

Contents lists available at [ScienceDirect](#)

Vaccine

journal homepage: [www.elsevier.com/locate/vaccine](http://www.elsevier.com/locate/vaccine)

## Recent vaccine mandates in the United States, Europe and Australia: A comparative study

Katie Attwell<sup>a,\*</sup>, Mark C. Navin<sup>b</sup>, Pier Luigi Lopalco<sup>c</sup>, Christine Jestin<sup>d</sup>, Sabine Reiter<sup>e</sup>, Saad B. Omer<sup>f</sup>

<sup>a</sup> Political Science and International Relations, University of Western Australia, 35 Stirling Highway, Crawley 6009, Australia

<sup>b</sup> Department of Philosophy, Oakland University, 146 Library Drive, Rochester, MI 48309-4479, USA

<sup>c</sup> Department of Translational Research on New Technologies in Medicine and Surgery, University of Pisa, Lungarno Antonio Pacinotti, 43, 56126 Pisa Pl, Italy

<sup>d</sup> Sante Publique France, 12 rue du Val d'Osne, 94415 Saint-Maurice Cedex, France

<sup>e</sup> Infectious Diseases, Antimicrobial Resistance, Hygiene, Vaccination Federal Ministry of Health, Bundesministerium für Gesundheit Referat, 322 Friedrichstraße 108, 10117 Berlin, Germany

<sup>f</sup> Rollins School of Public Health, Emory University, 1518 Clifton Road NE, Atlanta, GA 20211, USA

### ARTICLE INFO

#### Article history:

Received 18 June 2018

Received in revised form 3 October 2018

Accepted 4 October 2018

Available online xxxxx

#### Keywords:

Vaccination  
Immunization  
Mandatory  
Mandates  
Policy

### ABSTRACT

**Background:** In response to recent outbreaks of vaccine-preventable diseases and concerns around vaccine refusal, several high-income countries have adopted or reformed vaccine mandate policies. While all make it more difficult for parents to refuse vaccines, the nature and scope of 'mandatory vaccination' is heterogeneous, and there has been no attempt to develop a detailed, comparative systematic account of the possible forms mandates can take.

**Methods:** We compare the construction, introduction/amendment, and operation of six new high profile vaccine mandates in Australia, France, Germany, Italy, California, and Washington. We rank these policies in order of their relative restrictiveness and analyze other differences between them.

**Results:** New mandate instruments differ in their effects on behavior, and with regard to their structure, exemptions, target populations, consequences and enforcement. We identify diverse means by which vaccine mandates can restrict behaviors, various degrees of *severity*, and different gradations of intensity in *enforcement*.

**Conclusion:** We suggest that politico-cultural context and vaccine policy history are centrally important factors for vaccine mandate policymakers to consider. It matters whether citizens trust their governments to limit individual freedom in the name of public health, and whether citizens have previously been subjected to vaccine mandates. Furthermore, political communities must consider the diverse mechanisms by which they may construct vaccine mandate policies; whether through emergency decrees or ordinary statutes, and how (or whether) to involve various stakeholder groups in developing and implementing new vaccine mandate policies.

© 2018 Elsevier Ltd. All rights reserved.

### 1. Introduction

Outbreaks of vaccine preventable diseases have recently occurred in many countries, e.g. measles in France, mumps in Ireland, and pertussis in the US. Several governments have responded by introducing or strengthening vaccine mandates; other jurisdictions are considering similar policies. Mandate instruments are heterogeneous in how they operate to organise and change behavior, with regard to structure, exemptions, target populations, consequences and enforcement. Yet the nature and scope of 'mandatory vaccination' is indeterminate, and there has not yet

been a systematic comparative synthesis of mandate policy development, implementation and structure. Debates about vaccine mandates ought to be informed by accurate accounts of the diverse aims and requirements that vaccine mandate policies involve. In this article, we compare new vaccine mandate policies adopted in four countries and two US states in the last two years. We have chosen our case studies as high profile exemplars of policy changes in response to vaccine rejection and/or disease outbreaks; policymakers within these jurisdictions reference each other's policies as trends or templates [1]. We outline these new mandatory policies in order of their relative restrictiveness, based on how difficult they make it for parents to refuse vaccines for their children. Our comparison yields clear lessons for jurisdictions considering implementing or reforming vaccine mandates, including a need

\* Corresponding author.

E-mail address: [Katie.attwell@uwa.edu.au](mailto:Katie.attwell@uwa.edu.au) (K. Attwell).

to pay attention to political and policy considerations of path dependency.

## 2. Mandates come in different shapes and sizes

Courts in countries around the world have long recognized the legitimacy of liberty-infringing public health efforts, in light of the priority that communities place on avoiding disease [2,3]. Such efforts include vaccine mandates, which have only rarely been overturned by courts [1]. When considering mandates, policymakers must address divergent access and acceptance reasons that populations may remain under-vaccinated. Access refers to the availability, affordability and convenience of services; parental complacency may also fit here. Acceptance, by contrast, relates to vaccine hesitancy [4]. Parents fear ingredients, distrust authorities, or do not regard vaccination as congruent with their parenting practices [5]. Vaccine mandates can address acceptance by making it harder – or more consequential – for parents to refuse vaccines. However, mandates govern access (complacency) too, as we explain below.

We can better understand jurisdictions' vaccine mandates by locating them on an ideal-type continuum (Fig. 1). At one end, vaccination is voluntary, and state interventions merely nudge or persuade individuals to vaccinate. At the other end, vaccine refusers are fined or imprisoned. Here, the state's coercive power motivates individuals to utilise available vaccination services.

Between these ends of the continuum are positively framed requirements. The first links vaccine uptake to public goods such as state-subsidised daycare and public schools, while the second links uptake to financial incentives. Both function as 'carrots' that only the vaccinated can obtain; compliers are offered a benefit which is denied to non-compliers.

