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The New York City Childcare Influenza Vaccine Mandate: A Case Study

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THE NEW YORK CITY CHILDCARE INFLUENZA VACCINE MANDATE:

A CASE STUDY

A DISSERTATION

by

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ABSTRACT

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Background. In 2014, New York City (NYC) became the third jurisdiction in the United States (US) to enact a childcare influenza vaccine mandate, after the states of New Jersey and Connecticut. The mandate was enacted by the NYC Board of Health by amending the NYC Health Code. The mandate's goal was to increase vaccination rates among 6-59-month-olds attending city-regulated public and private childcare programs, including prekindergarten, to protect children, families, and the community against influenza. Children younger than 5 years are at high risk for severe illness and complications from influenza. Children are also known to be a major source of influenza transmission in communities. The mandate covered an estimated 122,430 children, representing approximately 24% (122,430/508,112) of all 6-59-month-olds in NYC. Five mothers brought a lawsuit against the mandate in November, 2015. In response, the New York State Supreme Court suspended the mandate in mid-December, 2015, in a ruling stating the NYC Board of Health did not have the authority to require a vaccine not authorized under state law. NYC appealed, but the suspension was upheld by the State Supreme Court, Appellate Division, in October, 2016. This court ruled that the NYC Board of Health had the authority to require the vaccine, but upheld the suspension because the mandate applied to city-

regulated childcare, not all childcare in NYC, and, in their opinion, it wrongly allowed childcare programs to opt out of excluding noncompliant children by paying fines. NYC is preparing a second appeal and is also continuing to advocate for the New York State Legislature to add the childcare influenza vaccine requirement by changing state law.

Objectives. This study had two aims. Aim 1 was to analyze the rationale and ethics of the mandate. The decision to mandate a childhood vaccine requires careful consideration because it infringes upon parental autonomy and can generate controversy that may undermine public acceptance of vaccines in general. Aim 2 was to assess the mandate's effect on influenza vaccination rates among 6-59-month-olds citywide. The findings were intended to guide future decisions to enact childhood vaccine mandates.

Methods. This research followed a convergent mixed methods study design in which qualitative and quantitative methods were used complementarily. A single-case study with record review was used to achieve Aim 1, along with an application of the Kass, and Field and Caplan conceptual frameworks to analyze the mandate's ethics. For Aim 2, a short, interrupted time-series method was used to examine influenza vaccination rates among 6-59-month-olds as of December 31 in 8 annual influenza seasons before the mandate (2006-07 through 2013-14), 2 seasons during the mandate (2014-15 through 2015-16), and one season after the mandate's suspension (2016-17). Vaccination rates were also assessed among a control group of 5-8-year-olds and among the aggregate groups of 6-59-month-olds and 5-8- year-olds stratified by one-year age groups.

Results. NYC gathered and analyzed scientific evidence, reached out to community partners, and deliberated for nearly one year before deciding to seek enactment of the mandate by the NYC Board of Health. The decision was reached only after advocacy to add the childcare

influenza vaccine requirement by changing state law was unsuccessful. The time-series analysis of vaccination rates showed the mandate had little impact on rates among the aggregate group of 6-59-month-olds. Among 4-year-olds, however, vaccination rates increased 11.4 percentage points, by far the largest increase among all age groups. The vaccination rate dropped by 12.1 percentage points among 4-year-olds after the mandate was suspended.

Conclusions. The rationale for the mandate was strong based on evidence of the health and economic burden of influenza, increased vaccination rates reported by New Jersey and Connecticut, and the support of pediatricians, nurses, and pro-vaccine parents. Application of the Kass framework found the mandate ethical because it was enacted through a democratic process, applied to all 6-59-month-olds attending city-regulated childcare and prekindergarten, allowed for legitimate medical or religious exemptions, and was effective in raising vaccination rates among 4-year-olds. Based on the Field and Caplan framework, the mandate was ethical because NYC's obligation for utilitarianism, beneficence, justice and nonmaleficence took precedence over parental autonomy in the context of the potentially severe disease of influenza. Despite the mandate's suspension and subsequent loss of gains realized in raising vaccination rates, NYC was able to demonstrate the mandate's success at increasing influenza vaccine uptake among 4-year-olds, the largest age group in childcare and prekindergarten. This evidence offers strong support for a change in state law to implement the childcare influenza vaccine requirement statewide. In the absence of such a change, alternatives to a mandate for increasing influenza vaccination rates among young children in NYC are needed.

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Section 1: Introduction and Background

The New York City Childcare Influenza Vaccine Mandate

In 2014, New York City (NYC) became only the third jurisdiction in the United States (US) to enact a childcare influenza vaccine mandate, after the states of New Jersey and Connecticut.[1-2] The mandate was enacted by the NYC Board of Health, at the urging of the NYC Department of Health and Mental Hygiene (DOHMH). The NYC Board of Health amended the NYC Health Code to add influenza vaccine to the list of vaccines required for city regulated public and private childcare programs for children younger than 6 years of age, including prekindergarten. The mandate's goal was to increase influenza vaccination rates among young children to protect individual children, their families, and the community against the highly contagious and potentially deadly disease of influenza. The mandate required children 6-59 months of age attending childcare to receive 1 dose of influenza vaccine between July 1 and December 31 of each year starting July 1, 2014.[3] The mandate covered approximately 122,430 children, representing an estimated 24% (122,430/508,112) of all NYC children 6-59 months of age.[4-6]

In November, 2015, five mothers brought a lawsuit against the mandate.[7] In response, the New York State Supreme Court suspended the mandate on December 16, 2015, in a ruling stating that the NYC Board of Health did not have the authority to require a vaccine that is not authorized under state law.[8-9] The NYC Law Department appealed the decision in June, 2016, but the State Supreme Court, Appellate Division, upheld the suspension in a decision announced in October 2016.[10] This court found that the NYC Board of Health had the authority to mandate the vaccine, but upheld the suspension because the mandate applied to only city-regulated childcare, not to state-regulated childcare in NYC as well, and, in their opinion, allowed

childcare operators to buy their way out of excluding noncompliant children by paying fines.[10] The NYC DOHMH and NYC Law Department are preparing a second appeal. The NYC DOHMH has also continued to advocate for the New York State Legislature to amend state law to add the childcare influenza vaccine requirement. The NYC DOHMH had advocated for a state law change in 2013 before seeking the amendment to the NYC Health Code but the proposal did not move forward. A bill to change state law to enact the childcare influenza vaccine mandate was introduced in May 2017.[11] The chances of its passage are unknown at this time.

The purpose of this study was to examine the rationale and ethics of the NYC DOHMH decision to ask the NYC Board of Health to enact the childcare influenza vaccine mandate, and to evaluate the mandate's effect on influenza vaccination rates among NYC children 6-59 months of age. Because vaccine mandates affecting children infringe upon parental autonomy, they raise ethical questions and often generate controversy. Public health professionals recognize that such controversy could result in public backlash against vaccines in general. Consequently, the decision to mandate a particular vaccine requires careful deliberation and consideration of alternatives for increasing vaccine uptake.

Public Health Significance of Influenza

Preschool-age children are at high risk of severe illness and complications from influenza. Among children younger than 2 years of age, hospitalization rates for influenza are comparable to those for people 65 years of age and older.[12-13] Annual hospitalization rates for laboratory-confirmed influenza among children 6 months of age or younger range from 240 to 720 per 100,000 children. Among children 2-5 years of age, these rates are approximately 20 per 100,000. Among children younger than 5 years of age with high-risk medical conditions,

hospitalization rates for laboratory-confirmed influenza climb to approximately 250 to 500 per 100,000.[13] Children 24-59 months of age have a lower risk of hospitalization from influenza but have a greater risk of influenza-associated visits to clinics and emergency departments.[12-13] Moreover, children are a major source of influenza transmission within communities.[12-14]

Congregate settings such as childcare programs and schools facilitate the spread of highly infectious diseases including influenza.[14] Among the general population in the US, influenza is associated with an average of over 200,000 hospitalizations annually.[12-13] Influenza-related deaths vary substantially by year depending on the types of influenza viruses circulating during the season. From 1976-2007, estimates of influenza-associated deaths ranged from a low of 3,349 in 1986-87 to a high of 48,614 in 2003-04.[12, 15]

Gaps in the Literature

Strong evidence supports vaccine mandates as effective interventions for raising vaccination coverage rates among children attending childcare and school. A large body of research has shown that childcare and school entry vaccine requirements are successful at achieving and maintaining high vaccination rates and low rates of vaccine-preventable diseases and associated morbidity and mortality.[16-19] However, some studies suggest that childcare vaccine mandates are not always effective at increasing vaccination rates.[20-21] This study adds new evidence on the effectiveness of childcare vaccine mandates by evaluating the impact of the NYC mandate on influenza vaccination rates among children 6-59 months of age.

Study Innovation

This was the first study to examine a childcare influenza vaccine mandate enacted through a city health code change, in contrast to the state policy-making process used by New Jersey and Connecticut. This difference had implications for enforcement of the NYC mandate, and was also the grounds for the New York State Supreme Court decision to suspend NYC's mandate.[8-9] Colgrove and colleagues (2010) pointed out the limitations of a state legislative process for mandating vaccines, which would have been necessary for a statewide childcare influenza vaccine requirement in New York. These authors suggested using an administrative process, such as a health code change enacted by a Board of Health, as a preferred approach to passing a state law because it may be less vulnerable to political influences and more likely to be grounded in scientific evidence.[22] This study examines the strengths and limitations of adding a vaccine requirement through a city health code change as well as other factors that influenced the enactment of NYC's mandate.

Conceptual Frameworks

This study was guided by the Kass framework for an ethics analysis of public health interventions (2001) [23] and the Field and Caplan ethical framework for vaccine mandates (2008).[24] The Kass framework is meant to help public health practitioners promote public health goals while increasing individual liberties and social justice to the extent possible. Kass's framework calls for answers to the following six questions. These questions will first be adapted to evaluate the ethics of vaccine mandates in general, and then used a second time to analyze the ethics of the NYC childcare influenza vaccine mandate specifically. Question 2 in the framework

will be informed by a quantitative analysis of influenza vaccination rates among 6-59-month-olds before, during, and after the mandate.

1. What are the public health goals of the proposed program?

2. How effective is the program in achieving its stated goals?

3. What are the known or potential burdens of the program?

4. Can burdens be minimized? Are there alternative approaches?

5. Is the program implemented fairly?

6. How can the benefits and burdens of a program be fairly balanced?

The Field and Caplan framework is based on the concept of balancing the competing values of autonomy and beneficence in the context of disease severity, as illustrated by their graphic illustration (Diagram 1, page 7).[24] This study applies the framework, which also includes the values of utilitarianism, justice, and nonmaleficence, to assess the ethical balance represented by the NYC childcare influenza vaccine mandate.

Specific Aims

This study included two specific aims:

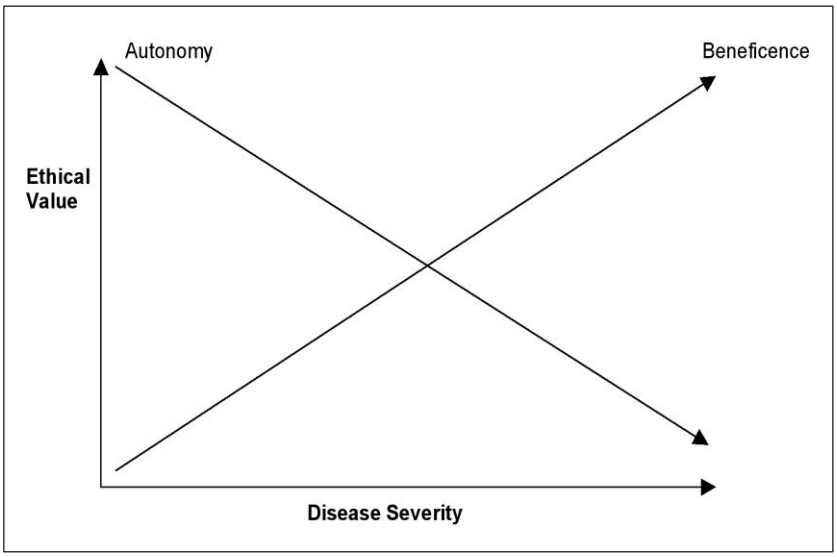
Aim 1. Analyze the Rationale and Ethics of NYC's Childcare Influenza Vaccine Mandate

This aim was achieved by developing a single-case study based on record review including a NYC DOHMH briefing and presentations, NYC Board of Health documents, court documents, media reports, and publications.

Aim 2. Evaluate the Effect of the NYC Childcare Influenza Vaccine Mandate on Influenza Vaccination Rates among 6-59-Month-Old Children Citywide

This aim was achieved by conducting a quantitative analysis of the mandate's impact on influenza vaccination rates among 6-59-month-olds, the age group directly affected by the mandate, compared to 5-8-year-olds, an age group also recommended to receive influenza vaccine but not covered by the mandate.

Diagram 1. Autonomy vs. Beneficence (Field and Caplan 2008)



Section 2: Literature Review

Childhood Vaccine Mandates

Purpose. Children in congregate settings such as childcare programs, preschools, and elementary through high schools are at risk of acquiring and spreading diseases transmitted through casual contact.[14] Many of these diseases are preventable with vaccines. One of public health's greatest achievements, vaccines are credited with dramatically reducing morbidity and mortality from diseases such as polio, measles, and pertussis.[16, 25] In the US from 1924 to 2012, an estimated 100 million cases of disease were prevented by vaccines, with only rare serious side effects.[26-28] The purpose of childhood vaccine mandates is to achieve high vaccination rates among preschool- and school-age children to protect individual children and their families, as well as the community, from vaccine-preventable diseases.[16-17, 19]

History. The first vaccine mandate in the US was a state law enacted in Massachusetts in 1809 to require children and adults to be vaccinated against smallpox to control outbreaks of the disease.[17, 29] In 1827, Boston became the first municipality to require children entering public schools to be vaccinated. In 1855, Massachusetts became the first state to pass a compulsory school vaccination law. Since then, immunization laws have remained state-based; there is no national immunization law.[17-18, 30] Today, all 50 states have laws requiring children to be vaccinated against a range of diseases to attend childcare and schools.[31-32] Medical exemptions from vaccination requirements are allowed in all 50 states and the District of Columbia (DC). As of 2016, religious exemptions are allowed in 46 states and DC, and 19 states allowed philosophical or personal belief exemptions.[33] In New York State, medical and religious exemptions are allowed but not personal belief exemptions. Mississippi, West Virginia, and California were the only states to allow only medical exemptions, i.e., no exemptions for

religious or personal beliefs are permitted by these states.[33] California eliminated nonmedical exemptions recently in response to the highly publicized 2015 Disneyland measles outbreak.[27]

Vaccines Required. The number and types of vaccines required for childcare, prekindergarten, and school attendance may vary by state or local jurisdiction. In NYC, a child attending licensed childcare or prekindergarten in 2016-2017 is required to receive the following vaccines: 4 doses of diphtheria and tetanus toxoids and pertussis (DTaP), 1 dose of measles-mumps-rubella (MMR), 3 doses of Hepatitis B, 1 dose of varicella, 3 doses of polio, 1 to 4 doses of *Haemophilus influenzae* type B (depends on age and vaccine doses previously received), and 1 to 4 doses of pneumococcal conjugate (depends on age and vaccine doses previously received).[34] The requirements are the same for children in the rest of New York State.[35] Influenza vaccine was required for NYC children attending city-regulated childcare and prekindergarten during the 2014-15 and 2015-16 school years.[1-3, 9-10]

Enforcement. In most states, including New York, childcare and schools are obligated to ask parents to produce documentation of the child's vaccination history or to obtain an exemption. Children may be admitted on a provisional basis if the child has received some but not all doses of mandated vaccines. Provisionally admitted children are required to follow an official catch-up immunization schedule to reach full compliance.[36] Childcare operators are required to exclude noncompliant children from their programs. School principals are required to exclude noncompliant children in grades kindergarten through 12. The state and/or local health departments enforce compliance with immunization requirements in childcare and schools by regularly reviewing a sample of or all enrollee vaccination records to identify noncompliant children. The health departments can issue a notice of violation, which can lead to a substantial fine, when a childcare operator or principal is found to fail to exclude noncompliant children.

Enforcement of exclusion may be uneven, however, and may vary by childcare program, school principal, and health department.[17, 20, 30]

Exemptions. In some states and local jurisdictions, the process for obtaining an exemption from required vaccines for a child attending childcare or school may simply require a parent signature on a form.[31-32] In others, such as NYC, the request is reviewed to determine the validity of a medical condition or that the parent has demonstrated sincerely held religious beliefs against vaccination.[37] Studies have shown that states which easily grant exemptions have higher nonmedical exemption rates and increased incidence of vaccine-preventable disease.[31-32]

In NYC, parents requesting a religious exemption for a child in public school must provide a letter explaining the foundation of their religious beliefs opposing immunization. This letter must be submitted to the school principal's office. It is then forwarded to the Office of School Health (OSH), which is run jointly by the NYC Departments of Education and Health and Mental Hygiene. OSH personnel review the letter to determine whether to approve or deny the exemption.[37] An estimated 77% of religious exemption requests are approved.[38] Despite this high approval rate, religious exemption rates in NYC public schools are very low. As of the end of the 2015-16 school year, among NYC public school children $\leq$18 years, a population of nearly 1.1 million students, only 0.21% had a religious exemption.[39]

Medical exemption requests for NYC public school students necessitate a letter or completed form from a New York State licensed physician certifying that one or more of the vaccines required are detrimental to the child's health, and for how long the vaccinations should be deferred.[37] OSH also reviews these requests and may approve or deny them. Data were not found

on the proportion of medical exemptions approved. The medical exemption rate was 0.02% among all NYC public school children at the end of the 2015-16 school year.[39]

There is no standard process for parents to apply for a religious or medical exemption from NYC non-public schools and childcare. Non-public schools and childcare programs decide on their own procedures but may consult the NYC DOHMH Bureau of Immunization for guidance. Based on self-reported data on the annual immunization compliance survey required by New York State, the NYC non-public schools had a medical exemption rate of 0.1% and a religious exemption rate of 0.6% for the 2013-14 school year. For the same year and data source, NYC regulated childcare had a rate of 0.1% for medical and 0.4% for religious exemptions. State regulated group family day care programs in NYC had a rate of 0.0% for medical and 0.3% for religious exemptions based on the New York State survey that same year.[4]

Controversy. Vaccine mandates have generated controversy since the 1800s.[40] Numerous legal challenges have been mounted against them but courts have mostly upheld vaccine mandates. A landmark case was Jacobson versus Massachusetts in 1905, brought by a man who refused smallpox vaccine. The US Supreme Court ruled against Jacobson, endorsing the rights of states to pass and enforce compulsory vaccination laws.[16, 30] In 1922, in a case brought on behalf of a girl excluded from school in Texas, the US Supreme Court found school vaccination requirements to be constitutional. Subsequent cases have reaffirmed this decision.[16, 30] A federal appeals court recently upheld New York State's authority to exclude unvaccinated children from school during disease outbreaks, including those from families with an approved religious exemption.[41]

Critics view vaccine mandates as government infringement on parental autonomy.[40-42] Childhood vaccine mandates captured the attention of candidates for the 2016 presidential election. Responding to stepped up efforts by states to vaccinate or exclude school children to control a multi-state measles outbreak, Rand Paul commented "The state doesn't own your children, parents do." [27]

Ethics. Childhood vaccine mandates limit parental autonomy and may understandably be seen as coercive. A legitimate question is, then, whether they are ethical. To consider this question, the Kass six-step framework for an ethics analysis of public health programs [23] is applied to childhood vaccine mandates.

