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Review

Mandatory infant & childhood immunization: Rationales, issues and knowledge gaps

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ABSTRACT

Globally, infant and childhood vaccine uptake rates are not high enough to control vaccine preventable diseases, with outbreaks occurring even in high-income countries. This has led a number of high-middle-and low income countries to enact, strengthen or contemplate mandatory infant and/or childhood immunization to try to address the gap. Mandatory immunization that reduces or eliminates individual choice is often controversial. There is no standard approach to mandatory immunization. What vaccines are included, age groups covered, program flexibility and rigidity e.g. opportunities for opting out, penalties or incentives, degree of enforcement, and whether a compensation program for causally associated serious adverse events following immunization exists vary widely. We present an overview of mandatory immunization with examples in high-, middle-, and low-income countries to illustrate variations, summarize limited outcome data related to mandatory immunization, and suggest key elements to consider when contemplating mandatory infant and/or child immunization. Before moving forward with mandatory immunization, governments need to assure financial sustainability, uninterrupted supply and equitable access to all the population. Other interventions may be more effective and less intrusive than mandatory. If mandatory is implemented, this needs to be tailored to fit the context and the country's culture.

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1. Introduction

There is a growing global recognition that infant and childhood vaccine uptake rates are not where they need to be for adequate control of vaccine preventable diseases [1]. The large measles outbreaks in high- and middle-income countries in the past decade have highlighted the dangers of the many coverage gaps. These outbreaks have led several countries to enact, strengthen, or contemplate mandatory childhood immunization legislation [2–5].

There are three main triggers that historically have prompted calls for a shift to mandatory immunization. One has been a failure of less coercive methods to motivate people to vaccinate, such as public health education campaigns, nudge strategies such as requesting documentation of immunization on school entry, and other interventions aimed at overcoming vaccine hesitancy. When interventions such as these do not lead to increased uptake rates, there can be increased pressure from public health and/or policy makers to move from persuasion and nudges to strategies that explicitly limit choice [6].

The second is an outbreak of one or more vaccine-preventable diseases, which results in harm and increased public concern about low vaccination coverage. The 2015 measles outbreak in the United States of America (USA) in California is an example, with ripples felt across the United States [7,8] and beyond (Canada [9]). This outbreak was associated with improved parental confidence in vaccines and good support for mandates among parents who were aware of the outbreak (USA [10]). In Italy, the move to change measles-mumps-rubella vaccine from voluntary to mandatory in 2017 was due in part to the large measles outbreak [3].

In the third instance, to achieve the global vaccine preventable disease elimination goal for wild polio, the mean uptake rates must be high enough to prevent transmission, pockets of unimmunized must be minimized and disease surveillance high in order to detect break through cases so further local rounds of immunization can be undertaken. Mandatory immunization has proven to be a compelling component in the polio global elimination plan. As this goal grows closer, the pressure on the remaining countries with cases has increased [11].

In these first two situations, the adoption of legislation or decrees to mandate childhood immunization can be appealing as this appears to be a straight-forward solution to addressing the important public health problem of low vaccine uptake with the failure to prevent outbreaks of vaccine-preventable disease. Even some countries with high uptake rates and no vaccine preventable disease outbreaks have considered this policy because of the high profile mandatory immunization has gained globally. However, as history has shown, mandatory immunization is neither a simple nor fail safe intervention [12]. Furthermore, the planning and implementation of a mandatory programme can be challenging, from both practical and operational perspectives.

In this article, we offer an overview of some policy considerations relevant to mandatory infant and/or child immunization in high-, middle-, and low-income countries with examples to illustrate differences. First, we briefly define mandatory immunization programs, elucidating the range of rigidity of these mandates from soft i.e. flexible to hard i.e. rigid. Second, we consider the primary ethical issues inherent in mandatory immunization. Third, we explore key legal components for consideration in a mandatory immunization framework and note the importance of tailoring these to fit a country's culture and the context. Fourth, we offer

some evidence of the effectiveness of hard mandates as well as evidence of unintended consequences. Fifth, we identify key knowledge gaps regarding mandatory childhood immunization. Lastly, we conclude by suggesting that careful thought should be exercised before mandating childhood immunization, as other interventions may be more effective and less intrusive. Governments need to assure financial sustainability, uninterrupted supply and equitable access (and more importantly, equitable extension of the benefits of vaccination and services) to all their child population before considering mandating immunization. If mandatory immunization is implemented, this needs to be tailored to fit the country's culture and the context.

2. Definitions of mandatory immunization and variations in frameworks

Broadly defined, mandatory infant and childhood immunization programs are immunization requirements implemented at the individual level to control a vaccine preventable disease(s) at the population level [13]. There is, however; no World Health Organization (WHO) definition of mandatory immunization. In 2010, a meeting in Europe (2010 Venice Study) exploring mandatory immunization proposed the definition that a 'mandatory' vaccine is one that every child in the country/state must receive 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 [14]. Regardless, immunization programs described as mandatory vary widely, even in high income countries, ranging from:

- Laws requiring immunization although anyone can opt out without penalty; no enforcement (soft i.e. flexible mandates e.g. France before changes in 2018 [4];
- Laws requiring immunization but can easily opt out with personal or philosophical objection without penalty (medium soft mandate e.g. Ontario, Canada before changes in 2016 [15];
- Laws requiring parental education about immunization (rather than immunization itself); may opt out with personal or philosophical objection but requires specific forms and notarization but no penalty for noncompliance (medium hard mandate i.e. "informed consent" mandates e.g. Ontario, Canada [16];
- Laws requiring immunization but can opt out with personal or philosophical objection that requires specific forms and added effort. There is a penalty for noncompliance and strict enforcement (higher medium hard mandate) e.g. Australia before changes in 2016 [17];
- Laws requiring immunization with serious financial penalties or social restrictions; only allow medical exemptions; strict enforcement (hard mandates e.g. State of California USA post 2016 [2,7], Australia after 2016 [17].

To illustrate the diversity of approaches to mandatory immunization we have summarized in Table 1 three frameworks; one from a high-income country, one from a middle-income country, and one from a low-income country, each of which have similar and differing mandatory elements.

3. Ethical justification of mandatory immunization

Mandatory immunization, particularly more rigid forms, has long been controversial predominately because of ethical concerns

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