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Considerations, challenges and gaps on mandatory childhood vaccination programs: A comprehensive analysis

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ABSTRACT

Childhood vaccine coverage rates are not optimal for controlling vaccine-preventable diseases (VPDs), as outbreaks of VPDs occur from time to time globally. To address this gap, many countries have enacted and strengthened childhood vaccination programs, which are often mandatory. Mandatory vaccination programs are often controversial because they may reduce or eliminate individual choice. A standard approach for evaluating the mandatory vaccination program is not available. Vaccine types, target age groups, program rigidity, incentives or penalties, enforcement, and compensation mechanism for adverse events following immunization vary across the world. This article reviewed the mandatory childhood vaccination, and presented examples to illustrate the variations among different programs, outcomes, and key considerations when contemplating these programs. Before implementing mandatory childhood vaccination programs, it is critical to ensure financial sustainability, a steady supply of vaccines, equitable access for all target population, and tailored implementation to fit the local culture and context.

KEYWORDS: Mandatory; Public health; Ethics; Health law; Vaccine hesitancy

1. Introduction

There is a growing recognition that vaccination coverage is necessary for sufficient control of vaccine-preventable diseases (VPDs) among children. In the past decade, the extensive measles outbreaks among high-income and middle-income countries have underscored the dangers posed by of the gaps in vaccination coverage, leading many countries to enact and strengthen the mandatory childhood vaccination legislation[1–4].

Historically, we found three triggers that prompt a call for a shift to mandatory vaccination. First, interventions or strategies aimed at reducing vaccination hesitancy could increase the vaccination coverage, such as education campaigns for public health, checking the vaccination documentation on school entry. Sometimes, these strategies have indicated as the ineffective measure as they are less coercive in motivating people to vaccinate. When these interventions cannot increase the vaccination coverage, they can may put the pressure on public health institution or shit the persuasive policy towards the strategies that explicitly limit choice[5]. Secondly, outbreaks of VPDs can result in increasing the public concern on poor vaccination coverage. An example was the 2015 measles outbreak in the California, with ripples felt across the US and Canada[6–7]. After that, vaccination confidence and positive support for mandatory vaccination were observed among parents who were aware of the outbreaks, which was found to be associated with the measles outbreak. Another evidence was the swift of voluntary

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to mandatory vaccination for measles-mumps-rubella vaccine in Italy in 2017, which was partly due to a measles outbreak[3]. Thirdly, achieving the elimination or eradication goal of VPDs need mandatory vaccination programs since the mean coverage rate should be above the threshold of herd immunity to stop the pathogen transmission. For example, mandatory vaccination had been proven to be a convictive component in global elimination plan of polio[8].

The adoption of legislation or decrees for mandatory childhood vaccination may be appealing since it is assumed to be a straightforward solution to close the gaps in low vaccination coverage rate and to address the failure on preventing VPDs outbreaks. Even in countries with the high coverage and no VPDs outbreaks, this policy is also considered since the important profile of mandatory vaccination has gained worldwide. However, mandatory vaccination is neither a simple nor a safe intervention in history. Sometimes, planning and implementing a mandatory vaccination program may be full of challenges, from both theoretical and practical perspectives.

In this review, we offered a summary of the considerations on mandatory childhood vaccination in high-, middle-, and low-income countries to state the differences among them. First, we made a definition for the mandatory vaccination program and elucidate the range of rigidity of the mandates, from soft to hard or from flexible to rigid. Second, we discussed the ethical issues inherent in a mandatory vaccination program. Third, the key legal components of the mandatory vaccination framework were explored and noted, subsequently tailoring them to fit the local context and culture. Fourth, both the evidence of effectiveness and the unintended consequences of rigid mandates were presented, as well as the key gaps were identified. Lastly, we suggested that comprehensive thought should be exercised before implementing the mandatory childhood vaccination if other interventions might be less intrusive and more effective. Uninterrupted supply of vaccine, sustainable financial support, and equitable access to the target population should be considered carefully before mandating vaccination. In any case, the mandatory vaccination program needs to be tailored to fit the local context and culture.

2. Definitions and framework of mandatory vaccination

Broadly defined, a mandatory childhood vaccination program is vaccination requirement conducted at the individual level to control the VPDs at the population level[9–10]. World Health Organization (WHO) has not provided a clear definition of mandatory vaccination. In 2010, Europe proposed a definition for mandatory vaccine as ‘every child in the country/state must receive the vaccine by law without the possibility for the parent to accept or refuse it, independent of whether a legal or economical implication or sanction exists for the refusal’[11]. Mandatory vaccination programs have been described om various ways, covering aspects as follow: 1)Flexible mandates: vaccination are required by laws, but there are no penalties for not strictly enforcing (France before changes in 2018)[4]. 2)Medium mandates: vaccination or education on vaccination are required by laws, but it can opt-out for personal or philosophical reasons by filling in specific forms and notarization without any penalty (“informed consent” mandates in Ontario, Canada)[12]. 3) Higher mandates: vaccination are required by laws, but it can opt-out with personal or philosophical reasons through filling in specific forms. There are serious financial penalties or social restrictions for non-compliance and only those with medical exemption are allowed for opt-out (Australia after changes in 2016)[13].

