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Helen Becz

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OVERVIEW

Research-evidence based decision-making is being increasingly used to inform public health policy. Defined as assessments explicitly linked to the best available scientific evidence and reflecting community preferences and feasibility, evidence-based practice in public health uses the best available evidence to make informed practice decisions. By considering a combination of multidisciplinary research and evaluation results, community beliefs and opinions, accumulated public health practice experience and other local considerations, public health practitioners can identify the programs that are most likely to be effective in a given jurisdiction. In recent years, the use of research evidence as the backbone of public health policy has been strongly promoted.¹ Harnessing and constantly improving the available science in support of effective public health action reflects a centuries-long public health tradition- many of the public health triumphs of the 21st century have resulted from the introduction of evidence-based programs that decrease the likelihood of transmission of communicable diseases.² However, to make good public policy, decision makers need reliable and consistent data. For the health of the public to be protected and improved, it is critical that interventions be based on the best possible scientific evidence, and that we continuously strive to improve and expand the scientific evidence base while actively promoting the use of the best-available, science-tested programs and policies in public health decision-making.

¹ Betty Kirkwood, *Making Public Health Interventions More Evidence Based*, 328 BRIT. MED. J., Apr. 24, 2004 at 966, 966-967 (2004).

² CENTERS FOR DISEASE CONTROL & PREVENTION, TEN GREAT PUBLIC HEALTH ACHIEVEMENTS --- UNITED STATES, 2001--2010 (2011), <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6019a5.htm>.

The importance of utilizing a rigorous evidence-based approach in crafting public policy decisions is especially evident in light of recent studies analyzing the efficacy of influenza vaccinations. Until fairly recently, the data used to make recommendations regarding influenza vaccination indicated a 70% to 90% efficacy rate³ and influenza-related public policy recommendations were largely built around those statistics. However, a number of recent studies have provided compelling evidence that those numbers are an over-estimation of the influenza vaccine's efficacy. More recent data indicates that influenza vaccines can provide moderate protection, but that such protection is greatly reduced or absent in some seasons. New Jersey and Connecticut recently enacted Childhood Influenza vaccination mandates to propagate vaccination-related public health benefits, based mainly on a desire to decrease transmittable disease related morbidity and mortality. The results of novel studies on Influenza vaccine efficacy, as well as of systematic reviews examining existing efficacy studies, cast a new light on the public health-based push for influenza vaccination mandates and highlight the importance of getting public health policy analysis 'right' beginning at the research and data level.

There exists a pervasive gap between public health decision-making and evidence-based data analysis. The Center for Infectious Disease Research and Policy's (CIDRAP) Comprehensive Influenza Vaccine Initiative (CCIVI), offers a good example of this gap; it is a systematic review of the Influenza vaccine's efficacy which demonstrates that a number of the claims on which public health organizations such as the ACIP have built an argument for influenza vaccination may be over-stated or inaccurate. Given how Constitutionally entrenched judicial deference to legislative decision-making in regard to public health is, it is important it is

³ MICHAEL T. OSTERHOLM ET AL., THE COMPELLING NEED FOR GAME CHANGING INFLUENZA VACCINES 21 (Ctr. for Infectious Disease Research & Policy 2012) [hereinafter CIDRAP].

for public health organizations to not only implement rigorous evidence-based mechanisms for policy creation, but to also be able to describe them during policy creation and proposal.

The Constitutionality of mandatory vaccination lies squarely in the police power of the States. While new data on the vaccine's effectiveness may not cast a new light on the Constitutionality of Influenza vaccine mandates, it does bring to the forefront questions about the relationship between our healthcare system, public health decisions, and the use of research evidence data.

This paper will attempt to touch upon a few examples of the gap between public health decision-making and evidence-based data analysis. It will then examine the CIDRAP study on Influenza vaccine efficacy to more closely understand type of research necessary for the creation of effective public health decisions. It will also examine the Constitutionality of vaccination mandates in order to demonstrate how entrenched State decisions regarding public health are, emphasizing the importance of 'getting it right' the first time.

Finally, this article will use New Jersey as a case study, looking at its 2008 Childhood Influenza Vaccination mandate, the reasoning behind it, and its effects. By examining the vaccination rates of New Jersey children from 2004-2012, specifically what effect New Jersey's addition of the seasonal influenza vaccine to its mandatory vaccination list has had on influenza-related hospitalization levels in the 65+ age group, this paper will look at whether or not New Jersey's decision to enact legislation making yearly influenza vaccinations mandatory for children has exhibited positive movement towards the legislation's Stated public policy goal of perpetuating herd immunity.

HOLES IN THE DATA MEANS HOLES IN THE PUBLIC POLICY

The past decade and through 2010 has seen the United States population recommended for annual influenza vaccinations grow from 185 million to a universal recommendation. In 2000, the Advisory Committee on Immunization Practices (ACIP) embarked on a series of recommendations that gradually increased the percentage of the general population recommended to receive the influenza vaccine.⁴ These changes culminated in 2010 with a universal recommendation for every 6 months of age and older to be vaccinated.⁵ In justifying the increased recommendation, the ACIP held a general consensus that if the vaccine was administered to more people, high immunization rates would provide enough herd immunity to protect those at greatest risk, even if they remained unvaccinated or unprotected by the vaccine.⁶ By 2020, the target for seasonal influenza vaccination coverage in the United States is 80% for children and adults and 90% for high-risk individuals.⁷ The ACIP's justification for these changes laid primarily in the desire to increase population coverage rates, bolster indirect benefits, and improve outcomes indirectly related to morbidity, such as antibiotic use for secondary infections or work absenteeism linked to influenza like illnesses (ILI).⁸

The Advisory Committee on Immunization Practices (ACIP) came into being in 1964, and under the Public Health Service Act was to “assist States... in the prevention and control of communicable diseases; to advise States on matters relating to the preservation and improvement

⁴ CENTERS FOR DISEASE CONTROL & PREVENTION, PREVENTION AND CONTROL OF INFLUENZA (Morbidity & Mortality Weekly Report 2000), <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr4903a1.htm>.

⁵ CENTERS FOR DISEASE CONTROL & PREVENTION, PREVENTION AND CONTROL OF INFLUENZA WITH VACCINES (Morbidity & Mortality Weekly Report 2010), http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5908a1.htm?s_cid=rr5908a1_w

⁶ Id.

⁷ DEPT. OF HEALTH & HUMAN SERVICES, HEALTHY PEOPLE 2020 OBJECTIVES (2010), <http://www.healthypeople.gov/2020/topicsobjectives2020/pdfs/HP2020objectives.pdf>.

⁸ Id.

of public health; and to make grants to States to assist in meeting the costs of communicable disease control programs.”⁹ The ACIP remains the key decision-making body within the Federal government on childhood immunization policy.¹⁰ Since the ACIP’s charter requires it to advise the public about vaccines against vaccine-preventable diseases, it quickly became the only Federal entity to make vaccination recommendations to the States for public health, and for children in particular.¹¹ States, including New Jersey, rely on ACIP’s recommendations for school vaccination mandates.

The ACIP has a mandate to advocate for health promotion behaviors, including routine immunizations. However, the progressive move towards a universal influenza vaccination recommendation was made because it was believed by the ACIP decision-making board to be in the best interest of the population, even in the absence of strong scientific data to support the claim.¹² A review of ACIP documents found that no data were presented at ACIP meetings or in other records from 1999 to 2011 that addressed the gaps in knowledge before its recommendation expanded to include universal influenza vaccinations. Even though research data to address these gaps was generally not available, the ACIP gradually developed a consensus that a universal vaccination policy would be beneficial to the public’s health.¹³

This type of ‘program first, data later’ behavior is not only restricted to the United States, or to the ACIP. A study of Ontario public health decision makers¹⁴ found consensus on the

⁹ DEPT. OF HEALTH & HUMAN SERVICES, CHARTER OF THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (2012), <http://www.cdc.gov/vaccines/acip/committee/charter.pdf>.

