

KEY ETHICAL ISSUES RELATED TO COVID 19 VACCINATION: PERSONAL CHOICE VS. GREATER PUBLIC WELFARE AND INFORMED CONSENT

Akram Almatarneh, American University in Dubai

ABSTRACT

Vaccination against various diseases has been widely practised for more than a century and on a more limited scale its use in a variety of forms stretches back far longer. During earlier eras disease spread more slowly along shipping lanes on water and traditional transport routes on land. Today, in an era of air transport, contagion spreads far more rapidly. Travelling far more rapidly (indeed instantaneously) is the spread of misinformation that hinders vaccination which can, in the instance of Covid-19, reduce disease impacts, including rates of severe illness and death.

This paper explores the ethical issue of informed consent in the context of the contest between personal choice and the greater public welfare. It also makes reference to a number of low, middle and high income countries where vaccine hesitance, and to a lesser extent refusal, has been fed by misinformation on a scale not previously observed but made possible by the proliferation of modern technology. This campaign of ignorance has further undermined trust in governmental health bodies and their attempts to implement quarantine and other measures such as vaccination that had already been damaged by early variations and vacillation in governmental approaches around the globe due in part to a reluctance by some governments to take actions that would have economic repercussions but also by the necessary evolution of their approaches as more became known about the disease and its variants.

The paper examines the historical background and the current situation and finds that more must be done to restore or increase trust levels between citizens and governmental authorities, including the dissemination of high quality accurate information in a form relevant to readers/viewers. While potential side-effects of vaccines must be disclosed to ensure informed consent, their incidence should also be clearly communicated (e.g., in vaccine information statements) so that clients/patients are aware that a risk is 1 in 100 or 1 in 1000 or 1 in 2 million etc.

Governments are urged to learn from their experience and better prepare for inevitable future pandemics to minimise vaccine hesitancy and refusal and maximise its acceptance where evidence is overwhelming as to the benefit to the community. Informed consent is part of the context of efforts to use vaccination to contain or eradicate any disease. Nevertheless, while better information for clients/patients/consumers may reduce vaccine hesitancy/refusal, it is unlikely that it would but eliminate the need for mandating vaccination in some circumstances for the benefit of the broader community, although strict quarantine of those reluctant to accept it is an alternative but one not generally accepted by those reluctant to be vaccinated. The information war is one that needs to be won to increase the voluntary uptake of vaccination in the context of voluntary informed consent.

Keywords: Personal Choice, Public Welfare, Informed Consent, Law.

INTRODUCTION

Vaccinations are not a new concept. Inhalation of contagious material had been practised as a means of preventing the worst manifestations of smallpox and deaths from it in China (and isolated communities in the Britain) in the 16th century and perhaps earlier (Boylston, 2012). Vaccination for smallpox had also been practised in North Africa and the Ottoman Empire in the 17th century (Boylston, 2012). It became more accepted in the Western world in the 18th century where it was regarded as an innovation. It has long been key to tackling contagious diseases. A prime example would be the eradication of smallpox through vaccination through the use of various Orthopoxvirus spp. This replaced an earlier practice of vaccination whereby material containing the smallpox virus (Variola Virus-VARV) itself had been introduced into the body through the skin via scarification or by inhalation (Carroll et al., 2011). While this produced a lower death rate below that expected in natural acquisition of smallpox, it was not as effective as cowpox (Cowpox Virus (CPXV) another Orthopoxvirus) and its successors which produced greatly reduced death rates among those subsequently exposed to smallpox. About 30% of those who contracted variola major died (and about 2% from variola minor) (Ochmann & Roser, 2018). The smallpox vaccine (CPXV) first used in 1796 was similarly introduced to the body via scarification. It was replaced in the 1800s by the Vaccinia Virus (VACV), very close relative to cowpox virus. In the second half of the 20th century, an international campaign intensified and achieved eradication, with the last natural transmission recorded in the 1970s (Filsinger & Dweek, 2021; Gillray, 1802).