We can then differentiate 'carrot' policies on the basis of exemptions. Towards the voluntary end of the spectrum, compliance means an individual attains the benefit, but non-compliers can obtain it after performing specified actions. This overcomes complacency, whilst constructing an exemption process for non-compliers to follow. Towards the coercive end of the spectrum, exemption processes are removed (except in the case of medical contra-indications to vaccination). As 'carrot' policies move along the spectrum towards coercion, there is no change to the governance of compliers, who might have access barriers or need motivation. However, vaccine rejection meets consequences that

cannot be 'worked around' with exemptions. In the next section, we compare mandate policies in six jurisdictions that have recently introduced or strengthened them, starting with what we rank as the most restrictive and moving to the least restrictive policies. We note that while we use a terminology of *restrictiveness*, other scholars have recently employed a terminology of rigidity (from hard to soft) [6].

## 3. Country case studies

### 3.1. California

All US states require children to receive vaccines to attend daycare or school (specific vaccines for the states in this study are listed in Table 1). Since September 23, 2010, the Affordable Care Act has required vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) to be covered by insurance. The Vaccines for Children Program (a federally-funded and state-administered program) provides free vaccines for children who are uninsured or Medicaid eligible. Most US states permit parents and guardians to receive nonmedical exemptions (NMEs) to immunization mandates [7]. A 2010 national survey of US parents found that 77% of parents with children aged 1–6 had a vaccine concern, which included beliefs that vaccine ingredients may be unsafe (26%) and that vaccines may cause learning disabilities such as autism (30%). In light of rising NME rates in California, the state legislature recently passed two laws to successively restrict parents' access to them.

Assembly Bill 2109 (in effect January 1, 2014 to January 1, 2016) made it more difficult for parents or guardians to receive NMEs by requiring applicants to submit an official state form on which a physician attested that they provided information regarding the benefits/risks of immunization [8]. At the time of Assembly Bill 2109's introduction, 90.2% of entering Kindergarteners were up-to-date on all required vaccines. The rate of nonmedical exemptions was 3.1% [9]. Assembly Bill 2109 aimed to reduce NME rates by targeting the complacent; parents and guardians with only moderate objections might decide to vaccinate rather than complete burdensome paperwork, as previous research indicated was likely [10]. Assembly Bill 2109 was associated with a 25% reduction in California's NME rates (from 3.1% to 2.3%), and significant increases up-to-date status for entering Kindergarteners,

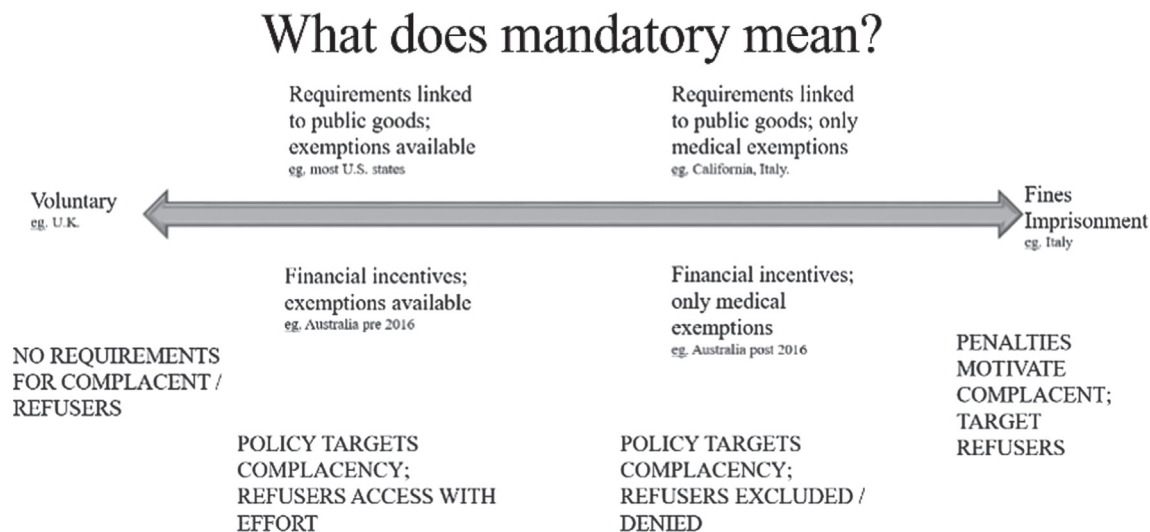


Fig. 1. The conceptual continuum of options available to policymakers for vaccine mandates.

**Table 1**  
Characteristics of recent vaccine mandates.

Jurisdiction	Implementation date	Antigens covered	Key reason for policy change	Policy development process	Exemptions	Penalties/enforcement	Gaps
California	January 2016	Diphtheria, Hepatitis B, Measles, Mumps, Pertussis, Polio, Rubella, Tetanus, Varicella	Large numbers of personal belief exemptions; Disneyland measles outbreak (2014–5)	Professional society lobbying; participation of State Senator Pan (physician) produced quick legislative response	Medical only	Exclusion from daycare and school	Children cared for/schooled at home
Italy	Jul 2017	Diphtheria, Hepatitis B, Hib, Measles, Mumps, Pertussis, Polio, Rubella, Tetanus, Varicella	Declining rates following increasing vaccine hesitancy	Ministry of Health decision (Government Decree)	Medical only	Exclusion from daycare and pre-school (3–5 years); fines €100–€500	Children cared for at home. No consequence after initial fine for children 6–16 years
France	Jan 2018	Diphtheria, Hepatitis B, Hib, Measles, Meningococcal C, Mumps, Pertussis, Pneumococcal, Polio, Rubella, Tetanus	Coexistence of mandatory and recommended vaccines; conclusion of the consultation; court case hastens harmonisation	Comprehensive consultation including citizen's juries; several reports; Government decision, parliament hearing and vote	Medical only	Exclusion from daycare, school, holiday camps. Potential legal proceedings for damages	Children cared for at home
Australia	January 2016	Diphtheria, Hepatitis B, Hib, Measles, Meningococcal C, Mumps, Pertussis, Pneumococcal, Polio, Rubella, Tetanus, Varicella	Media lobbying; Pertussis deaths	Parliamentary hearing, including consultation with experts/key stakeholders and consideration of submissions from general public	Medical; other limited exemptions	Loss of up to \$8350/year in financial assistance	High income earners; but annual consequence for others
Washington	July 2011	Diphtheria, Hepatitis B, Measles, Mumps, Pertussis, Polio, Rubella, Tetanus, Varicella	One of the highest rates of personal belief exemptions in USA; Pertussis outbreaks 2010	State Health Department request; stakeholder advocacy	Religious, personal belief after medical counselling	Exclusion from daycare and school unless exemption obtained	Children cared for/schooled at home. Those who claim appropriate religious affiliation
Germany	June 2017	Diphtheria, Hepatitis B, Hib, HPV, Measles, Meningococcal C, Mumps, Pertussis, Pneumococcal, Polio, Rotavirus, Rubella, Tetanus, Varicella	Measles outbreaks	Government led action plan involving key stakeholders	Must provide form at day care entry; no exemption for form but vax not required	Up to €2500 fine	Children cared for at home. No consequence after initial fine

