Title:

Do school or daycare vaccine mandates increase pediatric vaccination coverage?

A systematic review

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Abstract

Background: School or daycare vaccination mandates are present in two Canadian provinces, every US state, and are a growing strategy internationally in wealthy countries. However, the effectiveness of such laws for increasing population-level vaccine coverage is unclear.

Methods: MEDLINE, EMBASE, CINAHL, ERIC, Cochrane Database of Systematic Reviews, PAIS, and WPSA were searched for peer-reviewed empirical studies of school or daycare vaccine mandate policies published 1980-2017. Reference lists of relevant articles were also searched. Included studies were too heterogeneous for meta-analysis, thus data were extracted using a standardized rubric, and results narratively synthesized.

Results: Eight studies met inclusion criteria. Seven were conducted using data from one or more US state and 1 an Australian state. One was a prospective cohort study, 5 were retrospective cohort studies, and 2 were retrospective analyses of survey data. Data sources included the US National Immunization Survey-Teen, school databases, state registries, and a clinical data repository. Findings were varied. Three studies found no increase in vaccine coverage following adolescent vaccine mandates, with HPV appearing particularly resistant to mandate efforts. Five studies showed increases in vaccination that might be attributable, at least in part, to vaccination or documentation mandates, although four of these had data that did not include all children.

Interpretation: Although numerous studies have explored impacts of childhood vaccine mandates, the evidence regarding whether mandates are an effective intervention to increase population vaccine coverage remains inconclusive. Context-sensitive prospective studies with whole-population registry data and appropriate comparators are required.

Abbreviations

HBV – Hepatitis B vaccine

HPV – Human papilloma virus vaccine

MCV4 – Meningococcal vaccine against 4 strains (ACWY)

OECD – Organisation for Economic Co-operation and Development

PRISMA – Preferred Reporting Items for Systematic Reviews and Meta-Analyses

TDaP – Tetanus, diphtheria, and acellular pertussis vaccine

Introduction

A broad range of policy levers exist to encourage childhood vaccination. These range in nature and intrusiveness, from efforts to increase easy access to vaccination services to policies requiring vaccination under certain circumstances. Vaccine mandates for school or childcare attendance are ubiquitous in the USA and growing as a strategy in Europe and Australia. Currently, school vaccine mandate legislation exists in two Canadian provinces, Ontario (1) and New Brunswick (2). Mandate policies vary in what they require and in restrictiveness (3). Such policies might require, for example: documentation of immunization status so that vulnerable individuals may be identified in an outbreak, documentation of immunization status plus additional documentation to verify that non-vaccination is intentional, documentation of immunization status and required completion of vaccine education to verify that non-vaccination was an educated choice, or mandated immunization with limited exceptions (e.g, for medical reasons, religious reasons). Mandates may be incentivized with benefits (e.g., financial rewards) for those who comply, and/or consequences (e.g., fines, exclusion) for those who do not.

In 2015, at the 148th Annual Meeting, the CMA passed a resolution recommending documentation-with-education mandates, such "that governments authorize elementary and secondary schools to require a declaration of immunization status, to be followed by a conversation between public health officials and parents where children are shown to be inadequately immunized."(4) However, such policies have not at this time been adopted by the majority of Canadian provinces. Debate regarding best practices for mandate policies tends to draw largely on ethical arguments (5) regarding the optimal legislation for maximum vaccine coverage of school children without violating parental civil liberties, with some voices advocating strict policies with few permitted exemptions, others favoring a more libertarian approach, and many aiming to strike an acceptable balance (6). Often in these debates, the effectiveness of vaccination mandate laws in increasing population vaccine coverage is assumed. However, despite the existence of thousands of articles on the topic of mandate policies, a thorough and focused synthesis of the available literature has not occurred.

Our aim in this analysis is to inform the ongoing debates regarding optimal childhood vaccination policy by systematically identifying and synthesizing the existing evidence to answer

the question: *Does the implementation of school or daycare-based childhood vaccine mandate policies cause an increase in vaccination coverage?* In order to assess effectiveness of child vaccine mandates in real-life settings, studies with the appropriate outcome must be examined. Several cross-sectional studies have documented associations between existence of a child vaccination mandate (or difficulty of exemption from a mandate) and population vaccine coverage outcomes, suggesting that stricter policies around exemptions from mandates may increase compliance (7–10). These studies alone, however, cannot determine causality or directionality of the association. Other studies have explored the influence of mandates on outcomes such as exemption rate (11,12) or disease occurrence (13), without population vaccination data. A recent systematic review conducted by the United States Government attempted to synthesize findings of all research since 1980 on school vaccine mandates (14); however a review with more stringent inclusion criteria, which is focused on the actual effects of mandate implementation/changes, is merited to assess causality and inform jurisdictions that do not already have mandates in place. Population level vaccine coverage is the ideal outcome for implementation studies of vaccine mandates, since exemption rates may overlook unintended consequences such as clustering of unvaccinated children in private or home schooling not subject to mandates, and vaccine-preventable disease incidence is affected by many forces including temporal trends in outbreak cycles.

Methods

This systematic review was conducted according to PRISMA guidelines (15). No protocol was registered for this non-clinical review of public health policy interventions. We sought English, French, or Spanish language studies published in 1980 or later using any empirical method to obtain evidence on potential causal effects of implementation of school or childcare vaccination mandate policies for children on the outcome of childhood vaccination coverage in the population. Appropriate comparison groups included same-time comparators in locations without mandate changes or pre/post intervention comparisons. Studies that focused only on the policy of a specific school rather than a regional/government policy were excluded, as were mandates for non-pediatric populations, policies that only imposed mandates in cases of outbreaks, non-empirical papers (e.g., theory, commentary, projected modeling), and studies that only examined

outcomes other than population immunization or vaccine coverage (e.g., exemption rate only, hypothetical choice experiments). Figure 1 summarizes inclusion and exclusion criteria.

[--Figure 1. Inclusion and Exclusion Criteria about here--]

We searched the databases MEDLINE, EMBASE, CINAHL, the Cochrane Database of Systematic Reviews, ERIC (Education Resources Information Center), PAIS (Public Affairs Information Service), and WPSA (Worldwide Political Science Abstracts) in August 2016 and again to update in October 2017, in order to identify potentially-relevant articles (see Appendix A for full search details). References of relevant articles were searched for additional potentially-includable citations, and a Google Scholar alert was set to help identify new articles published during analysis and writing.