To demonstrate the variety of approaches to mandatory vaccination, Table 1 summarized the different frameworks from the high-, middle-, and low-income country, each of which had both similar and different mandatory elements.

3. Ethical consideration of mandatory childhood vaccination

Mandatory vaccination, particularly the rigid forms, has remained controversy in a long time as the ethical concerns on coercion[14]. An analysis of WHO/UNICEF Joint Reporting Form data showed the main reasons for vaccine hesitancy or refusal or anti-vaccine sentiment were related to concerns about vaccine risks and benefits, lack of knowledge, and barriers related to religion, culture, gender, or socioeconomic factors[15]. Its essence is that mandatory vaccination requires principled consideration, a prudent weighing of the evidence, indication and argument towards both the authority’s and individual’s responsibilities[16].

Governments have moral and legal responsibilities to safeguard the populations One way to achieve these responsibilities to population is through the vaccination programs. Herd immunity from vaccination program can benefit both individuals and public[17]. However, those who refuse vaccination are at risk of being infected persons and vectors for spreading VPDs in the community. Some persons who have contraindications or underlying medical conditions must rely on herd immunity protection since vaccines may not be safe or effective for them[18]. Those people who opt-out may put others at risk of VPDs. The risk can increase when the non-vaccinated people tend to cluster. Consequently, refusing vaccines can be seen as a risk spreading of VPDs in community, while mandating vaccination may be an appropriate intervention for fixing the problem[19]. Increased risk of harm to others by refusing

vaccination is an ethical justifications for mandatory vaccination policy.

Refusal to vaccination for conscientious reasons is considered comparable to objection to mandatory military service[20].The relevant authority may require those who refuse the mandated vaccination to make an appropriate contribution to society instead[21]. In some mandatory childhood vaccination programs, it may be the access restriction to specified societal services/benefits or financial penalties.

There may still be other ethical reasons to hinder the mandatory vaccination. The principle of the "least restrictive alternative", from the justification of restrictions on individual rights as articulated in the International Covenant on Civil and Political Rights, should be considered[22]. In terms of the mandatory vaccination, policies that retain the right to opt-out but make it more difficult to obtain may be one of the least restrictive alternatives.

These ethical arguments on mandatory vaccination assume that it is adopted to improve the low coverage due to vaccine refusal. However, low coverage may be due to other reasons such as barriers to accessingvaccination, which cannot be remedied by a mandatory vaccination decree[14,23]. It is uncertain that mandatory vaccination can improve the equity. However, rigid mandates for influenza vaccination among healthcare workers in hospitals, while controversial, have been shown to result in high coverage, leading to more protection for the vulnerable patients[24].

Given that no vaccine is neither 100% effective nor 100% safe, another consideration on evaluating the justification of the mandatory vaccination is the compensation policy for causally associated with adverse events following immunization (AEFI)[25]. There is a strong argument that a compensation mechanism for AEFI should be the presupposition of mandatory vaccination programs[25]. However, it is currently unclear that the proportion of countries with mandatory childhood vaccination programs also have compensation act on AEFI and how does it work.

4. Legal frameworks for mandatory childhood vaccination

There is no normative and uniform foundation for establishing the mandatory vaccination programs, nor a recognized scope for these programs, or a single model for what these programs should cover (Table 2). In terms of the way of foundation or implementation, the mandatory vaccination should be grounded in regulations, legislation, or a combination of regulation and legislation, or the informal governmental structures and practices[26]. Mandatory regulation and legislation are not static but should be changed as political or context varies. For example, an outbreak of measles could lead to a more rigid mandatory vaccination in Ontario and California[2]. The rigid mandatory vaccination program of Italy[3] became more flexible under the political context of anti-vaccine and the tendency of a more populist government. Regarding scope, it would be better for the mandatory vaccination were applied across nationwide, or in specific regions or provinces, or among specific sub-populations. In Saudi Arabia, the vaccination program requires that Hajj or Umrah pilgrims to show the record of meningococcal vaccination[27]. The components of the mandatory vaccination framework may differ widely. For example, some of the mandatory vaccination programs cover most, but not all the vaccines that WHO recommends, while others may cover a few of vaccines or only one vaccine[3,4]. Some mandatory vaccination programs may set the specific age group or set the milestone for vaccination schedule[28]. With regard to flexibilities, some allow the exemptions for medical contraindications only, but others contain the exemptions for philosophical or religious concerns[2,14]. With respect to the incentive or penalty, some focus on financial incentives to stimulate the compliance, while others enforce the financial or social penalties[14,26]. As mentioned above, some mandatory vaccination programs have the compensation mechanism for AEFI but others do not. The levels of enforcement and strictness of application can vary among different mandatory vaccination programs, some enforce the mandatory requirements rigorously, while others may not enforce the mandate severely, or may change the levels of enforcement based on the social context.