1. <u>What are the public health goals of childhood vaccine mandates?</u> Vaccine mandates are intended to protect individual children and the community from serious illness or death by vaccinating the majority of preschool- and school-aged children against vaccine-preventable diseases.[16-17, 19] Vaccine effectiveness relies on herd immunity, reached only after a critical mass of people in a community develop immunity so that a disease will be prevented from spreading because of the low probability that an infected person will encounter a susceptible person.[31-32] Herd immunity protects infants too young to be vaccinated, people who cannot be vaccinated because their immune systems are compromised by cancer or other chronic disease, people who do not mount an adequate immune response to vaccine or whose immunity wanes over time, individuals who choose not to be vaccinated, and children whose parents refuse vaccines.[30-31]

The proportion of individuals who must be vaccinated to prevent community transmission varies by infectiousness of the disease and other conditions, but it is generally between 75% and 95%.[16, 30-31] Because of the need for herd immunity, a parent's decision to accept vaccine for their child may not only affect their child's health but also that of people in the community. This

tension between individual rights and the responsibility to protect others is at the heart of vaccine policy ethical considerations.[42] Those who believe that the rights of communities to avoid potentially life-threatening diseases outweigh an individual's right to refuse vaccines will likely find vaccine mandates to be ethical.

2. How effective are childhood vaccine mandates in achieving their goals? Research has shown that childcare and school entry vaccine requirements are effective at achieving and maintaining high vaccination rates and low rates of vaccine-preventable diseases and associated morbidity and mortality.[16-18] Based on a systematic review, the US Task Force on Community Preventive Services recommended vaccination requirements for childcare and school attendance as an evidence-based public health intervention for increasing vaccination rates and decreasing morbidity and mortality resulting from vaccine-preventable diseases.[19]

Some studies, however, have found that childcare vaccination requirements are not always effective at raising vaccination rates. A national study by Stanwyck and colleagues (2004) found no significant difference in up-to-date vaccination rates between children in and not in childcare (73.1% versus 71.9%) at age 24 months.[20] The authors suggested these findings may be due to a lack of standard assessment and enforcement of vaccine policies among childcare facilities. They called for implementation of standards modeled on states demonstrating success at achieving high compliance.[20]

Kolasa and colleagues (2003) conducted a study of nearly 3,000 children younger than 5 years of age attending childcare centers in Philadelphia.[21] They saw no significant increase in vaccination rates between the date children enrolled and 60 days later, when state law required the children to be up-to-date on mandated vaccines to remain in childcare. Among children 19-35 months, 72% were up-to-date at enrollment compared to75% after 60 days.[21] However, a

limitation of this study may have been that the 60-day period for reaching up-to-date status was too short for children who were far behind on vaccines requiring multiple doses. For example, to be considered up-to-date for DTaP, a child would need 4 doses with each dose separated by at least 4 weeks (doses 1 to 2) or 6 months (doses 3 to 4).[36]

3. What are the known or potential burdens of childhood vaccine mandates? The main burdens of vaccine mandates on the public are: (1) curtailment of parental autonomy; (2) exposing children to health risks from vaccines; (3) costs, both monetary and time spent, that must be borne by parents to assure children receive multiple vaccinations over a series of visits to medical providers or to comply with administrative procedures for obtaining an exemption. Costs are also borne by the general public to support enforcement of vaccine mandates by public health entities as well as by childcare and prekindergarten personnel to promote and monitor compliance of enrolled children.

The burdens associated with childhood vaccine mandates are further described below.

4. Can the burdens of childhood vaccine mandates be minimized?

(1) Autonomy**.** Some parents argue that the decision to vaccinate their child rests with the parent alone, and that the parent should be able to opt out of a vaccine mandate should they wish to do so. To some degree, the burden of limiting parental autonomy is reduced by allowing for medical, religious, or personal belief exemptions. Medical exemptions must be allowed per the US Supreme Court's ruling in the 1905 Jacobson case that states may compel vaccination to control disease but may not jeopardize the health or life of an individual.[29] Religious or personal belief exemptions are not constitutionally required.[27, 44] Many states allow nonmedical exemptions, however, to limit the perception of state coercion.[45]

Personal belief exemptions are a topic of hot debate. Some public health leaders argue for their elimination because they threaten herd immunity while others want to maintain personal belief exemptions to avoid public backlash.[45-46] Public health leaders agree that caution must be exercised to ensure that exemption application procedures lead to approval of only those for individuals demonstrating sincerely held beliefs. States with simple applications for nonmedical exemptions have had high exemption rates and associated disease outbreaks due to clustering of exempted children.[32, 47] Washington State recently added a requirement to the nonmedical exemption application that parents must receive education from a medical provider. The purpose was to increase parents' understanding of vaccine benefits and risks and to discourage those who would seek an exemption out of convenience.[45]

Most pediatricians have encountered families deciding to delay or decline vaccination. Periodic surveys conducted by the American Academy of Pediatrics (AAP) show that 7 of 10 pediatricians report having had a parent refuse a vaccine for a child within the 12-month period before completing the survey.[48] These physicians are faced with the ethical dilemma of whether to respect the parent's autonomy, even though the physician believes vaccination is in the best interests of the child and community, or to decline to serve as the child's physician. The AAP offers the general recommendation to avoid discharging a patient solely for refusal of the parent to have the child vaccinated.[48] Evidence suggests most parents who choose not to follow the recommended vaccine schedule are able to get access to physicians who will maintain the physician-patient relationship.[49]

Some pediatricians, however, have decided to inform new families they will not be able to offer care if the family chooses to delay or refuse most vaccines. They cite several reasons: 1) to avoid exposing patients to unvaccinated individuals in waiting rooms, with the possibility of

transmitting highly infectious vaccine-preventable diseases such as measles; 2) to convey to parents the critical importance of vaccines; and 3) to be prevented from having to practice substandard pediatric care.[50] The AAP supports pediatricians having the option of terminating the physician-patient relationship but points out they cannot do so without giving sufficient advance notice to the family so care may be secured from a different provider. AAP also recommends that pediatricians make such decisions only rarely and do so only after attempts to work with the family.[50]

(2) Health risks. The risks of vaccine-preventable disease are far higher than the risks of vaccination. Vaccines are subject to pre-licensure clinical trials and post-licensure monitoring of adverse events to maximize their safety and efficacy.[51-52]

Although vaccines are considered very safe, adverse events related to vaccines do occur. Adverse events following vaccination are generally categorized by frequency (common, rare), extent (local, systemic), severity (hospitalization, disability, or death), causality, and preventability (intrinsic to vaccine, faulty production, faulty administration).[51] These events may be coincidental with vaccination or vaccination may be causally related. Examples of local adverse reactions, which may occur with up to 80% of vaccine doses, are pain, swelling, and redness at the site of injection. These reactions are typically mild and self-limited. Systemic adverse reactions include fever, malaise, headache, and rash. They commonly occur after vaccination with live attenuated vaccines which need viral replication to produce an immune response. Such reactions are usually experienced as symptoms of a mild form of the natural disease. Severe, life-threatening adverse events, such as an acute allergic reaction (anaphylaxis) to a vaccine, are very rare. Estimates are they occur with 1 in one million doses and can be minimized by screening.[51]

People harmed by vaccines are entitled to compensation. Claims may be filed and will be adjudicated under the current system of no-fault compensation for vaccine injury established by the Vaccine Compensation Injury Act of 1986.[53]

Better education about vaccine safety is needed for parents so they may more accurately assess the benefits and risks of vaccination. Parents choosing to delay or avoid vaccinations, a behavior now referred to as "vaccine hesitancy," has become common.[54-55] Recent national surveys indicated that 50% of parents have concerns about vaccines and 89% of physicians reported at least one vaccine refusal by a parent each month.[54] Multiple reasons contribute to this trend. Because vaccines have succeeded at reducing diseases to rare occurrences, parents are more focused on vaccine risks than benefits. Tolerance of risks related to vaccines, which are a preventive intervention for healthy children, is less than that for treatments used for children with disease.[51] Unfounded claims linking vaccines to autism received world-wide attention and undermined confidence in vaccines and trust in government and health care providers. False or misleading claims about vaccine risks are regularly touted by celebrities and widely available on the Internet and social media.[27, 54-57] Public health and the medical community are now challenged with restoring confidence in vaccines. More research into the social, psychological, and cultural factors affecting vaccine acceptance is needed, along with education tailored to the concerns of diverse groups of parents.[58]

(3) Costs. Financial burdens of childhood vaccination for families have been reduced by the Vaccines for Children (VFC) Program.[59] Under VFC, the federal government purchases vaccines and collaborates with state and local health departments to distribute them to public and private health care providers at no cost. The vaccines may be administered to children 0-18 years who are covered by Medicaid or are uninsured, underinsured, or American Indian/Alaska Native.

{Note that VFC vaccines may be administered to underinsured children only in Federally Qualified Health Centers (FQHCs) or at providers delegated by FQHCs. Some jurisdictions, such as NYC, purchase vaccines for underinsured children with other federal funding to distribute to all providers participating in VFC so that underinsured children may be vaccinated in their medical homes.} Vaccines purchased with state funds are also distributed through VFC to providers to vaccinate children covered by State Child Health Insurance Programs.[59] Financial barriers to vaccination for NYC children were further reduced by enactment of a New York State law requiring health insurance policies written in New York State to cover all vaccines recommended by the Advisory Council on Immunization Practices for children 0-18 years of age.[60]

Further improvements in access to vaccines are needed to help reduce the considerable effort required of parents to have their children vaccinated. For example, expanding school-located vaccination programs and school-based health centers may remove the need for parents to take off from work to bring school-aged children to a health care provider. Allowing children to be vaccinated at pharmacies would also ease the burden on parents since pharmacies may be conveniently located and open on nights and weekends. Expanding access should be accompanied by support of integrated public health immunization information systems, such as the NYC DOHMH Citywide Immunization Registry. These systems create a longitudinal record of an individual's vaccination history by collecting reports of vaccines administered by different providers over time. They offer primary care providers, schools, parents, and individuals access to vaccination histories so individuals may obtain needed vaccines and avoid over-immunizaton.[61]

5. Are childhood vaccine mandates implemented fairly? Vaccine requirements may be considered fair in that they apply to all children attending childcare, prekindergarten, and school in a particular jurisdiction. Enforcement may be inconsistent across overburdened health departments, childcare programs, prekindergarten programs, and schools, however.[62] These entities should strive to implement enforcement fairly and consistently, although this may necessitate the investment of more resources which may not be available.

In the case of the NYC childcare influenza vaccine mandate, the parents who brought the lawsuit against the mandate argued that the mandate was unfair because it applied only to children in NYC and not to all children in New York State. While this position may seem valid, it ignores the fact that NYC is a different environment than most of the rest of New York State. NYC is more densely populated, and many NYC residents may come into contact with other people frequently and closely by using public transportation to travel around the city. NYC residents, therefore, may be more susceptible to diseases such as influenza which are spread by casual contact. In other parts of the state, people may more easily travel in their own cars, separate from other people. Consequently, residents of New York State outside of NYC, particularly those living in suburban and rural areas, may be less vulnerable to disease transmission. In January, 2017, the Centers for Disease Control and Prevention reported that influenza cases were rising dramatically in US coastal cities, and that NYC, in particular, was seeing steep increases in influenza activity.[63]

6. How can benefits and burdens of childhood vaccine mandates be fairly balanced? Public health leaders and bioethicists call for balance and restraint in enacting vaccine mandates. They propose that the highest priority should be for vaccines protecting against serious diseases transmitted through casual contact.[16, 41] This approach favors mandating influenza vaccine, for

example, but would not support a mandate for human papillomavirus vaccine (HPV) which protects against a sexually transmitted disease.

Childhood vaccine mandates are enacted by democratically elected state lawmakers or appointed municipal authorities such as state health officials or the NYC Board of Health. Community involvement in the decision-making of these bodies can take place through public hearings and written comment periods. Parents and other concerned individuals from the public should be encouraged to participate. Based upon personal observations while attending NYC Board of Health meetings, public participation appears to be very low. Public notices of hearings and comment periods are posted on the NYC DOHMH Web site, but interested members of the public may not be aware of them. To encourage more public participation, notices should be published more widely in media with a large readership such as local newspapers and the free press.

Conclusion. The above analysis supports the conclusion that childhood vaccine mandates for school entry, which effectively protect communities against serious diseases,[16-17, 62, 64] are ethical when enacted through a democratic process, are fairly enforced, and allow for legitimate exemptions. Vaccine mandates for childcare may be less justifiable, however, because some studies cast doubt on their impact on raising vaccination rates.[20-21] More research is needed to determine whether the benefits of vaccine mandates for childcare outweigh the burdens.

Alternatives to Vaccine Mandates: Theory-Informed and Evidence-Based Interventions

Vaccine mandates should be used sparingly to avoid anti-vaccination outcry and action.[42] As seen when Texas governor Rick Perry issued an executive order in 2007 for HPV vaccine for girls entering middle school, mandates can touch off a major backlash that distracts from the important benefits of vaccines.[65-66] Alternatives to mandates are needed to increase vaccine

acceptance and avoid backlash. Health behavior theory and evidence-based recommendations may be powerful tools for understanding vaccination behavior and crafting interventions to increase vaccination rates.[67-70] Evidence-based recommendations for increasing vaccination rates, issued by the Task Force on Community Preventive Services, offer guidance on interventions found to be effective based on systematic reviews of the literature.[71-72]

Health Behavior Theories. Several theories of health behavior have been used to inform studies of vaccination behavior and to develop interventions aimed at promoting vaccination. These include the Health Belief Model, the Theory of Planned Behavior, and the Theory of Reasoned Action,[73-92] which are among the theories most widely used in public health.[67-69, 92-93] They focus on individuals and are concerned with the relationship between perceptions or intentions and health behaviors.[67-68, 92-93] Some argue that these theories have very similar constructs and differ primarily in their use of terminology.[92] Support for each of these theories may be found in literature reviews and meta-analyses; no one theory has been shown to be best at explaining health behavior.[67, 92] In the following paragraphs, the Health Belief Model, Ecological Models, Social Marketing, and Nudge Theory are briefly described along with examples of their application to vaccination.

Health Belief Model. The Health Belief Model (HBM) has emerged as possibly best suited to understanding why people use (or don't use) preventive services such as vaccination.[92] Studies have repeatedly demonstrated the ability of HBM constructs to predict vaccination behavior among both adults and parents on behalf of their children and adolescents.[73-87]

The HBM was developed in the 1950s as a conceptual framework to explain individuals' failure to participate in preventive services offered by public health departments.[67-68, 76, 83] One of

its first applications was to understand barriers to polio vaccination.[92] According to the HBM, individuals will (or will not) take recommended action to avoid a disease based on whether they perceive themselves (or their children) to be personally at risk for it, that the disease may be severe, and that the expected benefits of taking the action outweigh the costs or other barriers to performing the action.[79-80] The HBM's core constructs are perceived susceptibility, perceived severity, perceived benefits, perceived barriers, cues to action, and self-efficacy. The last construct was added after the model was initially developed.[67-68]

A recent example of the use of the HBM was a study of over 11,000 parents of children aged 24-35 months using data from the Centers for Disease Control and Prevention (CDC) National Immunization Survey.[80] This study found that HBM constructs successfully predicted vaccine acceptance. Parents who refused or delayed vaccines for their child were less likely to believe their child was susceptible to vaccine-preventable diseases or that the diseases were severe enough to warrant vaccination. These parents were also less likely to believe in the benefits of vaccines, i.e., that vaccines are effective at preventing diseases, or that vaccines are safe.[80] Vaccine safety concerns, fueled by unfounded claims of a link between vaccines and autism, have become a barrier to childhood vaccination.[94-96]

Although clearly useful, the HBM has several limitations. The model's predictive value has been proven, but the effectiveness of HBM-informed interventions is not well understood and needs further study.[67] The HBM does not provide guidance on how to change people's perceptions to increase acceptance of preventive services such as vaccination.[73] Constructs of the model can be difficult to measure in cross-sectional studies when temporality cannot be determined.[67, 75] For example, an inverse relationship between perceived susceptibility and vaccine acceptance may be due to vaccinated individuals perceiving themselves to be at low risk

for disease because they are already vaccinated.[67] Most importantly, as a model focusing on individuals, the HBM does not address the physical and social environments in which health behaviors are performed. Interventions aimed at changing individual behavior, without also reducing economic, physical, or social barriers, are less likely to succeed.[67, 93, 97-98]

Ecological Models. Limited impact of individual behavior interventions has shifted the focus of researchers and practitioners to ecological models.[97,99-100] Ecological theory is based on the premise that health results from a dynamic interplay between the demographic characteristics of individuals, with socioeconomic status being among the most important, and the individual's social and physical environment comprising his or her ecosystem.[100] Ecological models call for intervening at multiple levels beyond the individual to the group, organization, community, and policy.[93, 99-100] A recent study of influenza vaccination during the 2009 H1N1 influenza pandemic found that factors at the intrapersonal, interpersonal, institutional, and community levels each predicted vaccine acceptance, offering support for targeting multiple levels as a more effective approach than intervening at only one level.[87]

Limitations of ecological models are that they tend to be complicated and expensive. Further, researchers may find it difficult to tease out which aspects of the model produce the desired results.[99]

Social Marketing. The use of social marketing media campaigns, a community level intervention, is being promoted by CDC to increase vaccination rates.[72, 101] Immunization programs in several US states and other localities are using social marketing to promote influenza and human papillomavirus (HPV) vaccines, in particular.[101-102] Increasing uptake of HPV vaccine is a current CDC priority since series completion among adolescents remains

suboptimal. NYC's rate measured as of March 31, 2017 for the 3 recommended doses of HPV for 13-17 year-old females was 58.7%, [103] below the Healthy People 2020 goal of 80%.[104] (Note that the Healthy People 2020 goal of 80% is for females aged 13-15 years for 3 doses of HPV vaccine [104]). The Advisory Committee on Immunization Practices recently approved a 2-dose schedule for adolescents receiving the first dose before age 15 years, and with an interval of 5 months or longer between the first and second dose.[105] Completion rates are expected to improve with the new schedule.