Titles and abstracts of initially gathered citations were first screened by a single author (CVM) for relevance. Full texts of potentially-includable articles were obtained and all three authors (DG, JAB, CVM) reviewed for inclusion or exclusion. Discrepancies were resolved by discussion among the authors to reach consensus. Included articles were then subjected to a data extraction process by all authors (see Appendix B for all characteristics for which data was extracted), discussed by all authors, and synthesized in a narrative manner. All included studies were also assessed normatively for potential bias in study methods by two authors (JAB, DG) using the bias categories from the ROBINS-I (Risk Of Bias In Non-randomised Studies - of Interventions) tool (16).

Results

Database searches resulted in 2022 unique citations to screen and assess for eligibility, and reference lists of key articles on the topic revealed 5 additional studies. After screening for relevance and applying inclusion and exclusion criteria, 8 studies were selected for inclusion in this review (see Figure 1).

[--Figure 2. PRISMA Flow Diagram about here--]

Of the 8 included studies, 7 were conducted using data from one or more US states, and 1 focused on an Australian state. One was a prospective cohort study, 5 were retrospective cohort studies, and 2 retrospective analyses of vaccination coverage survey data. Data sources included various iterations of the US National Immunization Survey-Teen (NIS-Teen), school vaccination documentation databases, state vaccination registries, and a clinical data repository from a university health system.

The American studies assessed policies mandating adolescent vaccination (typically 5th or 6th grade level, 10-12 years of age), kindergarten-entrant vaccination (typically age 4-5 years), and parental education mandates (requiring education regarding certain vaccines for parents of adolescents). These policies had various exemption procedures, and while most examined the impact of the addition of new vaccine or education requirements, one looked at the impact of a change in exemption procedures. The Australian study focused on a school entry (kindergarten/grade 1, age 4-6 years) policy requiring parents to submit documentation of immunization.

In the American studies, coverage was assessed among adolescents for the following vaccines: hepatitis B (HBV), human papillomavirus (HPV)(girls only), meningococcal A/C/W/Y vaccine (MCV4), tetanus containing vaccines (e.g., TDaP), varicella, or "all required vaccines," while the Australian school entry study assessed rates of "fully immunized" students in the preparatory year through grade 2. Table 1 summarizes the included studies' methods, relevant findings, and limitations (including risks of bias).

[--Table 1. Included Studies--]

Findings of Included Studies

Findings of the included studies were varied, and the heterogeneity of study methods, data sources, populations, and unit of analysis precluded statistical meta-analysis. Thus, we report here a narrative synthesis of findings of the included studies, grouped by those that did not, and those that did, find an increase in coverage following implementation of a mandate policy..

Studies that showed no increase in coverage after mandates

Three included studies used survey or health system data and found no increase in vaccine coverage following adolescent vaccine mandates that were implemented over the 2007-2009 time frame. Bugenske and colleagues (17) used NIS-Teen telephone survey data to examine whether states that implemented middle-school vaccine requirements in 2008-09 experienced a larger change in coverage than states that already had a mandate prior to 2008 or those with no mandate in 2008-09. While states with existing or new mandates were associated with higher coverage rates of both TDaP and MCV4 than states with no mandates, all states in the analysis saw increases in coverage from 2008 to 2009, with overlapping confidence intervals among almost all of the groups. This pattern did not hold with HPV; however, only one state included in the analysis had an HPV vaccine mandate in 2008-09, and this was associated with a possible (statistically-insignificant) decrease in coverage upon implementation of a mandate policy, as compared with comparatively small but statistically significant increase in states with solely education mandates or no mandates.

HPV appeared particularly resistant to mandate efforts in other studies as well, both when examining within a jurisdiction before and after a mandate went into effect, and when comparing coverage uptake over time in jurisdictions with different policies. Perkins and colleagues (18) used NIS-Teen data 2009-2013 to conduct a contemporaneous comparison of HPV coverage among girls in two jurisdictions (one state and the District of Columbia) with vaccine mandates, 10 states with education mandates, and states without HPV mandates. All mandates for vaccination or education were implemented in 2007 or 2008. The authors found no difference in coverage in states with and without vaccine or education mandates. Cuff et al. (19) examined the VA state HPV mandate specifically, using clinical data from University of Virginia-supported medical practices in 2014 (five years post-mandate), and comparing this to pre-mandate data from 2008, found no effect on HPV coverage.

Studies showing increase in coverage following mandates

Two included studies used registries of school-enrolled children and found increases in vaccination among regional or state student populations following mandate policies: one in the 1990's in Chicago, another in 2009-2010 in Michigan. A third using a similar registry in Washington state found no decrease in vaccine coverage, and an increase in students who were

up-to-date for all vaccines, following imposition of stricter mandate exemption procedures. One study using the Arizona state vaccine registry, which is based on immunizer reporting rather than school enrollment data, found an increase in coverage following a mandate. The final study in this group, conducted in Victoria, Australia in the 1990's, found that implementation of a documentation mandate increased documentation of both vaccinated and unvaccinated students.

Morita and colleagues (20) used data from the Chicago public school system to retrospectively look at HBV vaccine coverage by grade 12 (age 17-18 years) over a six-year span in the 1990's during which a 5th grade mandate policy for HBV vaccination was implemented. They found that post-mandate cohorts had much higher coverage of HBV. Similarly, Potter et al. (21) retrospectively used the Michigan state immunization registry of school-enrolled children to assess the impact of a new 6th grade mandate for adolescent TDaP, MCV4, and varicella, finding that vaccine completion was higher in the post-mandate year (2010) compared with the previous year (2009) and time to completion was shorter.

Omer and colleagues (22) examined a policy that changed exemption procedures, rather than vaccines required for school enrollment. Using Washington state health data for kindergarten enrollment from 1997-98 through 2013-14, the authors found that after addition of the requirement to have a health care provider counsel/sign a form in order to exempt a child from the state vaccine mandate, there was a small increase in students who were complete for all vaccines. With access to population data for vaccines administered in the state of Arizona to children under 18 years, Simpson et al. (23) were able to track coverage of MCV4 vaccination among 11 and 12 year old children before and after implementation of the 2008 state requirement for students to be vaccinated before 6th grade entry. Simpson found that MCV4 coverage by Sept 1 among 12-year-olds increased after the mandate.

The one Australian study that was included in this analysis, by Thompson and colleagues (24), used state administrative data (education census) before and after a documentation mandate was imposed, finding a small increase in submitted documentation for incoming primary (kindergarten) students following implementation of a documentation mandate policy. This included a small increase in documentation of fully vaccinated students and a larger increase in documentation of incompletely vaccinated students.