5. Outcomes of mandatory childhood vaccination

A systematic review of mandatory childhood vaccination had defined mandate as a legal requirement that a child received routine immunization prior to childcare or school entry even if non-medical or medical exemptions existed[29]. This review concluded that increase in vaccination coverage was observed in target population that the mandatory policy was applied in both short- and long-term, while the degree of influence varied by vaccine types and age groups.

A more recent report from U.S. evaluated the effects of the non-mandatory recommendation for hepatitis A vaccine compared to mandating it in young children. Vaccine recommendation increased coverage by about 20% while mandatory policy increased it by 28%[30].

A another report provided the evidence on voluntary and mandatory vaccines use within a country and from multiple perspectives[31]. In Italy, some vaccines are mandatory and others were voluntary (self-paid). The voluntary vaccines may be perceived by vaccinee as being less important or necessary. In Italy, this to-dimension

Table 1. Three examples of rigid mandatory vaccination programs in a high-, middle-, and low-income country.

Country	Overview of the mandatory vaccination program
Australia (high-income)	The Australian government launched the National Immunization Program in 1997, with funding decisions informed by the Australian Technical Advisory Group on Immunization through evaluations of cost-effectiveness. Since 1998, the family assistance allowance has been linked to an individual's vaccination status. By 2012, this requirement was extended to include the family tax benefit, childcare benefit, and childcare rebate payments. The 2016 amendment to the 'No Jab, No Pay' legislation eliminated exemptions based on conscientious or religious beliefs. The compliance of vaccination has been evaluated for every year from ages 1 to 19 years.
China (middle-income)	In 1978, China launched the government-fund vaccination program with four vaccines (measles vaccine, oral polio vaccine, diphtheria, tetanus, BCG, and pertussis vaccine), and established a complete cold chain system for vaccine storage and transport. Only medical exemptions for vaccination can be acquired *via* a medical check from the provider. The compliance was evaluated for all children <7 years in every year. Recall/reminder with no penalty would follow for the non-compliance children. After four rounds of gradual expansion of vaccines from 1990 to 2008, 15 vaccines were included in the mandatory childhood vaccination program. Legislative changes to improve standardization practices, digital immunization register to document the vaccination information, AEFI surveillance, vaccination requirements on school entry were also comprised. In 2019, the national vaccine administration law was issued to strictly regulate the entire process of vaccination, thereby ensuring the safety, efficacy, and accessibility of vaccines and increasing the public's confidence in vaccination.
Kenya (low-income)	In 2013, Kenya established the national policy guidelines on immunization. The Division of Vaccines & Immunization, tasked with promoting and coordinating vaccination efforts, was established in 2017. The Kenya National Immunization Technical Advisory Group acted as the scientific and technical advisory committee on vaccination-related issues. Although there were no penalties for failing to vaccinate, verification of vaccination upon school enrollment was mandatory.

AEFI: Adverse events following immunization; BCG: Bacille calmette-guerin; VPDs: Vaccine-preventable diseases.

Table 2. Checklist of the components of the mandatory childhood vaccination program.

Component	Examples
Foundations and methods for implementing mandatory vaccination	1.Laws 2.Regulatory frameworks 3.Executive orders 4.Operational guidelines 5.Integrated policy approach
Scope of application	1.County/region 2.Specific age group 3.Institutional scope (*e.g*. school/military/healthcare) 4.Situational scope (*e.g*. international travelers/during outbreaks)
Mandate or exemption	1.Types of mandate: flexible; medium; rigid 2.Exemptions: medical contraindication; personal/philosophical; religious; opt-out
Type of mandeted vaccines	1.Childhood vaccines 2.Targeted vaccines 3.Single vaccines 4.Occupational vaccines 5.Boost vaccines 6.Travel vaccines 7.Emergency vaccines
Mandated enforcement	1.Yes 2.No 3.Pending
Incentive and penalty	1.Incentive payment or fines 2.Denial of school admission 3.Occupational restrictions 4.Legal action 5.Others (*e.g*. Mandatory training session for parents or caregivers)
Compensation for AEFI	1.Government no-fault compensation 2.Administrative no-fault compensation 3.Industry no-fault compensation 4.No compensation program

AEFI: Adverse events following immunization.

policy led to high coverage of > 90% for the mandatory vaccines (*e.g*. diphtheria, tetanus, poliomyelitis, hepatitis B vaccine), but the coverage of voluntary vaccines was relatively low (*e.g*. measles vaccine). However, Italy to move to broader mandatory vaccination which included the measles vaccine after the measles outbreaks.