Through the herd immunity achieved by vaccination, smallpox is now no longer a prominent disease. The only samples of variola remain stored in just two laboratories, one in the United States and the other in Russia. In 1980, WHO declared it eradicated (WHO)? Nevertheless, vaccines have been a controversial topic since the push for the smallpox vaccine back in the 19th century. Indeed, some argued that those vaccinated might acquire bovine characteristics; cartoonists had a field day portraying popular fears, medical establishment opposition etc. (Pikala & Burzyńska, 2022). Poliomyelitis has been almost eradicated similarly by vaccination although conflict-interrupted programs and misinformation have resulted in re-emergence of disease in Afghanistan and Pakistan, and there have been cases in the Asia Pacific. The goal remains eradication.

In the current era, vaccination is widely accepted for a number of diseases of bacterial and viral origin. The former includes bacterial pneumonia (cause: *Streptococcus pneumoniae*), diphtheria (*Corynebacterium diphtheriae*), whooping cough (*Bordetella pertussis*), and tetanus (*Clostridium tetani*). The latter includes poliomyelitis (poliovirus), viral pneumonia (various viruses), chicken pox/shingles (varicella zoster virus), influenza (influenza virus spp.), mumps (Mumps orthorubulavirus), measles (Measles morbillivirus), rubella (rubella virus) and herpes (Herpes simplex virus type 2). Some vaccines have been opposed more than others over time (Thomas et al., 2018), sometimes with people expressing unfounded fear of a threat to reproductive health and confounding mild symptoms prevalence with those of rare more severe reactions. The proliferation of vaccines and administration to young infants and children may have contributed to some unease with rare impacts widely publicized. Their success in reducing

incidence and severity of disease may also have worked against vaccination, especially in developed countries where people were no longer familiar with the worst effects of particular diseases (e.g., polio, whooping cough) or as elsewhere have accepted a nature or faith centred philosophy of health management where vaccines may be seen as unnecessary or undesirable. In the developing world, reliance on traditional remedies and fear of western medical innovation are fed by misinformation emerging from developed country sources and spread rapidly across vast distances among populations which are now globally connected online. Into this space erupted the recent and on-going Covid pandemic?

The COVID-19 coronavirus first emerged in Asia and has spread worldwide, creating a global pandemic from 2019 to the present day. Following allocation of unprecedented research funding, existing research into vaccine development escalated, and by the beginning of 2021, several vaccines had been approved in various jurisdictions (e.g., Russia, China, US, UK, Australia and Europe) for distribution. The COVID-19 vaccines have caused quite a controversy not just among the anti-vaxxers (this includes persons who oppose vaccination in principle as well as those who may only oppose only more recent vaccines for various reasons) but also others from various sectors who expressed concerns about different aspects of vaccination. This paper will cover the research on the ethical issues related to vaccinations, specifically COVID-19 vaccines. This study will focus on two sectors of the ethics of vaccinations: personal choice vs. the greater public welfare and informed consent.

Personal Choice Vs. The Greater Public Welfare

The world today is gripped by a crisis related to the COVID-19 and its emerging variants. Each country, each city is trying its best to cope with the health, economic and social impacts of the contagion. Varying approaches taken over time by governments reflect not only the increasing knowledge about Covid-19's severity (not simply a normal cold or flu as some appeared to hope and then continued in error to maintain despite the surge in cases and rising number of deaths that outstripped normal flu events) but also the degree to which a government chose to prioritize maintaining the economy over taking measures that while lessening health impacts were feared would substantially damage economic life (Om-Prakesh et al., 2021; Jung et al., 2021). Yet failing to prioritize health could severely impact the economy as more and more employees fell ill, health systems were overwhelmed and failing confidence reduced consumption (Sanjaya, 2020). Others contend that it is a false dichotomy as lockdowns delay diagnostics and treatment and also generally in the longer term impact the poor in wealthy economies at a scale yet to be measured, and also developing and least developed countries more generally.