¹⁰ Mary Holland, *Compulsory Vaccination, the Constitution, and the Hepatitis B Mandate for Infants and Young Children*, 12 YALE J. OF HEALTH POLICY, LAW, & ETHICS 54 (2013). [hereinafter HOLLAND].

¹¹ *Id.* AT 54.

¹² CIDRAP, *supra* note 3, at 52.

¹³ CIDRAP, *supra* note 3, at 56.

¹⁴ Alison Ritter, *How Do Drug Policy Makers Access Research Evidence*, 20 INT’L J. OF DRUG POL’Y 75 (2009).

definition of evidence-based decision making. It was generally perceived as “a process whereby multiple sources of information, including research evidence, were consulted before making a decision to plan, implement, and alter (if necessary) programs and services.”¹⁵ In practice, however, managers were likely to make a decision and subsequently seek evidence to justify it. There have been a number of other studies examining the gap between what research shows is effective and the public health policies that are enacted and enforced. In a systematic search of model public health laws focusing on the disclosure of research-based decision making in public health, 107 model public health laws were identified, covering 16 topics. In only 44% of the model laws did the sponsors present any information on the methods that they used to develop their model laws.¹⁶ Out of those 44%, none of the studies provided more than a topical glance at the model law’s basis in current scientific or practice-based knowledge. While a lack of information does not necessarily mean that public health lawmaking is not rooted in evidence-based research, the lack of disclosure regarding the methods and scientific evidence used only makes it more difficult to judge the value of proposed legislation.

An easily identifiable example of the gap between public health decision making and solid data analysis in the context of vaccine mandates is the ‘common knowledge’ herd immunity connection between mandated influenza vaccinations and positive public health consequences that has been widely used to justify expanded vaccination recommendations and mandates. Despite clear evidence regarding herd immunity and other traditional childhood diseases, Influenza researchers are still not clear on how influenza vaccination affects herd

¹⁵ *Id.* at 75.

¹⁶ DeKeely Hartsfeld ET AL, *A Review of Model Public Health Laws*, 97 AM. J. OF PUB. HEALTH 97 (2007).

immunity.¹⁷ The concept of herd immunity rests upon the claim that when a large percentage of a population is vaccinated against a pathogen, the entire community –including those too young or ill to be vaccinated – receives additional protection.¹⁸ It is a cornerstone of immunization strategies for diseases of childhood, where vaccine coverage rates typically exceed 85% and individual vaccines have efficacies of over 90%.¹⁹ The drastic reduction over the past century in morbidity and mortality due to traditional vaccine preventable illnesses can be credited in large part to the commitment of lawmakers to the principle of compulsory vaccination as a pre-requisite to school enrollment.

States institute mandatory immunization requirements as a pre-requisite to public school enrollment because it is the most efficient way of perpetuating herd immunity. Since achieving herd immunity is an inherently preventive measure, mandating school vaccinations as a method of perpetuating herd immunity is far less costly for governments, health care providers, and the economy than treating victims of a disease after it has appeared in a community. From a public health perspective, traditional State school vaccination laws have been very successful. The rate of fully immunized school-age children in the United States (>95%) is as high as or higher than most other developed countries.²⁰

Presumably, based on the demonstrable herd immunity benefits of ‘traditional’ mandated childhood vaccinations, Public Health officials have assumed that herd immunity plays a role in population protection following widespread influenza vaccination; however, given the varied

¹⁷ CIDRAP, *supra* note 3, at 13.

¹⁸ CENTERS FOR DISEASE CONTROL & PREVENTION, COMMUNITY IMMUNITY ("HERD IMMUNITY") (2012), <http://www.vaccines.gov/basics/protection>.

¹⁹ CIDRAP, *supra* note 3, at 28.

²⁰ JAMES G. HODGE & LAWRENCE O. GOSTIN, SCHOOL VACCINATION REQUIREMENTS: HISTORICAL, SOCIAL, AND LEGAL PERSPECTIVES 53 (Ctr. for Law & the Public's Health at Johns Hopkins & Georgetown Universities 2002) [hereinafter HODGE].

coverage rates following vaccination campaigns and the wide ranges of efficacy and effectiveness of influenza vaccines in any given season, it remains unclear whether or not herd immunity plays a significant role in influenza prevention and control.²¹ While several studies suggest that influenza vaccination campaigns provide some level of herd immunity specifically in reducing influenza morbidity and mortality in those 65 years of age and older, data from these studies are based on nonspecific outcomes such as ILI.²² Further, studies on herd immunity conducted on relatively closed populations such as the Amish, Mennonites, or Hutterites, cannot be extrapolated to the general population.²³ Recently, a reanalysis of country-level data in Japan provided evidence for a significant reduction in influenza-related mortality in those 65 years of age and older because of childhood influenza immunization effort.²⁴ These findings suggest that vaccinating children for influenza may provide some protection to those 65 years of age and older. However, the existing data are not compelling, and the impact that influenza vaccination in children has on influenza outcomes at the population level remains uncertain.²⁵ It would appear that, in regards to contemporary influenza vaccination public policy, Public Health officials may have been, to a certain extent, extrapolating facts about herd immunity to the Influenza vaccine's effects.

Public health leaders should provide with clarity the scientific evidence supporting the effectiveness of the influenza vaccines by type of vaccine and recipient age/underlying health conditions. If the general public or professional groups such as healthcare workers perceive that

²¹ CIDRAP, *supra* note 3, at 28.

²² CIDRAP, *supra* note 3, at 29.

²³ Mark Loeb & Margaret Russell, *Effect of Influenza Vaccination of Children on Infection Rates in Hutterite Communities A Randomized Trial*, 303 THE J. OF THE AM. MED. ASS'N, Mar. 10, 2010 at 303 (2010).

²⁴ VIVEK CHARU, CECILE VIBOUD & , INFLUENZA-RELATED MORTALITY TRENDS IN JAPANESE AND AMERICAN SENIORS: EVIDENCE FOR THE INDIRECT MORTALITY BENEFITS OF VACCINATING SCHOOLCHILDREN 6 (PLOS 2011), <http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0026282>.

²⁵ CIDRAP, *supra* note 3, at 29.

public health officials have ‘oversold’ the effectiveness of the vaccine, then they risk losing the trust of the general population. Without trust, public officials will not be able to persuade the public to take even the most reasonable precautions during an emergency. The public will support reasonable public health interventions if they trust public health officials to make sensible recommendations that are based in science.

PERCEPTION VS. REALITY: THE EFFICACY OF THE INFLUENZA VACCINATION

More than 500 infectious diseases are known to occur in people, but in the United States public health officials recommend routine childhood or adult vaccinations for only 17 of these diseases.²⁶ Out of those 17, influenza is the only disease for which a universal annual vaccination recommendation exists.²⁷ Influenza virus is the causative agent of influenza infection, and three types of influenza viruses cause infections in humans.²⁸ Small mutations (referred to as antigenic drift) result in slight changes to antigens in each subtype between influenza seasons.²⁹ Because of antigenic drift, the influenza vaccine is reformulated annually on the basis of the most likely strains that are predicted to circulate during the upcoming influenza season.³⁰ There are two different types of influenza vaccine licensed in the United States – TIV and LAIV. Available formulations for both the trivalent inactivated influenza vaccine (TIV) and the live attenuated influenza vaccine (LAIV) both contain antigens for three influenza strains predicted to circulate

²⁶ CENTERS FOR DISEASE CONTROL & PREVENTION, 2013 RECOMMENDED IMMUNIZATIONS FOR CHILDREN FROM BIRTH THROUGH 6 YEARS OLD, <http://www.cdc.gov/vaccines/parents/downloads/parent-ver-sch-0-6yrs.pdf>.