Interpretation

Research on whether the implementation of school or childcare based vaccine mandate policies cause an increase in vaccination coverage among children provide mixed evidence. Overall, studies using school enrollee data appeared to find increases in vaccination after mandates were implemented or tightened, while those using survey or health system data and those looking at HPV mandates, did not. In the included studies, while implementing a mandate for vaccine coverage was often associated with higher vaccination coverage among school-enrolled children, the causal effects of such mandates on population vaccine coverage were unclear.

Based on the evidence to date, it remains an open question whether implementation of childhood school- or daycare-based vaccine or documentation mandates increase vaccination coverage in a population. In several studies, there appeared to be a possible positive impact on vaccine coverage, while in others there appeared to be no impact. Context, which was rarely fully described in the included articles, may play an important role in the success or failure of such mandate policies. For example, while Simpson and colleagues found an increase in MCV4 coverage following implementation of a mandate, the exact contribution of the mandate—as compared with an increase following Advisory Committee on Immunization Practices (ACIP) recommendation changes in 2005 and 2007, and concurrent interventions such as an educational campaign and provider behavior changes—was not possible to reliably ascertain with these data alone. Similarly, the increase in students with up-to-date immunization status observed by Omer et al. (22) may have been influenced by the restrictions on mandate exemptions, but also potentially by changes in state vaccine purchasing and provider reimbursement, community vaccine promotion activities, retraction of the infamous Wakefield study from Lancet, and changes to the vaccine schedule as well as the exemption form. The particular lack of success of the HPV mandates studied in this body of research may relate to the highly charged political discourse surrounding the introduction of that particular vaccine (25).

While the limitations of the included studies were not uncommon within the research context, study conclusions often glossed over such limitations, overstating the findings regarding intervention effectiveness. This was primarily due to two main issues, both of which may be remedied with additional high-quality future research. First, many of these studies, including all

but one of those with positive results, relied on data gathered from school-enrollees. This data may be more accurate than that gathered from a survey such as NIS-Teen; however, using school-level data to evaluate a state-level policy does carry several limitations related to the sample. Key among these is the issue of missing data. In several of these studies, home learners, private school enrollees, and those who simply did not comply with documentation requirements were omitted from the analysis. The population of compliant, public school-enrolled children, however, may not be an appropriate proxy for the whole school-aged population of a city, district, or state. Lack of measurement of whose data are missing, and where they spend their time, risks overlooking potentially-dangerous clustering of unvaccinated populations who are vulnerable to disease outbreaks. While not all included studies showed an increase in vaccine coverage after mandate imposition/tightening, many did. Unfortunately, those that did often noted an accompanying increase in exemptions or missing/incomplete data, which raises questions regarding whether these improved coverage rates may, at least in part, reflect reclassification or exclusion of out-of-compliance children, rather than any true increase in population vaccine coverage and also may be hinting at a shifting or clustering of unvaccinated populations.

Second, as with most implementation science that uses natural policy experiments, the studies in this body of research are vulnerable to secular trends and ecological fallacies. Few studies adequately measured pre- and post-intervention periods, included appropriate comparator jurisdictions, or fully considered factors external to the vaccine mandate policies that may have influenced vaccination rates. Some factors that may have confounded findings of studies such as those reviewed in this study include (but are not limited to): outbreaks of vaccine-preventable disease, the retraction of Andrew Wakefield's notorious Lancet paper, growing population familiarity with and corresponding acceptance of newer vaccines over time (e.g., HBV, varicella), changes in data source (e.g., starting of a new state registry), immunization promotion efforts or access improvements that may accompany a mandate policy without being officially part of the policy, improved immunization documentation being misinterpreted as increased coverage, new availability of vaccines for a given age group (e.g., TDaP for adolescents), media-popularized fears about specific vaccines (e.g., HPV), and growing popularity of home learning in the USA.

To better understand the effectiveness of mandates, comparisons between school enrollment and whole population/representative samples should be conducted. Simpson (23) contrasts results calculated from census data versus state immunization registry data, and finds very different coverage rates estimated using these different population data sources. Additionally, more studies on the impact of HPV mandates should be conducted now that the vaccine is universally recommended to all genders, to assess whether it remains resistant to mandate policies. Vaccine researchers should also be encouraged to consult with local and regional immunization program managers and to work with social scientists to better understand the impact of potentially-confounding contemporaneous interventions (e.g., those that affect access to vaccination) as well as other ecological factors (e.g., outbreaks, media scares about adverse events) that might affect policy effectiveness.

Future studies of immunization documentation mandates should also explore population immunization coverage outcomes. Other Australian studies (26,27) not eligible for inclusion in this review have also found that documentation mandates appear to increase student immunization documentation, potentially enabling better identification of at-risk children in the case of an outbreak. However they did not measure any potential immunization coverage changes in the population, although this is commonly one of the stated objectives of such policies. Further, since childcare and preschool are not mandatory, restricting access risks increasing population inequities related to early child education and development without increasing vaccine coverage.

Much recent attention has been paid to issues of mandate exemptions and "opting out" considerations in terms of political (28) and ethical implications (29), as well as impacts on exemption rates (30) and ultimately vaccine confidence and coverage impacts (31). Less attention has been paid to the question of whether mandates themselves are an effective tool for increasing vaccination in pediatric populations. This may be due to the fact that the vast majority of childhood vaccine mandate policy research focuses on US jurisdictions, where mandates are already in place. Removing an established mandate has not to our knowledge been studied, and certainly raises concerns regarding stoking vaccine hesitancy. However, as policy makers in Canada, as well as other countries, increasingly discuss and implement vaccine mandates for school (32,33) or childcare (34) attendance, broader questions of whether mandates are indeed

effective policy levers for increasing population vaccination are important on a global scale. Concerns raised regarding, for example, potential 'backfire effects' of increasing resistance, clustering unvaccinated children, weakening trust in the government and health professionals, or diversion of resources away from addressing structural barriers to vaccine access (35–38) should be taken seriously—particularly given that, while implementation of a mandate may or may not increase coverage, removal or weakening of an existing mandate may decay vaccine confidence (12). If it is the case that an improved system of vaccine documentation and prompting is the main effect of most vaccine mandates, population vaccination registries may achieve the same effect with a much lower risk of increased resistance and clustering. In order to answer the question of whether mandates are an effective immunization promotion strategy for a country such as Canada, further research—context-sensitive prospective studies with whole-population registry data and appropriate comparators both temporal and contemporaneous—is required.