Governments are establishing measures to reduce the risk of the pandemic by encouraging people to get vaccinated to protect themselves and those around them by reducing the speed of spread as well as the seriousness of disease impacts that threaten to overwhelm health services in both the developed and developing world as wave after wave of infection by Covid-19 and its emerging variants affect each country. The ability to achieve widespread vaccination is in part determined by the availability of vaccines in any given country, Wealthier countries took precedence as developers sought to recoup investment; less developed and least developed nations had far less access to life saving vaccines and treatment options while also

having fewer doctors and hospital beds per hundred thousand of population. It is only in late 2021 that the call for suspension of patents has fallen on less than deaf ears but the TRIPS waiver still faces opposition, while governments appear to struggle to even meet their promises of donations of doses to developing and least developed countries via Covax, prioritizing their own third doses and roll out to younger less vulnerable population segments over the needs of vulnerable populations in developing and least developed countries. These ethical issues are not examined in detail here but should not be ignored as availability affects ability to even have a choice of vaccination. It may also permit a greater space for misinformation to develop where vaccines are lacking (Maxmen, 2021). In Tanzania, for example, the government seemed to initially deny the presence of the virus (Buguzi, 2021). The then president, after a national period of prayer, declared the nation Covid-free. Comment on Covid deaths was banned in the media, so doctors and others were effectively gagged; health workers practiced without being provided personal protective equipment supplies. The president's apparent confidence and government policy remained unchanged for months, even after the Tanganyika Law Society issued a statement that 25 members had died in a month, and the Catholic Church urged the government to change its stance after 25 priests and 60 nuns died in a two-month period following a brief illness associated with breathing difficulties, and the Episcopal Church advocated policy change (Buguzi, 2021). The president suddenly died, having had a change of heart regarding vaccination (around the time he was himself allegedly ill) but did not live long enough to implement it. Policy then changed more substantially with vaccination now supported. However, having abjured vaccination and previously supported only natural preventive methods, the administration found that when later more fully reversing their stance under a new president, that the earlier policy had fuelled continued vaccination hesitancy and refusal (Buguzi, 2021). Accepting Covid-19 vaccination has been and still is almost seen as unpatriotic (Syriacus, 2021). So damaging has been the initial stance that in what had been one of the African states previously successfully highly vaccinated against childhood diseases that even with vaccines are increasingly available, some fear that take-up of vaccination will be less than optimal (Buguzi, 2021).

Where vaccines are available, the question of the competing interests of those wanting to get vaccinated and those who prefer not to be a difficult one and the answer (and the ethics of any answer) is subject to on-going debate. Even though government bodies generally want to accord people the right to choose what is best for them, during a pandemic situation the reasoning shifts to an emphasis on the overall protection of the population as a whole, where the threat to others' continued enjoyment of life itself or health is weighed against the rights of individuals to bodily integrity and self-determination and found by governments to have greater importance. Historically too, quarantine/isolation has been imposed in times of pandemic with the freedom of movement of individuals restricted to reduce the risk to others (e.g., imposition of quarantine regulations, isolation of persons affected). In terms of mandatory imposition of vaccination, it has been noted that US President George Washington imposed the first mass military inoculation (an early form of vaccination for variola major or smallpox) in 1777 during the Revolutionary War, which markedly reduced his army's vulnerability to the disease and subsequent death rate (Filsinger & Dweek, 2021). It was a policy that was not universally welcomed then; nor, despite the progress since, now.

The balance between personal choice and protection of at-risk members in a population differs based on social and cultural beliefs. Most governments have made it mandatory to wear masks and practice physical distancing when indoors and permit a little flexibility when outdoors. Some have made vaccination mandatory where a person works in close contact with vulnerable populations (e.g., frequently, aged care, health care; less often, education; in a few jurisdictions their entire public service sector). Critics of such measures often ignore that vaccination for various diseases has frequently already existed in such settings as health care and education. When they are aware of this, it is the recency of the vaccine development that tends to cause them great reservation, with critics often referring to the Covid-19 vaccines as experimental, despite their building on existing research and having undergone extensive testing prior to release. Some reluctant to accept an mRNA vaccine have been reported to be more accepting of a more traditional vaccine, but that has yet to come to market (Tamie, 2021). Distortion of information also affects vaccine acceptance. Some ill-informed critics appear to confound mild and major complication rates, publicize rare serious complications and deaths associated with vaccination while failing to acknowledge that deaths in the absence of vaccination are far higher and ignore statistics on excess deaths (this last available only for developed states where relevant data is routinely collected; figures for developing and least developed countries can be expected to be grossly underestimated) (Chagla & Pai, 2021).