²⁷ CIDRAP, *supra* note 3, at 2.

²⁸ Frank Carrat, *Influenza Vaccine: The Challenge of Antigenic Drift*, 25 VACCINE, Sept. 28, 2007 at 6852-6862 (2007).

²⁹ *Id.* at 6860.

³⁰ *Id.* at 6860.

during the upcoming influenza season.³¹ Influenza is the only human infection for which we must routinely re-formulate the vaccine to accommodate the mutational process and maximize the potential protective immune response.³² In and of itself, this prediction process means that on certain years the vaccine will be wrongly matched to the circulating virus, and the effectiveness of the vaccine could be markedly decreased.

Public health and medical communities generally accept the premise that currently licensed influenza vaccines are largely effective in preventing influenza infection in most populations. In 2012, the Center for Infectious Disease Research and Policy (CIDRAP) released its CIDRAP Comprehensive Influenza Vaccine Initiative (CCIVI), which represents one of the most exhaustive Systematic Reviews of any vaccine ever undertaken. The ultimate conclusion made by CIDRAP was that during some influenza seasons, vaccination offers substantially more protection for most of the population than being unvaccinated; however, influenza vaccine protection is markedly lower than for most routinely recommended vaccines and is suboptimal. The primary reason for this discrepancy appears to be issues with the methodologies of previous studies.

The public policy decision-making process involves a series of steps: problem delineation, option development, and then implementation. The evidence required at each step must draw from systematic reviews, accurate qualitative data, and corroborated quantitative evidence. In the case of vaccine mandates, the evidence required to make a decision must cover not just the question of an intervention's effectiveness, but also implementation, organization,

³¹ Comm. on Infectious Diseases, *Prevention of Influenza: Recommendations for Influenza Immunization of Children, 2008-2009*, 122 PEDIATRICS NUMBER 5, Nov. 5, 2008

³² CIDRAP, *supra* note 3, at 10.

and feasibility. Basing public policy decisions on healthcare data pre-supposes that the data being used is accurate and up to date.

Hundreds of influenza vaccine efficacy and effectiveness studies have been conducted since the 1940s. The design of these studies has varied widely, with most not meeting the minimal requirements for unbiased recruitment and outcome ascertainment. The results most of those studies, therefore, offer little value in understanding contemporary vaccine effectiveness and efficacy.³³ Most notably, the frequently cited estimate of 70% to 90% for influenza vaccine efficacy in healthy adults was originally documented in studies conducted mostly in military personnel between 1943 and 1969, and is inapplicable to contemporary flu vaccines.³⁴ The CIDRAP study was required to filter through all studies that evaluated vaccine efficacy and effectiveness published from 1967 -2012 and select then summarize those that used rigorous methodology and specific infection outcome end points.³⁵ The researchers identified 5,707 studies on influenza vaccines in humans through a PubMed search. Of those, 992 were identified as cohort studies, case-control studies, clinical trials, or RCTs. A review of those studies identified 176 (18%) potentially eligible studies which estimated vaccine efficacy and/or effectiveness. From the 176 potentially eligible studies, the researchers identified 31 (18%) studies that met the criteria for adequate study design and conduct³⁶

Most studies since the 1940s that have assessed influenza vaccine efficacy or effectiveness have relied on suboptimal methodology. The few remaining studies, which provide the highest quality of evidence to assess the true impact of influenza vaccines, have found a level

³³ CIDRAP, *supra* note 3, at 21.

³⁴ *Id.* at 21.

³⁵ *Id.* at 6.

³⁶ *Id.* at 21.

of protection lower than often attributed to the vaccine.³⁷ The CCIVI study differs in several ways from previous analyses of the efficacy and effectiveness of influenza vaccines licensed in the United States. Traditional studies use efficacy to refer to the relative risk-reduction in which symptomatic laboratory confirmed influenza is the outcome, whereas effectiveness is used for influenza-like illness. Such illness is a non-specific clinical outcome associated with a wide range of respiratory viruses. The CCIVI study uses the classic epidemiological definitions of efficacy and effectiveness, in which efficacy refers to the relative risk reduction attributed to vaccination as estimated from a randomized controlled trial, and effectiveness refers to the same measure of effect from an observational study.³⁸ In short, the CCIVI study included only studies whose endpoints were laboratory-confirmed influenza on RT-PCR or viral-culture.

The new analysis estimated a vaccine efficacy against influenza in adults of 59% (95% CI 51-67), compared with an estimated efficacy in healthy adults of 73% (51-84) in ‘traditional’ studies, for years when circulating and vaccine strains were well matched, and 44% (23-59) in years when they were not well matched.³⁹ When broken down by vaccine type, For TIV, results demonstrated (1) evidence of moderate protection (pooled estimate of 59%) for healthy adults 18 to 64 years of age, (2) inconsistent evidence of protection in children aged 2 to 17 years, and (3) a paucity of evidence for protection in adults 65 years of age and older. For LAIV, results demonstrated (1) evidence of high protection (pooled estimate of 83%) for young children 6 months to 7 years of age, (2) inconsistent evidence of protection in adults 60 years of age and older, and (3) a lack of evidence for protection in individuals between 8 and 59 years of age.⁴⁰

³⁷ CIDRAP, *supra* note 3, at 30.

³⁸ MICHAEL T. OSTERHOLM, DOI:10.1016/S1473-3099(11)70295-X, EFFICACY AND EFFECTIVENESS OF INFLUENZA VACCINES: A SYSTEMATIC REVIEW AND META-ANALYSIS (The Lancet 2011).

³⁹ *Id.* at 1

⁴⁰ CIDRAP, *supra* note 3, at 6.

This type of systematic review indicates that the ACIP, and other public health organizations issuing recommendations based on similar data, may have been choosing the ‘wrong’ studies to support their claims. In the public health sphere, single studies and evaluations are more commonly used to support policy than are systematic reviews,^{41 42} despite the fact that systematic reviews provide a broader viewpoint prior to decision-making by summarizing the results of primary scientific studies that meet explicit criteria. In a systematic review of model public health laws, Moulton et al. identified 65 systematic reviews published over the past 5 years, and found that when the results of the systematic reviews were examined against 52 public health laws, 27 were found effective, 23 had insufficient evidence to judge effectiveness, 1 was harmful, and 1 was found to be ineffective.⁴³

It is clear that public health officials need to better understand and describe the evidence-based elements supporting existing or proposed policy. Public health mandates traditionally have strong judicial and Constitutional backing in their favor. Reversing any legislative decision regarding the public’s health may be difficult or impossible to do without direct intervention from the legislature which enacted it, and because of this it is especially important that public health proposals and recommendations clearly present and explain the research and evidence supporting them.

⁴¹ Philip Davies, Kathryn Newcomer & Haluk Soydan, *Government As Structural Context for Evaluation*, in THE SAGE HANDBOOK OF EVALUATION 170 (Ian F. Shaw, Jennifer C. Greene & Melvin M. Mark eds., SAGE Publications Ltd 2006).

⁴² MARIE-HELENE ADRIEN ET AL., BRIDGING THE GAP. THE ROLE OF MONITORING AND EVALUATION IN EVIDENCE-BASED POLICY MAKING (Marco Segone ed., UNICEF 2008), http://www.unicef.org/ceecis/evidence_based_policy_making.pdf.

⁴³ Anthony D. Moulton et al., *The Scientific Basis for Law As a Public Health Tool*, 99 AM. J. OF PUB. HEALTH 17-24 (2009).