from 90.2% to 92.9% [9]. However, this decline was not uniform, and left major geographic exemptions clusters undisturbed [11].

Subsequently, Senate Bill 277 (enacted June 30, 2015) eliminated access to NMEs entirely in California [12]. With this new law, California joined West Virginia and Mississippi as the only US states not to provide NMEs [7]. Advocates argued that eliminating NMEs was necessary to further increase California's immunization coverage [13]. However, it seems likely that they were also motivated by the high-profile 2014–15 Disneyland measles outbreak [9,14], which may explain why the Bill's authors (Richard Pan and Ben Allen) were unwilling to wait to see the impact of the earlier Assembly Bill 2109 on California's NME rates (outlined above) [9].

While there is some preliminary evidence that SB 277 has further increased immunization coverage beyond the gains realized by AB 2109, questions remain about enforcement and unintended consequences. Financially vulnerable private schools may decide not to enforce immunization requirements rather than risk school closure due to declining tuition revenues from vaccine refusers [15]. Some physicians may support marginal or fraudulent claims for *medical* exemptions, which likely explains why medical exemption rates in California have tripled since the passage of Senate Bill 277 [16]. Also, Senate Bill 277 may cultivate political polarization surrounding vaccination policy and science: most Democrats in the California Senate voted for it, while most Republicans voted against it, reversing a history of bipartisan vaccination policies in the US [17].

### 3.2. Italy

Italy has a history of mandates for some vaccines for older children, including diphtheria (1939), polio (1966), tetanus (1968), and hepatitis B (1991). Mandated vaccines were offered at no cost, and statutes authorized fines and school exclusion for children who did not receive them. Persistent parents, however, could receive permission for non-compliant children to enrol in school, after parents attended meetings with public health officers or the Minors Court. Fines were rarely applied. A suite of additional 'recommended' vaccines were also offered for free, notably MMR and pertussis.

Policy shifts occurred from 1999 onwards, with a Ministry of Education decree that children who had not received mandatory vaccinations should still be allowed to attend school. This was based on Italy's constitution, in which a right to education is equal to the right to health. From here, mandates remained 'on the books', but not enforced.

In 2007, the Veneto region piloted a mandate suspension, reflecting popular opinion that the state ought to affirm the importance of vaccination, but not mandate it [18]. However, in 2013, a local court in Rimini ruled that vaccines caused a child's autism, which prompted significant media coverage and internet search activity [19]. The subsequent 2015 overturning of the case did not receive the same media coverage [20]. Starting from 2013, nation-wide vaccination coverage dropped significantly (Fig. 2). In 2016 a cross-sectional survey showed that 15.6% of Italian parents were vaccine hesitant and 0.7% strongly vaccine opposed [21].

In 2016 the Ministry of Health and Istituto Superiore di Sanita began to deliberate emergency measures to address this. In July 2017, the Italian parliament passed a Ministerial Decree establishing new mandates for kindergarten attendance covering six vaccines that had previously only been ‘recommended’. The emergency measure was justified by both the worrying vaccine coverage drop and by the serious measles outbreak that spread across the country, causing approximately 5000 cases and four deaths in 2017 [22,23]. The policy came into effect immediately. Furthermore, parents who refuse vaccines for nonmedical reasons now face fines of €100–500 [24]. Only medical exemptions are available. However, Italy’s mandatory vaccination policy has evolved following a change of government, with the Senate amending the bill in August 2018. Parents can now verify their children’s vaccines for themselves [24]. The ‘mandate’ now moves to being the least restrictive in our analysis, but we have left in the place it occupied until these very recent changes.

The policy change imposing mandates was influenced by political factors, with large populist parties supporting and emboldening anti-vaccination groups. (The subsequent watering-down of the mandate follows the political ascendancy of these forces.) Notwithstanding strong reactions by the latter – with a mob assaulting pro-vaccine physicians after the law was passed [25] – a survey conducted by *Observa* and published in the national newspaper *Repubblica* reported rising acceptance of mandatory vaccines by the majority of Italians, with only 8.1% averse to mandates [26]. A study of pregnant women conducted in 15 Italian cities just prior to the new mandatory policy found that 81.6% of them favoured mandatory vaccination [27].

### 3.3. France

As in Italy, France has a history of vaccine mandates, including smallpox (1902), diphtheria (1938), tetanus (1940), tuberculosis (1950) and polio (1964). Vaccination was required for admission to schools, kindergartens, daycare centres and summer camps. While non-compliers faced punishment of two years imprisonment and a €30,000 fine, enforcement was rare [28].