Some individuals who do not want to have their freedom curtailed, however, not only delay or reject vaccination but are willing to take risks by not opting for the basic prevention methods that the governing bodies have recommended or mandated. These include social distancing and mask wearing where social distancing is difficult to achieve (as on public transport, in shopping-centres). This omission on their part poses numerous risks for themselves and others, and the governing bodies face substantial challenges. They need to balance the risk to society versus individual rights. How should individuals balance their own rights and at the same time not is a risk to others and their own family members?

When the enormity of the current pandemic became clear, with its severely affected victims beginning to crowd hospitals (and intensive care units) then mortuaries, with bodies consigned to funeral pyres (or even rivers) or filling graveyards, governments had to introduce or reinforce measures that sometimes seem to curtail individual freedom to slow down the transmission of the virus and in turn reduce mortality that is associated with COVID19 (Oaten & Patidor, 2020). Lockdowns were introduced in both the developing and developed world to varying degrees especially in the period where research was being undertaken and/or vaccines unavailable, but later to facilitate the roll-out of vaccination across populations, in a bid to reduce illness. In India, millions of workers walked to their home states or rural homes when the country abruptly closed down its industry and transport in the March 2020 21-day lockdown in a bid to stop the spread of Covid-19 and a rising death toll (Biswas, 2020). However, this could have served to spread the disease even further. (Shutdowns again occurred about 12 months later in 2021 as employment opportunities in the cities declined due to the downturn in trade due to the pandemic, only this time, transport continued to operate) (Kakade, 2021). A higher level of excess deaths has been recorded for the delta variant than for the initial wave of Covid-19 (Beaney et al., 2021) in India and Bangladesh. With successive waves of contagion now evident, earlier strategies are being revisited e.g., imposition of mask wearing, social distancing as well as new strategies (Bhaduri, 2021).

An excellent example of the adoption of an innovative strategy that seemed to curtail individual freedom to slow virus transmission and thereby reduce mortality was seen in France, where the fourth Covid-19 wave in August 2021 saw the government introduce a COVID-19 health passes for citizens fully vaccinated against the virus or those who had recently recovered from the disease. These health passes were designed to help people stay protected by separating them from otherwise unnecessary contact with those who had not had the vaccine and were therefore more prone to contracting/spreading the virus. The health pass acts as a ticket to access public areas such as swimming pools, cinemas, restaurants, trains, air travel, bars etc. The government introduced these measures to encourage people to accept the vaccine, there were repercussions as some citizens were not happy with this and protested across France to make their voices heard (Reuters, 2021b). But the government's strategy did have a positive impact overall: there was a definite increase in the number of individuals who were vaccinated after the health pass was introduced. Subsequently, in November 2021, a fifth wave fuelled by a new Omicron variant) erupted, involving both the vaccine hesitant (the unvaccinated now comprising less than 10% of the eligible population) and those whose earlier vaccination acquired immunity was waning. This again has caused concern to overburdened health systems and their tiring workforces in France and elsewhere. It was posited that the situation might require a third and perhaps even a fourth vaccination for the already vaccinated to reduce impacts (Reuters, 2021a). Breakthrough infections plus the extreme contagiousness of (the perhaps milder) Omicron variant fuelled further concern on one hand and dissent on the other. For health authorities it was a reminder that variants could emerge, both more or less contagious and more or less severe in impacts; and in a world connected by air travel spread could be almost lightning fast. For some critics, the need for yet further vaccination undermined claims to vaccine effectiveness and the need for a vaccine passport. They appealed for less rather than more segregation and more rather than less freedom for all citizens. Governments in France and Germany agreed that their countries had perhaps come to rely too heavily on vaccination and began to reintroduce social distancing and mask mandates in the face of the latest wave (Reuters, 2021a) while England has reintroduced working from home, mask mandates and proof-of-vaccination/testing a broad multi-pronged approach. Nevertheless, mandatory vaccination has the effect of increasing vaccination among vulnerable persons but increasing resistance among the hesitant or vaccination-averse (Shahzad et al., 2019).