Except for the potential impact on vaccination coverage, there may be other advantages with mandatory vaccination. For example, verification of vaccination records on childcare or school entry is of great value to public even there is no penalty for the violation. During an outbreak of VPD, public health institution can decide who should be kept out of school until get the specific vaccination.

6. Unintended consequences

An important consideration relating to mandatory vaccination is the recognition of the unintended consequences.

In Australia, the "No Jab No Pay amendment bill" removed non-medical exemptions from existing vaccination requirements. This clause had been linked to family assistance allowance since 2015[14]. For persons with the lowest tax rate, the policy could induce an amount of 15 000 AUS$ per year. Some states then passed "No Jab No Play" legislation strengthening the vaccination requirements in the settings of daycare or nursery attendance, which excluded the non-vaccinators without any conscientious exemptions. During the same period, a range of initiatives from federal or state level want to improve the vaccination coverage. The specific interventions included establishing the recall/reminder systems, and intensive efforts to promote the quality of register records. After these interventions, an increase in coverage among children under 5 years from 92.59% to 94.34% was observed[14]. Of the children who had registered conscientious objection, 19% were vaccinated in 9 months of the new policy implementation. However, during the second year after the new policy, the medical exemptions increased from 635 to 1 401, with a growth rate of 220.63% at national level[14].

In California, U.S., non-medical exemptions was removed, which led to an increase in medical exemptions[2]. The highest increase of medical exemptions was observed in jurisdictions with previous high rate of personal exemptions.

The Serbia government made a policy of tightening of mandatory vaccination and harsher penalties in response to the fall in measles vaccination coverage as well as the 2014/2015 outbreak of measles. However, the tightened policy induced the anti-vaccine protest and attracted the attention to negative vaccination messages in the media since the concerns from public had not been fixed by government. Although this outcome was predictable for the poor communication, low coverage problem compounded by the low confidence in vaccines were observed following the mandatory measles vaccination, and the country 's vaccination program might be further undermined[32].

A recent study from German showed that partial compulsory vaccination could impact the intention for the voluntary vaccines[33]. Mandatory vaccination could increase the resistance of individuals through the negative attitude and decreasing the intention to accept the voluntary vaccines.

Although many experts considered the mandatory vaccination would polarize the vaccination issues in public, there were no evidence to assure if it was similar in other settings. Serbia and German examples noted above suggested that mandating vaccines might exacerbate negative sentiments for some of persons with hesitancy prior to the mandatory policy.

7. Evidence and research gaps

The evidence for or against mandatory childhood vaccination is meager. Specifically, there is no universal framework, compendium of components, implementation cost, or the influence on vaccination coverage, which can contemplate the mandatory childhood vaccination. We suggest that the following questions should be answered in the future studies: Which factors is most effective in what contexts? Does having the compensation mechanism of AEFI make a difference in acceptability? What method of mandate is most cost-effective under what settings? The unintended consequences of mandatory vaccination, as well as the justice and equity problems need to be researched in other settings if the consequences being suffered elsewhere were similar. The increase in medical exemptions is also disturbing, and it is not clear if it is happening. Does mandatory vaccination program lead to an attitude that these vaccines are more important than the voluntary ones? What happens when a vaccine is compulsory but it is in short supply or stock-out? Will mandatory vaccination increase inequity as it is mandatory only for a specific sub-population? Is mandatory vaccination the best use of resources, or do we have alternatives that increase the vaccination coverage more efficiently? What contextual and cultural factors influence the knowledge, attitude and behavior of the community when mandatory vaccination policy is introduced?

8. Conclusions

Mandatory vaccination can be an appropriate solution to the suboptimal vaccination coverage. The propriety of specific programs is dependent on the evidence of effectiveness, an absence of negative impact on other public health programs and the sufficient compensation schemes for AEFI. Furthermore, uninterrupted vaccine supply, equitable access and financial sustainability should be evaluated before mandating vaccination. If mandatory vaccination

is the preferred route, prudent thought, rigorous plan, and follow up are critical. Studies on impact of mandatory childhood vaccination in settings with different income levels are needed, since many countries have enacted or are contemplating these programs.

Conflict of interest statement

The authors declare that there is no conflict of interest.

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Data availability statement

The data supporting the findings of this study are available from the corresponding author upon request.

Authors' contributions

Shen JY and Hu Y concepted and designed of the study. Chen FX and Luo XF acquired the data. Ji C and Shen JY analyzed and interpretated the data. Hu Y drafted the article. Shen JY contributed to the final version to be submitted. All the authors have read and approved the manuscript.

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