Conclusions

Although numerous studies have attempted to assess whether childhood vaccine mandates increase population vaccination coverage, the evidence remains uncertain. Future studies investigating this question may prove more conclusive if they are able to use whole-population data, triangulate data sources, include sufficient temporal and contemporaneous comparators, and more fulsomely take into account environmental confounders. At this time, the evidence cannot support either a recommendation for or against implementing vaccine mandate policies for children's attendance in school or daycare programs.

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Figure 1. Inclusion and Exclusion Criteria

Included	Excluded
Language: English, French, or Spanish	Other languages
Publication date: 1980-2017	Publication date before 1980
Population: any general pediatric population, including adolescent populations	Adult or mixed adult-pediatric populations, specific populations (e.g., those with a disease, in hospital)
Intervention: any government-imposed general mandate for documentation and/or vaccination, with or without education requirements	Interventions imposed by individual schools, mandates that only come into effect in case of disease outbreak
Comparator: same-time comparators in locations without mandate changes or pre/post intervention comparisons	No comparator
Outcomes: childhood vaccination coverage in the population	Outcomes such as disease occurrence, policy exemptions
Study methods: Any empirical method, qualitative or quantitative	Non-empirical methods (e.g., theory, commentary, projected modeling)

Figure 2. PRISMA Flow Diagram

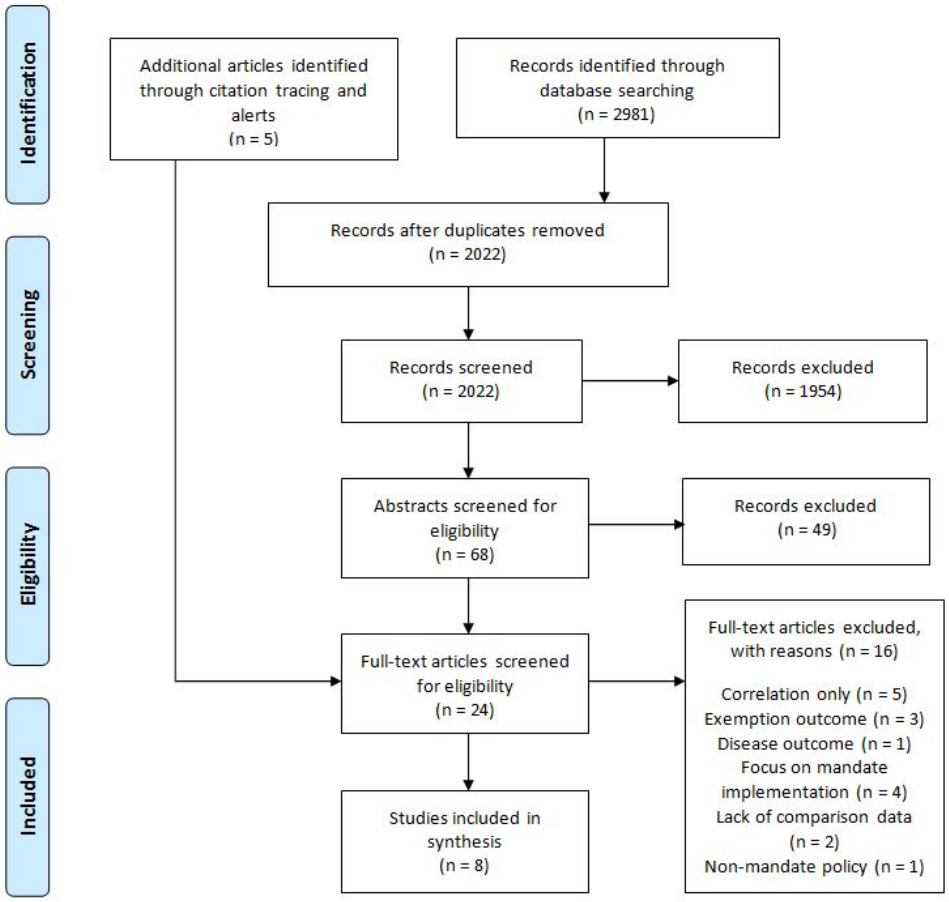

Table. Included Studies

Lead Author	Date	Journal	Method	Setting	Data source (population)	Mandate studied (year)	Exemptions	Outcome of interest	Main Findings	Limitations
Bugenske	2012	Pediatrics	Retrospective analysis of vaccination coverage survey data	US states	2008-2009 National Immunization Survey-Teen (2008 n=17,835; 2009 n=20,066)	Middle school vaccination mandate (2008-2009)	Various	Increase in coverage of 1) TDaP, HPV and MenACWY vaccines and 2) increase of all recommended vaccines in adolescents 13-17 years of age	TDaP and MenACWY coverage increased from 2008 to 2009 in all states. States with existing or new mandates had significantly higher coverage of TDaP and MenACWY than states without mandates. But coverage did not differ among states with new and old mandates. HPV and MenACWY coverage did not differ in states with educational requirements compared to states without educational requirements (no states had educational requirements for TDaP). Presence of vaccine mandates were not associated with increase in all recommended vaccines.	Survey population was limited to land-line telephones and may not be representative. Vaccine coverage may be underestimated in the survey data used for the analysis, as NIS-Teen uses a combination of parent report and parent-referred health care provider report and only included respondents with adequate vaccination history information. Sample size for HPV and MenACWY mandates was small. Follow-up time for policies was limited. Policies were grouped together, not allowing for subtle differences in implementation or context. Ecological analysis: increase or decrease in coverage may be due to factors other than the mandate. Vaccine up-to-date was defined as 1 dose.