In 1966, with the introduction of pertussis vaccine, French health authorities began to embrace recommendations rather than mandates as preferred means for increasing vaccination compliance, but the older vaccines remained mandatory. Both mandatory and recommended vaccines are subsidised by the Health Insurance

system and complementary insurance, and provisions for children without social protection mean that families do not have to pay for vaccines. In recent times, coverage was high for mandatory vaccines (and recommended vaccines combined with them) but lower for vaccines that were only recommended (Table 2). For example, in 2017, coverage at 2 years of age was 73% for meningococcus C and in 2016, coverage for MMR was 90.3% (first dose) and 80.1% (second dose) [29]. Since 1992, regular attitudinal studies have shown significant changes in vaccine confidence and vaccine hesitancy. In 2016, almost 75% of respondents said they were favourable to vaccination in general [30]. While this was a significant increase from the low of 61.2% in 2010, when there had been controversy regarding the influenza A (H1N1) pandemic vaccination campaign, it still did not represent support akin to the coverage required for community immunity. A measles outbreak occurring between 2008 and 2012 is predicted to have generated over 40,000 cases, resulting in 10 deaths, and a resurgence was reported in 2017–8 resulting in three further deaths. Most deaths were attributed to insufficient community immunity [1], especially among young adults who did not receive the vaccination and the second dose (introduced in 2011 for people born before 1992).

These epidemiological drivers [1] were a factor in consolidating France’s new mandatory vaccination policy, but change was already in motion due to factors arising in previous years regarding the mix of recommended and required vaccines. Specifically, DTp-polio was still classified as mandatory, but was only available combined with recommended vaccines (Hib, pertussis, hepatitis B). In 2015, a government report recognised a need for France to harmonize vaccine status either by making recommended vaccines mandatory, or by removing mandates [31]. In January 2016, the Health Minister announced a citizen consultation process to consider the issue [32]. The consultation process, which aimed to improve vaccine confidence and coverage, included juries of citizens and health professionals, a web platform for public contributions, and qualitative and quantitative studies [33]. A summary report showed that qualitative study participants wanted to retain vaccine mandates because they did not want the burden of making decisions about individual vaccines [33]. Individual decision-making requires information, and participants were concerned about equity in accessing it; they also feared that cost-cutting could restrict it. Rather than being ‘left alone’, then, participants preferred the state to make the decision for them. Additionally, quantitative studies found that if mandates were abolished, 13%

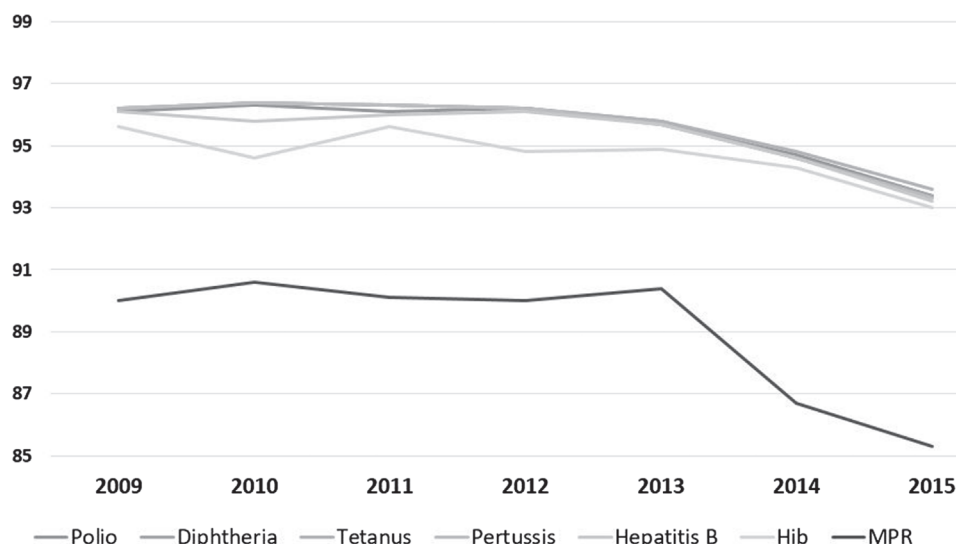


Fig. 2. Trends in vaccine coverage – Italy. Figure produced by authors using data publicly available from Ministry of Health, Italy.

**Table 2**

French vaccination uptake figures for 2 years of age, 2015 (Meningococcus C 2016). Source: Sante Publique France, reproduced with permission.

Vaccine	Introduction	Status	Coverage Rate	Uptake and Compliance
DT Polio (3 doses)	1938; 1940; 1964	Required	98.9%	Stable
Pertussis (3 doses)	1966	Recommended; vaccine combined with other antigens	98.6%	Stable
Hib	1993	Recommended; vaccine combined with other antigens	98.0%	Stable
Hepatitis B (3 doses)	1995	Recommended; vaccine combined with other antigens	88.1%	42% in 2007
Pneumococcal (3 doses)	2006	Recommended; not combined with other antigens	91.6%	Increasing
MMR - 1st dose	1983	Recommended	90.5%	Stable
MMR - 2nd dose	2005	Recommended	78.8%	Increasing
Meningococcal C	2010	Recommended	70.90%	Increasing

of parents would no longer vaccinate their children for DTPolio, and that socio-economically disadvantaged parents would be over-represented in that population [33]. As a result, participants favoured extending mandatory vaccination to all vaccines for a limited period. In return, they required transparency, information, listening and communication, an official website, education and training for health professionals to enhance their commitment, vaccine education at schools, simplification of access, and expansion of a vaccine injury compensation scheme [33].

The issue came to a head in February 2017. Vaccine refusers had contested the mix of mandatory/recommended vaccines, and the Council of State advised that the state must make mandated vaccines available without combined recommended vaccines within six months [34]. Thus, on 5 July 2017 the Health Minister announced that all recommended vaccines for children under 18 months age old would become mandatory in 2018 (see Table 1). While the specific criminal sanction for refusing vaccines has been abolished [1], parents can still be prosecuted for putting their children or others at risk [35]. The decision was made to focus on new birth cohorts rather than catch up schemes for older children, for epidemiological and enforcement reasons. Regarding the latter, excluding older children from school was regarded as socially unacceptable and risked inflaming the anti-vaccination movement [1]. Further detail and perspectives on the French policy response and process can be found here [36,37].