Social marketing applies commercial marketing concepts to persuade individuals to perform a recommended action for the benefit of the individual as well as the broader community or society.[101-102] Social marketing campaigns seek to increase social acceptability of a recommended behavior.[68] A key component of these campaigns is to target audiences which have been segmented based on demographic characteristics, culture, environments and other factors. Social marketing campaigns are based on the four "Ps": Product, Price, Place, and Promotion.[100-101, 106] Nowak and colleagues applied the four "Ps" to vaccination: (1) product is the behavior of accepting vaccination; (2) price is the financial cost of vaccine, the investment in time and effort to get vaccinated, perceptions of vaccine safety and efficacy, and the social value of adhering to a perceived community norm or the social costs of noncompliance; (3) place is the setting for vaccine delivery, such as a physician's office, school, or retail pharmacy, which may or may not offer convenient access to vaccines; and (4) promotion is the relaying of messages to encourage vaccination, often emphasizing personal stories that resonate with people's emotions.[101]

Storey and colleagues (2008) point out that health behavior theories are commonly used to guide the planning and evaluation of social marketing interventions. As examples, they cite the

following theories: (1) Integrated Model of Behavioral Prediction, which is mainly concerned with cognitive or rational processes related to decision-making; (2) the extended parallel processing model, which focuses on the effect of emotion on behavior and is often referred to as fear management theory; (3) social learning theory, which posits that people learn behaviors by observing others; and (4) diffusion of innovations, which focuses on dissemination of information within a social environment and its impact on adoption of new behaviors.[106] The HBM and Theory of Planned Behavior may also be used to inform social marketing programs.[102]

Lessons learned from the application of social marketing to changing behaviors such as tobacco use suggest that social marketing may be a promising strategy to increase vaccine acceptance.[101] A limitation of social marketing may be the financial resources typically needed to support large-scale campaigns. Such an investment may be beyond the means of many immunization programs.[101]

Nudge. The Nudge Theory, developed by behavioral economists Thaler and Sunstein (2008), may also be applied to the challenge of increasing vaccine acceptance.[107] This theory, grounded in behavioral science research, posits that people can be influenced or "nudged "to make the best decisions about their health and welfare by "choice architecture." Governments may use choice architecture to steer people toward adopting healthy behaviors by making small changes in interventions to reduce barriers or leverage people's desires to conform to social norms or follow the path of least resistance. An example pertaining to vaccination involved a lecture given to Yale University seniors about the risks of tetanus and the benefits of vaccination against tetanus.[107] Following the lecture, most students reported they were persuaded of the importance of vaccination and planned to go to the student health center to get the vaccine. Only 3% actually did so, however. A different group of seniors was given the same lecture, but these students were

also given a campus map with the location of the health center circled and were asked to look over their weekly schedules to plan a time get the vaccine. Of this group, 28% got vaccinated. Both groups were likely to have known where the health center was, since they were seniors, but small changes to allow them to see the health center on the map and think about the quickest and easiest way to get there, and to plan when to fit the vaccination into their schedules, were associated with a nine-fold increase in students getting vaccinated.[107]

Public health would benefit from wider application of theories such as the HBM, social marketing, and Nudge. However, public health practitioners often lack exposure to theory, are preoccupied with practical concerns, [67, 92-93] and may not have the time or resources to test and apply theory. More work is needed to make theory accessible to practitioners and encourage its use.[92-93]

Evidence-Based Recommendations to Increase Vaccination Rates

An additional source of guidance for improving vaccination rates in the absence of mandates is the list of evidence-based recommendations issued by the US Task Force on Community Preventive Services. These recommendations are based on results of a systematic review of the literature on population-based interventions aimed at improving vaccination rates. Studies reviewed include those which were, and were not, informed by health behavior theories. Recommendations focus on three major categories of interventions: (1) increasing community demand for vaccinations; (2) enhancing access to vaccinations; and 3) provider-based interventions.[71-72, 108-109] Since these recommendations together target multiple levels, including the individual, group, organization, community, and policy, they may be thought of as an ecological model for increasing vaccination rates.

An example of a recommended intervention to increase demand would be community-wide education combined with sending patient or provider reminder notices as a cue to action for vaccination. One example of enhancing access would be reducing administrative barriers in clinics by offering walk-in vaccination and expanding clinic hours to evenings and weekends. An example of a provider-based intervention would be a physician issuing standing orders to allow nurses to vaccinate patients by protocol without the need for a physician to be present.[71-72]

The Task Force cautions that although evidence demonstrates the effectiveness of recommended interventions, they may not fit every population or context. Practitioners are urged to tailor interventions to local conditions and use multiple, complementary interventions.[71-72] Use of tailored interventions is strongly supported by other researchers [93, 108-109] along with involving staff members and clients in the planning and implementation of interventions.[69, 93, 108]

Vaccine mandates remain one of the most widely used evidence-based interventions to increase vaccination rates and prevent disease. In the following sections, the rationale for NYC's childcare influenza vaccine mandate is examined as well as the mandate's impact on vaccination rates among NYC children 6-59 months of age.

Section 3: Methodology

Study Design: Convergent Mixed-Methods

The two aims of this dissertation guided a mixed methods explanatory study of the rationale, impact, and ethics of the NYC childcare influenza vaccine mandate. The study followed a convergent mixed methods research design in which qualitative and quantitative methods were used complementarily.[110] Findings from each method were analyzed independently and then integrated in the discussion and conclusion sections of the dissertation. A mixed methods approach was ideally suited to examining the mandate's context, i.e., why the mandate was enacted, as well as the mandate's content, [110] i.e., the impact of the mandate on influenza vaccination coverage rates among NYC 6-59-month-olds.

Aim 1: Single-Case Study with Record Review. Qualitative methods, specifically a single-case study with record review, [111] were used to achieve Aim 1. The single-case design was selected because the NYC mandate is unusual in that it was enacted and implemented by a city instead of a state and NYC is the only such jurisdiction to do so to date.

Aim 2: Short Interrupted Time-Series. Quantitative methods, specifically a short interrupted time-series, were used to achieve Aim 2. The interrupted time-series is considered one of the strongest quasi-experimental research designs.[112] In this design, data are collected and analyzed at regularly spaced intervals over time before and after the introduction of an intervention to determine whether the intervention produced effects greater than underlying secular trends. The interrupted time-series may be considered an effective alternative to an experimental design when random assignment of the study population to an intervention versus a control condition is not feasible.[112] A special type of time-series, the interrupted time-series is

used to assess the effects of an intervention occurring at a specific point in time on a dependent variable of interest. Interrupted time-series studies have been widely used to examine the impact of policy changes on the health behaviors and outcomes of targeted populations.[112-127] Hence, this design was appropriately suited to an investigation of the effect of the NYC childcare influenza vaccine mandate on influenza vaccination rates among NYC 6-59 month olds.

A limitation of interrupted time series studies is that a minimum of 8 time points before and 8 points after the intervention are needed to assess changes statistically.[128] In general, 12 time points before and 12 points after the intervention are recommended for a statistical analysis using segmented regression.[129] More data points over a longer period of time better inform an assessment of secular trends before an intervention and the duration of effects following an intervention.[112]

This study was a short time series because it included fewer data points: 8 before the mandate, 2 during the mandate, and 1 after the mandate's suspension. Although less rigorous than a longer time series, the short time series may still support causal inference.[112] The use of 8 pre-intervention data points reduced threats to internal validity compared to a design relying on only 1 or 2 pre-intervention data points. This study was also strengthened by the use of a control group: children 5-8 years of age who are recommended to receive annual influenza vaccination but were not directly affected by the childcare mandate. A limitation was that the number of data points in the time series was not sufficient for a statistical analysis using segmented regression. The chi-square test was used to assess the statistical significance of differences in vaccination rates in age groups before and during the mandate. Limitations were encountered in the use of the chi-square test. (See Limitations section).

There were several reasons for the short time series. First, the NYC DOHMH's goal for the mandate was to raise influenza vaccination rates among children 6-59 months of age in each annual influenza season (July 1 - June 30). Vaccination rates are measured by the NYC DOHMH two times each season: at the mid-point on December 31, and at the end of the season on June 30. These measurement intervals allowed for a maximum of 2 data points per annual season. The vaccination rate as of December 31 in each season was chosen as the outcome or dependent variable because: 1) the mandate required a child to receive vaccine by December 31 of each season; and 2) the mandate was suspended on December 16, 2015, [8-9] close to December 31 of the second season following enactment of the mandate.

The first data point for the pre-mandate period was December 31 in the 2006-07 season. Influenza vaccine was recommended for all 6-59-month-olds starting with that season. (Influenza vaccine was recommended for 6-23-month-olds in the 2004-05 season, [130] but the recommendation for the full age range of 6-59-month-olds began in 2006-07. [131]) In 2008-09, the recommendation was expanded further to include all children 6 months through 18 years of age.[132] The season immediately before the NYC childcare influenza vaccine mandate took effect was 2013-14, allowing for a pre-mandate examination of the influenza vaccination rate as of December 31 from 2006-07 to 2013-14, a total of 8 annual seasons. The mandate was enacted in January, 2014, and began July 1 of the 2014-15 season. It was then suspended near the mid-point of its second season (2015-16), on December 16, 2015.[8-9] Thus, vaccination rates as of December 31 in two seasons while the mandate was in effect were available for examination. One data point, December 31, 2016, allowed for examination of vaccination rates at the mid-point of one season after the mandate was suspended.

Data Sources

Aim 1: Records. The data sources included in the review of records for the single-case study included a NYC DOHMH briefing, presentations by NYC DOHMH and the states of Connecticut and New Jersey, NYC Board of Health documents, public comments to the NYC Board of Health, information on the Web sites of NYC DOHMH and other states, a published study of the impact of Connecticut's childcare influenza vaccine mandate, and other literature reviewed by NYC DOHMH on influenza disease burden, the safety and effectiveness of influenza vaccines, and other topics. Court case arguments and rulings were also examined. These sources were reviewed over the timeframe leading up to the NYC mandate's enactment, from approximately 2012 through January 2014, as well as afterwards, from February 2014 to date. Literature on influenza disease burden and influenza vaccine safety and effectiveness primarily included papers published from the year 2000 and later. The results of the quantitative study conducted for Aim 2 was also a data source for the single-case study.

Aim 2: The NYC Citywide Immunization Registry. The data source for the quantitative study conducted for Aim 2 was the Citywide Immunization Registry, which is the NYC DOHMH's immunization information system (IIS). The main purposes of an IIS are to collect and consolidate reports of vaccinations administered to individuals by all health care providers in a jurisdiction and share these records with other health care providers, health plans, schools, parents, and individuals to promote increased vaccination coverage rates. Operated by public health departments in 49 of 50 states, 5 cities, and the District of Columbia, IISs are supported by funding from the Centers for Disease Control and Prevention (CDC), states, and local governments.[133]

The Citywide Immunization Registry started citywide in 1997 after the NYC Board of Health amended the NYC Health Code to require health care providers to report all vaccinations administered to children in NYC to the DOHMH.[134] (A law was enacted by New York State in 2006 requiring reporting of childhood immunizations statewide.[135]) The Citywide Immunization Registry currently receives reporting of an estimated 90% of vaccinations administered to NYC children 0 - 18 years of age.[103] All children born in NYC are enrolled in the Citywide Immunization Registry via a file upload of birth certificate data from the DOHMH Office of Vital Records twice weekly. Children born outside of NYC but living in NYC are enrolled in the Citywide Immunization Registry when they are vaccinated in NYC and a provider reports the vaccination. The Office of Vital Records also provides the Citywide Immunization Registry with updates on deaths and adoptions.[103]

Currently, most vaccinations are reported by health care providers who document vaccinations in their electronic health record (EHR) system which automatically sends the information in real-time to the Citywide Immunization Registry based on national Health Level 7 (HL7) messaging standards.[136-137] The Citywide Immunization Registry database includes a range of patient and provider demographic variables and detailed vaccination data. Citywide Immunization Registry data have been used in many published studies to examine vaccine uptake and effectiveness, provider immunization practices, methods to improve vaccine safety, and interventions to increase accountability for publicly purchased vaccines distributed to health care providers through the federal Vaccines for Children program.[138-141] The Citywide Immunization Registry, as an administrative data source, had limitations for this study. (See Limitations section.)

Variable Definitions

Aim 1: Themes and Framework Concepts. The variables in Aim 1 were the themes identified from record review using a grounded theory approach, [142] as well as the concepts included in the Kass[23] and Field and Caplan[24] frameworks. For the Kass framework, these included the six questions related to the goals of a public health intervention as they applied to the NYC childcare influenza vaccine mandate. Specifically, the six questions informed an examination of the mandate's effectiveness in achieving its goals, benefits and burdens, potential alternatives, and capacity to be implemented fairly.[23] Application of the Field and Caplan framework focused on the competing ethical values of parental autonomy and the NYC DOHMH obligation for beneficence, utilitarianism, justice, and nonmaleficence.[24]

Aim 2: Dependent Variable: Influenza Vaccination Rates over Time. The dependent variable for Aim 2 was influenza vaccination rates among children 6-59 months and 5-8 years of age as of December 31 in each annual influenza season from 2006-7 through 2016-17. This variable was calculated by the number of children in the age group who had one or more doses of seasonal influenza vaccine administered during July 1 through December 31 in each annual influenza season documented in the Citywide Immunization Registry (numerator) divided by the US Census Bureau Vintage 2016 population estimate for the age group (denominator).[143] (Note that the US Census Bureau vintage population estimates take into account annual population change based on data for births, deaths, and domestic and international migration. These data are used to update the estimates from the most recent decennial census. The vintage estimates have been shown to be very accurate. The average absolute difference between the final total resident population estimates from 2000 to 2010 and the 2010 Census counts was approximately 3.1 percent for all counties.[144])

Some children, based on age and history of influenza vaccination, are recommended to receive two doses of influenza vaccine in a season for full protection against the disease.[132] The NYC childcare mandate required only one dose, however. Monovalent H1N1 influenza vaccine doses administered to children during the H1N1 pandemic in 2009-10 were excluded.

Aim 2: Independent (Exposure) Variable: **The NYC Childcare Influenza Vaccine Mandate**. Influenza vaccination rates as of December 31 in each annual influenza season before the mandate, from 2006-7 through 2013-14, while the mandate was in effect, from 2014-15 through 2015-16, and after the mandate was suspended, 2016-17, were examined. The mandate required children 6-59 months of age attending NYC-regulated childcare programs and public school prekindergarten to receive 1 dose of influenza vaccine during the period of July 1 through December 31 of each annual influenza season. In the first season of the mandate (2014-15), education was the only mode of enforcement for childcare programs and public school prekindergarten. In the second season (2015-16), starting January 1, 2016, operators of childcare programs were subject to fines for failing to exclude children without a documented dose of influenza vaccine.[1, 8-10] Public school prekindergarten programs were not subject to fines, and the NYC Department of Education (DOE) decided against requiring principals to exclude unvaccinated children. DOE staff did inform parents of public school prekindergarten students that influenza vaccine was required. Fines against childcare program operators and exclusion of children attending childcare programs never took place, however, because the mandate was suspended December 16, 2015, approximately 2 weeks before these enforcement measures would have begun.[8-9] The impending threat of these measures was in effect from July 1, 2015, through December 16, 2015, however.

Aim 2: Study Population. Children included in the Aim 2 study were 6-59 months or 5-8 years of age for each entire annual influenza season. Children who would have aged in or out of the age groups during the season were excluded. This method of selecting the population for studies of influenza vaccination rates by age group, called the period of time assessment – not allowing aging in or out method, is used by researchers at the Centers for Disease Control and Prevention and recommended by the American Immunization Registry Association.[145-146] Using this method, all children included have the same opportunity to be vaccinated during the annual influenza season.[145-146] In addition, the children 6-59 months of age in this study were subjected to the mandate for the entire time it was in effect. The age groups are defined by a date of birth range in this method.[145-146] For example, in this study, children aged 6-59 months during the 2016-17 annual influenza season were born during 7/1/2012 to 1/1/2016.

Excluded from the study population were: 1) children living outside NYC, defined as those children whose most recent address in the Citywide Immunization Registry included a zip code outside of NYC; 2) children for whom a provider indicated that they had moved out of NYC; and 3) children known to be deceased based on a vital record indicator or report from a provider.

The 6-59-month-olds were the intervention group because they were specifically covered by the mandate. A limitation of this study was that it was not possible to identify which individual 6-59 month-old children were attending childcare and prekindergarten. (See Limitations section.) The 5-8-year-olds were selected as a non-equivalent control group because the Advisory Committee on Immunization Practices also recommends that they receive annual influenza vaccination[132] but they were not directly affected by the mandate. Since the children in both age groups lived in NYC, they would have been affected similarly by history, maturation, and other contextual factors apart from the mandate which may have influenced vaccination rates.

Data Analysis

Aim 1: Use of Grounded Theory and Application of Conceptual Frameworks

Data gleaned from record review was analyzed using a grounded theory approach.[142] Concepts and themes were identified and coded for analysis using a manual system. The findings from record review were integrated with those of the Aim 2 quantitative analysis in the discussion and conclusion sections of this dissertation. The Kass[23] and Field and Caplan[24] frameworks were applied for an ethical analysis of the mandate. The second question in the application of the Kass framework, pertaining to how effective the mandate was in achieving its public health goal, was informed by the findings from the Aim 2 quantitative study.