LEGAL AND SOCIAL CONTEXT OF VACCINE MANDATES

Mandatory vaccinations have been around since as early as 1802, when an outbreak of smallpox in New Orleans forced the mayor to enact a compulsory vaccination law.⁴⁴ Many existing school vaccination laws were enacted in the 1960s and 70s because at the time State legislatures were influenced by the significantly lower incidence rates of measles among school children in States with comprehensive immunization laws.^{45 46} Since the first mandatory school vaccination laws in the 1960s, the list of recommended childhood vaccinations has expanded to cover 17 separate transmittable illnesses.⁴⁷

Contemporary school vaccination requirements are seen as critical to ensuring high rates of vaccination in the United States. Incidents of communicable diseases among children have significantly declined since the introduction and regular enforcement of school vaccination laws.⁴⁸ Public health officials cite a number of reasons for this belief, but the primary logical thread is herd immunity. Linking vaccination with school attendance, which is itself required by law, ensures that vaccines reach the greatest number of children. Schools are a prime venue for the transmission of vaccine-preventable disease, and active school-age children can further spread disease to others with whom they interact.⁴⁹ Therefore, vaccinating as a condition of school attendance is believed to be the most efficient way of perpetuating herd immunity.

⁴⁴ HODGE, *supra* note 20, at 18

⁴⁵ HODGE, *supra* note 20, at 47

⁴⁶ Kenneth B. Robins, *Low Measles Incidence: Association with Enforcement of School Immunization Laws*, 71 AM. J. OF PUB. HEALTH 270 (1981).

⁴⁷ CENTERS FOR DISEASE CONTROL & PREVENTION, 2013 RECOMMENDED IMMUNIZATIONS FOR CHILDREN FROM BIRTH THROUGH 6 YEARS OLD (2013), <http://www.cdc.gov/vaccines/parents/downloads/parent-ver-sch-0-6yrs.pdf>.

⁴⁸ HODGE, *supra* note 20, at 5.

⁴⁹ Comm. on Infectious Diseases, *Prevention of Influenza: Recommendations for Influenza Immunization of Children, 2008-2009*, 122 PEDIATRICS (2008).

Historical and modern patterns of the real, perceived, and potential harms of vaccination, governmental abuses underlying its widespread practice and strongly-held religious beliefs have led to school vaccination laws being challenged by parents and other interested parties on legal, ethical, social, and epidemiological grounds.⁵⁰ Vaccination programs have been legally challenged as (1) inconsistent with federal Constitutional principles of individual liberty and due process (2) an unwarranted governmental interference with individual autonomy; and (3) an infringement of personal religious beliefs under 1st Amendment principles.⁵¹ Out of this litigation, a balancing act inherent in the Constitutionality of mandatory immunization has emerged – the State’s interest in protecting public health must be balanced against concepts of informed consent and personal autonomy. At the crux of the public debate about mandated vaccinations are tensions between the public health benefits and the infringements on individual and parental freedoms arising from the mandated vaccination of school children in the United States.

Laws and regulations that restrict individual liberties are routinely enacted to protect and promote public health and welfare. These laws and regulations pervade our society, including sanitation laws, traffic laws, occupational health and safety laws, and environmental regulation. Under the US Constitution, the power to restrict individual liberties for public health purposes is primarily reserved for individual States through police power. The police power of the State is “the inherent authority of the State to enact laws and promulgate regulations to protect, preserve and promote the health, safety, morals, and general welfare of the people.”⁵² For the purposes of public health, the federal government's authority is generally limited to regulating interstate

⁵⁰ HODGE, *supra* note 20, at 6.

⁵¹ HODGE, *supra* note 20, at 6.

⁵² LAWRENCE O. GOSTIN, *PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT* 48 (Univ. of Cal. Press 2008).

commerce, taxing, and spending. Historically, the judiciary has affirmed mandatory vaccination as a proper exercise of State police power. In Jacobson v Massachusetts, the United States Supreme Court articulated a series of standards in affirming a Massachusetts law requiring smallpox vaccination: public health necessity, reasonable means, proportionality, and harm avoidance.

The United State Supreme Court Case Jacobson v. Massachusetts established the right of the State to compel an individual to receive a vaccination. In doing so, the Court recognized that the need to serve the ‘common good’ confers to States broad powers that may restrain the rights of individuals. However, the court did not envision a boundless State power to protect the public’s welfare. Jacobson stands firmly for the proposition that while police powers authorize States to compel vaccination for the public good, government power must be exercised reasonably to avoid Constitutional scrutiny. The Jacobson decision describes a State power that balances public health protections with the principles of necessity, reasonableness, proportionality, and harm avoidance.

Public Health Necessity – Justice Harlan in Jacobson insisted that police powers must be based on the ‘necessity of the case’ and could not be exercised in an arbitrary, unreasonable manner or go beyond what was reasonably required for the safety of the public.⁵³ *Reasonable Means* – The Jacobson court introduced a means/end test that required a reasonable relationship between the public health intervention and the achievement of a legitimate public health objective.⁵⁴ Even though the objective of the legislature may be valid and beneficent, the methods adopted must have a ‘real or substantial relation’ to protection of the public health, and

⁵³ Jacobson v. Commonwealth of Massachusetts, 197 U.S. 11, 27, 25 S. Ct. 358, 362, 49 L. Ed. 643 (1905)

⁵⁴ Id. at 361.

cannot be a ‘plain, palpable invasion of rights.’⁵⁵ *Proportionality* – The police power of a State may be exerted in such circumstances or by regulations so arbitrary and oppressive in particular cases as to justify the interference of the courts to prevent wrong, injustice, oppression, or absurd consequences.⁵⁶ *Harm Avoidance* – while those who pose a risk to a community can be required to submit to compulsory measures, including vaccination, for the common good, the measure itself should not pose a health risk to its subject.⁵⁷

Thus, the more specific questions posed to the court by Jacobson were whether the safety of the public justified this particular restriction and whether it was enforceable by reasonable regulations. The Court answered *yes* to both questions. It noted that the vaccination law applied “only when, in the opinion of the Board of Health, that was necessary for the public health or the public safety.”⁵⁸ The board of health was qualified to make that judgment, and, consistent with its own precedents, the Court said that it was the legislature’s prerogative to determine *how* to control the epidemic, as long as it did not act in an unreasonable, arbitrary or oppressive manner.⁵⁹ Vaccination was a reasonable means of control: “The State legislature proceeded upon the theory which recognized vaccination as at least an effective if not the best known way in which to meet and suppress “the evils of a smallpox epidemic that imperiled an entire population.”⁶⁰

After Jacobson, The U.S. Supreme Court subsequently determined that States and localities have the power to take significant steps to protect children from communicable disease, even to the extent of denying children the ability to attend public school. In Zucht v. King, the

⁵⁵ Id. at 365.

⁵⁶ Id. at 366.

⁵⁷ Id. at 366.

⁵⁸ Id. at 358.

⁵⁹ Id. at 359.

⁶⁰ Id. at 363.

Supreme Court specifically upheld a local government mandate for vaccination as a pre-requisite for attendance in public school.⁶¹ In his terse opinion, Justice Brandeis held that States may delegate to a municipality the power to order vaccination consistent with the Constitution and prior decisions of the court.⁶² Furthermore, through its ruling in Prince that “the right to practice religion freely does not include liberty to expose the community or the child to communicable disease or the latter to ill health or death”⁶³ the Supreme Court further upheld the right of States to require that children receive immunizations, even when such obligations conflict with both parental rights and religious rights as conferred by the Establishment and Free Exercise clauses of the First Amendment of the U.S. Constitution. Seen together, Jacobson, Zucht, and Prince form the backbone of the common law principle supporting the State’s power to require the general public and children in particular to vaccinate.