### 3.4. Australia

Australian vaccination policy has linked vaccination compliance to financial incentives since 1998. This started with a non-means-tested designated vaccination payment at age-based milestones. In 2012 the financial incentive was instead linked to annual means tested end of financial year supplements [38]. Since 1998 vaccination status has also determined eligibility for childcare subsidies, including a non-means-tested annual rebate [39]. Vaccine refusers could submit a Conscientious Objector Form following counselling by an immunisation provider, and still access incentives and benefits. All recommended vaccines were covered by these policies, and were available free of charge. Vaccination coverage in Australia sat around 91% but refusers clustered in regions with coverage as low as 50% [40]. In 2012, a representative national study found that over one-fifth of adult Australians believed were concerned that vaccines were insufficiently safety-tested, could cause autism, or would weaken their child's immune system [41].

In 2013, the main newspaper in New South Wales began campaigning to deny vaccine refusers access to uptake-linked benefits. They mobilised a discourse of collective responsibility and utilised the high profile pertussis deaths of Australian infants in low coverage areas [42]. The 'No Jab, No Pay' campaign achieved popular and government support. The latter aligned with a discourse of 'mutual obligation' linking benefits to responsibilities [43], and recognition that budget savings of over \$500 million in five years could be made by withdrawing resources from refusers [44].

The sole purpose of the policy change was to govern vaccine refusal; access and complacency were already governed by existing administrative procedures. The 'No Jab, No Pay' law – named after the *Daily Telegraph's* campaign (to which the Prime Minister explicitly alluded in his announcement) – came into effect on 1 January 2016 [45,46]. In its journey through Parliament, it was referred to the Senate Community Affairs Legislation Committee, which invited submissions and held two 25 min public hearings [47]. Experts, activists and members of the public presented a range of views, but the legislation passed, removing Conscientious Objection and leaving medical exemptions as the only way for the unvaccinated to access entitlements [48]. Refusers stood to lose up to approximately \$8350 per year, which increased with changes to childcare subsidies in 2018 [49]. Neither the old nor the new policy delivered any consequences for medium-to-high income vaccine refusers whose children were not in daycare, which is attended by approximately one quarter of Australian children [50].

'No Jab, No Pay' met popular approval, although some public intellectuals lamented the loss of parental choice [51]. The Government claimed the policy's success in a subsequent release of figures showing vaccination coverage had climbed to 92–93% [52,53]. State-based 'No Jab, No Play' policy changes, advocated by the Federal Government, limit unvaccinated children's access to childcare centres [54]. It is beyond the scope of this article to analyze these additional state-level policies, suffice to say that they, like the other mandates explored here, vary with regard to structure, severity and enforcement.

### 3.5. Washington

We have provided an overview of US vaccination policy and national rates of vaccine hesitancy in the section on California, above. Washington state was one state that made nonmedical exemptions readily available, and historically had some of the highest rates in the US [55]. In the three years leading up to the introduction of a new policy, exemption rates for school entry mandates in Washington ranged from approximately 7–9%. (While this figure includes medical exemptions, these made up a very small fraction of the total number of exemptions.) [56]. In the context of large pertussis outbreaks in multiple states in 2010 that included Washington, the state health department submitted an agency request to the legislature for a change in the state's exemption law. They sought to "Reduce the convenience of nonmedical exemptions only to the extent exempting is equal to the effort required to vaccinate (or provide proof of vaccination)" and "Increase public education and awareness of the dangers of vaccine-preventable disease and the benefits of immunization." [57].

Senate Bill 5005 (SB5005) was implemented in July 2011 and required parents seeking an exemption to submit a "Certificate of Exemption" or a letter signed by a licensed healthcare provider (23) verifying that the provider has discussed the benefits/risks of vaccines with the parent(s). However, parents who demonstrate affiliation with a religious entity that does not permit medical

treatment to children are exempted. This bill passed with the support of a substantial majority of both houses of the state legislature. While a substantially higher proportion of Democratic legislators voted for this bill compared to their Republican peers, there was still significant Republican support [58,59].

Support from local immunization groups, and state affiliates of professional medical associations, such as the Washington chapter of American Academy of Pediatrics, played a major role in generating support for this legislation. Moreover, Washington's Vaccine Advisory Committee – an advisory body comprised of professional organizations, government agencies, and other healthcare stakeholders – and local health departments supported this legislation.

After SB5005 was implemented, there was a relative decline of more than 40% in nonmedical exemptions [56]. Moreover, with the exception of Hepatitis B vaccine, state-level vaccine coverage increased for all vaccines required for school entrance. Equally importantly, SB5005 was associated with a decline in geographic clustering of children with vaccine exemptions [56].

### 3.6. Germany

In West Germany, smallpox vaccination was mandatory until 1982. In East Germany, all childhood vaccines were mandatory, but a generous list of medical contraindications was generally interpreted to include religious objections. Following reunification in 1990, all vaccines became voluntary. Vaccines recommended by Germany's Standing Committee of Vaccination, its technical advisory body, are free of charge since they are covered by a universal health insurance scheme (Table 1).

German vaccine coverage at school entry has been high; over 90% for all vaccines except hepatitis B. However, coverage in younger children has been lower and variable across Germany's decentralised federal regions, demonstrating that children are not being vaccinated in accordance with the vaccine schedule [60]. Attitudinal studies show that up to 18% of people are undecided about vaccines and are rejecting some, such as varicella [61]. Germany has repeatedly faced outbreaks of measles, including amongst poorly reached migrant communities. This led to an update of the National Action Plan for the Elimination Measles and Rubella Elimination (2015) with all important stakeholders involved and legal initiatives to improve vaccination coverage.

In 2015 the Federal Government passed the National Preventative Healthcare Act to strengthen health promotion. Parents now have to provide evidence of routine check-ups, which include counselling by a physician about vaccination, before their children can attend daycare. This provision was tightened in July 2017 with a requirement that kindergartens notify public health authorities if parents have not provided the required evidence. Public health authorities can then invite non-compliant parents for consultations or fine them up to €2500. A similar policy had already been employed in some Länder, where it was associated with increased vaccination coverage [62].