Aim 2: Vaccination Rate Trends

Influenza vaccination rates as of December 31 each season among the intervention group of 6-59-month-olds were examined and compared to those of the control group of 5-8-year-olds from the 2006-7 influenza season through the 2016-17 season. Rates were calculated based on the number of children with $\geq$ 1 influenza vaccination documented in the Citywide Immunization Registry as of April 20, 2017 for all children in the age groups in all influenza seasons divided by the Census Vintage 2016 population estimates for the age group in the corresponding year. The date of April 20, 2017 was selected to allow ample time for vaccinations administered during July 1 - December 31, 2016 to be reported to the Citywide Immunization Registry. Reporting to the Citywide Immunization Registry is timely. A recent analysis found that of all vaccinations administered to children 0-18 years of age in 2016 and reported to the Citywide Immunization Registry, 96% were reported within $\leq$ 30 days of date of administration.[147]

A stratified analysis of influenza vaccination rates by one-year age groups was conducted among the aggregate groups of 6-59-month-olds and 5-8-year-olds. Children were assigned to a one-year age group based on age as of December 31 each season. Children in the stratified 6-59-month-old group were 1, 2, 3, and 4-4.5 years. The 5-8-year-olds were 5.5 to <6 years, 6, 7, and 8-8.5 years. As mentioned earlier, the chi-square test was conducted to assess the statistical significance of differences in vaccination rates between different (independent) age groups before and during the mandate. Limitations were encountered with the test. (See Limitations section.)

The purpose of all analyses was to determine whether the mandate was associated with an increase in influenza vaccination rates among 6-59-month-olds, and the subgroups of 1, 2, 3 and 4-year-olds, above the secular tend in response to the mandate and whether vaccination rates may have declined due to the mandate's suspension. SAS version 9.4 (SAS Institute, Inc.) and Microsoft Excel 2013 (Microsoft Corp.) were used for analyses.

Section 4: Results

Aim 1 Findings: Themes Identified

Experience in Connecticut and New Jersey. NYC DOHMH's interest in pursuing a mandate for influenza vaccination of children attending childcare began in June 2012 when the Health Commissioner was briefed by a colleague from Connecticut on data following that state's mandate.[148] In 2010, Connecticut became the second state in the US (after New Jersey) to implement a childcare influenza vaccine mandate and was seeing evidence of a rise in vaccination rates and a reduction in influenza-associated hospitalization rates among children ≤ 4 years post-mandate. Connecticut is one of the CDC's 11 Emerging Infections Program (EIP) surveillance sites and evaluates influenza-associated hospitalization rates annually.[2]

The Connecticut mandate required all children 6-59 months of age attending licensed childcare and preschool to receive at least 1 dose of influenza vaccine by January 1 each year. (Connecticut originally required children 6-59 months of age who had not received influenza vaccine in a previous season to receive 2 doses, as recommended by the Advisory Council on Immunization Practices.[13] Connecticut later determined it was not feasible to enforce a 2-dose requirement, however, because it was too difficult for childcare personnel to identify which children needed 2 doses.[149-150])

The impact of Connecticut's mandate on influenza vaccination rates was seen in a comparison of data from the National 2009 H1N1 Flu Survey for 2009-10 and the National Immunization Survey-Influenza (NIS-Flu) for 2011-12. Among all Connecticut children 6-59 months of age, rates increased from 67.8% (95% confidence interval [CI] = 61.1% - 74.5%) in 2009-10, [2] the season before the mandate, to 83.9% (CI = 77.5% - 90.3%) in 2010-11, the first season of the

mandate. EIP data was showing a sharp decline in the influenza-associated hospitalization rate among 0-4-year-olds in the 2010-11 and 2011-12 seasons.[148] (Connecticut later published an analysis of EIP data showing the rate of influenza-associated hospitalizations among Connecticut children ≤ 4 years declined 12% when comparing 2007-08 to 2012-13, two severe seasons with the same predominant circulating strain of influenza virus. This was the largest percentage decrease among all 11 EIP sites.[2])

The Connecticut data prompted the NYC Health Commissioner to direct the DOHMH Bureau of Immunization to research the possibility of a childcare influenza vaccine mandate in NYC. An early step was to invite an epidemiologist from the Connecticut Department of Public Health to speak at the Bureau of Immunization's quarterly childhood coalition meeting in December 2012. The childhood coalition includes pediatricians and other immunization providers from the community, health plan representatives, DOHMH staff, and other immunization stakeholders.

In addition to presenting Connecticut's data on vaccination and hospitalization rates, the speaker described Connecticut's legal process for enacting the mandate.[149] Connecticut's Department of Public Health (DPH) added influenza vaccine to the list of vaccines required for childcare settings without a regulatory change. This was possible because immunization requirements for childcare are tied by state law to the standard of care, which is determined by the national Advisory Committee on Immunization Practices. This Committee recommended annual influenza vaccination for 6-23-month-olds in 2004 and expanded the recommendation to include 24-59-month-olds in 2006.[130-131] The Connecticut DPH is authorized to decide when to enforce a newly recommended vaccine. The decision is based on vaccine supply, established uptake (≥ 50% vaccination rate), provider acceptance, and vaccine safety.[151]

The Connecticut DPH needed to make a regulatory change to add the requirement for 24-59-month-olds attending school-based programs accredited by the state Department of Education. School immunization requirements are in state laws, thus requiring a regulatory change. Little opposition was voiced at public hearings. The DPH speculated this was likely because the hearings occurred soon after the 2009-10 H1N1 influenza pandemic and the public's perception of influenza as a potentially serious disease was still fresh. [151] Changing the regulation took an additional year, delaying the mandate's start for school-based preschool to 2011-12.[2,150-151]

The Connecticut DPH communicated the influenza vaccine requirement by sending notices to childcare and healthcare providers seven months in advance of the January 1 deadline. The DPH also held workshops with several large childcare programs the summer before the mandate started. The state Department of Education sent notices to the schools. Printed materials were posted to the DPH Web site. Childcare providers and schools were asked to notify parents and collect children's immunization records throughout September through December. School nurses, who were accustomed to checking immunization records once at the beginning of the school year, expressed concerned about the burden of continuous monitoring.[149-151]

As of January 1 each season, childcare providers and schools in Connecticut were required to exclude unvaccinated children. State childcare licensing employees, who were already conducting routine inspections and checking compliance with other vaccine requirements, were authorized to issue citations when children who had not received influenza vaccine were found in attendance. Timely monitoring of the new requirement was a challenge for the DPH because state immunization surveys completed by childcare programs and schools were due in the fall, months after influenza seasons ended in June. Consequently, collection of influenza vaccine data

was separated from the other vaccines and the influenza survey was moved to January of the current season.[149-151]

The Connecticut epidemiologist also described the public's response to the mandate. The DPH received an average of 10-15 telephone calls per day for 6-7 months after the mandate started.[150-151] Calls came from parents, childcare providers, and some physicians inquiring about influenza vaccine safety, effectiveness, access, and compliance with the new requirement. In retrospect, Connecticut staff realized it would have been helpful to send out posters to childcare programs and provide other educational materials for parents. Of considerable concern was that the DPH saw an increase in religious exemptions in response to the influenza vaccine requirement. A later analysis showed that religious exemptions specifically for influenza vaccine increased from 2.1% in 2010-11 to 3.8% in 2013-14.[150]

Despite the challenges, Coalition members found Connecticut's presentation to be a persuasive argument in favor of a mandate. Limitations of the data on vaccination rate increases and the decline in hospitalization rates were discussed by the Connecticut epidemiologist and coalition members, however. NIS-Flu data is based on unverified, parent self-report of child's vaccination status and has a small sample size. (Unlike NYC, Connecticut did not have immunization registry data to support a local analysis of vaccination rates.) Comparisons of influenza–associated hospitalization rates in different seasons must be interpreted with caution because circulating influenza strains and vaccine formulations change each season. Disease burden in different influenza seasons ranges from mild to severe, and the match between the vaccine and circulating influenza virus strains is good in some years and poor in others. Consequently, conclusions about the impact of vaccination rates on influenza-associated hospitalizations are difficult to draw. A further limitation was that influenza vaccination trends in

the pre-mandate period were not evaluated, leaving open the possibility that rate increases may have been at least partially due to an underlying secular trend.

The NYC DOHMH Bureau of Immunization also reached out to the New Jersey Department of Health. Through phone calls and materials sent, New Jersey shared that they first implemented a childcare influenza vaccine mandate in 2008-09. The policy required children 6-59 months of age attending licensed childcare or preschool to receive at least 1 dose of influenza vaccine between September 1 and December 31 each year. Immunization requirements for childcare and school were in state law, so enacting the mandate required a regulatory change and support of the state legislature. The process took two years to complete, from 2006 to 2008.[151-153]

The proposal for New Jersey's mandate was initially met with public pushback.[151, 152] Anti-vaccine groups organized a protest in the state capitol which led to media coverage.[152] Despite evidence to the contrary, parent activists claimed that influenza was not a serious disease, that the vaccine was not effective, and that the vaccine was harmful because it contained thimerosal, a preservative containing mercury. These parents also complained that too many vaccines were being mandated.[151, 153]

In response, the New Jersey State Vaccine Preventable Disease (VPD) Program held meetings throughout the state with school nurses, parent organizations, and childcare staff. State VPD staff developed educational materials for posting on Web sites and held conference calls and webinars to educate nurses and other medical professionals. State VPD staff also conducted outreach to professional organizations to build support, and worked collaboratively with the State Department of Education on implementation strategies.[152]

Anti-vaccine activists eventually challenged the mandate in the New Jersey Supreme Court. The mandate was upheld, but New Jersey state staff reported they lost public goodwill during the heated debates.[154] An additional setback was that the protest and debates led New Jersey state legislators to weaken requirements for religious exemptions to vaccines.[151-154] Religious exemptions increased among children attending preschool programs from 0.4% before the mandate (2007-08) to 2.0% after it (2011-12).[155]

New Jersey reported that estimating the vaccination rate among 6-59-month-olds before the mandate was a challenge. The state did not collect influenza vaccination data from childcare programs at that time and national surveys of influenza vaccination had not yet begun. However, the New Jersey Collaborative for Excellence in Public Health conducted a study which estimated the influenza vaccination rate among New Jersey children was 57% before the mandate.[154] Despite experiencing poor compliance with the mandate in its first season (2008-09), and needing to suspend the mandate in 2009-10 because of a seasonal influenza vaccine shortage related to the H1N1 pandemic, [152, 154] New Jersey achieved success in increasing vaccination rates quickly. In 2010-11, the influenza vaccination rate for New Jersey 6-59-month-olds reached 77.1% (CI = 70.3% - 83.9%), based on NIS-Flu data.[156]

Later results from NIS-Flu indicated that the post-mandate vaccination rate increases in New Jersey and Connecticut continued. In 2012-13, the rate among 6-59-month-olds in New Jersey rose to 88.0% (CI = 82.6 % - 93.4%), and Connecticut's rate increased slightly to 84.1% (CI = 78.2% - 90.0%).[2, 156] In alignment with the NIS-Flu estimates, Connecticut's state survey of childcare programs estimated that 87.1% of the 55,640 children aged 6-59 months enrolled in licensed childcare in 2012-13 had received $\geq$ 1 dose of influenza vaccine.[2] In contrast to the New Jersey and Connecticut rates, New York State's influenza vaccination rate in 2012-13 for 6-59-

month-olds was far lower at 70.2% (CI = 65.4% - 75.0%), according to NIS-Flu.[156] NYC estimates were not available; NIS-Flu began producing estimates of influenza vaccination rates for 6-59-month-olds in NYC in 2013-14. NYC's rate for 6-59-month-olds in 2013-14, the year before NYC's mandate, was 73.6% (CI = 67.0% - 80.2%).[156]

What Would Success Look Like? Informed by the experience in New Jersey and Connecticut, the NYC DOHMH Bureau of Immunization roughly estimated that a childcare influenza vaccine mandate in NYC had the potential to raise influenza vaccination rates among all NYC 6-59-month-olds by 4.6 percentage points. The Bureau calculated this estimate based upon the assumption that the vaccination rate for the approximately 89,307 children 6-59 months of age attending city-regulated private childcare and preschool in 2012-13 would rise in response to the mandate from approximately 60% (53,584/89,307) to 84%, (75,018/89,307), resulting in an additional 21,434 children receiving vaccine. This would produce an increase in the proportion of all NYC 6-59- month-olds vaccinated against influenza annually from 60% (279,000/465,000) to 64.6% (300,434/465,000). (Note that different methods and census denominators were used for these vaccination rate estimates than those used in the Aim 2 analysis.)

The approximately 22,014 children in public school pre-kindergarten in NYC in 2012-13 [4] were not included in the estimate because the NYC DOHMH was not able to enforce the mandate in public schools in the same way as it could for childcare. In city-regulated childcare, the NYC DOHMH Bureau of Child Care conducts inspections and issues violations against operators for failing to exclude unvaccinated children. Violations could result in fines ranging from $200 to $2,000.[10] NYC DOHMH does not issue violations against public schools, and the NYC Department of Education (DOE) decided against excluding noncompliant children. (Note

that the NYC DOE would have been required to exclude noncompliant children had the influenza vaccine requirement been included in state law in addition to the NYC Health Code.)

The Basic Rationale. The Bureau conducted an extensive literature search, and combined the findings with information gathered from New Jersey and Connecticut, to prepare a briefing document for the Commissioner.[154] The document covered: a) disease contagiousness; b) health and economic burden of disease; c) vaccine safety, effectiveness, and availability; d) vaccine uptake; e) potential for producing herd immunity; f) methods for monitoring and enforcement; g) compliance with other current immunization requirements; h) legal issues; and i) potential for public backlash.

The NYC Health Commissioner and other DOHMH leaders used the briefing document to inform deliberations for seeking the mandate. Over the course of nearly one year, from mid-year, 2012, to spring, 2013, the DOHMH leadership reached the decision to proceed. The Commissioner presented the proposal for the mandate to the Mayor in March, 2013.[157] The NYC Mayor, Michael Bloomberg, was well known to be a strong supporter of public health. Shortly thereafter, in September, 2013, the Assistant Commissioner of the Bureau of Immunization presented the proposal to the NYC Board of Health.[158] The following is a summary of information considered by the DOHMH leadership in making their decision.

a) <u>Contagious of disease</u>. Influenza is a highly contagious disease transmitted by respiratory droplets from coughing and sneezing.[12] Childcare programs and schools are congregate settings in which the spread of infectious diseases such as influenza occurs easily.[14, 158-159] In these settings, a large number of people are brought together increasing the chances of an infected person coming into contact with an uninfected person.[158] Children exhibit poor respiratory hygiene, facilitating rapid spread of the virus. Keeping children home when they are sick does

not prevent disease transmission because individuals are typically infectious before symptoms begin.[158, 160] Attack rates for influenza among children younger than 5 years of age have been found to range from 35% to 45%.[161] Moreover, children are a major source of influenza transmission within communities. Compared to adults, children shed larger amounts of influenza virus for longer periods of time.[14, 158, 162]

The risk of acquiring influenza often starts to increase in October, highlighting the need for vaccination early in the annual influenza season. Reported cases of influenza usually peak between December and February, although influenza activity may continue into May.[163]

b) <u>Health and economic burden</u>. Among the general population in the US, influenza is associated with an average of over 200,000 hospitalizations each year.[12] Influenza-associated deaths range from 3,000 to 49,000 annually, depending on the types of influenza viruses circulating during the season.[12, 15] The majority of influenza-related deaths occur among people age 65 years and older,[12] but an average of 92 children <5 years die of influenza-associated causes each year in the US.[164] Pediatric deaths ranged from 35 to 282 annually over four seasons from 2009-10 to 2013-14. Of the children who died, 40% had no recognized chronic health condition and 90% had not received influenza vaccine.[158] Children 0-4 years of age make up 6% of the US population but account for 10-18% of influenza associated hospitalizations.[158] Estimates are that one influenza case in a child younger than 5 years results in out-of-pocket costs of $52- $178 and loss of parent wages ranging from $222 to $1,456. For every 100 children with influenza, an estimated 195 parent work days are lost.[158, 165]

c) <u>Vaccine safety, effectiveness, and availability</u>. Vaccination has been shown to reduce the risk of a medical visit for influenza by 56% among healthy children 6 months - 5 years of age.[166]

Annual influenza vaccination is necessary because immunity following vaccination may be less than one year due to waning vaccine-induced antibodies and because influenza viruses often change each year. Influenza vaccine effectiveness varies each year depending on the match between the virus strains in the vaccine produced and the circulating strains that year.[12] In children younger than 6 years, influenza vaccine efficacy has ranged from 59% to 82% while vaccine effectiveness ranged from 25% to 36%.[154, 167] Studies have shown that influenza vaccines are effective in children older than 2 years but less beneficial in 6-24-month-olds.[154, 167] Injectable and nasal spray influenza vaccines were available for use in children, and both had good safety records. Before 2015, the nasal spray vaccine was found to be more effective at preventing influenza in children.[154] (In the 2015-16 and 2016-17 seasons, the Centers for Disease Control and Prevention recommended against use of the nasal spray because studies indicated it had been ineffective in recent seasons.[160, 163]) Influenza vaccines have been available in sufficient supply, and early in the season, for the 6-59 month-old age group in recent years.

d) <u>Vaccine uptake</u>. Influenza vaccination rates among NYC 6-59-month-olds had increased from approximately 47% in 2008-09, when it was routinely recommended for the full age group, to about 60% in 2011-12, according to the NYC DOHMH Citywide Immunization Registry.[103] The progress made signaled acceptance of the vaccine by many parents and health care providers. More than one-third of children younger than 5 years remained unvaccinated, however.[103, 154]

e) <u>Potential for producing herd immunity</u>. Several major studies have indicated that vaccinating children produces herd immunity and interrupts community transmission of influenza.[154, 162, 168-171] One example was from Tecumseh, Michigan, in which 85% of school-aged children were vaccinated against influenza before the 1968-69 influenza epidemic. The rate

of influenza-associated illness was 67% lower in Tecumseh compared to a neighboring town which had not vaccinated its children.[168] Research using modeling techniques has suggested that influenza vaccination coverage of just 20% among schoolchildren reduces overall mortality in adults aged 64 years and older more effectively than a vaccination rate of 90% for older adults.[170] Children's immune systems respond better to influenza vaccine than those of elderly people, so vaccinating children may be the best approach to protecting those most vulnerable to influenza-associated complications and death.[170]

A limitation of the research on herd immunity was that it was mostly conducted among school-aged children.[154] Few studies have examined the impact of vaccinating younger children on preventing community transmission of influenza. One study found that vaccinating children in childcare against influenza was associated with a 42% reduction in febrile respiratory illness among unvaccinated household contacts, but the study was limited by a small sample size.[159]

f) <u>Methods for monitoring and enforcement</u>. The NYC DOHMH Bureau of Immunization is responsible for enforcing vaccination requirements in schools. Compliance among children attending pre-kindergarten programs in public schools is monitored through data provided by the NYC Department of Education from their Automate the Schools (ATS) database. DOE sends ATS data to the Bureau monthly, allowing for timely monitoring of compliance and prompt outreach to schools with suboptimal compliance. The Bureau sends notices to schools with less than 95% of children in grades kindergarten through 12 who meet vaccination requirements throughout the school year. School principals are reminded that they may be subject to fines for failing to enforce immunization requirements. The Bureau's outreach has been very effective: nearly 99% of public school children are in compliance with immunization requirements by the end of a typical school year.[172]

Monitoring and enforcement of vaccination requirements among non-public school programs cannot be done in a timely manner. The Bureau monitors compliance among children attending childcare and preschool in non-public school settings primarily with aggregate data reported on an annual survey to the New York State Department of Health. The Bureau of Immunization also conducts audits among a sample of non-public school programs to supplement the self-reported state survey data. The audits do not cover all programs, and do not allow for identification of individual, noncompliant children for exclusion. The NYC DOHMH Bureau of Child Care conducts routine inspections of city-regulated, non-public school childcare and preschool programs, however, and is authorized to issue violations for failing to exclude unvaccinated children.