Although the principles articulated in the cases of Jacobson, Zucht, and Prince continue to inform analysis of public health actions, the standards for the Constitutionality of State action have evolved significantly since 1905. Today, the US Supreme Court evaluates the Constitutionality of laws burdening individual liberties by applying an explicit hierarchy of rights and corresponding standards of review. For Constitutionally protected liberty, the Supreme Court has recognized that some aspects of liberty are more important than others. The most important aspects of liberty, deemed ‘fundamental’ are subjected to strict scrutiny: the court determines (1) whether the government could prove that a challenged law served a purpose so ‘compelling’ that it was justified in taking action⁶⁴ and (2) whether what the law required or

⁶¹ Zucht v. King, 260 U.S. 174, 175, 43 S. Ct. 24, 67 L. Ed. 194 (1922)

⁶² Id. at 67.

⁶³ Prince v. Massachusetts, 321 U.S. 158, 166, 64 S. Ct. 438, 442, 88 L. Ed. 645 (1944)

⁶⁴ Wisconsin v. Yoder, 406 U.S. 205, 215, 92 S. Ct. 1526, 1533, 32 L. Ed. 2d 15 (1972)

forbade was ‘narrowly tailored’ to achieve that purpose as did so with as little interference with individual liberty as possible.⁶⁵

Aspects of liberty that do not qualify as fundamental are subjected to a ‘rationality review’ – a test that displays the Court’s deference to the legislature. Laws that restrict non-fundamental liberty rights need only be rationally related to any legitimate State interest,⁶⁶ and the court continues to accept almost any plausible reason as justification⁶⁷. Between these two extremes of strict scrutiny and rational basis review, the Supreme Court has required an intermediate level of scrutiny or a ‘pumped up’ rational basis test.⁶⁸ It is unclear what standard of review the Supreme Court would apply to a State compulsory vaccination mandate today. The Supreme Court decided Jacobson before explicit standards for review of government authority were adopted. Several prominent public health scholars have suggested that a case like Jacobson, tried today, would require intermediate scrutiny because of the clear liberty interests at stake⁶⁹

Assuming intermediate scrutiny would be applied, in order to survive a Constitutional challenge mandatory health immunization laws first must show a legitimate State interest. The State's interest is clear: reducing morbidity and mortality resulting from spread of influenza. Second, States must show that mandating influenza vaccination is rationally related to reducing the influenza burden. The Supreme Court does not require large-scale, randomized trials to support the Constitutionality of a State’s action; rather, to meet the rational basis standard a State must establish only a plausible scientific relation between the proposed action and the State's interest. Existing scientific evidence, including the CIDRAP study, supports the conclusion that

⁶⁵ Gratz v. Bollinger, 539 U.S. 244, 123 S. Ct. 2411, 156 L. Ed. 2d 257 (2003)

⁶⁶ United States v. Carolene Products Co., 304 U.S. 144, 153, 58 S. Ct. 778, 784, 82 L. Ed. 1234 (1938)

⁶⁷ Id. At 785.

⁶⁸ Craig v. Boren, 429 U.S. 190, 97 S. Ct. 451, 50 L. Ed. 2d 397 (1976)

⁶⁹ HOLLAND, *supra* note 10, at 54.

vaccinating against influenza reduces both the transmission and the incidence of influenza better than not vaccinating. It is plausible that courts would, regardless of any amount of evidence indicating the relative weakness of data upon which the decision to institute vaccination mandates was made, very likely find that State laws and regulations mandating vaccination of school children are Constitutional exercises of State power.

Modern requirements for compulsory school vaccination coupled with exemptions for medical, religious, and philosophical reasons are a product of political objections and judicial resolution of legal challenges to vaccination policies. While the statutory provisions vary from State to State, all school immunization laws grant exemptions to children with medical contraindications to immunization, consistent with the judicial and ethical principles of harm avoidance asserted by the Supreme Court in Jacobson v. Mass.⁷⁰ Virtually all States also grant religious exemptions for persons who have sincere religious beliefs in opposition to immunization. A minority of States also grant exemptions for parents that profess philosophical convictions in opposition to immunization.⁷¹ Children who have not received all required vaccinations or a valid exemption are not permitted to attend school⁷², although enforcement varies widely among States.

The States' power to restrict public liberties via the police power does not begin or end with vaccination mandates. This exercise in Constitutional analysis of childhood influenza mandates illustrates just how much deference the Supreme Court gives State legislatures regarding public health decisions. In light of this, it is especially important to rigorously focus on evidence-based decision-making during the creation of public health policy.

⁷⁰ HODGE, *supra* note 20, at 51.

⁷¹ HODGE, *supra* note 20, at 51-52.

⁷² HODGE, *supra* note 20, at 5.

NEW JERSEY CASE STUDY: APPLYING THE ABOVE INFORMATION

In 2008 New Jersey added the seasonal influenza vaccine to its State-wide schedule of immunizations that children must receive in order to attend school, preschool and licensed child care centers. In doing so New Jersey became the first State in the nation to require flu shots for young schoolchildren. The requirement applies to children between six months and five years (6-59 months) who attend licensed day care and preschool programs.⁷³ As with all other vaccinations, The NJ Department of Health and Senior Services (“the Department”) has made exceptions to the rule by offering exemptions for medical⁷⁴ or religious⁷⁵ reasons, sparing children with allergies from being forced to take the shot and preventing the State from infringing on spiritual beliefs.

The compulsory vaccination for children 6-59 months was intended to promote public health and promote herd immunity in the general population. In the Department’s Rule Proposals for NJAC 8:57-4:19, it stated that its objectives in establishing rules as a condition for children entering or attending school as follows:

“1) To ensure that all children attending school have been immunized against specific vaccine-preventable diseases with recommended vaccines; 2) to prevent the transmission of vaccine-preventable diseases by maintaining high immunization rates in school-aged and preschool-aged children.”⁷⁶

The importance of having solid research-based decision-making in the public policy creation process cannot be overstated. An evidence-based practice in public health uses the best available evidence to make informed practice decisions, and well-informed decisions are more

⁷³ N.J.A.C. 8:57-4.19

⁷⁴ N.J.A.C.8:57-4.3

⁷⁵ N.J.S.A.26:1a-9.1

⁷⁶ 2006 NJ REG TEXT 53824, Department of Health and Senior Services Rule Proposals.

likely to establish effective programs and reap maximum benefits from State public health efforts. In the case of New Jersey's vaccine mandate, the State Department of Health appears to have relied heavily on a single study, as well as on recommendations made by the ACIP and CDC regarding childhood influenza vaccination, in its decision-making process.

In support of its decision the Department cites heavily to a single study in the American Journal of Epidemiology supporting the recommendation to vaccinate all preschool children. The study tracked influenza cases by age groups and found that preschoolers were the first to be seen in flu-related doctor visits, with sick adults following about 29 days later.⁷⁷ The findings revealed that flu-like illnesses in children under age five, compared with all other age groups, was the most predictive of pneumonia and influenza deaths in the general population.

Further, the Department's decision-making exhibits a heavy reliance on the ACIP's and CDC's guidance, noting that both organizations have recommended the use of the Influenza vaccine as part of a mandated immunization schedule.

“The Department follows the periodically-revised recommendations of the ACIP for the routine administration of each communicable disease vaccine to the pediatric population, as applicable to New Jersey. The Department continues to follow the annual “Recommended Childhood and Adolescent Immunization Schedule.”⁷⁸

In explaining its decision to mandate influenza vaccination for school attendance, the Department quotes directly from an October 2002 and February 2002 release by the ACIP issuing national recommendations for the administration of the influenza vaccine for preschool aged children.

⁷⁷ NEW JERSEY DEPARTMENT OF HEALTH, VACCINE PREVENTABLE DISEASE PROGRAM, QUESTIONS AND ANSWERS ON IMMUNIZATION REGULATIONS PERTAINING TO CHILDREN ATTENDING SCHOOL/HIGHER EDUCATION, http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0CDAQFjAA&url=http%3A%2F%2Fwww.state.nj.us%2Fhealth%2Fcd%2Fdocuments%2Fvaccine_qa.pdf&ei=hlaBUdiwJsW90AH2iIFw&usg=AFQjCNH_tgFXD3yTntIuDiI6LdIqTSwCdA&sig2=d8S73nqtiqBHeW-KZ7tdzA&bvm=bv.45921128,d.dmQ&cad=rja

⁷⁸ 2006 NJ REG TEXT 53824, Department of Health and Senior Services Rule Proposals.