In India, the COVID-19 vaccination rollout had been an on-going ethical issue for several months for many reasons. It should, however, be recognized that personal choice was initially a luxury enjoyed by those in the developed world where vaccines were available far earlier and more widely than in the developing world (Chagla & Pai, 2021). In India, vaccination was initially only for those who could afford it, as people had to pay for vaccinations. This meant that whoever could not afford to pay for the vaccine would not get it. It was only in late 2020, that the government of India made the COVID-19 vaccine free for all, as the number of affected individuals reached record heights. Unfortunately, this also led to massive gatherings of locals at all available hospitals as they waited in line without social distancing for vaccination. This provided an opportunity for spread and, again, not all citizens want to be vaccinated. People in certain rural areas still do not believe that the vaccine protects them in any way and hence many villagers are still not vaccinated. This is mainly due to the personal/cultural beliefs of the locals in those areas, while here and elsewhere around the developing and least developed world; lack

of supply severely restricts vaccination roll-out (Padma, 2021). In cities and among otherwise educated people, vaccine hesitancy or even refusal has been fed by misinformation or distorted and misleading statistics spread via social media. Around the world, conspiracy theorists and misinformation have contributed to vaccine refusal (Machingaidze & Wiysonge, 2021) and threaten future vaccine acceptance (Burki, 2020).

Yet throughout recent history vaccines have played a major role in reducing the occurrence of infectious diseases in the world. Morbidity and mortality from many contagious diseases has fallen markedly due to these efforts. In reality, to maintain the balance of individual and collective rights, from a global perspective it should be harder to get an exemption than to get a vaccine.

The question “*Would you be willing to give up your individual rights for the sake of the common good?*” will always be the subject be subject to debate; however, in the face of the on-going pandemic and the dual need to preserve lives and health and to maintain economic and social functioning, we need to forge ahead in a way that preserves our privacy and civil liberties as much as possible and ensures that there are safeguards in place. To sum it all up is a quote by Dr Seuss (T.S. Geisel) “*So be sure when you step, step with care and great tact. And remember that life is a great balancing act*” (Tetsekela, 2021). Although this is a quote from a children’s author, it applies in so many ways to the approach that must be taken with Covid vaccination policies in regard to not only the acceptability by individuals and minimization of ill-founded hesitancy or rejection but especially in relation to the ethical issues involved in informed consent.

All individuals who are being administered a Covid vaccine or their surrogate (e.g., parent, caregiver, nominated decision-maker for those of diminished responsibility) must be informed of its benefits and risks for consent to be genuine and informed (i.e., not obtained in the absence of information or by deception). A client/patient must be able to access knowledge about its composition prior to administration to clarify any concerns they may have. They must be informed of the possible side effects, their frequency and severity. In the absence of competence on the part of the client/patient, their surrogate must be competent to make such a decision and similarly informed and consent voluntary. Consent should include all the information needed for the client and entail the benefits of vaccination both in the short and long run as well as the negative effects that have a likelihood of occurring post-administration. Informed consent with regards to vaccination is controversial for many reasons (Zagaja et al., 2018) such as first, existing medical condition (earlier strokes, existing clotting irregularity); secondly, risk of medical side-effects (e.g., rare complications with different vaccines in relation to cytokyne storms (Themba, 2021), thrombocytopenia, and myocarditis and very rare Guillain-Barre syndrome); thirdly, religious concerns (e.g., use in vaccine research of cell lines derived from fetal cells deters some; despite vaccination arising from such research having been encouraged by Pope Francis in the absence of an alternative (Watkins, 2021), a minority of Catholics continue to reject vaccination by any of the five vaccines derived from such research) (Giubilini et al., 2021); and fourthly, personal reasons. This creates potential conflict with the public health sector and obligatory vaccines as it causes a divide with individuals who choose to not take the vaccine and limits the reach of vaccination campaigns for the country as a whole. This is a substantial issue between individual’s rights and public safety as with informed consent this becomes apparent. Informed consent proposes a solution and informs clients about the

