for informed consent. At least some of these conditions are: (1) the individual is not competent to give informed consent; (2) it is not possible to gain informed consent; (3) there is a risk of harm to the individual if he or she refuses to give informed consent; (4) the individual is unable to understand the reasons given; (5) there is a grave risk to the community that compels action. It is not necessary that all these conditions have to be fulfilled, it is sufficient that one of them is fulfilled.

It is evident that if individuals are not competent to give informed consent that the requirement would need to be waived. Children, for example, may be too young to be able to give informed consent since they are unable to make decisions about vaccination. In such a case, parents will be required to make the decision for them. Others who may not be able to give informed consent will be those suffering from dementia or other mental illnesses which render them unable to agree to vaccination. The second condition would apply in a situation where researchers were seeking anonymised responses or where there is a retrospective study in which all the participants were dead, were not contactable or the data being used has been de-identified. It would not apply in the case of vaccination against Covid-19. The third condition, namely that there is risk of harm to the individual, could apply in situations, for instance, where someone suffers from anorexia, and might need to be force fed in order to save his or her life. He or she needs to eat, but refuses to give his or her consent to be fed. Other cases could involve individuals refusing to take medications or have blood transfusions which would save their lives. Such cases are not always to be resolved by overriding informed consent, but provide examples of cases where the risk of harm to the individual is such that their refusal of treatment could be overridden. The fourth condition is arguably quite common, since understanding complex medical treatment is generally beyond the competence of most individuals. The fifth and final condition refers to a grave risk to the community should individuals refuse to be vaccinated that Covid-19 will spread unchecked, resulting in many deaths and serious illness.

Although the first two conditions are important, it is the last three conditions which are of interest, since they directly address the question of compulsion. Of central concern is whether the risk of harm to the individual is so great that there is a prima facie case, like that of the anorexia, that force-feeding is justified. There is no question that the Covid-19 virus, particularly the Delta variant, is

highly contagious and that unvaccinated people are at greater risk of infection as well as more serious illness from the disease or death. (Ahmed, D.A. et. al., 2021; Katella, 2021; Telenti, et. al., 2021) The risk of harm is therefore heightened and it is, all things being considered, in the interests of individuals to be vaccinated. It is not, however, a situation in which failure to be vaccinated will inevitably lead to infection or to serious illness. It is therefore not an instance where someone's refusal to be vaccinated will lead to his or her death, unlike the refusal to eat in the case of anorexia will lead to the person's death. Moreover, given that there are serious side effects that might occur as a result of receiving a particular vaccine, there are grounds, however, slight, which might convince someone to refuse vaccination. (Rommel, 2021) For example, some individuals may fear that vaccination might affect their fertility. (Diaz, et. al., 2021) During the roll-out of the Astra-Zeneca vaccine, much was made of the rare cases where people died from blood-clots after receiving the vaccine. (ABC News, 2021) The threats from side effects are real but need to be seen in context. For example, the risk of serious side effects from the AstraZeneca vaccine are estimated to be 0.01% for a 25 year old, while the risk of dying in car accident is 0.038%. (Cuffe, 2021) Risk, as the *National Statement on Ethical Conduct in Human Research* states, is not just an assessment of the likelihood that a harm will occur, but also the severity of the harm, including its consequences. It adds that in any assessment of risk, the perception of those involved of the risk should also be taken into account. (*National Statement*, 2007, updated 2018, 12) There are, therefore, grounds for taking seriously someone's reluctance to take a vaccine: (1) that it is not relevantly a case where refusal to be vaccinated will lead to the individual's death, and (2) that some side-effects, though rare, could be severe.