Cuff	2016	American Journal of Obstetrics & Gynecology	Prospective cohort study using administrative data and telephone survey	Virginia, USA	University of Virginia clinical data repository (n=908 girls)	6th grade HPV mandate for girls (2009)	Low barrier to obtain philosophical exemptions	HPV vaccine initiation (≥ 1 dose) in girls11-12 years of age and proportion vaccinated in 2009 and 2014 cohorts.	State school entry mandate had no effect on HPV coverage 5 years after mandate implementation.	Only 1 year of baseline (pre-mandate) data. Single-center study. Participants included only parents seeking care for well-child care visits. May not be representative.
Morita	2008	Pediatrics	Retrospective cohort study using administrative data	Chicago, Illinois, USA	Chicago public schools' vaccination database (n=106,541 students total; with 14,950 to19,703 in each year)	5th grade HBV mandate (1997)	Medical or religious exemptions permitted	HBV coverage by grade 12 (overall, and racial/ethnic disparities in coverage)	Postmandate cohorts had significantly higher HBV coverage rates. Coverage rate disparities by race and ethnicity also decreased post-mandate.	Ecological analysis: Likely inconsistent enforcement of policy, not captured by study data collection methods. Potential outcome bias: Losses to follow up (i.e.: students who left school before grade 12) excluded from the analysis. Only two years of post-mandate data.
Omer	2017	Pediatrics	Retrospective cohort study using administrative data	Washington, USA	Washington State Department of Health 1997-98 – 2013-14 (number of students not reported)	Parents seeking exemption from any school vaccine mandates must submit certificate signed by a licensed health care provider indicating discussion of benefits and risks of vaccination occurred (2011)	Medical, personal, or religious (with signed certificate)	Kindergarten vaccination rates, exemption rates and clustering of vaccine exemptions	Vaccination rates stayed the same or increased after the policy. Exemption rates decreased. Non-compliance increased. Probability of a kindergartener interacting with an exempted kindergartener decreased.	Ecological analysis: Other changes (e.g., in vaccine schedule, exemption forms) prior to the policy change appear to have had impact on trends. Home learners may not be included in this data (selection bias).
Perkins	2016	Human Vaccines & Immuno-therapeutics	Retrospective analysis of vaccination coverage survey data	Various US States	National Immunization Survey-Teen 2009-2013	HPV mandate for girls (DC, VA) HPV education	Low barrier to obtain philosophical exemptions to mandate	HPV vaccine coverage (series initiation, completion) in girls.	No difference in HPV vaccination coverage between girls in states with and without	Vaccine coverage may be underestimated in the survey data used for the analysis, as NIS-

					(n = 47,845, with 1,649 in vaccine mandate jurisdictions and 12,579 in education mandate states)	mandate (LA, MI, CO, IN, IA. IL, NJ, NC, TX, WA)			education or school entry mandates.	Teen uses a combination of parent report and parent-referred health care provider report and only included respondents with adequate vaccination history information. Only 1 year of baseline (pre-mandate) data. Policies were grouped together, not allowing for subtle differences in implementation or context. Ecological analysis: increase or decrease in coverage may be due to factors other than the mandate.
Potter	2014	American Journal of Public Health	Retrospective cohort study of administrative data	Michigan, USA	Michigan Care Improvement Registry (statewide immunization registry) 2009-2010 (2009 n=133,738; 2010 n=131,051)	New mandate at grade 6 entry for TDaP, MCV4, varicella	Low barrier to obtain philosophical exemptions	Completion of all required vaccines (as a single variable); time to completion (up-to-date status) of all required vaccines; initiation of HPV vaccine (girls only)	Vaccine completion was higher in post-mandate year and time to completion was shorter.	Ecological analysis: increase in coverage may be due in part to factors other than the mandate. Only 1 year of baseline (pre-mandate) and one year of follow up (post-mandate) data. Home learners may not be included in this data (selection bias). Losses to follow-up (i.e. children who moved out of state) were included.
Simpson	2013	Public Health Reports	Retrospective cohort study of administrative data	Arizona, USA	Arizona State Immunization Information System	New mandate for MCV4 for grade 6 entry if 11 years or older	Medical and religious/philosophical	MCV4 coverage	Vaccine coverage for 12-year-olds was higher in postmandate years than before	Ecological analysis: increase in coverage may be due in part to factors other than the mandate, for example

					(n=954,953 records)				mandate.	the 2005 ACIP recommendation and education/awareness campaign that accompanied the mandate. Comparison with census data indicates that the registry possibly underestimated coverage.
Thompson	1994	Australian Journal of Public Health	Retrospective cohort study of administrative data	Victoria, AUS	Victoria Directorate of School Education mid-year census 1991 (kindergarten), 1992 (kindergarten) (1576 schools included; 1992 n=45,049 student enrolments)	Documentation mandate for school entry.	No exemptions to required documentation for public school enrolment.	Submitted documentation of immunization status; documentation of complete (up-to-date) immunization for age.	There was a small increase in submitted documentation following policy mandate. This included a small increase in documentation of fully immunized students, and a larger increase in documentation of incompletely vaccinated students.	Selection bias: data not available from non-governmental schools. Only schools with kindergarten enrollment included. Not possible to know reason for missing documentation, therefore unclear whether this presents bias in coverage outcome. Indications some schools more compliant than others. Limited pre and post data.

Appendix A: Search Strategy Detail

Database: MEDLINE(R) In-Process & Other Non-Indexed Citations and MEDLINE(R) 1946 to Present (Ovid)

Search: (((vaccin* OR inocul* OR immunis* OR immuniz*) OR exp immunization/ OR exp immunization programs/ OR exp vaccines/)
AND ((law* OR regulat* OR legal* OR polic* OR mandate* OR requir* OR compliance OR uptake OR enforce* OR compulsory) OR Jurisprudence/ OR Informed Consent/ OR Parental Consent/ OR Coercion/ OR Behavior Control/ OR Mandatory Programs/ OR Voluntary Programs/ OR Public Policy/ OR Health Policy/ OR Legislation/ OR Guideline Adherence/)
AND (school* OR college* OR universit* OR postsecondar*)
AND (parent* OR guardian*))
OR (Immunization/legislation & jurisprudence AND Schools)
Limit Date to 1980-2017

Results: 613

Database: EMBASE (Excerpta Medica) (Ovid)

Search: ((vaccin* OR inocul* OR immunis* OR immuniz*) OR exp immunization/ OR Preventive Health Service/ OR exp Vaccine) AND ((law* OR regulat* OR legal* OR polic* OR mandate* OR requir* OR compliance OR uptake OR enforce* OR compulsory) OR Jurisprudence/ OR Informed Consent/ OR Mandatory Program/ OR Voluntary Program/ OR Policy/ OR Health Care Policy/ OR Law/ OR Parental Consent/ OR Persuasive Communication/ OR Behavior Control/ OR Parental Attitude/ OR Public Opinion/) AND ((school* OR college* OR universit* OR postsecondar* OR day-care* or day care* OR daycare*) OR exp School/ OR School Health Service/ OR Day Care/) AND ((parent* OR guardian*) OR exp Parent/ OR Legal Guardian/)
Limit Date to 1980-2017

Results: 1272

Database: CINAHL (Cumulative Index to Nursing and Allied Health Literature) 1982-present (EBSCOhost)