requirements and enables people to feel at ease both before and after the administration of the vaccine (Zagaja et al., 2018). Informed consent has two main purposes which are to protect individuals and inform them of all the risks/benefits that will be provided as well as protecting the society (Zagaja et al., 2018).

But with consent, it is broadly considered there should be choice, that is, the ability to accept to or reject the proposed vaccination. While the vast majority in many developed countries are voluntarily accepting vaccination, having been convinced of its medical (and ethical) necessity, there remains hesitancy among some and refusal among a smaller minority. This is despite overwhelming evidence that compared to those who have been vaccinated, they are more likely to contract Covid-19, suffer severe illness and a larger proportion of them die if they contract the disease. This poses a threat to their own health and that of others directly and indirectly (in both the shorter and longer term). The impact of otherwise avoidable pandemic morbidity and mortality reduces others' access to diagnostics/surgery, increasing their disease burden and death rate (Lai et al., 2020). It displaces others who require critical care (e.g., Yuguero et al., 2021), and threatens overall health care systems in both the high-income countries and in lower- and middle-income countries where the existing medical facilities are fewer and resources scarcer. The pandemic has also hampered routine childhood vaccinations worldwide with millions of children missing pertussis, measles and mumps vaccinations-related disease risk has increased markedly.

This situation has pushed governments to adopt what their critics deride as needless authoritarian measures in relation to Covid vaccination (measures deemed needless as such persons as generally they do not recognize the value of vaccination). Many individuals are being put under pressure to be vaccinated by advertising campaigns, the threat of exclusion from public events or venues, and if employed in areas such as the health sector where contact with vulnerable persons is inevitable, they may face relocation or even termination should they refuse vaccination and/or repeated testing. Health authorities and governments have broadly concluded that the right of such persons to employment is tempered by the right of other members of the public to continued life and health and the government's obligation and ability to provide health care to its citizens.

Nevertheless, with their objections to vaccination, the vaccine hesitant and vaccine refusers are themselves exerting pressure on authorities by insisting that informed consent is vital prior to any vaccine administration. Through this, the presence of willingness is included in the procedure and its absence does not later become cause for concern. Although consent is vital, this creates a dynamic in the economy that could impede government immunization efforts. Obligatory (mandatory) vaccinations create a complication when accompanied by the requirement for consent, as some individuals develop a dissatisfaction with the vaccination process or their existing reluctance hardens into refusal, lowering the total health standards of the population (Zagaja et al., 2018). The ability to exercise individual decision-making and consent (freedom of choice, willingness to accede) can come at a price. Research remains ambivalent regarding cash payment for vaccination with a Swedish intervention showing a positive result but others arguing that such measures may be counter-productive (Campos-Mercade et al., 2021), undermining confidence in the value of the vaccine. Governments have largely adjoined the carrot and adopted the stick. As Zagaja et al. (2018) have stated, "*Vaccination coercion exists at various levels... not accepting unvaccinated children to public schools or being denied*