Few individuals have the capacity to understand complex medical research. This could mean that in practice, no one can give informed consent, so the government is justified in making vaccination mandatory on the grounds that they know best, since they have access to expert advice on the best way to handle the pandemic. This relies on citizens trusting their government. Not everyone is likely to do so and a reasonable response is to be cautious about vaccination or decline it. Since medical research is complex, the ordinary citizen must rely on a simplified version that is offered by the media or government information sheets. In relation to Covid-19 vaccination, there has been competing narratives. On the one hand, the media has reported rare side effects whenever they have occurred, which has had the effect of focussing the minds of the public on these so that the impression has been gained that the vaccines are dangerous. On the other hand, there continue to be government assurances that there was no need to worry. Statements such as, "trust the science", are mere slogans, and do nothing to reassure those with doubts about vaccination. Few analyses are provided of the variables in play in assessing the efficacy, potential side effects of the vaccines and the probability of any individual succumbing to a side effect. Recourse to medical research studies about the vaccines is generally not very helpful since they require a high level understanding of statistics, as well as sufficient medical understanding to interpret the results of the research. Most people will rely on what is reported in the media. As a result, the ability to give genuine informed consent is constrained. For some individuals, reluctance to be vaccinated could be due to a realisation that they are unable to assess in a reasonable way the contradictory information that they have received. It is not unreasonable to hesitate. Since it is not unreasonable to hesitate, the government is not justified in overriding the grounds that people might have to refusing to be vaccinated.

The final reason proposed for waiving the need for consent and compelling citizens to be vaccinated is the grave danger to the population if the pandemic is allowed to spread unchecked through the community. The Covid-19 virus, especially its Delta variant, has been shown to be both contagious and virulent, and the experience of many countries has been that unless it is controlled, both case numbers, hospitalisations and deaths have the potential to escalate rapidly. (Mikszewski, et al., 2021) Since there are efficacious vaccines available, the rapid vaccination of the population is a key

weapon against Covid-19. In many parts of the world slow vaccination rates have meant that the virus has been able to infect many more people and has caused more deaths than it otherwise might have. The devastating effects lockdowns and restrictions have had on people's movement and ability to work are a common experience. The longer that the pandemic continues, the worse the effects on human populations everywhere not only through the illness that it causes, but also the economic and social harms it brings about. Lockdowns are of dubious efficacy, and certainly have led to an increase in mental health problems. (Ahmed, et al., 2021) It is safe to conclude that there is a grave risk if the population remains unvaccinated.

Since there is a grave risk, governments would seem to have a strong case for mandating vaccination. On the contrary, since there are strong rational and reasonable reasons for vaccination, compelling people to be vaccinated is unnecessary unless it is assumed that people are unable to make rational decisions based on good evidence. Waiving of consent is only normally done where individuals are incapable of making decisions for themselves, and as we have already indicated, this is restricted to young children (who are nevertheless asked to give their assent) and those who living with a mental disability that prevents them from being able to give consent. In such cases, the state might reasonably act *in loco parentis*. Obduracy or opposition to vaccination does not mean that people are not capable of making rational decisions based on evidence. The same may be said of those who are vaccination hesitant. In NSW and Victoria, the most populous states, the number of those who are double vaccinated has reached 90%, so the vast majority of the population have accepted vaccination as the means of controlling the virus and enabling a return to some form of normality to their lives. There is no need for compulsion.

Since 90% of the population, at least in the two most populous states, has been fully vaccinated and both those states have lifted most restrictions it is evident that the unvaccinated do not pose a major threat. Indeed, as more people are vaccinated, the grave risk declines, if vaccines are efficacious. With a vaccination rate of 90%, the threat from the virus is significantly diminished. The same is not the case in other countries in the northern hemisphere that are now entering their winter season and people congregate together indoors with high densities. Austria, with a relatively low fully vaccination rate of 65% and Germany with 68% fully vaccinated are seeing a surge in cases mostly among the unvaccinated. There are good reasons for introducing some restrictions on unvaccinated people for their own protection, but this does not include mandating vaccination. (Greene, 2021)