Search: ((vaccin* OR inocul* OR immunis* OR immuniz*) OR MH "Immunization+" OR MH "Vaccines+") AND ((law* OR regulat* OR legal* OR polic* OR mandate* OR requir* OR compliance OR uptake OR enforce* OR compulsory) OR MH "Parental Attitudes+" OR MH "Jurisprudence" OR MH "Consent" OR MH "Public Policy+" OR MH "Legislation" OR MH "Coercion" OR MH "Public Opinion") AND ((school* OR college* OR universit* OR postsecondar* OR day-care* or day care* OR daycare*) OR MH "Schools+" OR MH "School Health Services" OR MH "Child Day Care") AND ((parent* OR guardian*) OR MH "Parents+" OR MH "Guardianship, Legal")

Limit Date to 1980-2017

Results: 288

Database: EconLit (EBSCOhost)

Search: ((ZU "state and local government: health; education; welfare; public pensions") or (ZU "health behavior") or (ZU "health, education, and welfare: general") or (ZU "health: general") or (ZU "health: government policy; regulation; public health") or (ZU "health: other") or (ZU "policy objectives; policy designs and consistency; policy coordination") or (ZU "public health")) AND (school* OR college* OR universit* OR postsecondar* OR day-care* OR day care* OR daycare*) AND (vaccin* OR inocul* OR immunis* OR immuniz*) AND (law* OR regulat* OR legal* OR mandate* OR requir* OR compliance OR uptake OR enforce* OR compulsory)
Limit Date to 1980-2017

Results: 72

Database: Education Resources Information Center (ERIC) (EBSCOhost)

Search: ((vaccin* OR inocul* OR immunis* OR immuniz*) OR (SU.EXACT("Immunization Programs"))) AND ((law* OR regulat* OR legal* OR polic* OR mandate* OR requir* OR compliance OR uptake OR enforce* OR compulsory) OR (SU.EXACT("School Law") OR SU.EXACT("Laws") OR SU.EXACT("Informed Consent") OR SU.EXACT("Legislation") OR SU.EXACT("Health Behavior") OR SU.EXACT("Health Programs") OR SU.EXACT("Public Policy") OR SU.EXACT("Parents") OR SU.EXACT("Parent Rights") OR SU.EXACT("Parent Attitudes") OR SU.EXACT("Parent Responsibility") OR SU.EXACT("Child Health"))) AND ((school* OR college* OR universit* OR postsecondar* OR day-care* or day care* OR daycare*) OR (SU.EXACT.EXPLODE("Schools") OR SU.EXACT("Universities") OR SU.EXACT("Colleges") OR SU.EXACT("Postsecondary Education") OR SU.EXACT("Child Care Centers"))) AND ((parent* OR guardian*) OR (SU.EXACT.EXPLODE("Parents")))
Limit Date to 1980-2017

Results: 251

Database: PAIS Index (PAIS International and PAIS Archive) (ProQuest)

Search: (school* OR college* OR universit* OR postsecondar* OR day-care* OR day care* OR daycare*) AND (vaccin* OR inocul* OR immunis* OR immuniz* OR SU.EXACT("Vaccination and Vaccines") OR SU.EXACT("Epidemiology") OR SU.EXACT("Prevention") OR SU.EXACT("Intervention")) AND (parent* OR guardian* OR SU.EXACT("Fathers" OR "Homosexual Parents" OR "Mothers" OR "Parents" OR "Single Fathers" OR "Single Mothers" OR "Surrogate Parents" OR "Working Mothers")) AND (law* OR regulat* OR legal* OR mandate* OR requir* OR compliance OR uptake OR enforce* OR

compulsory OR SU.EXACT("Legislation") OR SU.EXACT("Informed Consent") OR SU.EXACT("Jurisprudence") OR SU.EXACT("Health Behavior") OR SU.EXACT("Parental Attitudes") OR SU.EXACT("Coercion") OR SU.EXACT("Health Care Services Policy") OR SU.EXACT("Health Policy") OR SU.EXACT("Compulsory Participation") OR SU.EXACT("Law") OR SU.EXACT("Regulation"))
Limit Date to 1980-2017

Results: 165

The following databases were also searched preliminarily, but due to lack of relevant, includable results were not included in the review: Campbell Collaboration, Cochrane Databases of Systematic Reviews, EPPI-Centre: DoPHER, Networked Digital Library of These and Dissertations (NDLTD), Proquest Dissertation and Theses Global, Would Political Science Abstracts.

Appendix B: Data Extraction Fields

Publication Metadata Sumary
M1. Lead author
M2. Date of publication
M3. Title
M4. What does the study do?

Mandate Policy Attributes
QP1. When was this policy implemented (year)?
QP2. Is this a new mandate or a modification of a previous mandate?
a. New
b. Modification to add vaccine(s)
c. Modification to change exemption procedures
d. Modification of other type:
e. [blank field to allow for input of other]
QP3. What vaccine(s) are regulated by the policy?
a. All recommended
b. HepB
c. Hib
d. HPV
e. Influenza
f. Meningococcal (any)
g. Measles only
h. MMR
i.Pneumococcal
j. Polio
k. Rotavirus
l.TDaP/DTaP
m. Varicella
n. Other
o. [blank field to allow for input of other]
QP4. What population is targeted by the policy?
a. Day Care Students (pre-K)
b. K-12 Students
c. Postsecondary
d. Other
e. [blank field to allow for input of other]
QP5. Who is the administrator of the policy?
a. Federal Government
b. Provincial/State Government
c. Regional Health Entity
d. School
e. Other
f. [blank field to allow for input of other]
QP6. For whom are there consequences if the policy is not complied with/met?
a. Government Body
b. School
c. Parents
d. No one
e. Other

f. [blank field to allow for input of other]

QP7. What type of consequences are applied for non-compliance?

a. Financial
b. Legal
c. School/daycare conditional enrolment
d. School/daycare enrolment banned
e. Other
f. [blank field to allow for input of other]

QP8. Are there exemptions allowed from the policy?

a. No
b. Yes – unspecified
c. Yes – medical
d. Yes – religious
e. Yes – philosophical
f. Yes – for homeless/military/transient populations
g. Yes – other:
h [blank field to allow for input of other]

QP9. What is needed for exemption?

a. Self-report
b. Authorization: non-medical
c. Authorization: health professional
d. Education
e. Nothing
f. Other
g. [blank field to allow for input of other]

QP10. Who has the power to authorize exemptions?

a. Governmental body
b. School
c. Doctor
d. Other
e. [blank field to allow for input of other]

QP11. How often to exemptions need to be resubmitted/reauthorized?

a. Never
b. Annually
c. Other
d. [blank field to allow for input of other]

QP12. Did immunization rates rise following implementation of this policy?