various benefits.” This creates a conflict between consent, which include the benefits and the risks, and the inclusion of individuals in society. With the need for consent comes a struggle for individuals to debate whether they would integrate into the economy and society more broadly, or be excluded in one way or another. Consent should be given without any threat of exclusion to be deemed “*freely given*” or an indication that a person truly favours the proposed course of action. In the United States, many states have a specific legislation governing informed consent, and in this way, patients have rights. Advocates believe that informed consent is an ethical and appropriate way for physicians and others to be obligated to inform clients (especially parents of children) about the benefits and risks of any vaccine as for any other medical treatment. In this manner, patients and caregivers are also given the opportunity to ask any questions they feel the need to. In regards to vaccination, the vaccine information statement provides basic information about vaccine risks and benefits and is required to be supplied to a person so that person is able to make an informed decision before accepting the vaccine for themselves or a person for whom they have legal responsibility (whether young child or someone who is elderly or ill or not deemed *compos mentis*). Nevertheless, the same source is clear that a number of vaccines are mandatory in the United States and comments that tension remains where individuals do not wish to comply due to their desire to refuse vaccination for themselves or their children, whether because they “*do not accept existing medical or safety evidence, or... their ideological beliefs do not support vaccination*”.

Informed Consent

Around the world, immunization programs are increasingly including in their national immunization schedules, vaccines that target age groups beyond infancy and early childhood. In the United States, a number of: US Supreme Court decisions established “*both the constitutionally protected rights of parents and the inherent constitutional authority of the state to provide for public health and welfare*” in that country. Under *Meyer v Nebraska*; *Pierce vs. Society of Sisters*, parents have extensive, constitutionally protected rights to provide for their children’s welfare with substantial freedom from government interference (Hussain et al., 2018). In regard to children’s welfare and vaccinations, complex computations must be done by medical researchers and authorities to determine whether the balance of benefits from a vaccine or other treatment and potential detriment. Vaccinations for smallpox, for example, ceased when after decades of vaccination campaigns around the globe, the disease was essentially eradicated and the risk of vaccination side effects (rare contraction) outweighed the possibility of contracting it naturally and subsequently being ill or dying. It is this type of work that helps build trust in health advice and vaccination compliance. When detrimental effects outweigh benefits or a drawback is discovered, the development of a vaccine may be abandoned (e.g., an early Covid vaccine was abandoned when it resulted in positives in subsequent HIV testing) or, if already in use, withdrawn from the market. Even prior to the current pandemic, however, an apparently effective vaccine ceased production due to a combination of wide publicity for adverse events, subsequent court cases, the confusion of minor and major effects, and the falling sales that resulted from this coverage (a Lyme disease vaccine). Parental decision-making comes increasingly into play as vaccine rollouts move on to assume first those 16–18 years of age, then 12 and over, and later 5-12, and lastly infants.

In regards to health care and legal protection for parental decision-making, or in our case, when it comes to the COVID-19 vaccine and parental/caregivers decision-making or consent, it is presumed that “*parents invariably act in their children’s best interests and that both children and young teenagers lack autonomy to best decide for themselves*”. US legislation broadly protects parental rights in their children’s health care, but make exceptions “*when parental decisions risk serious harm to the child*”. With younger persons reported generally to experience only mild disease effects (frequently attributed to their healthy immune systems), some critics question the advisability of their immunization. However, research has shown that rare complications (including multi-system inflammatory syndrome which involves hospitalization and intensive care and has a death rate of 1%-2%) justify vaccinating teens while the aim of herd immunity prompts vaccinating an even younger cohort, though researchers urge lower dose vaccination, longer follow up and closer monitoring due to the young age of participants (Zou & Cao, 2021). Vaccination has become a cultural norm and expectation as a result of governments undertaking programs over decades to achieve national herd immunity for numerous childhood illnesses and what has become routine parental agreement. In some countries, pockets of resistance have developed (such as in north-eastern NSW in Australia) that predated the pandemic. This has resulted in outbreaks of childhood illnesses almost extinguished elsewhere, while disadvantaged groups experiencing poverty and disengagement also require additional encouragement (e.g., outreach programs among the disadvantaged in NSW: Beaney et al. 2021; mobile prompts in Kenya). In both developed and developing countries authorities have adopted additional vaccination encouragement (or non-vaccination discouragement (access to childcare or additional funding) to achieve the desired required higher vaccination rate.