The NYC DOHMH Bureau of Immunization recognized that an influenza vaccine requirement would be particularly difficult to monitor and enforce because, unlike other vaccines, it is required every year.

g) <u>Compliance with other current immunization requirements</u>. In 2013, children attending childcare and preschool were required to be vaccinated against diphtheria, pertussis, tetanus, polio, measles, mumps, rubella, hepatitis B, *Haemophilus influenzae* type b, pneumococcus, and varicella. By the end of the 2011-2012 school year, 99.1% of public school children and 92 % of children attending non-public school childcare programs were in compliance. Less than 1.0% of children were exempt from immunization requirements for medical or religious reasons.[4]

h) <u>Legal issues</u>. Childcare and school immunization requirements are in New York State law. Adding a vaccine to the list of required vaccines would normally require the state legislature

to approve the change. NYC DOHMH officials had advocated for changing state law but the proposal was not taken up by the New York State Department of Health and did not move forward. The NYC Health Commissioner asked the NYC DOHMH General Counsel to determine whether the NYC Board of Health had the authority to require influenza vaccine for childcare and preschool by amending the NYC Health Code. There was a precedent: NYC required 4 doses of diphtheria, tetanus and acellular pertussis (DTaP) vaccine for kindergarten compared to 3 doses required by state law.

The General Counsel determined that the influenza vaccine could be mandated for childcare and preschool by amending the NYC Health Code. Developing the legal strategy was a challenge because not all childcare facilities in NYC were city-regulated, however. The General Counsel decided to require influenza vaccine for children attending city-regulated childcare and preschools but not New York State-regulated facilities or unregulated facilities.

Facilities included were those covered under NYC Health Code Articles 47 and 43.[158] The Article 47 facilities are childcare centers (non-residential) for 0-5-year-olds that have an average of 45 children enrolled, and private and religious school-based programs for 0-2-year-olds with 3 or more enrollees. Combined, Article 47 facilities had a capacity of 124,000 children. Article 43 facilities are public school-based programs for children 3-5 years with approximately 32,000 children enrolled (2012-13 school year). Facilities not covered were state-regulated family childcare, serving a maximum of 6 children aged 0-5 years, and group family childcare serving a maximum of 12 children aged 0-5 years. Total capacity for family childcare is 20,000 and group family childcare is 60,000. Unregulated childcare includes home-based providers serving less than 3 children aged 0-5 years and parent/guardian/nanny care. The capacity of home-based providers is estimated at approximately 15,000 children, and parent/guardian/nanny care capacity

is approximately 23,000. In sum, the legal approach positioned the mandate to cover 156,000 children and not cover 118,000 children. The largest congregate care settings, which presented the greatest risk of disease transmission, were the Article 47 childcare centers which were covered.[158]

j) <u>Potential for public backlash</u>. Based on lessons learned from New Jersey and Connecticut, the NYC DOHMH Bureaus of Immunization and Child Care collaborated on a plan for a community-wide education campaign for parents, childcare providers, schools, and health care providers to prevent public backlash. The plan included meetings at childcare facilities to educate staff and parents, and widespread distribution of printed materials. Posters would be developed for display in all childcare and preschool programs. In the first year of the mandate, education would be the only means of enforcement; issuance of violation notices would begin in the mandate's second year. To build support, the NYC DOHMH would engage the NYC chapters of the American Academy of Pediatrics and the American Academy of Family Physicians, and collaborate with the Bureau of Immunization's community advisory group, the NYC Coalition for Immunization Initiatives.[154]

Enactment and Implementation

Figure 1 (page 58) shows the timeline of major activities leading to the mandate's enactment and implementation. The NYC DOHMH presented the proposal for the mandate to the NYC Board of Health at the Board's public meeting in September 2013.[158] The Board agreed to move forward with a public hearing and written comment period. The public hearing was held October 23, 2013.[173] A total of 19 people commented at the hearing – all opposed.[174-176] Following the written comment period, the NYC DOHMH Deputy Commissioner for Disease Control appeared

before the Board on December 11, 2013, to respond to the comments at the hearing and the written comments submitted. He also presented the final proposal for the mandate.[175] A total of 276 written comments had been submitted: 27 in support and 249 opposed. Those opposed included parents, two lawyers, three autism activist organizations, and anti-vaccine advocates. The supporters were individual physicians and several organizations, including the American Academy of Pediatrics, the NYC Coalition for Childhood Immunization Initiatives, pro-vaccine parent and nurse advocacy groups, including Nurses Who Vaccinate, health clinics and hospitals, and one school. Of the comments in opposition, 127 (46%) were form letters; 62 (25%) were from individuals who lived outside NYC.[174-176]

The NYC Board of Health approved the childcare vaccine mandate at the meeting on December 11, 2013. The decision was published in the city record and took effect 30 days later in mid-January, 2014.[177] To allow sufficient time for childcare programs and parents to learn about the mandate and prepare to comply, DOHMH began outreach and education in spring, 2014, based on the plan it had developed while deliberating the decision to seek the mandate. Childcare and prekindergarten programs were asked to implement the new vaccine requirement starting July 1, 2014, the beginning of the 2014-15 influenza season.

Suspension

Five NYC mothers filed suit against the mandate in November, 2015.[7] The attorney representing the mothers used the same argument that led to the suspension of the NYC DOHMH's soda container policy. In that case, which was decided in 2013 and upheld in June 2014, the courts ruled that the NYC Board of Health did not have the authority to enact a requirement not specified in state law. The New York Supreme Court ruled to suspend the NYC

childcare influenza mandate on the same grounds in a decision issued on December 16, 2015.[9] NYC appealed, but lost again. In a decision issued October 6, 2016, the Appellate Court agreed with DOHMH that the NYC Board of Health had the authority to add a vaccine requirement, but upheld the suspension because the mandate did not apply to all NYC childcare facilities and wrongly allowed, in their opinion, childcare facilities to opt out of excluding noncompliant children by paying fines.[10]

Aim 2 Findings: Effect of Mandate on Influenza Vaccination Rates

Population and Peak Vaccination Rates

The number of children 6-59 months of age who received ≥ 1 influenza vaccination by December 31 in each annual influenza season ranged from 97,568 in 2006-7 to 191,753 in 2015-16 (Table 1, page 63). Although the largest number of 6-59-month-olds were vaccinated in 2015-16, the second season of the mandate, the vaccination rate of 48.5% that season was below the highest rate of 50.3% reached in 2009-10, the season of the H1N1 influenza pandemic. The rate in the mandate's second season among 6-59-month-olds was also below rates reached in two other seasons before the mandate: 49.4% in 2010-11 and 49.1% in 2011-12. Among 5-8-year-olds, children receiving influenza vaccine ranged from 35,088 in 2006-7 to 117,047 in 2014-15, the first season of the mandate (Table 2, page 63). The vaccination rate of 40.3% in the mandate's first season was also the highest rate among 5-8-year-olds across all seasons.

Vaccination Rate Trends among Children 6-59 Months and 5-8 Years

In the early seasons of 2006-7 through 2009-10, which were soon after influenza vaccine was recommended by the Advisory Committee on Immunization Practices for all children in both age groups, vaccination rates among 6-59-month-olds and 5-8-year-olds increased sharply (Figure 2, page 59; Tables 1 and 2, page 63). Over the four seasons thereafter, rates among 6-59-month-olds mostly declined from the peak of 50.3% in 2009-10 to 46.2% in 2013-14, the season before the mandate. After the mandate took effect, vaccination rates among 6-59-month-olds increased 2.2 percentage points in the mandate's first season (2014-15), and an additional 0.1 percentage point in the mandate's second season (2015-16), for a total increase of 2.3 percentage points to 48.5%. The average vaccination rate of two seasons before the mandate (46.1%) compared to the

average rate of two seasons during the mandate (48.5%) indicated the mandate was associated with a vaccination rate increase of 2.4 percentage points (Figure 3, page 60).

Among 5-8-year-olds, vaccination rates mostly increased over the four seasons before the mandate from 32.6% in 2009-10 to 37.0% in 2013-14, a gain of 4.4 percentage points (Figure 2, page 59; Table 2, page 63). After the mandate took effect, rates among 5-8-year-olds increased 3.3 percentage points in the mandate's first season, followed by a decline of 1.3 percentage points in the second season. The average vaccination rate of two seasons before the mandate (35.1%) compared to the average rate of two seasons during the mandate (39.6%) indicated the mandate was associated with a vaccination rate increase of 4.5 percentage points among 5-8-year-olds (Figure 3, page 60).

Among both 6-59-month-olds and 5-8-year-olds, vaccination rates dropped after the mandate's suspension (Figure 3, page 60). The decline was greater among 6-59-month-olds. Rates fell by 6.9 percentage points among 6-59-month-olds from 48.5%, the average rate of the mandate's two seasons, to 41.6% in the season after the mandate's suspension. Among 5-8-year-olds, the same comparison showed a decline in the vaccination rate of 3.9 percentage points from 39.6% to 35.7%.

Vaccination Rate Trends among One-Year Age Groups

Figure 4 (page 61) and Tables 3-6 (pages 64-65) show vaccination rate trends among the 6-59-month-olds stratified by one-year age groups. Rates among the 1- and 2-year-olds mostly declined slightly over the four seasons before the mandate. After the mandate took effect, rates among 1-year-olds continued to decrease. The average vaccination rate of two seasons before the mandate (54.7%), compared to the average rate of two seasons during the mandate (51.9%),

indicated the mandate was associated with a vaccination rate decrease of 2.8 percentage points among 1-year-olds (Figure 3, page 60). Among 2-year-olds, the average vaccination rate of two seasons before the mandate (44.0%), compared to the average rate of two seasons during the mandate (44.4%), indicated the mandate was associated with a slight rate increase of 0.4 percentage points (Figure 3, page 60).

Vaccination rates went slightly up and down among 3- and 4-year-olds in the four seasons preceding the mandate (Figure 4, page 61). Rates rose in both groups after the mandate took effect, with the steepest increases seen among 4-year-olds. The average vaccination rate of two seasons before the mandate (43.0%), compared to the average rate of two seasons during the mandate (54.4%), indicated the mandate was associated with a vaccination rate increase of 11.4 percentage points among 4-year-olds (Figure 3, page 60). Among 3-year-olds, the same comparison indicated the mandate was associated with a vaccination rate increase of 5.5 percentage points from 40.7% to 46.2% (Figure 3, page 60).

Vaccination rates declined among all age groups 1-4 years after the mandate was suspended (Figures 3 and 4, pages 60-61). The drop in rates was most pronounced among 3- and 4-year-olds. The rate among 3-year-olds declined by 10.0 percentage points from 46.2%, the average rate of two seasons during the mandate, to 36.2% in the season after the mandate was suspended. Based on the same comparison, the rate among 4-year-olds fell 12.1 percentage points from 54.4% to 42.3%. Among the younger groups, the same comparison showed vaccination rates declined among 1-year-olds by 3.2 percentage points and among 2-year-olds by 5.2 percentage points.

Figure 5 (page 62) and Tables 7-10 (pages 66-67) show vaccination rates among 5-8-year-olds stratified by one-year age groups. Among all age groups, rates increased in the first season of the mandate and slightly declined in the second season. Rates changed most among 8-year-olds after the mandate took effect. The average vaccination rate of two seasons before the mandate (33.5%), compared to the average rate of two seasons during the mandate (39.6%), indicated the mandate was associated with a vaccination rate increase of 6.1 percentage points among 8-year-olds (Figure 3, page 60). Based on the same comparison, the mandate was associated with an increase in rates among 5-year-olds of 4.1 percentage points, among 6-year-olds of 3.7 percentage points, and among 7-year-olds of 4.9 percentage points (Figure 3, page 60).

Vaccination rates declined moderately among all groups 5-8 years of age after the mandate was suspended (Figure 3, page 60; Figure 5, page 62). Among 5-year-olds, the rate declined 5.3 percentage points from 41.3%, the average rate of two seasons during the mandate, to 36.0% in the season after the mandate was suspended. The same comparison in the other age groups showed rates fell 3.4 percentage points among 6-year-olds, 3.9 percentage points among 7-year-olds, and 3.9 percentage points among 8-year-olds.

Figure 1. Timeline of New York City Childcare Influenza Vaccine Mandate

June 2012. Connecticut briefed New York City (NYC) Health Commissioner on increasing vaccination rates and declining influenza-associated hospitalization rates after implementation of Connecticut childcare influenza vaccine mandate.

June - November 2012. NYC Department of Health and Mental Hygiene (DOHMH) Bureaus of Immunization (BOI) and Child Care (BCC) held internal meetings and collaborated with the NYC DOHMH General Counsel on legal strategy to amend NYC Health Code. BOI reached out to Connecticut and New Jersey to learn of experience with mandate and completed literature review; prepared briefing for Commissioner.

December 14, 2012. Connecticut presented experience with mandate at NYC Coalition for Immunization Initiatives.

March 2013. NYC Health Commissioner presented proposal for NYC Health Code amendments to NYC Mayor.

September 10, 2013. NYC DOHMH BOI and BCC presented proposal for NYC Health Code amendments to NYC Board of Health. Board approved going forward with public hearing and posting for public comment.

October 23, 2013. NYC Board of Health held public hearing. 19 people commented – all opposed.

December 11, 2013. NYC DOHMH Deputy Commissioner responded to comments at the NYC Board of Health's December meeting. A total of 276 written comments were submitted: 27 in support and 249 opposed. Opposed were parents, two lawyers, autism activists, and anti-vaccine advocates. Supporters were individual physicians and organizations, including the American Academy of Pediatrics, the NYC Coalition for Childhood Immunization Initiatives, pro-vaccine parent and nurse advocacy groups, including Nurses Who Vaccinate, health clinics and hospitals, and one school. Of the comments in opposition, 127 (46%) were form letters; 62 (25%) were from individuals who lived outside NYC. The NYC Board of Health voted to approve the NYC Health Code amendments. The amendments were posted in the City Record and became effective 30 days after meeting.

January 14, 2014. Mandate took effect. NYC DOHMH BOI and BCC started outreach and education. Implementation began July 1, 2014.

November 9, 2015. Five NYC mothers filed lawsuit against mandate.

December 16, 2015. New York State Supreme Court suspended mandate.

October 6, 2016. State Supreme Court, Appellate Division, upheld suspension of mandate.

Figure 2. Effects of Childcare Influenza Vaccine Mandate on Influenza Vaccination Rates among Children 6-59 Months and 5-8 Years