“The proposed new rule...would positively affect the personal, family, child-care centers’ and public health by reducing the transmission of influenza. Infants and preschoolers are among the most efficient incubators and transmitters of disease to susceptible persons. Preschool facilities are a high risk setting for influenza transmission” ... The Department believes that widespread use of influenza vaccine among preschool-aged children will decrease the incidence of influenza among children and adults.”⁷⁹

The reliance of State legislature on Federal health policy advisories and opinions heightens the importance of clear and understandable evidence-based decisions in the public health sphere. State Courts have increasingly abdicated the role of assessing the reasonableness of a State’s exercise of its police powers. The New Jersey Supreme Court upheld a school vaccination mandate in Sadlock vs. Board of Ed, holding that “the question of the desirability or efficacy of compulsory vaccination and whether it is wise or unwise is strictly a legislative and not a judicial question.”⁸⁰ The Court seemed to read Jacobson as justifying all vaccine mandates, disregarding its instructions to reject unreasonable, arbitrary, or oppressive State actions.

Courts have expanded the original Jacobson precedent dramatically, and though arguments can be made against the Constitutionality of the influenza mandate, precedent dictates that the Courts will not move to restrict a State’s police powers, regardless of evidence indicating the relative weakness of data on which the decision to institute Influenza vaccination mandates was made. New Jersey’s Influenza mandate displays heavy reliance on the decision-making of the ACIP and CDC, who in turn are responsible for making sure that all recommendations should be based in solid research-based evidence.

⁷⁹ 2006 NJ REG TEXT 53824, Department of Health and Senior Services Rule Proposals. p 11

⁸⁰ Sadlock v. Bd. of Ed. of Borough of Carlstadt in Bergen Cnty., 137 N.J.L. 85, 88, 58 A.2d 218, 220 (Sup. Ct. 1948)

DATA ANALYSIS: EFFECTS OF THE NEW JERSEY INFLUENZA VACCINATION MANDATE

My analysis was based on data sets of NJ- wide hospital discharges citing Influenza as the primary diagnosis. Prior to settling on hospital discharge data, I e-mailed the New Jersey department of Health and attempted to get more State-specific data regarding reported cases of Influenza or ILI data broken down by age groups. My correspondence was with Lisa McHugh, a research scientist and Influenza Surveillance Coordinator for the Department. She informed me that the Department posts a weekly general data set to its website⁸¹, however the data offered on the site is general and only goes back to 2011. Further, she informed me that if I was interested in the more specific data collected by the department then I would need to provide that my project was submitted to and deemed appropriate by an IRB. Further, if I did have IRB approval, I would need to submit information to the NJDOH data custodian who would review my information and make a determination as to whether this data could be released from the department. Unfortunately, this was not feasible within the timeframe of a semester. Aware of the limitations to my analysis stemming from the use of hospital discharge data rather than reported illness data, I hope to nonetheless look at New Jersey's stated goals of perpetuating herd immunity and protecting 'at risk' populations in passing a Childhood Influenza Vaccination mandate, and compare them against the effects of the program

New Jersey instituted a vaccination mandate for children aged 6-48 months on the theory that this would create a herd immunity benefit, protect 'at risk' populations, and decrease the influenza rate in the overall population. The vaccination mandate was enacted in 2008, while the

⁸¹ <http://nj.gov/health/flu/fluinfo.shtml>

years covered by this data analysis are the period between 2004 and 2012. Prior to the mandate, the vaccination rate for the age group in question hovered around 20-30%, sitting at 32.3% in 2008 and rising to 79.9% between 2008 and 2012.⁸² Given the fact that in 2012 the vaccination rate sat at almost 80%, it is clear that there has been a marked increase in vaccinations in the targeted age group.

Referring back to CIDRAP’s statistics regarding vaccine efficacy, the CCIVI indicated that LAIV was the only vaccine to have demonstrable protective effects for the 6 months to 7 years age groups (an 83% efficacy rate⁸³) with TIV showing inconsistent evidence of protection for that age group. It important to note that LAIV is only licensed for use on humans 2-49 years of age, while New Jersey’s vaccination mandate is inclusive of children beginning at 6 months. Further, the available regarding influenza-diagnosis hospital discharges only looks at children between the ages of 1 – 12 months.

LAIV CIDRAP Efficacy % Age	6 months – 84 months
LAIV Licensed Use Age	24 months and older
NJ Childhood Influenza Mandate Age	6 months – 56 months
NJ Hospital Discharge Age	1 month – 12 months

Despite the uneven age overlap in targeted groups, vaccinated groups, and hospitalized children, it is clear that hospital discharges related to influenza for the youngest children, who are an ‘at risk’ group, did decrease.⁸⁴ In 2008, the first year of the mandated vaccination, Influenza hospital discharges for children ages 1-12 months were 23.84% of all influenza discharges in that year. By 2011, a steady decline in the percentage of influenza discharges for children aged 1-12 months left the total number at 15.02%. A possible theory for this decrease is that children 1-12

⁸² SEE TABLE 1

⁸³ CIDRAP, *supra* note 3, at 6.

⁸⁴ SEE TABLE 2

months of age are most in contact with the targeted group for vaccination via their presence in child care centers.

In the 65+ age group, the up and down cyclical pattern in influenza-related hospital discharges is worth delving deeper into.⁸⁵ 2009 was the year of the H1N1 ‘pandemic’. During that year the targeted groups for vaccination and illness were > 6 months, 6 months – 24 years, and 24-64 years with chronic conditions. Studies at the time indicated that those 65+ were less likely to fall ill with H1N1. So, the ‘targeted groups’ were vaccinated first, and then the 65+ age group received the influenza vaccine, which runs contrary to the vaccination pattern during years in which the normal influenza virus is prevalent. Certainly, the percentage of hospitalization discharges made up of adults 65 years and older has exhibited much more variability than the percentage of hospital discharges made up of infants 1- 12 months old. In 2008, the year the mandate was enacted, New Jersey saw 19.34% of all influenza-related hospital discharges coming from adults 65 – 84 years of age. That number shuttled down to 6.83% during the 2009 H1N1 pandemic, then back up to 15.56% in 2010 and 18.47% in 2011. The data for adults 85 years of age exhibits a similar pattern.⁸⁶ Is the up and down pattern of influenza related hospital discharges for the 65+ age group a result of the antigenic drift guessing game inherent in the creation of yearly influenza vaccines? Without further research, it is difficult to tell. However, in regards to the question of whether or not New Jersey’s Childhood Influenza Vaccination Mandates has increased the benefits of herd immunity to the wider population? In the 5 years since NJ has enacted its mandate, no discernible pattern has emerged that is demonstrable from my admittedly topical data. I am hesitant to engage the topic more, due to the clear limitations of my data.

⁸⁵ SEE TABLE 3, TABLE 4

⁸⁶ SEE TABLE 4

CONCLUSION

As clearly evidenced by the data regarding the efficacy of influenza vaccines, there exists a gap between the public health policies that are enacted and what research says about the effectiveness of those policies, which is indicative of flaws in the approach to public health policy creation. Looking again at the Hartsfeld et al systematic review of evidence-based data in model public health laws, the authors found that only 44% of the model laws examined presented any information on the methods that they used to develop their laws.⁸⁷ This number does not mean that only 44% of the studies used research-based guidelines, only that those were the groups that made their data available. However, once the gap between evidence and policy in regards to influenza vaccination is looked at with knowledge of the deference given to Legislative decisions about public health, it should be evident that public health officials must do a better job of understanding and describing the evidence-based research data used in existing and proposed policy in order to judge their technical soundness.