COVID-19 vaccination apprehension and alarmism constitute substantial barriers to adequate coverage, placing both adolescents and communities at risk. In the US, however, there are specific means to exploit when parents refuse vaccination for those older children. “*There are explicit laws to permit teenage agreement to vaccination when parental permission is lacking, following the lead of the District of Columbia*” (Haelle, 2021). Policymakers should also look into how current laws may be used to allow teenage consent to COVID-19 vaccination. Some legal scholars counsel that minor consent laws are best construed narrowly and that independent consent requires express or strongly supported legal basis. Therefore, adolescent consent to COVID-19 vaccination requires specific legislation. There are many other scholars who “*contend that minor consent laws can sometimes be construed, such as through regulation, to reflect ethical norms in support of adolescent autonomy*”. In the end it all depends on what the person’s perspective is on the matter and the legislation or regulation in the particular jurisdiction.

When making any type of important life decision, consent is so important. When it comes to age, who can give consent is also so important. “*For consent to be valid, it must be informed, understood and voluntary, and the person consenting must have the capacity to make the decision*”. Since the almost global acceptance of the United Nations International Convention on the Rights of the Child, adulthood is generally regarded as anyone 18 years or over. This would mean as long as a person is over 18 and able to make decisions for them, consent is in their own hands on most jurisdictions. For children or those under the age of 18, a parent or legal guardian would be in charge of giving consent. This normally works fairly well. Parents are generally doing what they want the best outcomes for their children. It must be acknowledged, however, that some

parents will prioritize their ideology or beliefs over what most would consider the health of their child (e.g., blood product refusal for their children by Jehovah's Witnesses even in life threatening situations) although a mature minor may be accorded the right to accede to such treatment. A child in their later teen years may have opposing views to their parents and their ability to be involved in decision-making in relation to medical procedures is recognized in several jurisdictions in the United States, Australia and elsewhere (e.g., European Union member states). The participation of mature minors in decision-making regarding their medical treatment, and indeed in vaccination acceptance, is recognized by the World Health Organization: "*Assent refers to the process of children's and adolescent's participation in the decision-making on vaccination*". In the United States, 16 states have given teenagers, roughly above the age of 16, the ability to make their own health care decisions. At this point in their lives, they are able to make decisions on their own based on their own belief system. In the United States, an organization called VaxTeen helps teenagers and young adults who missed out on childhood and other vaccines because of their parent's views (VaxTeen.com). Fueled by fear and misinformation, vaccine refusal among US adults and their unwillingness even if vaccinated themselves to subject their children to vaccination has risen markedly in the years preceding the pandemic but is now at an all-time-high. VaxTeen works to encourage vaccination among such adolescents and assist end the stigma of unvaccinated teenagers. Those who are able to make a decision while being well informed should be able to do so.

CONCLUSION

Throughout history, vaccines have played a major role in reducing the occurrence of infectious diseases in the world. In reality to maintain the balance, from a global perspective, it should be harder to get an exemption than to get a vaccine. In the world of medicine, ethical questions and dilemmas continue to exist, particularly when it comes to vaccination. Government actions in administering vaccination should be guided by the goal of the greater good for society as a whole, and what is in the best interest of those receiving the vaccination. In the case of COVID-19, imposing vaccination on some specific groups of individuals (e.g., minors, those with philosophical or purportedly religious objections) presents a number of serious difficulties. As COVID continues to develop, it becomes apparent that the need to foster consent to the vaccine and the consent process itself prior to vaccination are significant. People need to be aware of the benefits of any vaccine, its components, and potential side effects (and their incidence rate), and the balance of benefits and risks to themselves, their families and communities, their country and global health. It is an immense task that must be addressed as epidemiologists and virologists warn that it is not a question of if but when a major and even deadlier pandemic may arise. Next time we ought to be better prepared. A well-informed population (rather than a misinformation driven one) that feels once again able to trust health authorities and their advice is among the keys to securing a timely effective response that involves vaccination among other measures.

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