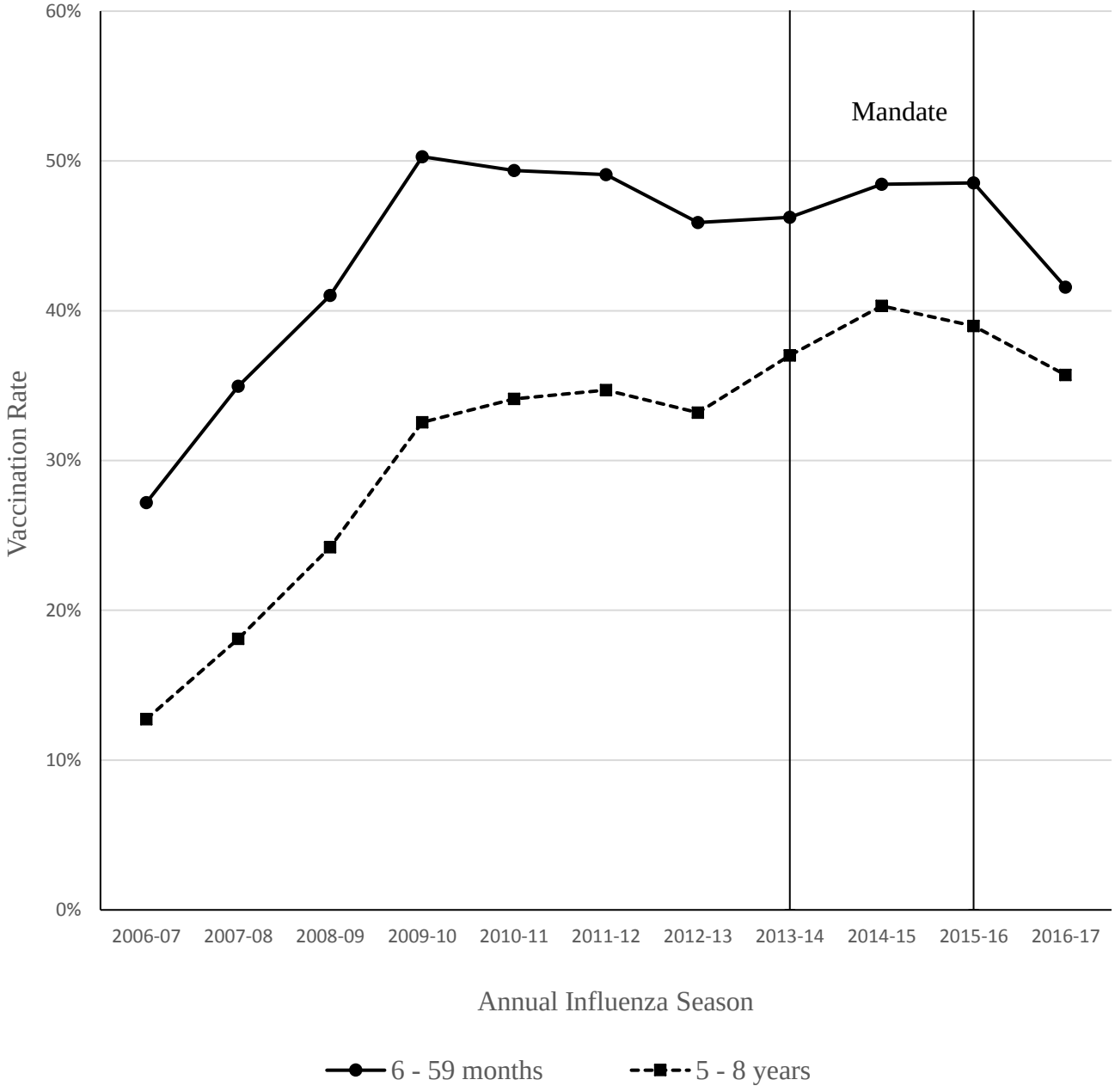
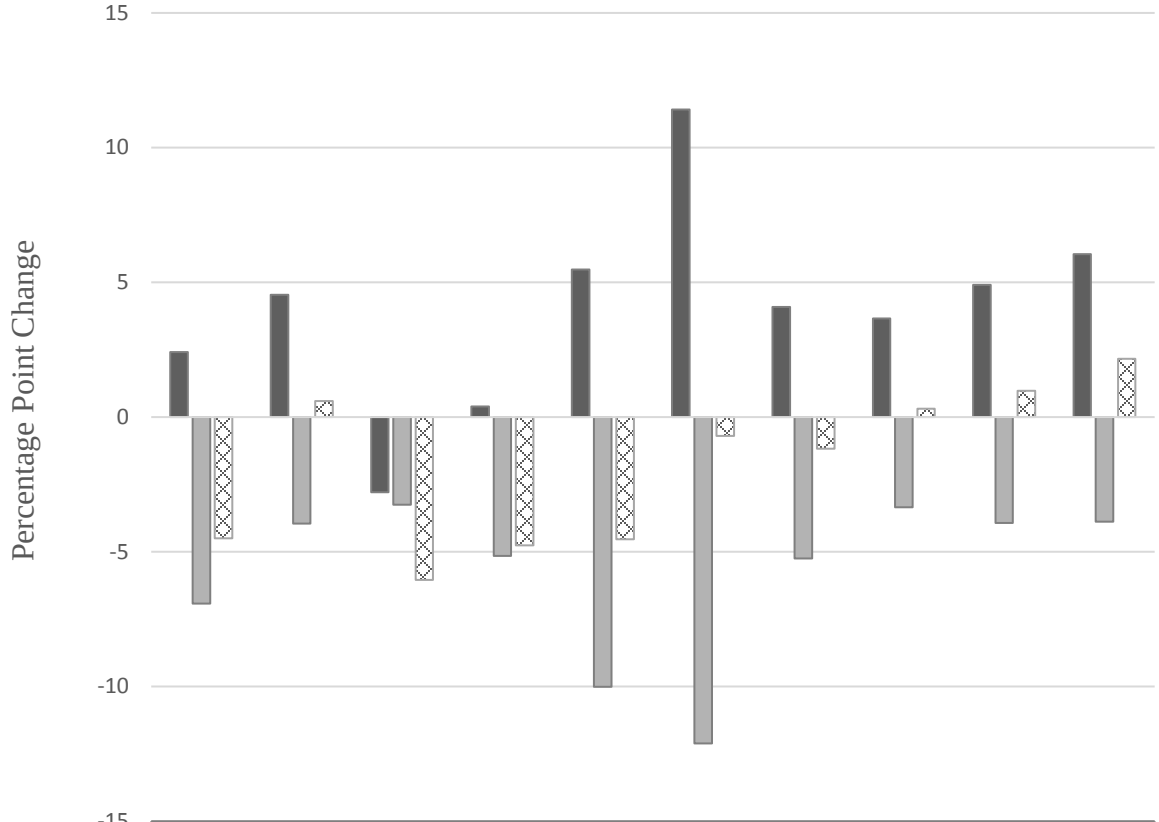


Figure 2 shows influenza vaccination rates as of December 31 in each annual influenza season by intervention group (6-59 months) and control group (5-8 years), New York City, 2006 – 2017. Rates were calculated based on number of children with $\geq$ 1 influenza vaccination documented in the New York City Department of Health and Mental Hygiene's Citywide immunization Registry divided by the Census Vintage 2016 population estimate for the age group.

Figure 3. Vaccination Rate Change by Age Group and Period Relative to Mandate



	6-59 Months	5-8 Years	1 Year	2 Years	3 Years	4 Years	5 Years	6 Years	7 Years	8 Years
Mandate Effect	2.4	4.5	-2.8	0.4	5.5	11.4	4.1	3.7	4.9	6.1
Suspension Effect	-6.9	-3.9	-3.2	-5.2	-10.0	-12.1	-5.3	-3.4	-3.9	-3.9
Net Effect	-4.5	0.6	-6.0	-4.8	-4.5	-0.7	-1.2	0.3	1.0	2.2

Mandate Effect: Percentage point change in vaccination rate = difference between average rate of two seasons during mandate (2014-15 and 2015-16) and average rate of two seasons before mandate (2012-2013 and 2013-14).

Suspension Effect: Percentage point change in vaccination rate = difference between rate in the season after suspension of mandate (2016-2017) and average vaccination rate of two seasons during mandate.

Net Effect: Percentage point change in vaccination rate = difference between rate in season after suspension of mandate and average rate of two seasons before mandate.

4. Effects of Childcare Influenza Vaccine Mandate on Influenza Vaccination Rates among One-Year Age Groups, 1-4 Years

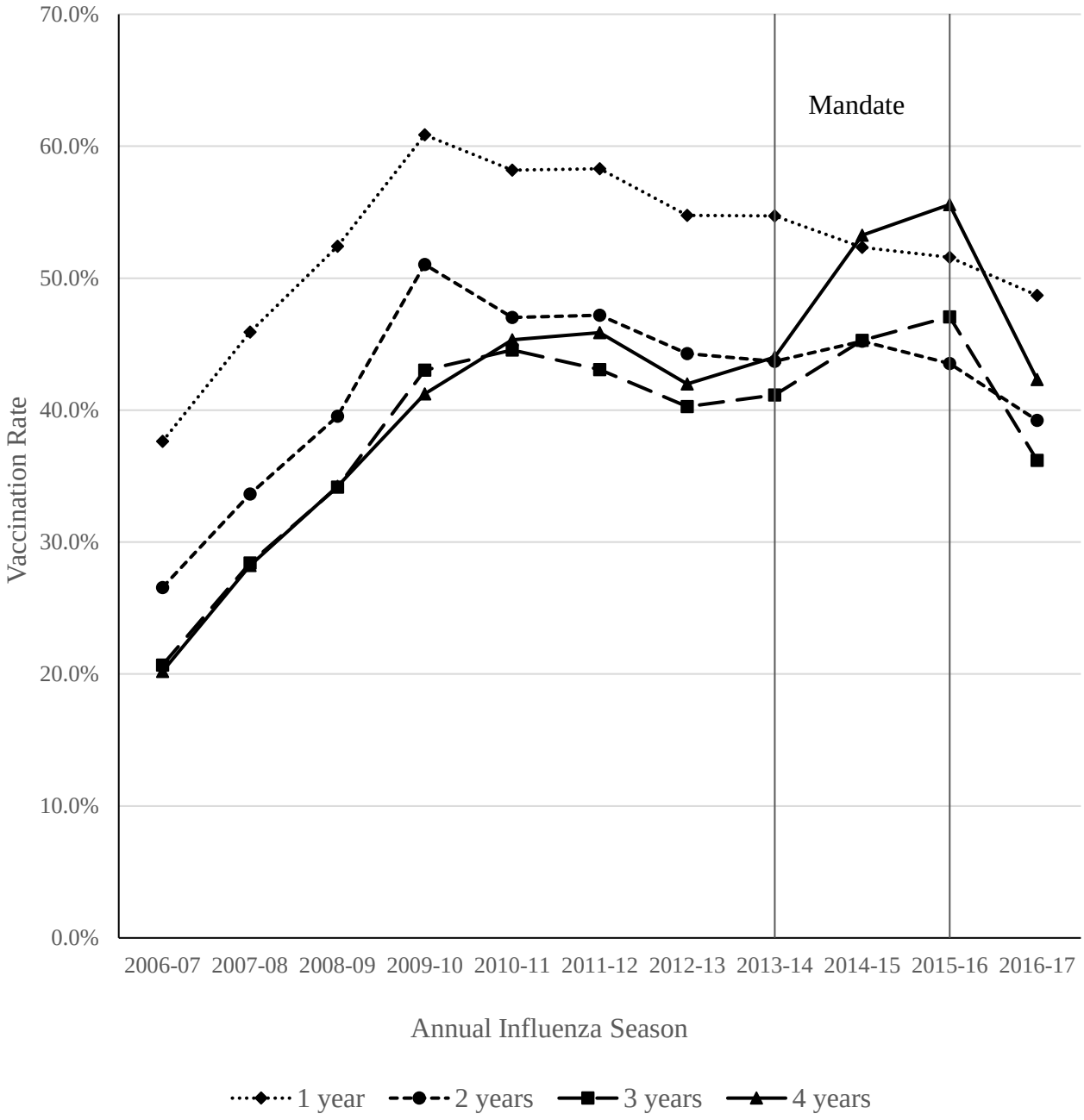


Figure 4 shows influenza vaccination rates as of December 31 in each annual influenza season by one-year age groups, 1-4 years, New York City, 2006 – 2017. Rates were calculated based on number of children with $\geq$ 1 influenza vaccination documented in the New York City Department of Health and Mental Hygiene's Citywide immunization Registry divided by the Census Vintage 2016 population estimate for the age group.

Figure 5. Effects of Childcare Influenza Vaccine Mandate on Influenza Vaccination Rates among One-Year Age Groups, 5-8 Years

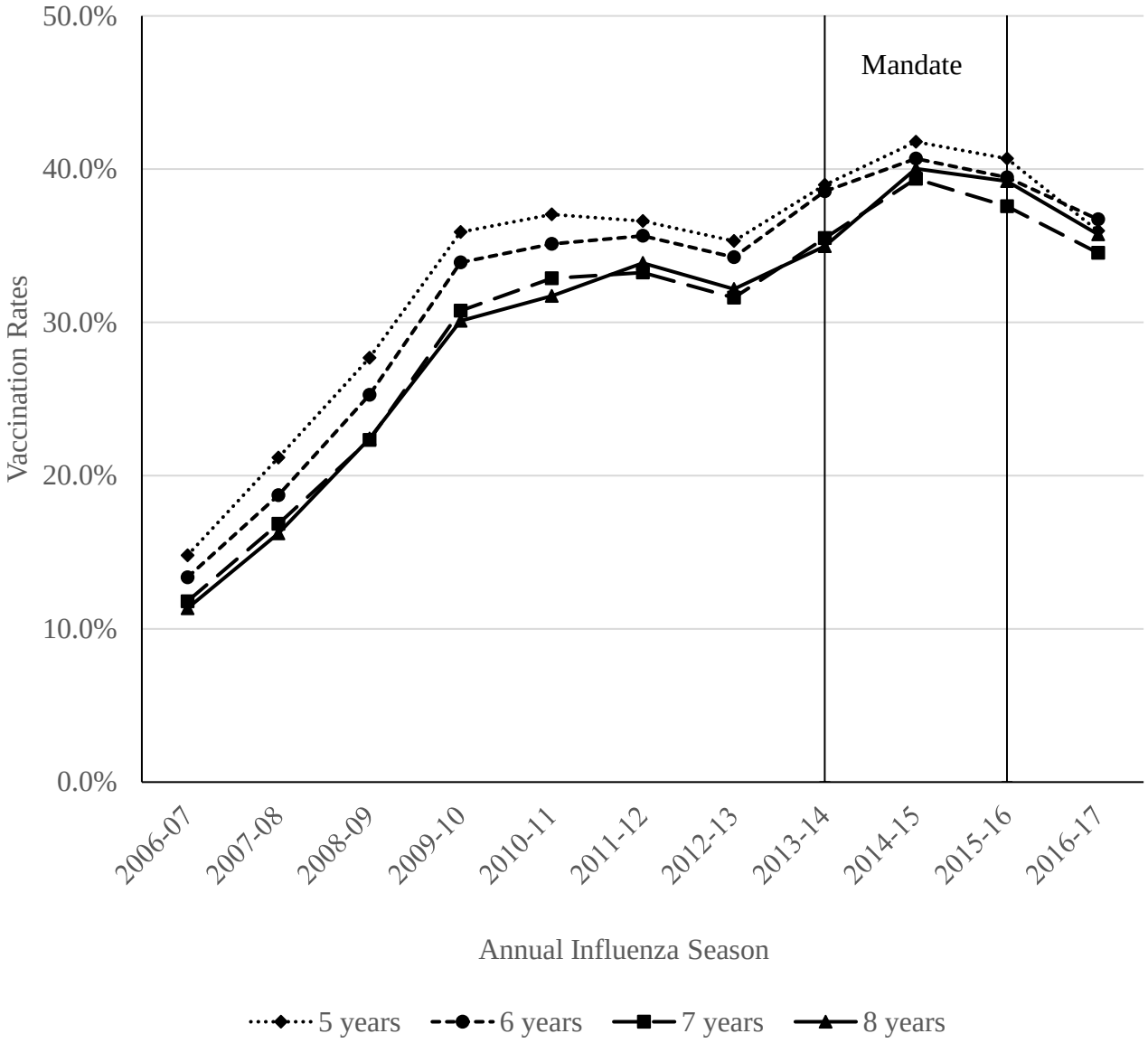


Figure 5 shows influenza vaccination rates as of December 31 in each annual influenza season by one-year age groups, 5-8 years (control), New York City, 2006 – 2017. Rates were calculated based on number of children with $\geq$ 1 influenza vaccination documented in the New York City Department of Health and Mental Hygiene's Citywide immunization Registry divided by the Census Vintage 2016 population estimate for the age group.

Table 1. Influenza Vaccination Rates as of December 31 in Each Annual Influenza Season among Children 6-59 Months, New York City, 2006 – 2017

Annual Influenza Season	Children 6-59 Months with ≥1 Influenza Vaccination by 12/31 Each Season	Census Population Estimate (Vintage 2016)	Influenza Vaccination Rate
2006-7	97,568	358,803	27.2%
2007-8	124,246	355,422	35.0%
2008-9	146,411	356,956	41.0%
2009-10	180,791	359,560	50.3%
2010-11	178,128	360,940	49.4%
2011-12	182,851	372,502	49.1%
2012-13	174,172	379,512	45.9%
2013-14	178,516	386,061	46.2%
2014-15	**189,666**	**391,605**	**48.4%**
2015-16	**191,753**	**395,091**	**48.5%**
2016-17	164,221	395,091	41.6%

Table 2. Influenza Vaccination Rates as of December 31 in Each Annual Influenza Season among Children 5-8 Years, New York City, 2006 – 2017

Annual Influenza Season	Children 5-8 Years with ≥1 Influenza Vaccination by 12/31 Each Season	Census Population Estimate (Vintage 2016)	Influenza Vaccination Rate
2006-7	35,088	275,420	12.7%
2007-8	49,637	274,412	18.1%
2008-9	67,179	277,463	24.2%
2009-10	92,114	282,987	32.6%
2010-11	97,802	286,624	34.1%
2011-12	99,309	286,105	34.7%
2012-13	95,942	288,979	33.2%
2013-14	107,629	290,825	37.0%
2014-15	**117,047**	**290,294**	**40.3%**
2015-16	**113,950**	**292,256**	**39.0%**
2016-17	104,346	292,256	35.7%

Table 3. Influenza Vaccination Rates as of December 31 in Each Annual Influenza Season among Children Aged 1 Year, New York City, 2006 – 2017

Annual Influenza Season	Children Aged 1 Year with ≥1 Influenza Vaccination by 12/31 Each Season	Census Population Estimate (Vintage 2016)	Influenza Vaccination Rate
2006-7	38,929	103,465	37.6%
2007-8	47,175	102,753	45.9%
2008-9	54,210	103,437	52.4%
2009-10	63,546	104,422	60.9%
2010-11	61,128	105,056	58.2%
2011-12	63,217	108,451	58.3%
2012-13	60,521	110,513	54.8%
2013-14	61,519	112,432	54.7%
2014-15	**59,676**	**114,040**	**52.3%**
2015-16	**59,328**	**115,045**	**51.6%**
2016-17	56,027	115,045	48.7%

Table 4. Influenza Vaccination Rates as of December 31 in Each Annual Influenza Season among Children Aged 2 years, New York City, 2006 – 2017

Annual Influenza Season	Children Aged 2 Years with ≥1 Influenza Vaccination by 12/31 Each Season	Census Population Estimate (Vintage 2016)	Influenza Vaccination Rate
2006-7	27,478	103,465	26.6%
2007-8	34,571	102,753	33.6%
2008-9	40,899	103,437	39.5%
2009-10	53,293	104,422	51.0%
2010-11	49,407	105,056	47.0%
2011-12	51,168	108,451	47.2%
2012-13	48,934	110,513	44.3%
2013-14	49,120	112,432	43.7%
2014-15	**51,582**	**114,040**	**45.2%**
2015-16	**50,077**	**115,045**	**43.5%**
2016-17	45,124	115,045	39.2%

Table 5. Influenza Vaccination Rates as of December 31 in Each Annual Influenza Season among Children Aged 3 Years, New York City, 2006 – 2017

Annual Influenza Season	Children Aged 3 Years with ≥1 Influenza Vaccination by 12/31 Each Season	Census Population Estimate (Vintage 2016)	Influenza Vaccination Rate
2006-7	20,937	101,248	20.7%
2007-8	28,392	99,944	28.4%
2008-9	34,178	100,055	34.2%
2009-10	43,237	100,478	43.0%
2010-11	44,803	100,553	44.6%
2011-12	44,677	103,733	43.1%
2012-13	42,538	105,658	40.3%
2013-14	44,224	107,464	41.2%
2014-15	**49,377**	**109,016**	**45.3%**
2015-16	**51,780**	**110,001**	**47.1%**
2016-17	39,798	110,001	36.2%

Table 6. Influenza Vaccination Rates as of December 31 in Each Annual Influenza Season among Children Aged 4-4.5 Years, New York City, 2006 – 2017

Annual Influenza Season	Children Aged 4-4.5 Years with ≥1 Influenza Vaccination by 12/31 Each Season	Census Population Estimate (Vintage 2016)	Influenza Vaccination Rate
2006-7	10,224	50,624	20.2%
2007-8	14,108	49,972	28.2%
2008-9	17,124	50,028	34.2%
2009-10	20,715	50,239	41.2%
2010-11	22,790	50,276	45.3%
2011-12	23,789	51,867	45.9%
2012-13	22,179	52,829	42.0%
2013-14	23,653	53,732	44.0%
2014-15	**29,031**	**54,508**	**53.3%**
2015-16	**30,568**	**55,000**	**55.6%**
2016-17	23,272	55,000	42.3%