a. No
b. Inconclusive
c. Yes
d. Other
e. [blank field to allow for input of other]

QP13. What other measures were implemented with this policy?

a. Improved immunization coverage (e.g., free, reduced cost vaccines)
b. Improved immunization access (e.g., additional clinics, providers)
c. Other
d. [blank field to allow for input of other]
e. None known

QP14. Has Other Research Been Done on the Policy?

a. Yes
b. None known

Study Attributes

RQ1. Lead author
- a. Institution
- b. Country
- c. Discipline (of primary appointment)

RQ2. Research Method
- a. Quant: Survey/Questionnaire
- b. Quant: Descriptive statistical methods (e.g., simple associations)
- c. Quant: Time series
- d. Quant: Before/after (with or without control)
- e. Quant: RCT
- f. Quant: statistical regression analysis (any type)
- g. Qual: Interviews
- h. Qual: Focus groups
- i. Qual: ethnographic
- j. Mixed-methods
- k. Other
- l. [blank field to allow for input of other]

RQ3. Study funding type
- a. Public
- b. Private foundation
- c. Industry
- d. No funding
- e. Other:
- f. [blank field to allow for input of other]

RQ4. Major findings

[text box for brief free response]

RQ5. Major limitations/biases

[text box for brief free response]

Figure 1. Inclusion and exclusion criteria

Included	Excluded
Language: English, French, or Spanish	Other languages
Publication date: 1980-2017	Publication date before 1980
Population: any general pediatric population, including adolescent populations	Adult or mixed adult-pediatric populations, specific populations (e.g., those with a disease, in hospital)
Intervention: any government-imposed general mandate for documentation and/or vaccination, with or without education requirements	Interventions imposed by individual schools, mandates that only come into effect in case of disease outbreak
Comparator: same-time comparators in locations without mandate changes or pre/post intervention comparisons	No comparator
Outcomes: childhood vaccination coverage in the population	Outcomes such as disease occurrence, policy exemptions
Study methods: Any empirical method, qualitative or quantitative	Non-empirical methods (e.g., theory, commentary, projected modeling)

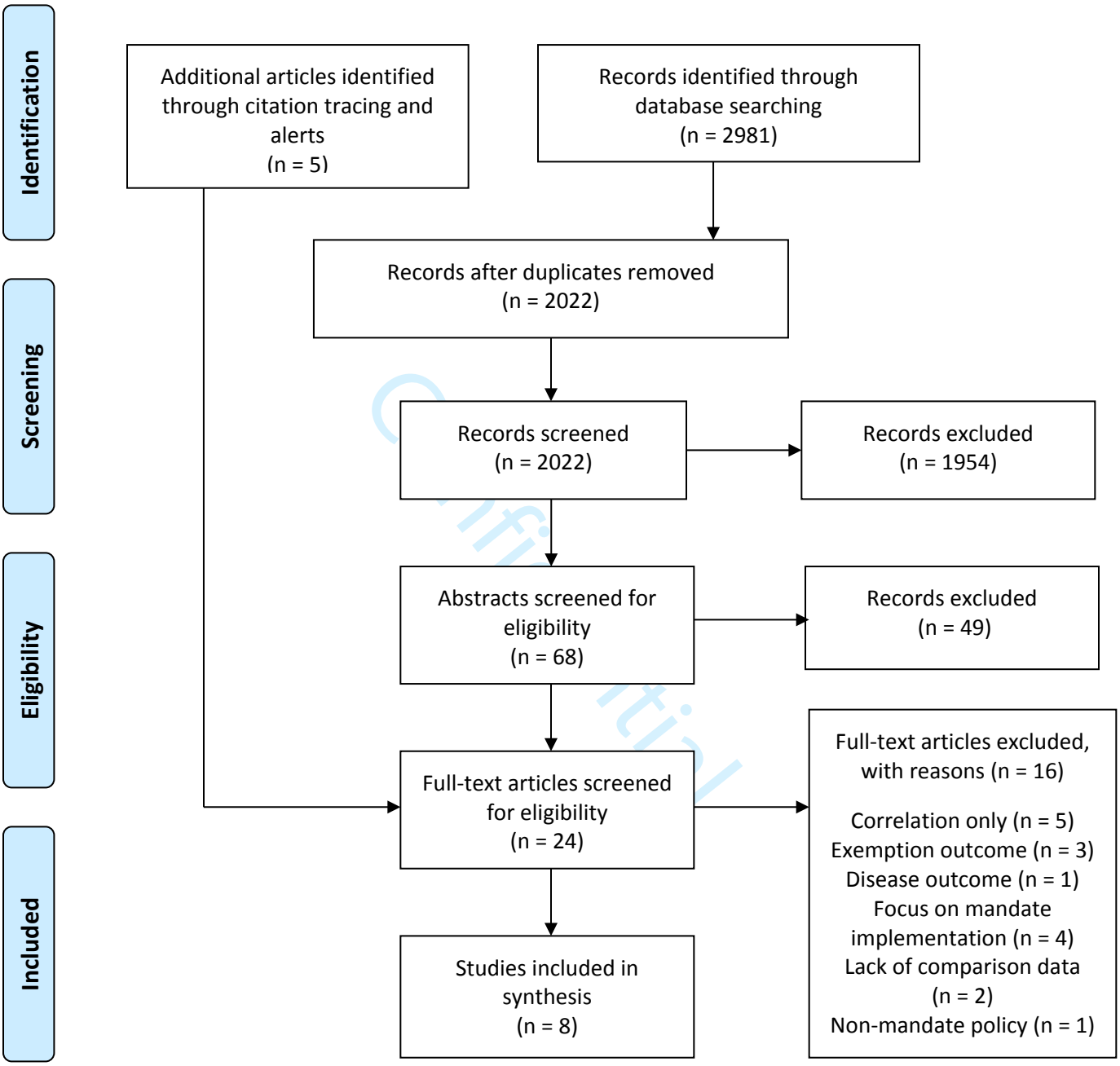
Identification
Screening
Eligibility
Included
Additional articles identified through citation tracing and alerts (n = 5)
Records identified through database searching (n = 2981)
Records after duplicates removed (n = 2022)
Records screened (n = 2022)
Records excluded (n = 1954)
Abstracts screened for eligibility (n = 68)
Records excluded (n = 49)
Full-text articles screened for eligibility (n = 24)
Full-text articles excluded, with reasons (n = 16)
Correlation only (n = 5)
Exemption outcome (n = 3)
Disease outcome (n = 1)
Focus on mandate implementation (n = 4)
Lack of comparison data (n = 2)
Non-mandate policy (n = 1)
Studies included in synthesis (n = 8)