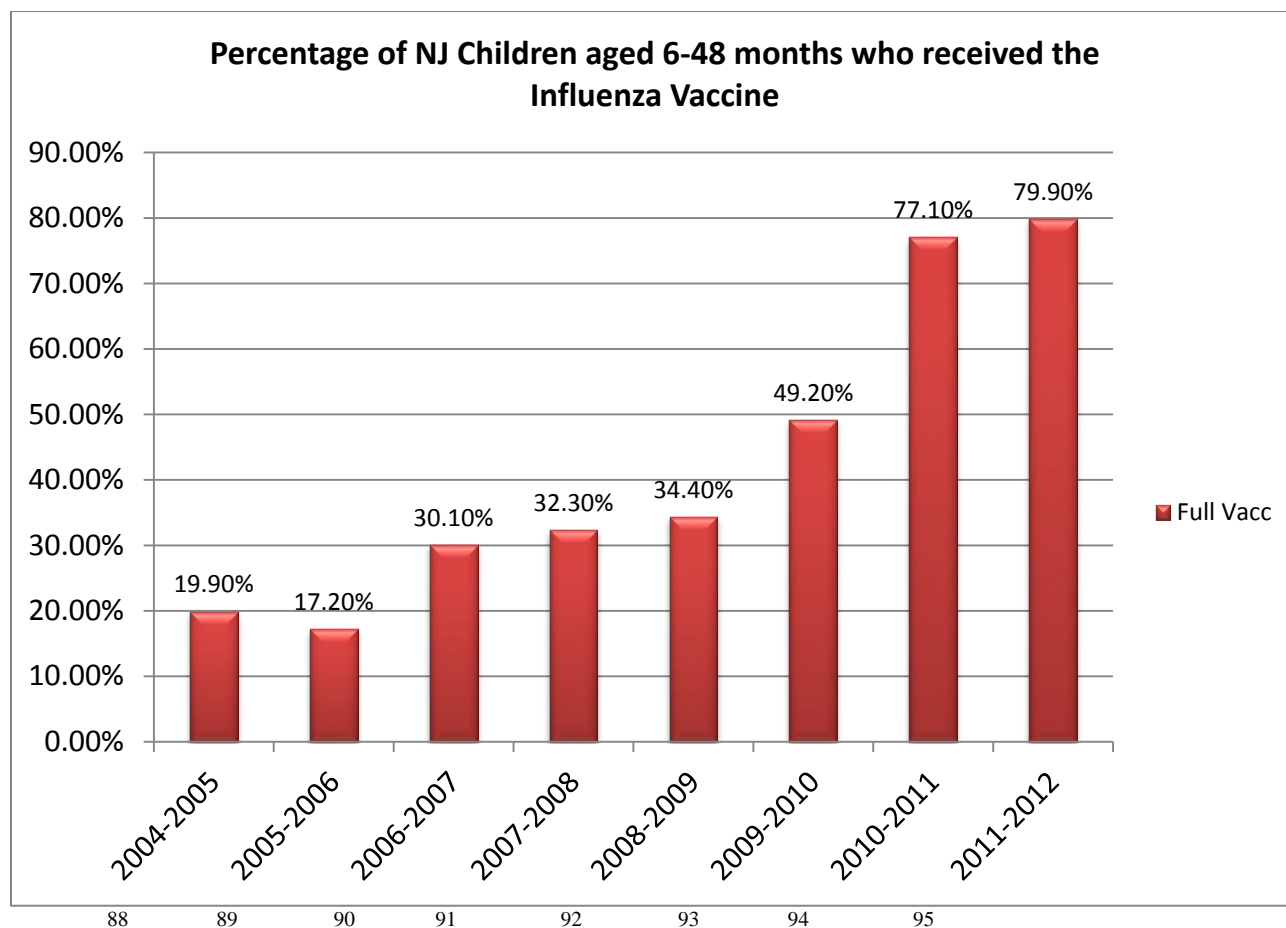
Present vaccines have a track record of substantial safety and moderate efficacy in many seasons. Because of this, current influenza vaccines will continue to have a role in the reduction of influenza morbidity until more effective interventions are available. Maintaining public support for present vaccines is clearly an important goal, however, part of maintaining support is keeping the continued trust of the public. If the primary goal of vaccination mandates is to secure greater public health benefits, then the present approach to influenza vaccination plans allows for a gross over-estimation of those plans benefits, with no marked improvement in the situation. If there truly is a consistent over-estimation of vaccine efficacy embedded in US public health

⁸⁷ DeKeely Hartsfeld ET AL, *A Review of Model Public Health Laws*, 97 AM. J. OF PUB. HEALTH 97 (2007).

decisions and messages, then we will have reached a plateau in influenza related illness/morbidity and mortality prevention.

CHARTS

Table 1.



⁸⁸ Ctr. for Disease Control and Prevention, *Childhood Influenza Vaccination Coverage – United States, 2004-05 Influenza Season*, Morbidity and Mortality Weekly Report (Oct. 6, 2006)

<http://www.cdc.gov/MMWR/preview/mmwrhtml/mm5539a1.htm>

⁸⁹ Ctr. for Disease Control and Prevention, *Influenza Vaccination Coverage Among Children Aged 6-23 Months – United States, 2005-06 Influenza Season*, Morbidity and Mortality Weekly Report (Sept. 21, 2007)

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5523a2.htm>

⁹⁰ Ctr. for Disease Control and Prevention, *Influenza Vaccination Coverage Among Children Aged 6-23 Months – United States, 2006-07 Influenza Season*, Morbidity and Mortality Weekly Report (Sept. 26, 2008)