Table 7. Influenza Vaccination Rates as of December 31 in Each Annual Influenza Season among Children Aged 5.5 - <6 years, New York City, 2006 – 2017

Annual Influenza Season	Children Aged 5.5 - <6 Years with ≥1 Influenza Vaccination by 12/31 Each Season	Census Population Estimate (Vintage 2016)	Influenza Vaccination Rate
2006-7	6,790	45,903	14.8%
2007-8	9,684	45,735	21.2%
2008-9	12,802	46,244	27.7%
2009-10	16,926	47,164	35.9%
2010-11	17,693	47,771	37.0%
2011-12	17,454	47,684	36.6%
2012-13	17,005	48,163	35.3%
2013-14	18,893	48,471	39.0%
2014-15	**20,216**	**48,382**	**41.8%**
2015-16	**19,815**	**48,709**	**40.7%**
2016-17	17,524	48,709	36.0%

Table 8. Influenza Vaccination Rates as of December 31 in Each Annual Influenza Season among Children Aged 6 Years, New York City, 2006 – 2017

Annual Influenza Season	Children Aged 6 Years with ≥1 Influenza Vaccination by 12/31 Each Season	Census Population Estimate (Vintage 2016)	Influenza Vaccination Rate
2006-7	12,264	91,807	13.4%
2007-8	17,128	91,471	18.7%
2008-9	23,370	92,488	25.3%
2009-10	31,980	94,329	33.9%
2010-11	33,550	95,541	35.1%
2011-12	34,004	95,368	35.7%
2012-13	32,996	96,326	34.3%
2013-14	37,376	96,942	38.6%
2014-15	**39,370**	**96,765**	**40.7%**
2015-16	**38,438**	**97,419**	**39.5%**
2016-17	35,771	97,419	36.7%

Table 9. Influenza Vaccination Rates as of December 31 in Each Annual Influenza Season among Children Aged 7 years, New York City, 2006 – 2017

Annual Influenza Season	Children Aged 7 Years with ≥1 Influenza Vaccination by 12/31 Each Season	Census Population Estimate (Vintage 2016)	Influenza Vaccination Rate
2006-7	10,830	91,807	11.8%
2007-8	15,406	91,471	16.8%
2008-9	20,644	92,488	22.3%
2009-10	29,013	94,329	30.8%
2010-11	31,409	95,541	32.9%
2011-12	31,701	95,368	33.2%
2012-13	30,445	96,326	31.6%
2013-14	34,414	96,942	35.5%
2014-15	**38,093**	**96,765**	**39.4%**
2015-16	**36,596**	**97,419**	**37.6%**
2016-17	33,645	97,419	34.5%

Table 10. Influenza Vaccination Rates as of December 31 in Each Annual Influenza Season among Children Aged 8-8.5 years, New York City, 2006 – 2017

Annual Influenza Season	Children Aged 8-8.5 Years with ≥1 Influenza Vaccination by 12/31 Each Season	Census Population Estimate (Vintage 2016)	Influenza Vaccination Rate
2006-7	5,204	45,903	11.3%
2007-8	7,419	45,735	16.2%
2008-9	10,363	46,244	22.4%
2009-10	14,195	47,164	30.1%
2010-11	15,150	47,771	31.7%
2011-12	16,150	47,684	33.9%
2012-13	15,496	48,163	32.2%
2013-14	16,946	48,471	35.0%
2014-15	**19,368**	**48,382**	**40.0%**
2015-16	**19,101**	**48,709**	**39.2%**
2016-17	17,406	48,709	35.7%

Section 5: Discussion and Conclusions

Summary of Results: Aims 1 and 2

The NYC DOHMH spent over a year deliberating its decision to seek a childcare influenza vaccine mandate. Its efforts to advocate for a change in state law to require influenza vaccine for childcare statewide were unsuccessful. NYC DOHMH asked the NYC Board of Health to amend the NYC Health Code to enact the mandate only after careful consideration of the mandate's potential health and economic impact. The decision was informed by a thorough literature review and extensive information-gathering from the states of Connecticut and New Jersey, the only other jurisdictions in the US to mandate influenza vaccine for childcare. Strong evidence indicated the mandate would raise influenza vaccination rates among children younger than 5 years, thereby protecting an age group at high risk of serious complications from influenza.[12] The increase in vaccination rates among young children was also expected to reduce community-wide transmission of influenza. Other high risk groups, including infants too young to be vaccinated, people with chronic health conditions, and those 65 years of age or older were expected to be better protected from the potentially deadly disease after the mandate.

NYC faced a challenge not confronted by the other jurisdictions. As a city, not a state, NYC needed to find a legal solution to add an immunization requirement for childcare that would normally be accomplished by changing state law. The DOHMH General Counsel crafted a legal strategy for applying the mandate to city-regulated childcare and prekindergarten facilities only. The strategy was well-justified from a public health perspective. These facilities included the largest childcare programs, which would pose the highest risk to children for acquiring influenza due to the large numbers of children in attendance.[158-159]

NYC DOHMH's legal approach met the approval of the NYC Board of Health but did not stand up in the courts. The New York State Supreme Court suspended the mandate mid-way through its second season in response to a lawsuit filed by five NYC mothers.[9] The State Supreme Court ruled that the NYC Board of Health did not have the authority to mandate a vaccine not required by state law. NYC appealed, but the Appellate Court upheld the suspension for different reasons than the one cited by the State Supreme Court. The Appellate Court judges agreed with NYC DOHMH that the NYC Board of Health was authorized to mandate the vaccine. They maintained the suspension because the mandate did not cover all childcare facilities in the NYC and, in their opinion, wrongly allowed childcare operators to opt out of the vaccine requirement by paying fines.[10] NYC DOHMH is preparing a second appeal which will be filed soon.

The mandate's suspension appears not to have undermined the public's confidence in vaccines in general. NYC's vaccination rates for routine childhood and adolescent vaccines are stable or increasing.[103] With only one season after the mandate available for examination, it is too soon to tell whether the suspension inflicted long-term damage on acceptance of influenza vaccine for young children in NYC. Research has shown that some health care providers do not routinely recommend influenza vaccine for their pediatric patients.[178] Education is needed to counter common misconceptions held by providers and parents, e.g., influenza is not a serious disease, influenza vaccine causes influenza, and influenza vaccine is not safe or effective.[178]

The quantitative analysis in this study indicated the NYC childcare influenza mandate had little impact on increasing influenza vaccination rates among the aggregate group of 6-59-month-olds. The average vaccination rate of two seasons before the mandate (46.1%), compared to the average rate of two seasons during the mandate (48.5%), indicated the mandate was associated

with a vaccination rate increase of only 2.4 percentage points among all NYC 6-59-month-olds. This increase fell short of NYC's expectations that vaccination rates would rise by 4.6 percentage points among all 6-59-month-olds in response to the mandate.

Among 5-8-year-olds, who were not covered by the mandate, vaccination rates increased 4.5 percentage points during the mandate. This may have been an indirect effect of the mandate or due to other factors. The possibility of a sibling effect, whereby children in the 5-8 year-old group were vaccinated because a sibling in the 6-59-month-old group was required to receive vaccine, was investigated and ruled out. Siblings in both age groups were removed from the analysis and vaccination rate trends remained the same (data not shown).

After the mandate's suspension, influenza vaccination rates among 6-59-month-olds fell 6.9 percentage points, a larger decrease than the 3.9 percentage point decline seen among 5-8-year-olds. The greater decrease in the vaccination rate among 6-59-month-olds may suggest an effect of the mandate. It is possible that the mandate propped up vaccination rates among 6-59-month-olds, which were slightly declining over the four seasons before the mandate. When the mandate's support was removed, rates plummeted.

The stratified analysis by one-year age group showed that the influenza vaccination rate among 4-year-olds increased 11.4 percentage points. This was by far the largest increase among all age groups, suggesting the mandate succeeded for 4-year-olds. The 12.1 percentage point drop in the vaccination rate among 4-year-olds after the mandate's suspension was also the largest post-mandate change in rate among all age groups, further supporting an effect of the mandate among 4-year-olds. The rate among 3-year-olds increased by 5.5 percentage points

during the mandate, and fell 10.0 percentage points after the mandate's suspension, indicating the mandate may have also affected 3-year-olds.

The mandate's larger effect among 3- and 4-year-olds is supported by evidence showing that a greater proportion of children in these age groups attend licensed childcare and prekindergarten compared to 1- and 2- year-olds. Children 4 years of age are the largest single age group in childcare and preschool programs for children younger than 6 years of age.[179] Further, in NYC, the implementation of the childcare influenza vaccine mandate coincided with Mayor de Blasio's initiative for expanding universal prekindergarten.[180] These publicly funded programs are available for free to families of all NYC children turning 4 years of age in the calendar year. Hence, more 3- and 4-year-olds were entering prekindergarten and would have been directly affected by the influenza vaccine mandate.

Among 5-8-year-olds, the vaccination rate rose 6.1 percentage points in 8-year-olds during the mandate, the largest increase among all one-year age groups except 4-year-olds. The decline in vaccination rate after the mandate's suspension among 8-year-olds (3.9 percentage points), compared to the decline among 3-year-olds (10.0 percentage points) and 4-year-olds (12.1 percentage point), does not support an impact of the mandate on 8-year-olds, however.

An interesting question is why, during the mandate, NYC's influenza vaccination rates did not appear to reach the high levels seen in Connecticut and New Jersey. One important factor to consider is that different data and methods were used to measure vaccination rates in this study as compared with those used by the two states. The rates in Connecticut and New Jersey were based on the NIS-Flu Survey, while NYC's rates in this study were based on its Citywide Immunization Registry. NIS-Flu data for NYC shows different rate levels and increases in rates

than seen in the results of this study. (Note that NIS-Flu data is based on a random digit dial telephone survey and vaccinations reported are not verified against medical records.[156] Citywide Immunization registry data are reported by health care providers, primarily from electronic medical records. NIS-Flu is based on a random sample, while the population in this study included all children who met the no aging in or out criteria and who had received one or more influenza vaccinations during July 1 – December 31 each season that were documented in the Citywide Immunization Registry).

From 2013-14, the season before NYC's mandate and the first season in which NYC-specific estimates were available from NIS-Flu, the influenza vaccination rate among NYC 6-59-month-olds as of May increased 6.5 percentage points from 73.6% (CI = 67.0% - 80.2%) to 80.1% (CI = 75.2% - 85.0%) in 2015-16,[156] the second season of NYC's mandate. This is a larger increase than the 2.3 percentage points rise seen among NYC 6-59-month-olds in this study based on a comparison of the same two seasons. The increases observed in NIS-Flu data were not significant, however, because of overlapping confidence intervals.

Ethics Analysis: Application of Conceptual Frameworks

Kass Framework

In the following pages, Kass's six-question framework[23] is adapted to the NYC childcare influenza vaccine mandate to guide an ethics analysis of the mandate. Questions are answered based upon the results of the record review and analysis of vaccination rate changes before, during, and after the mandate.

1. What were the public health goals of the NYC childcare influenza vaccine mandate?

The goal of the NYC mandate was to increase influenza vaccination rates among 6-59-month-olds attending childcare. NYC DOHMH set the target of a 4.6 percentage point increase in influenza vaccination rates among all 6-59-month-olds. The increase in vaccination rates was expected to accelerate progress toward herd immunity against influenza which would protect individual children, their families, and the broader community against the potentially deadly disease.

The mandate specifically required children attending city-regulated childcare and preschool to receive influenza vaccine during the period of July 1 through December 31 each year.[177] This timeframe was specified because influenza activity tends to increase in October and peak between December and January.[163] Influenza viruses may still circulate through May.[163] The mandate called for vaccination by December 31 to protect children, families and the community against influenza earlier in the season and for a longer period within each annual season.

Because evidence has shown that children younger than 5 years are at high risk for serious complications from influenza,[12-13] attack rates for influenza among this age group are high (i.e.,

35% to 45%),[161] and that influenza vaccines are effective among children older than 2 years [167] (the majority of children attending childcare and preschool are 4 years of age [179]), the public health goals of the mandate may be considered ethical and justified. Detracting from the justification somewhat was that most of the evidence for effectiveness of vaccinating children to achieve herd immunity was based on school-aged children.[154] Studies focusing on pre-school-aged children are needed to examine the impact of vaccinating children younger than 5 years on herd immunity against influenza.

2. How effective was the mandate in achieving its stated goals?

Influenza vaccination rates among all NYC 6-59 months-olds increased 2.4 percentage points during the mandate, short of DOHMH's 4.6 percentage point target. Rates among 4-year-olds increased 11.4 percentage points, however, suggesting the mandate was effective for this age group. The results of this study also suggest that the mandate may have indirectly brought up vaccination rates among 5-8-year-olds. Rates among all 5-8-year-olds rose 4.5 percentage points during the mandate, with the largest increase seen among 8-year-olds at 6.1 percentage points. It is also possible that the mandate propped up rates among 6-59-month-olds, which were trending slightly downward before the mandate, and dropped precipitously by 12.1 percentage points after the mandate's suspension. These findings lend support to the conclusion that the mandate was ethical and justified based on its success, particularly among 4-year-olds.

3. What were the known or potential burdens of the mandate?

The main burdens of the childcare influenza vaccine mandate were: (1) curtailment of parental autonomy; (2) exposing children to potential health risks from influenza vaccines; and (3) costs, both monetary and time and effort, borne by parents to assure their children receive influenza vaccine between July 1 and December 31 of each year or to comply with

administrative procedures for obtaining a medical or religious exemption. Burdens were also imposed upon childcare and prekindergarten programs, and public health, to implement and enforce the mandate. Influenza, unlike other vaccines, must be received annually so efforts to comply with the mandate on the part of parents, childcare and prekindergarten programs, and public health must be undertaken every year. Burdens are further described below.

4. Can burdens be minimized? Are there alternative approaches?

(1) Autonomy. The parents who brought the lawsuit against NYC's childcare influenza vaccine mandate argued that they should have the right to decide against vaccinating their child. If this decision were to affect only themselves and their own child, this argument would be convincing. But because the effectiveness of vaccines relies on herd immunity, which requires a majority of individuals to be vaccinated, a parent's decision to accept vaccine affects other children, families, and the community. Reaching a high vaccination rate is especially important to protect infants too young to be vaccinated, people who cannot be vaccinated because their immune systems are compromised by cancer or other chronic disease, and elderly people who may not mount an adequate immune response to the vaccine. Consequently, it is important for healthy children who can be vaccinated to receive the vaccine. Parents who refuse a vaccine for their child, but look to other parents to accept vaccine to protect their own unvaccinated child through herd immunity, are unjust "free riders." The health risks of influenza vaccine, though very small, must be fairly shared along with the vaccine's benefits.

The burden of limiting parental autonomy may be reduced, however, by allowing a parent to obtain a legitimate exemption from the influenza vaccine requirement. The childcare influenza vaccine mandate did not change the existing policy for exemptions from vaccine requirements.

Exemptions are approved when a child has a physician-verified medical condition that could result in injury from influenza vaccine or the family demonstrates sincerely held religious beliefs in opposition to the vaccine. In New York State, a parent may request a medical or religious exemption; philosophical or personal belief exemptions are not permitted.[33, 37]

(2) Health risks. The risks of influenza disease are far higher than the risks of influenza vaccination. As with all vaccines, influenza vaccines are subject to pre-licensure clinical trials and post-licensure monitoring of adverse events to maximize their safety and efficacy.[51]

Influenza vaccines are considered very safe, but adverse events related to influenza vaccination do occur. Adverse events following vaccination are generally categorized by frequency (common, rare), extent (local, systemic), severity (hospitalization, disability, or death), causality, and preventability (intrinsic to vaccine, faulty production, faulty administration).[51] Such events may be coincidental with vaccination or vaccination may be causally related. Examples of common local adverse reactions to influenza vaccine are soreness, swelling, and redness at the site of injection. Systemic problems are also known to occur after influenza vaccination and include fever, headache, and fatigue. Most local and systemic reactions are mild and go away on their own after 1 or 2 days. Serious problems following influenza vaccination such as Guillain-Barre Syndrome or a life-threatening event, such as an acute allergic reaction (anaphylaxis) to a vaccine, are very rare. Estimates are they occur with 1 in 1million doses and can be minimized by screening.[51, 181] People who believed they may have been harmed by a vaccine may file a claim for compensation through the National Vaccine Injury Compensation Program. This program was established by the Vaccine Injury Compensation Act of 1986.[53]

(3) Costs: Financial, Time, and Effort

As described earlier, the financial burden of childhood vaccination has been reduced by the Vaccines for Children (VFC) Program.[59] Under VFC, the federal government purchases vaccines and collaborates with state and local health departments to distribute them to health care providers at no cost for administration to children 0-18 years of age who are covered by Medicaid or are uninsured, underinsured, or American Indian/Alaska Native. Vaccines purchased by states such as New York are also distributed through VFC to providers to vaccinate children covered by the State Child Health Insurance Programs.[59] The cost of vaccination has been further reduced for NYC children by the enactment of a state law requiring health insurance written in New York State to cover all vaccines recommended by the Advisory Committee on Immunization Practices for children 0-18 years.[60] Further, the NYC DOHMH distributes vaccines purchased with public funding to all NYC providers participating in VFC for underinsured children so they may be vaccinated in their medical homes. {Per VFC policy, underinsured children may receive vaccines purchased with VFC funds only in a Federally Qualified Health Center (FQHC) or at a FQHC-delegated provider.[59]}

Further improvements in access to influenza vaccines, in particular, are needed, however. Because influenza vaccine is needed every year, parents must spend time and effort to take their children to a medical provider for influenza vaccine year in and year out. This added burden may be relieved by expanding school-based health centers and school-located vaccination programs in schools with pre-kindergarten classes so parents can avoid having to take off from work to visit a health care provider. Allowing children to be vaccinated at pharmacies would also ease the burden since these sites may be more conveniently located and open on nights and weekends

outside of work hours. Currently, New York State allows pharmacists to vaccinate only adults aged 18 years and older.[182]

Alternatives. As described in this paper's literature review, there are a range of theory-informed and evidence-based interventions for raising vaccination rates. The NYC DOHMH uses these interventions up to the limit of its resources, which have declined over the years as public health funding has fallen. Despite DOHMH's efforts, influenza vaccination rates were decreasing among 6-59-month-olds over the four influenza seasons preceding NYC's childcare influenza vaccine mandate. In light of the trend, an attempt to raise influenza vaccination rates with a mandate was ethical and justified. Some argue that vaccine mandates may not be necessary in a society in which the health care system covers everyone and emphasizes prevention.[16-17] The US fails to meet these criteria, so vaccine mandates will likely still be needed to reach high vaccination rates in the future.