The mandating of vaccination would need to be justified on serious and persuasive reasons that override the rights of human beings to make independent choices about their health. These reasons are not the same as those which justify vaccination itself and are unjustified in a democratic state. In seeking informed consent to a medical treatment patients need to be given appropriate information that outlines the benefits as well as the harms that might arise from treatment. The government has provided such information and individuals are able to seek further advice from their medical practitioner. In most cases, this has been sufficient for the vast majority of people. That it has not persuaded the remaining minority does not constitute grounds for excluding them from society. By mandating that the unvaccinated cannot work or engage in normal social activities, the government – with some corporations and other institutions, such as higher education institutions, agreeing – a dangerous precedent is being set that threatens democracy.

There are limits to the authority of the state over the individual. Libertarians such as Robert Nozick argued for a minimalist form of government in which it was responsible for a limited range of services, such as defence of the nation and private property. Citizens were responsible for looking after themselves. (Nozick, 1974) Modern democracies are far from minimalist states and take responsibility, rightly, for the health and welfare of their citizens. The question, however, is how far

modern states should go in ordering the lives of citizens for their own good. Compelling individuals to be vaccinated starts society on the path to totalitarianism since it accepts that the state has an overriding right to determine what is best for individuals and to shape their lives accordingly. Liberal democracies were founded on the idea that human beings should be left as far as possible to determine their own good, rather than have it decided by the state. There is a balance to be found between a laissez faire society of the Nozickian kind and an authoritarian socialist welfare state. Turning the unvaccinated minority into an oppressed group is an abhorrent abuse of power that is divisive and denies them their basic human right to work and to be equal members of society. The complicity of society in oppressing the unvaccinated through insisting on “vaccine passports” to enter shops, restaurants, and schools is deplorable and must be resisted since it creates an underclass of human beings. Because they are unvaccinated does not mean that they have lost their human rights. It should also be noted that being unvaccinated does not mean that someone will have the virus, it only increases their risk of contracting the virus and a higher likelihood of serious illness. The unvaccinated appear to be another oppressed minority in the making, which, it is to be hoped, the champions of identity politics will defend.

Mill argued that society was not founded on a contract, but nevertheless proposed that anyone receiving the protection of society owed a return to society for that benefit. (Mill, 2003) This means that each person has to observe a certain standard of behaviour towards others. Society is within its rights to enforce these standards of behaviour, but not at the expense of constraining liberty, unless absolutely necessary. As a result, where someone’s conduct threatens the good of the community then he or she becomes subject to punishment for violating the rights of others. It is not just a matter of punishment, however, human beings need to be trained to support each other. Like Bentham, Mill did not think that cooperation could be coerced, but could be attained through education. Every individual has a right to practise what he or she wants but cannot presume to impose on others what is only of interest to him or her. In most instances it is the individual who will know what is best for himself or herself and if society is to interfere it will be according to certain general rules. Mill, however, thought that these might well be misapplied, and it would be better that individuals suffer the consequences of their actions. For instance, if a person is grossly deficient in good qualities, then he is likely to be avoided by others and be regarded with contempt. Most people will want to avoid condemnation, so will alter their behaviour. Mill’s general point here was that rather than suppress people’s liberty by forcing them to act in particular ways we can exercise our liberty by avoiding people who we find disagreeable.

Mill points to the importance of cooperation and collaboration in enabling society to operate harmoniously for the benefit of all. During the pandemic, people have been forced into lockdowns, wearing of masks, restricted in their ability to work and to socialise. Most to varying degrees have accepted their necessity. Similarly, when vaccinations became available, the vast majority have been inoculated. A minority, for various reasons, have not. It should not be assumed that these reasons are not good reasons, since there are medical grounds why some people are not able to be vaccinated. Others may have spurious reasons. Despite that, there is more to be lost in terms of freedom and democracy in coercing people against their will. As Mill says, we can just avoid them. Coercion is the refuge of the tyrant and harms the respect we owe all human beings.

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