It is noteworthy that, as in Washington, the policy instrument governing uptake penalises non-compliance with *administrative process*, rather than vaccination. The policy therefore permits parental rejection of vaccines, but only following counselling. It governs access (parents must visit a physician either way) and governs acceptance with a focus on informed refusal. It also resembles the Australian policy prior to 'No Jab, No Pay,' although non-compliance in Germany attracts sanctions rather than the loss of entitlements or benefits. However, 93% of German children aged 3–6 and 32% of children aged 0–3 are enrolled in daycare, meaning that the sanctions should have a wide reach [63]. Germans continue to debate the merits and disadvantages of mandatory vaccination [64]. However, at present the strategy remains one of

enhancing trust, improving service delivery, filling adult immunity gaps and utilising the daycare certificates.

## 4. Discussion

The new mandate instruments adopted by governments come in a variety of shapes and sizes. Some govern vaccination itself; others merely require rejecters to comply with administrative burdens, which themselves can vary. Mandate instruments also operate across several dimensions that cannot be captured by merely analysing written laws or regulations. The simplified continuum we introduced earlier could be supplemented with additional axes, relating to the *severity* of consequences for non-compliance, and the intensity of *enforcement*. This would help us to consider the complexity of how mandates operate. For example, fines for non-compliance might seem like a severe outcome of refusal, but if they are low and only applied once, then that particular mandate instrument may prove less consequential than one which excludes unvaccinated children from school for the duration of their education. Likewise, a mandate that is not enforced (as was the case with some European regimes prior to recent changes) might not really 'exist', although its presence likely affects social norms.

Politico-cultural context and vaccine policy history are also relevant to governments' decisions about vaccine mandates. East Germany's history of oppressive state control may inform a unified Germany's current commitment to voluntarism. Meanwhile, the phenomenon of path dependency can help to explain why other jurisdictions in this study implemented mandatory systems building upon and modifying earlier regimes, and hence retaining differences with regard to target populations and instruments. Path dependency illuminates how earlier decisions inform later ones, directing decision-makers to continue down established pathways [65]. For example, Australia has a decades-old policy of providing financial incentives to parents for their children's vaccination status from birth, which is one reason why its recent reforms focused on this system of incentives, and therefore had impact on even very young children. Meanwhile, the practice in the US of linking vaccination to primary school entry is a primary reason why school immunization requirements are the 'obvious' site for mandatory policy tightening in jurisdictions there, which results in policies that cannot effect mass change on the vaccination coverage rates of infants and toddlers. Path dependency can also inform publics' levels of familiarity or comfort with mandates, emboldening policymakers to institute them. For example, the uncontroversial history of selective (and largely unenforced) vaccine mandates in Italy and France may have primed the populace for their reinvigoration in the face of measles outbreaks [1], even if this did generate some vocal opposition. Australia also has compulsory voting for Federal and State elections, suggesting some level of comfort with compulsion that serves the collective there. Finally, it is also noteworthy that public commitments to promote equality and eradicate disadvantage informed citizen consultation participants' support for mandates in France, a country whose nationalist myths centre on collective action and solidarity.

There are also distinctions in enforcement mechanisms and agents responsible for enforcement between the mandate models explored here. There is a comprehensive research program evident even just focusing on the latter. Do health-care workers responsible for signing exemption forms work directly for the state or receive arms-length subsidies? How does the state regulate their actions with regard to reporting non-compliance? What about the administrators of schools and daycare centres, now co-opted as enforcement agents in some jurisdictions and required to pass information about non-compliance to authorities? Clearly, there are far greater level of complexity than we have the opportunity

to elaborate here, demonstrating mandates' contextual specificity and the need for further research in order to compare and contrast their operation.

The stated driver for new mandates in every jurisdiction explored in this article was concerns regarding vaccine refusal. However, the mechanisms by which mandates became law varied considerably. They ranged from a hastily executed emergency decree (Italy) to a comprehensively designed consultation process (France). Process matters for the ultimate legitimacy of mandates policies to the broad populace (we recognise that there will always be an element within society that remains vehemently opposed to both vaccination and mandatory vaccination). French citizens were prepared to relinquish their choice to the state (with a suite of protections), their trust likely enhanced by the state's inclusion of them in decision-making.

Further distinctions apparent here, such as the role of elected officials versus bureaucrats as policy instigators, will be the subject of future research. In their global overview of mandatory vaccination policies, MacDonald et al also draw attention to differences in government level (evident here in our analyses of state and sub-state units) and the question of which vaccines are included in the mandatory policy [6]. Clearly, there are many more questions to be asked and answered about mandatory vaccination policies.

## 5. Conclusion

Vaccine mandate instruments present a variety of strategic choices for policy makers. While vaccination social scientists worry about the impact of mandates on public trust and attitudes [66], mandates may be suitable for some scenarios. It is hard to critique the consultative process that led to their temporary implementation in France, for example, nor to dispute states' long-established legitimacy to limit individual liberty for the benefit of increased community health [1–3,67–70]. However, whether mandates are wise is a different question.

This question can be answered in part by considering whether mandates work, and whether more restrictive mandates are more effective than less restrictive mandates. We are not specifically measuring effectiveness here – indeed it is too early in most cases to do so. While studies of US school entry mandates indicate a 'sweet spot' in which stricter mandates with less accessible exemptions result in improved coverage and reduced outbreaks [10], it does not necessarily follow that restrictive mandates in all jurisdictions will produce better coverage rates than less restrictive alternatives. Specifically, results may be confounded by differences (such as the severity of consequences or strictness of enforcement) which are only evident through forensic policy analysis and comparison.

This is closely related to the question of necessity. Although mandates that impose negative consequences on vaccine refusers are associated with lower refusal rates [10], it may be possible to increase vaccination without imposing the most restrictive vaccine mandate policies. For example, California's AB 2109 was associated with dramatic increases in immunization, though it did not eliminate nonmedical exemptions, as did the later SB 277. Policymakers may be subject to a 'diligence heuristic', believing that 'tougher' mandates deliver the goods [14], but more minimalist mandates can avert social conflict and avoid unnecessary coercion. We suggest that vaccine mandates should be accompanied by broader efforts to increase public trust and support, and they should be as minimally coercive as is necessary, otherwise they risk being repealed, with significant harms to public health.