Table 1. Included Studies

Lead Author	Date	Journal	Method	Setting	Data source	Mandate studied (year)	Exemptions	Outcome of interest	Main Findings	Limitations
Bugenske	2012	Pediatrics	Retrospective analysis of vaccination coverage survey data	US states	2008-2009 National Immunization Survey-Teen	Middle school vaccination mandate (2008-2009)	Various	Increase in coverage of 1) TDaP, HPV and MenACWY vaccines and 2) increase of all recommended vaccines in adolescents 13-17 years of age	TDaP and MenACWY coverage increased from 2008 to 2009 in all states. States with existing or new mandates had significantly higher coverage of TDaP and MenACWY than states without mandates. But coverage did not differ among states with new and old mandates. HPV and MenACWY coverage did not differ in states with educational requirements compared to states without educational requirements (no states had educational requirements for TDaP). Presence of vaccine mandates were not associated with increase in all recommended vaccines.	Survey population was limited to land-line telephones and may not be representative. Vaccine coverage may be underestimated in the survey data used for the analysis, as NIS-Teen uses a combination of parent report and parent-referred health care provider report and only included respondents with adequate vaccination history information. Sample size for HPV and MenACWY mandates was small. Follow-up time for policies was limited. Policies were grouped together, not allowing for subtle differences in implementation or context. Ecological analysis: increase or decrease in coverage may be due to factors other than the mandate. Vaccine up-to-date was defined as 1 dose.
Cuff	2016	American Journal of Obstetrics & Gynecology	Prospective cohort study using administrative data and telephone survey	Virginia, USA	University of Virginia clinical data repository	6th grade HPV mandate for girls (2009)	Low barrier to obtain philosophical exemptions	HPV vaccine initiation (≥ 1 dose) in girls11-12 years of age and proportion vaccinated in 2009 and 2014 cohorts.	State school entry mandate had no effect on HPV coverage 5 years after mandate implementation.	Only 1 year of baseline (pre-mandate) data. Single-center study. Participants included only parents seeking care for

										well-child care visits. May not be representative.
Morita	2008	Pediatrics	Retrospective cohort study using administrative data	Chicago, Illinois, USA	Chicago public schools' vaccination database	5th grade HBV mandate (1997)	Medical or religious exemptions permitted	HBV coverage by grade 12 (overall, and racial/ethnic disparities in coverage)	Postmandate cohorts had significantly higher HBV coverage rates. Coverage rate disparities by race and ethnicity also decreased post-mandate.	Ecological analysis: Likely inconsistent enforcement of policy, not captured by study data collection methods. Potential outcome bias: Losses to follow up (i.e.: students who left school before grade 12) excluded from the analysis. Only two years of post-mandate data.
Omer	2017	Pediatrics	Retrospective cohort study using administrative data	Washington, USA	Washington State Department of Health 1997-98 – 2013-14	Parents seeking exemption from any school vaccine mandates must submit certificate signed by a licensed health care provider indicating discussion of benefits and risks of vaccination occurred (2011)	Medical, personal, or religious (with signed certificate)	Kindergarten vaccination rates, exemption rates and clustering of vaccine exemptions	Vaccination rates stayed the same or increased after the policy. Exemption rates decreased. Non-compliance increased. Probability of a kindergartener interacting with an exempted kindergartener decreased.	Ecological analysis: Other changes (e.g., in vaccine schedule, exemption forms) prior to the policy change appear to have had impact on trends. Home learners may not be included in this data (selection bias).
Perkins	2016	Human Vaccines & Immuno-therapeutics	Retrospective analysis of vaccination coverage survey data	US States	National Immunization Survey-Teen 2009-2013	HPV mandate for girls (DC, VA) HPV education mandate (LA, MI, CO, IN, IA. IL, NJ, NC, TX, WA)	Low barrier to obtain philosophical exemptions to mandate	HPV vaccine coverage (series initiation, completion) in girls.	No difference in HPV vaccination coverage between girls in states with and without education or school entry mandates.	Vaccine coverage may be underestimated in the survey data used for the analysis, as NIS-Teen uses a combination of parent report and parent-referred health care provider report and only included respondents with adequate vaccination history information.

										Only 1 year of baseline (pre-mandate) data. Policies were grouped together, not allowing for subtle differences in implementation or context. Ecological analysis: increase or decrease in coverage may be due to factors other than the mandate.
Potter	2014	American Journal of Public Health	Retrospective cohort study of administrative data	Michigan, USA	Michigan Care Improvement Registry (statewide immunization registry) 2009-2010	New mandate at grade 6 entry for TDaP, MCV4, varicella	Low barrier to obtain philosophical exemptions	Completion of all required vaccines (as a single variable); time to completion (up-to-date status) of all required vaccines; initiation of HPV vaccine (girls only)	Vaccine completion was higher in post-mandate year and time to completion was shorter.	Ecological analysis: increase in coverage may be due in part to factors other than the mandate. Only 1 year of baseline (pre-mandate) and one year of follow up (post-mandate) data. Home learners may not be included in this data (selection bias). Losses to follow-up (i.e. children who moved out of state) were included.
Simpson	2013	Public Health Reports	Retrospective cohort study of administrative data	Arizona, USA	Arizona State Immunization Information System	New mandate for MCV4 for grade 6 entry if 11 years or older	Medical and religious/philosophical	MCV4 coverage	Vaccine coverage for 12-year-olds was higher in postmandate years than before mandate.	Ecological analysis: increase in coverage may be due in part to factors other than the mandate, for example the 2005 ACIP recommendation and education/awareness campaign that accompanied the mandate. Comparison with census data indicates that the registry possibly underestimated coverage.
Thompson	1994	Australian Journal of Public Health	Retrospective cohort study of administrative data	Victoria, AUS	Victoria Directorate of School Education	Documentation mandate for school	No exemptions to required documentati	Submitted documentation of immunization status;	There was a small increase in submitted documentation following policy	Selection bias: data not available from non-governmental schools. Only schools with

					mid-year census 1991 (kindergarten), 1992 (kindergarten)	entry.	on for public school enrolment.	documentation of complete (up-to-date) immunization for age.	mandate. This included a small increase in documentation of fully immunized students, and a larger increase in documentation of incompletely vaccinated students.	kindergarten enrollment included. Not possible to know reason for missing documentation, therefore unclear whether this presents bias in coverage outcome. Indications some schools more compliant than others. Limited pre and post data.