5. Was the mandate implemented fairly?

The childcare influenza vaccine requirement may be considered fair in that it applied to all children attending city-regulated childcare and prekindergarten in NYC. Children attending state-regulated and unregulated childcare were not covered by the mandate, a reasonable decision given NYC would not be in the same position to enforce the mandate in those facilities. It would have been fairer for all facilities to have been covered, but the practical reality was that the DOHMH needed to implement and enforce the mandate and it determined it could not do so in facilities it does not regulate. In addition, DOHMH was not able to require the public school-based prekindergarten programs to exclude unvaccinated children because the influenza vaccine requirement was not in state law. Hence, enforcement was not uniform across covered facilities.

The better and fairer approach would have been for all facilities to exclude unvaccinated children, but this was also not possible from a practical standpoint. Further, enforcement may have been inconsistent among the covered facilities because resources available for this purpose in the DOHMH and among childcare program staff were likely limited.

6. How could the benefits and burdens of the mandate be fairly balanced?

The benefits of the influenza vaccine mandate are fairly balanced against the burdens when the vaccine is easily available, safe, and effective. Major strides toward achieving broad access to vaccines have been made with the VFC program. Influenza vaccines currently have a strong safety record and are known to be effective in children older than 2 years.[51, 167] Efforts to ensure influenza vaccine safety and effectiveness must continue. Insufficient research has been done on influenza vaccine effectiveness among children younger than 2 years. Studies on this important subject are needed.[167]

The NYC childcare influenza vaccine mandate was enacted by the NYC Board of Health, whose members were appointed by democratically elected mayors. Community involvement in the decision-making took place through a public hearing and written comment period. Considering that only 276 written comments were received, public participation was very low. Efforts to encourage public participation in Board of Health decision-making are needed.

Conclusions. The above analysis supports the conclusion that the NYC childcare influenza vaccine mandate, which was intended to protect individual children and communities against a serious diseases, was ethical because it was enacted through a democratic process, applied to all NYC children age 6-59 months in city-regulated childcare and prekindergarten, allowed for

exemptions for legitimate medical or religious reasons, and was effective at increasing vaccination rates among 4-year-olds, the largest age group in childcare and prekindergarten.[179]

Field and Caplan Framework

This framework facilitates an analysis of the ethics of vaccine mandates based on competing ethical values of autonomy, beneficence, utilitarianism, justice, and nonmaleficence in the context of disease severity. Autonomy is a cherished American value that, when applied to childhood vaccine mandates, holds that the right to make a decision about vaccinating a child rests with that child's parent.[24] The parent has the right to liberty, meaning the parent should be free from government coercion. The parent must also have agency: the ability to understand the consequences of an action or the alternatives to action. Beneficence is the moral imperative to act for the benefit of another and emphasizes the best outcome for the individual. Utilitarianism focuses on the best outcome for the greatest number of people. Justice calls for fair distribution of scarce goods, requiring equal access to vaccines. The VFC program is an important means of facilitating equitable access by reducing cost barriers to vaccines. In the case of a medical intervention such as vaccination, justice also requires health risks to be fairly distributed among members of the community. Nonmaleficence is a directive against harming others, requiring vaccines to be generally safe for the majority of people.[24]

Autonomy takes precedence when an individual's action causes no harm to himself or others. As the risk of harm from a severe disease such as influenza increases, the importance of autonomy declines. Beneficence and utilitarianism become more prominent. Children younger than 5 years are at high risk of serious complications from influenza, and influenza attack rates in this age group are high.[12, 161] In this context, beneficence supports vaccination to protect the

individual child. Utilitarianism supports a mandate to require widespread vaccination to protect the community.[24]

The NYC childcare influenza vaccine mandate was just in that it provided for the risks of influenza vaccination, although small, to be equally shared among all children attending city-regulated childcare and prekindergarten. The unjust "free rider" outcome, occurring when a parents chooses not to vaccinate a child and instead relies on herd immunity based on risks borne by other children, is avoided in the context of a vaccine mandate. The childcare influenza mandate also met the directive for nonmaleficence because influenza vaccine has a strong safety record among children.[12-13, 51-52]

Conclusion. An analysis of the NYC childcare influenza vaccine mandate using the Field and Caplan framework demonstrates that the mandate was ethical. In the authors' graphic (page 91), the NYC mandate would fall in the lower right, based on the NYC DOHMH's obligation for utilitarianism, beneficence, justice, and nonmaleficence taking precedence over parental autonomy in the context of the potentially severe disease of influenza.

Limitations

The quantitative analysis for Aim 2 used a short interrupted time-series design, and administrative data from the Citywide Immunization Registry. Consequently, the study was subject to the limitations of these methods and data, as described below.

Interrupted Time-Series. Biases typically affecting the results of interrupted times-series studies are history, maturation, selection bias, instrumentation, cyclical or seasonal patterns, duration of the intervention, random fluctuations in data points, and autocorrelation of data, i.e., the tendency for data collected at consecutive time points to be dependent on each other.[112]

Autocorrelation, or serial dependency, of time-series data is common Consequently, ordinary statistics may not be used because they assume observations are independent of each other.[112] (Techniques are available to take autocorrelation into account in interrupted time-series studies with a sufficient number of data points.) This study encountered challenges in completing a valid statistical analysis; details are described in the later section entitled Citywide Immunization Registry Data.

Perhaps the greatest threat to internal validity is history,[112] i.e., the potential for factors other than the mandate to influence influenza vaccination rates among 6-59-month-olds at the same time the mandate was in effect. Examples of such factors are annual variation in severity of the influenza season, media coverage of pediatric deaths from influenza, the timing of availability of influenza vaccine, and whether the vaccine was a good match for the circulating virus strains. To reduce validity threats, the study design included the use of a control group, the 5-8-year-olds. Vaccination rates among the control group, who were not directly affected by the mandate, would be expected to respond to many validity threats in the same way as they would among 6-59-month-olds.

Non-equivalent Control Group. It should be acknowledged that the control group of children 5-8 years of age differs from the 6-59 month-old intervention group in several notable respects. Children younger than 5 years of age are at higher risk for influenza-association complications, which may motivate health care providers to prioritize influenza vaccination of the 6-59-month-olds over that of the 5-8-year-olds. The Advisory Committee on Immunization Practices recommended annual influenza vaccination for 6-23-month-olds in 2004,[130] and for 24-59-month-olds in 2006,[131] while expansion of the recommendation to all children 6 months of

age and older was issued in 2008.[132] Longer-standing recommendations are often associated with higher vaccination rates.

Younger children typically visit health care providers more often to receive other vaccines within the first 2 years of life and at 4-5 years of age before starting school.[36] Children older than 5 years are not typically due for other routine vaccinations, unless they are behind schedule, until age 11 years.[36] Consequently, the 6-59-month-olds have more opportunities to receive influenza vaccine during those visits. Co-administration of all recommended vaccines due at a visit is strongly encouraged. On the other hand, the 5-8-year-olds are of school-age and therefore likely to be in congregate settings while children younger than 5 years may still be cared for at home. These differences between the two age groups were not expected to change in response to the mandate, however, so they should not be considered a threat to a valid comparison of vaccination rates between the two groups.

Citywide Immunization Registry Data

Missing variable. There is no variable in the Citywide Immunization Registry indicating which children are in childcare and pre-kindergarten. A comparison of vaccination rates among 6-59-month-olds in childcare or prekindergarten to those not attending these programs is not possible using Citywide Immunization Registry data alone. Hence, the change in influenza vaccination rates among all NYC 6-59-month-olds was the primary outcome variable.

Population data versus sample and statistical analysis. Some researchers consider data from immunization information systems such as the Citywide Immunization Registry to be population data, and therefore do not conduct statistical analyses when using these data. However, data in these systems do not meet the full definition of population data. Even for well-

established systems like the Citywide Immunization Registry, which is estimated to capture over 90% of immunizations administered to NYC children,[103] some vaccination providers do not report 100% of vaccinations administered. Further, denominators are inflated by out-migration and duplicate records, necessitating use of census population estimates as denominators for vaccination rate calculations. (See details in Denominator measurement section.)

The Citywide Immunization Registry data used in this study was also not a random sample, and the size of the study population was very large. Chi-square tests comparing vaccination rate changes before and during the mandate among one-year age groups were all highly significant due to population size (data not shown). Other statistical methods were explored but were not a good fit for the data. There were too few data points in the time series to use segmented regression or Joinpoint software, and a difference in differences analysis was ruled out because vaccination rate trends among the intervention and control groups were not parallel before the mandate. Consequently, it was not possible to complete a meaningful statistical analysis of vaccination rate changes in this study.

Denominator measurement. The Citywide Immunization Registry, as with all immunization information systems, is challenged by determining an accurate denominator to measure proportion of children vaccinated. The main problem is that all children born in NYC are automatically enrolled with birth certificate information in the Citywide Immunization Registry but many may move away and the Citywide Immunization Registry is not notified. Providers have the capability of indicating in the Citywide Immunization Registry that children have moved or gone elsewhere (MOGE), but most don't because they do not know or will not take the time to indicate it. Hence, these children remain in the denominator. The extent of this problem is not fully known and requires study.

A further challenge to determining an accurate denominator is duplicate (i.e., unmatched) records. In the Citywide Immunization Registry, duplicate records are estimated at between 5% and 10% of all patient records.[103] The creation of duplicate records may be more common when influenza vaccinations are reported because children may receive influenza vaccine outside of their regular medical home and the vaccination is reported with minimal identifying information, preventing matching. The combination of the MOGE and duplicate records challenges results in inflated denominators. Researchers using immunization information system data often use census denominators for calculations of vaccination rates.

In this study, the Census Vintage 2016 population estimates were used for denominators in calculations of influenza vaccination rates. These estimates show an increase in the number of children in the younger age groups, which had the effect of lowering vaccination rates calculated for those groups. It is not clear at this time whether the estimates are accurate. The number of births in NYC has not increased during the study period, however, but rather has declined.[183] An increase in the size of the younger age groups would need to have resulted from a net in-migration of families with young children and/or an increase in families with young children born in NYC remaining in NYC. Based upon past experience, the US Census Bureau considers the vintage population estimates to be very accurate. The average absolute difference between the final total resident population estimates from 2000 to 2010 and the 2010 Census counts was only 3.1%.[144] Given the large sample size in this study, and the low error rate expected for the Census Vintage 2016 population estimates, future adjustments to the vaccination rate calculations in this study will likely change the vaccination rate estimates very little. The rates will be higher if the population estimates are reduced. If the adjustments are small, however, and

fairly even across the years, the vaccination rate trends observed in this study will remain unchanged. Hence, this study's findings will likely remain the same.

Reporting bias. There may be reporting bias in Citywide Immunization Registry data related to the linking of publicly purchased vaccine distribution to Citywide Immunization Registry reporting.[141] Nearly 80% of pediatric immunizing providers in NYC participate in the Vaccines for Children (VFC) program,[147] which distributes vaccines to providers at no cost for administration to children of low income families.[59] When the provider orders VFC vaccine from the NYC DOHMH, the number of doses the provider received from VFC previously is compared to the number of doses the provider reported administering to eligible children. Providers who reported less than 80% of vaccine doses as having been administered to eligible children may have their orders reduced.[141] Providers may therefore be more likely to report vaccinations administered to VFC-eligible children than to privately insured patients. The majority of NYC children are eligible for vaccines distributed through VFC, however. Approximately 74% of NYC children 0-18 years of age meet eligibility criteria for publicly purchased vaccines.[103, 141] Moreover, most providers are reporting through their electronic health records and these systems send all documented vaccinations to the Citywide Immunization Registry whether the child is eligible for VFC or is privately insured.[136]

DOHMH is aware that some providers, in particular those who do not participate in the VFC program, are not reporting to the Citywide Immunization Registry. These providers are contributing to bias in the data because their patients' vaccinations are not in the Citywide Immunization Registry. Unfortunately, DOHMH lacks the leverage that VFC vaccine distribution offers to incentivize reporting by these providers, other than the threat of fines for violating the NYC Health Code and State law. DOHMH resources for enforcement are very

limited, making it possible for some providers to remain noncompliant. The bias introduced by providers who do not report to the Citywide Immunization Registry is not expected to be a serious threat to internal validity of the interrupted time-series study, however. This is because the lack of reporting is not expected to differentially affect 6-59-month-olds compared to 5-8-year-olds or to have changed from 2011 forward. Further, the number of non-reporting providers is estimated to be less than 10% of all childhood immunizing providers in NYC.

Citywide Immunization Registry data may also be subject to bias related to underreporting of influenza vaccinations by providers who report regularly. Influenza vaccinations, in particular, are thought to be less well reported to the Citywide Immunization Registry than other vaccinations. One possible reason is that providers may offer influenza vaccine during special clinics held outside of their regular workflow and do not document influenza vaccination in the child's electronic health record so the vaccination does not get reported to the Citywide Immunization Registry. The extent of underreporting is not known and is not expected to differentially affect 6-59-month-olds compared to 5-8-year-olds.

Generalizability

This study was based on NYC data alone so generalizability may be limited. The results may be generalizable to other cities or jurisdictions similar to NYC. The findings and lessons learned contribute to the knowledge base related to the effectiveness of childcare vaccine mandates and factors to consider when weighing the pros and cons of mandating a childhood vaccine.

Lessons Learned

The results of this study add to the evidence base showing that childcare vaccine mandates are effective at raising vaccination rates. The results also confirm that a childhood vaccine

mandate, even when carefully deliberated and planned, can prompt powerful pushback. As few as five parents, along with a savvy lawyer who knew how to exploit the recent soda container ruling, were able to negate all of NYC DOHMH's efforts to put the mandate in place. The gains in influenza vaccination rates realized from NYC's mandate among 4-year-olds were quickly lost – in their entirety -- after the mandate's suspension.

Conclusions

This study found that NYC's rationale for the childcare influenza vaccine mandate was strong and carefully deliberated. Based upon the evidence of health and economic burdens of influenza, the increase in vaccination rates reported by New Jersey and Connecticut, and the support of pediatricians, nurses, and pro-vaccine parents, NYC's decision to seek the mandate was justified. The mandate was also ethical based on the application of both the Kass and Field and Caplan conceptual frameworks. An important factor was that the mandate was successful in raising vaccination rates among 4-year-olds, the largest age group in childcare and prekindergarten.[179]

An interesting question is whether the NYC DOHMH made the right decision to seek the mandate from the NYC Board of Health, given the mandate's suspension and the loss of all gains in influenza vaccination rates among 4-year-olds. The answer is complicated by several factors. The advantage of asking the NYC Board of Health to enact the influenza vaccine requirement was that the Board is made up of public health experts who are more likely to make decisions based on scientific evidence rather than political concerns, compared to the New York State Legislature. The Board enacted the mandate within a few short months of its introduction. In contrast, years of efforts to persuade the New York State Legislature to add the childcare

influenza vaccine requirement have not progressed beyond getting a bill introduced in committee.

There were several disadvantages to seeking the mandate from the NYC Board of Health, however. First, NYC's mandate was vulnerable to a court challenge because it was enacted soon after the NYC Board of Health's authority was undercut by the soda container court decision. A further complicating factor was that while it made sense to apply the mandate to only childcare facilities regulated by NYC, since NYC was able to enforce the mandate in these facilities, this decision amplified the mandate's vulnerability to a legal challenge because it did not cover all childcare facilities in NYC. In addition, because the mandate was enacted by a change to the NYC Health Code and not a change in state law, differential enforcement between the private childcare and prekindergarten programs and public school-based prekindergarten programs occurred. The NYC DOHMH was able to require the private programs to exclude noncompliant children, while the NYC Department of Education had the ability to decide against excluding noncompliant children in public prekindergarten because the vaccine requirement was not included in state law. The more effective and equitable approach would have been for all childcare and prekindergarten programs to enforce the vaccine requirement by excluding noncompliant children.

Despite the mandate's suspension, enacting the mandate may be considered the right decision in that it gave NYC the opportunity to demonstrate the mandate's effectiveness in increasing influenza vaccination rates among 4-year-olds, the largest age group in childcare and prekindergarten.[179] This evidence strengthens the argument for a childcare influenza vaccine requirement statewide and may help to move the proposal for state law change forward. In the

absence of such a change, however, alternatives to a vaccine mandate for increasing influenza vaccination rates among young children in NYC are needed.

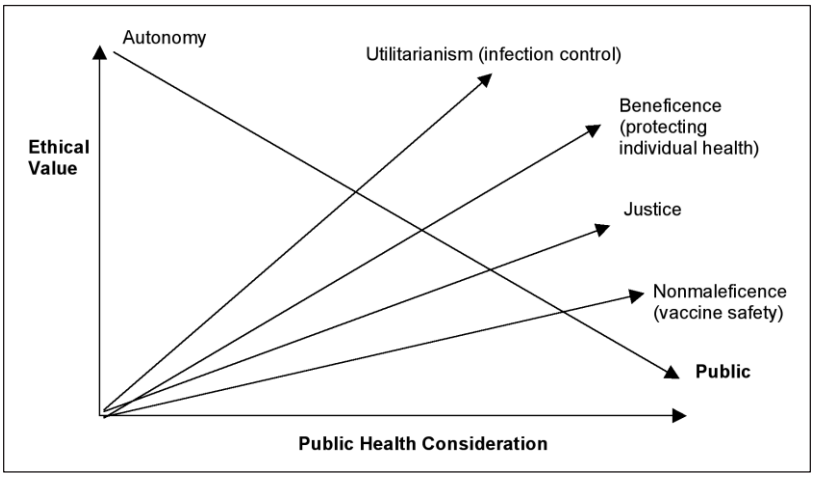
Directions for Future Research

This study pointed to gaps in research related to influenza vaccination of children. The effectiveness of influenza vaccine among children younger than 2 years requires more research. The impact of vaccinating children younger than 5 years of age against influenza to produce herd immunity against the disease is not known and needs study. Finally, in light of NYC's experience, research is needed to identify interventions to increase influenza vaccination rates among young children in the absence of a vaccine mandate.

Human Subjects

The Institutional Review Boards of the New York City Department of Health and Mental Hygiene and City University of New York determined that this study was exempt from the federal regulations under 45 CFR §46.101 (b)(4).

Diagram 2. Competing Ethical Concerns in Combination (Field and Caplan 2008)



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