Another factor to consider is the importance of preventing exemptions or punishments from becoming commodities. Analysts are often concerned that mandates inordinately affect those with

less economic and social capital to get around or absorb them [66]. If mandates enhance social inequality or do not change the behavior of the wealthy, then they fail to achieve public health goals and their legitimacy is undermined. It would be unfortunate if poorly designed mandate instruments became embroiled in ongoing debates about rising inequality occurring in many developed world jurisdictions.

It matters whether vaccine mandates work, but political and ethical considerations matter, too; and these broader considerations are not reducible to data about vaccination coverage. Vaccine mandates are not only a population health instrument, but a political one. We must study their continued evolution closely.

## 6. Declaration of interest

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors. KA has previously received travel and accommodation funding from GSK. She was previously employed by the Immunisation Alliance of Western Australia to conduct vaccination social science research funded by an unrestricted grant from Sanofi. PL reports grants from Shionogi, grants and personal fees from GSK, grants and personal fees from Pfizer, grants and personal fees from Sanofi, personal fees from MSD, outside the submitted work. The other authors have nothing to disclose.

## References

- [1] Lévy-Bruhl D et al. Extension of French vaccination mandates: from the recommendation of the Steering Committee of the Citizen Consultation on Vaccination to the law. *Eurosurveillance* 2018;23(17):18–00048.
- [2] Gostin L, Wiley L. *Public health law: power, duty, restraint*. 3rd ed. Oakland: California University of California Press; 2016.
- [3] Goodman R. *Law in public health practice*. 2nd ed. New York: Oxford University Press; 2007.
- [4] Bedford H et al. Vaccine hesitancy, refusal and access barriers: the need for clarity in terminology. *Vaccine* 2017.
- [5] Dube E et al. Vaccine hesitancy: an overview. *Human Vaccines Immunother* 2013;9(8):1763–73.
- [6] MacDonald NE et al. *Mandatory infant & childhood immunization: rationales, issues and knowledge gaps*. *Vaccine* 2018.
- [7] Legislators. N.c.o.S. States with religious and philosophical exemptions from school immunization requirements 2017 20/10/2017. Available from: <<http://www.ncsl.org/research/health/school-immunization-exemption-state-laws.aspx>> [cited 2017 23/11/2017].
- [8] Assembly Bill 2109. Communicable disease: immunization exemption. California Legislative Information California; 2012 [chapter 821].
- [9] Bутtenheim AM et al. Conditional admission, religious exemption type, and nonmedical vaccine exemptions in California before and after a state policy change. *Vaccine* 2018;36(26):3789–93.
- [10] Omer SB et al. Vaccination policies and rates of exemption from immunization, 2005–2011. *New Eng J Med* 2012;367(12):1170–1.
- [11] Jones M et al. Mandatory health care provider counseling for parents led to a decline in vaccine exemptions in California. *Health Aff* 2018;37(9):1494–502.
- [12] Senate Bill 277 Public health: vaccinations. California Legislative Information California; 2015.
- [13] Pan R. Senate bill 277 introduced to end California's vaccine exemption loophole; 2015.
- [14] Pan RJ. Restoring community immunity in America. *Pediatrics* 2018;141:1.
- [15] EdSource. Schools consider impact of ending vaccination opt-outs; 2015.
- [16] Anti-vaxxers have found a way around California's strict new immunization law. They need to be stopped in Los Angeles Times 2017. Los Angeles, United States
- [17] Legiscan. Roll Call: CA SB277 | 2015–2016 | California Senate Bill 277; 2015.
- [18] Martinelli D et al. Are we ready to abrogate compulsory vaccinations for children? *Human Vaccines Immunother* 2015;11(1):146–9.
- [19] Aquino F et al. The web and public confidence in MMR vaccination in Italy. *Vaccine* 2017;35(35):4494–8.
- [20] Health, I.M.o. Vaccino e autismo, nessuna correlazione. I giudici ribaltano in appello la sentenza del 2012; 2015.
- [21] Giambi C et al. Parental vaccine hesitancy in Italy – results from a national survey. *Vaccine* 2018;36(6):779–87.
- [22] Signorelli C et al. Childhood vaccine coverage in Italy after the new law on mandatory immunization. *Annali di igiene : medicina preventiva e di comunità* 2018;30(4 Suppl 1):1–10.
- [23] Istituto Superiore di Sanita. Morbillo e Rosolio News – Report n.37. Istituto Superiore di Sanita; 2018

- [24] Paterlini M. Italy suspends mandatory vaccination of nursery children after Senate vote. *BMJ* 2018;362.
- [25] Day M. Doctor and MPs in Italy are assaulted after vaccination law is passed. *BMJ: British Med J (Online)* 2017;358.
- [26] Bucchi M. La vittoria dei pro-vax: raddoppiati gli italiani che credono alla scienza 2017, <<http://www.repubblica.it/scienze>>.
- [27] Gualano MR et al. Attitudes towards compulsory vaccination in Italy: results from the NAVIDAD multicentre study. *Vaccine* 2018;36(23):3368–74.
- [28] LegiFrance. Loi n 2007-293 du 5 mars 2007 Réformant la Protection de l'Enfance – Missions de la Protection de l'Enfance. 2007: France
- [29] Sante Publique. Synthèse des couvertures vaccinales chez l'enfant de 2 ans. N. D. [cited 2018 1 October]; Available from: <http://invs.santepubliquefrance.fr/Dossiers-thematiques/Maladies-infectieuses/Maladies-a-prevention-vaccinale/Couverture-vaccinale/Donnees/Synthese-des-couvertures-vaccinales-chez-l-enfant-de-2-ans>.
- [30] Gautier A, Chemlal K, Jestin C. Adhesion à la vaccination en France: résultats du Baromètre santé 2016 [Acceptance of Immunization in France: results from the 2016 Health Barometer]. *Bull Epidemiologique Hebdomadaire* 2017; October 19:21–7.
- [31] Ministère des affaires sociales de la santé et des droits des femmes France, Rapport sur la politique vaccinale. France; 2016.
- [32] Citizen Consultation on Vaccination, F. Présentation du plan d'action pour une rénovation de la politique vaccinale en France 2016 30/11/2017]; Available from: <http://concertation-vaccination.fr/>.
- [33] Santé publique France, Vaccination des jeunes enfants – des données pour mieux comprendre. 2017: France
- [34] Le Conseil D'Etat et la Juridiction Administrative, Vaccination obligatoire. 2017.
- [35] Assemblée Nationale France, Projet de loi de financement de la sécurité sociale pour 2018 (Texte définitif). 2017: France
- [36] Ward JK, Colgrove J, Verger P. Why France is making eight new vaccines mandatory. *Vaccine* 2018;36(14):1801–3.
- [37] Yang YT, Reiss DR. French mandatory vaccine policy. *Vaccine* 2018;36(11):1323–5.
- [38] Department of Health Australia, National Immunisation Strategy for Australia 2013–2018. Australia; 2013.
- [39] Ward K, Hull B, Leask J. Financial incentives for childhood immunisation – a unique but changing Australian initiative. *Med J Aust* 2013. 198(11).
- [40] National Health Performance Authority, Healthy Communities. Immunisation rates for children in 2012–13. Australia: National Health Performance Authority; 2014.
- [41] Chow MYK et al. Parental attitudes, beliefs, behaviours and concerns towards childhood vaccinations in Australia: a national online survey. *Aust Fam Physician* 2017;46(3):145–51.
- [42] Hansen J. No jab, no play campaign reveals vaccination refusals high as babies die, in *Daily Telegraph* 2013.
- [43] ABC Radio, No-jab, no pay laws to be strengthened if new bill passes; 2017.
- [44] Parliament of Australia, Social Services Legislation Amendment (No Jab, No Pay) Bill 2015 Explanatory Memorandum 2015.
- [45] Abbott T. Prime Minister Tony Abbott announces 'no jab, no play and no pay' policy for child vaccination, in *The Daily Telegraph* 2015.
- [46] Department of Health Australia. No Jab No Pay Factsheet – New Immunisation Requirements for Family Assistance Payments; 2015.
- [47] Senate Community Affairs Legislation Committee. Official Committee Hansard Senate Community Affairs Legislation Committee – Social Services Legislation Amendment (No Jab No Pay) Bill 2015. Australia
- [48] Parliament of Australia. Social Services Legislation Amendment (No Jab, No Pay) Bill 2015: Australia. p. 7.
- [49] Department of Education Australia, The new child care package brochure. 2017.
- [50] Statistics A.B.o. 4402.0 – Childhood Education and Care in Australia; 2014.
- [51] Aly W, In opposing the anti-vaccination movement, a sledgehammer cannot win battle of the needle, in *The Sydney Morning Herald* 2015.
- [52] National Health Performance Authority, Healthy Communities: Immunisation Rates for Children in 2015–16. 2017, National Health Performance Authority: Sydney, NSW.
- [53] Porter C. No Jab, No Pay lifts immunisation rates [Media Release], Human Services, Editor. Canberra: Commonwealth of Australia; 2016.
- [54] National Centre for Immunisation Research and Surveillance. No Jab No Play, No Jab No Pay Policies – national and state legislation 2017 30/11/2017]; Available from: <http://www.ncirs.edu.au/consumer-resources/no-jab-no-play-no-jab-no-pay-policies/>.
- [55] Omer SB et al. Nonmedical exemptions to school immunization requirements: secular trends and association of state policies with pertussis incidence. *JAMA* 2006;296(14):1757–63.
- [56] Omer S et al. Exemptions from mandatory immunization after legally mandated parental counseling. *Pediatrics* 2018;141:1.
- [57] Department of Health. Agency Request Legislation Proposal: Exemptions from immunizations required for schools and childcare centers, D.o. Health, Editor. Washington (US): Department of Health; 2011.
- [58] Washington State Legislature. House Roll Call on 2011 Senate Bill 5005: Certification of exemption from immunization.
- [59] Washington State Legislature, Senate Roll Call on 2011 Senate Bill 5005: Certification of exemption from immunization. 2011. .
- [60] VacMap- Measles Vaccination Coverage in Germany G. Federal Health Ministry, editor; 2017.
- [61] Horstkötter N., et al. Einstellungen, Wissen und Verhalten von Erwachsenen und Eltern gegenüber Impfungen – Ergebnisse der Repräsentativbefragung 2016 zum Infektionsschutz. 2017, BZgA-Forschungsbericht. Köln: Bundeszentrale für gesundheitliche Aufklärung 2017: Germany
- [62] Robert Koch Institut. Epidemiologisches Bulletin. Robert Koch Institut; 2011. p. 49–53.
- [63] Statistisches Bundesamt (destatis). Statistisches Jahrbuch 2017 2017, Statistisches Bundesamt (destatis).
- [64] Online, Z. Wer die Eltern entscheiden lässt, riskiert Menschenleben in Zeit Online 2017.
- [65] Pierson P. Increasing returns, path dependence, and the study of politics. *Am Political Sci Rev* 2000;94(2):251–67.
- [66] Leask J, Danchin M. Imposing penalties for vaccine rejection requires strong scrutiny. *J Paediatr Child Health* 2017;53(5):439–44.
- [67] Zeigler K.E. Cicero: De Legibus 1963, Heidelberg
- [68] Locke J. *Second treatise of government and a letter concerning toleration*. United Kingdom: Oxford University Press; 2016.
- [69] United Nations Universal Declaration Human Rights U. Nations, editor. Geneva; 1948
- [70] International Covenant Civil and Political Rights U. Nations, editor. Geneva; 1966.