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5738a2.htm>

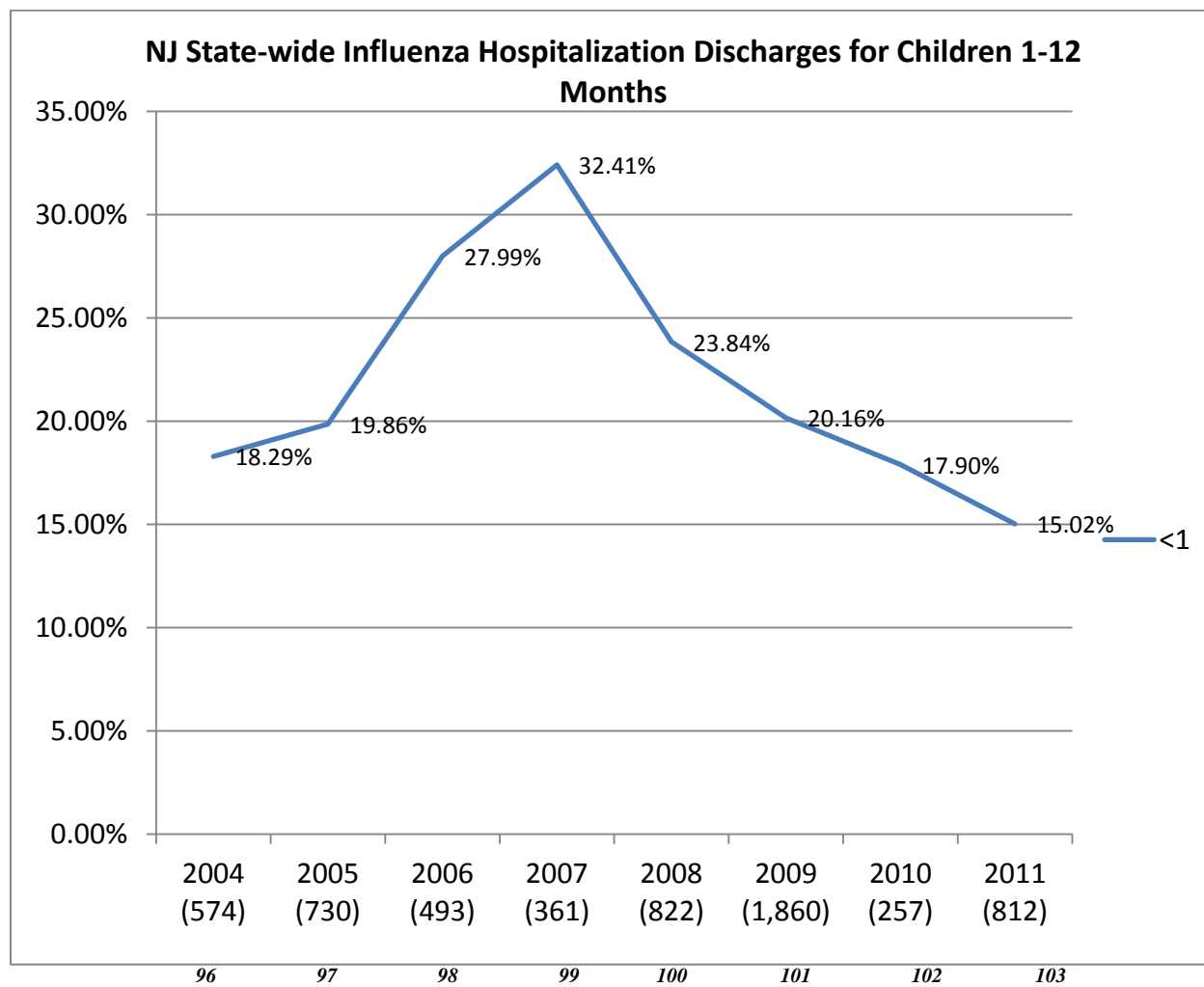
⁹¹ Ctr. for Disease Control and Prevention, *Influenza Vaccination Coverage Among Children Aged 6-23 Months – United States, 2007-08 Influenza Season*, Morbidity and Mortality Weekly Report (Last Updated: Oct. 5, 2010)

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5838a2.htm>

⁹² Ctr. for Disease Control and Prevention, *Influenza Vaccination Coverage Among Children Aged 6-23 Months – United States, 2008-09 Influenza Season*, Morbidity and Mortality Weekly Report (Last Updated: Oct. 5, 2010)

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5738a3.htm>

Table 2.



⁹³ CDC, *State-Level Cumulative Influenza Vaccination Coverage Estimated for the 2009-2010 Season, United States, May 2010*, Fluvaxview, <http://www.cdc.gov/flu/professionals/vaccination/reporti1112/reportii/index.htm> (last updated Oct. 5, 2012)

⁹⁴ *Id.* at (2010-2011)

⁹⁵ *Id.* at (2011-2012)

⁹⁶ Agency for Healthcare Research and Quality, *Outcomes by patient and Hospital Characteristics for CCS Principal Diagnosis Category Influenza/State Statistics – 2004 New Jersey – Principal Diagnosis Only*, HCUP State Inpatient Databases (2004) <http://hcupnet.ahrq.gov>

⁹⁷ *Id.* at (2005).

⁹⁸ *Id.* at (2006).

⁹⁹ *Id.* at (2007).

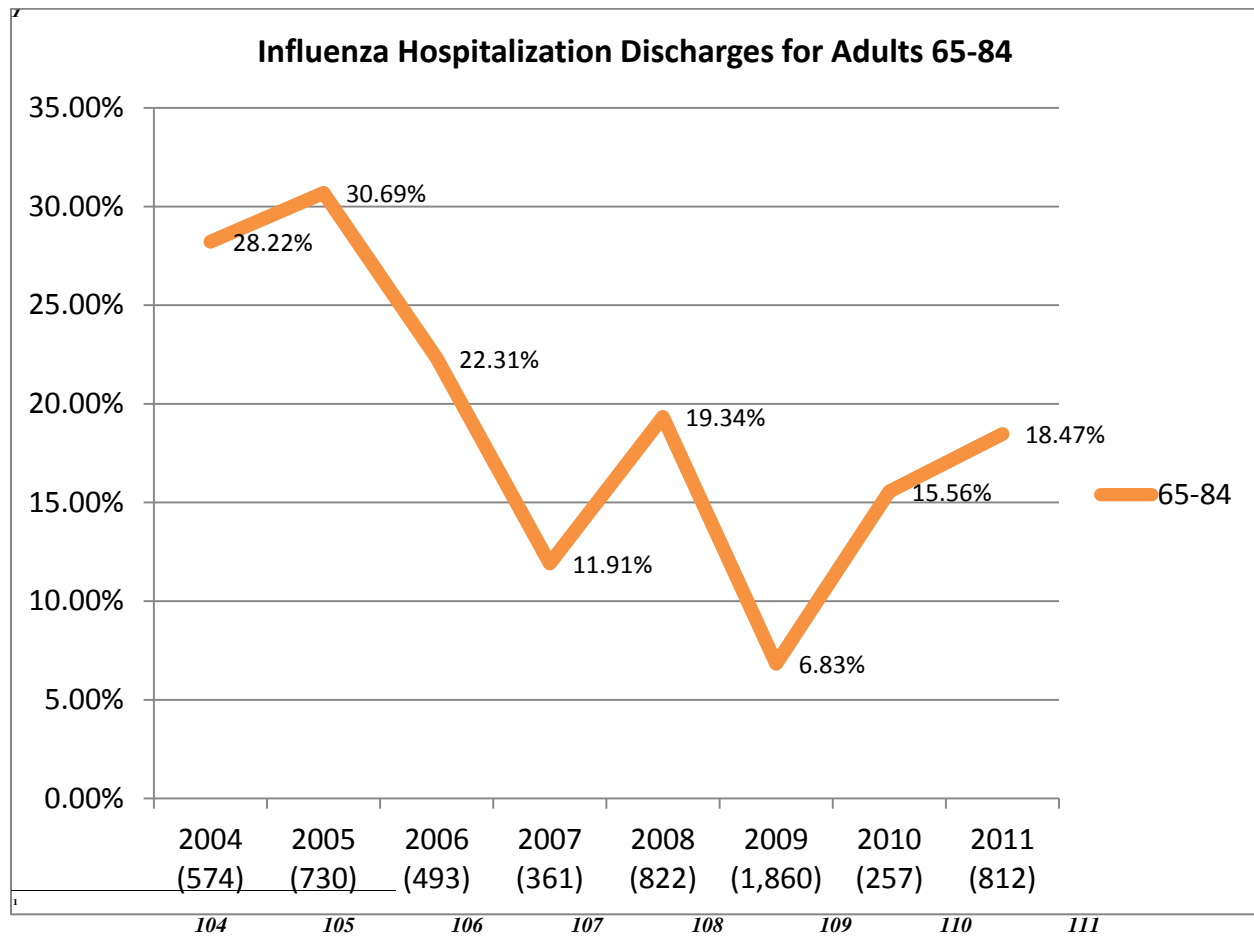
¹⁰⁰ *Id.* at (2008).

¹⁰¹ *Id.* at (2009).

¹⁰² *Id.* at (2010).

¹⁰³ *Id.* at (2011).

Table 3.



¹⁰⁴ Agency for Healthcare Research and Quality, *Outcomes by patient and Hospital Characteristics for CCS Principal Diagnosis Category Influenza/State Statistics – 2004 New Jersey – Principal Diagnosis Only*, HCUP State Inpatient Databases (2004) <http://hcupnet.ahrq.gov>

¹⁰⁵ *Id.* at (2005).

¹⁰⁶ *Id.* at (2006).

¹⁰⁷ *Id.* at (2007).

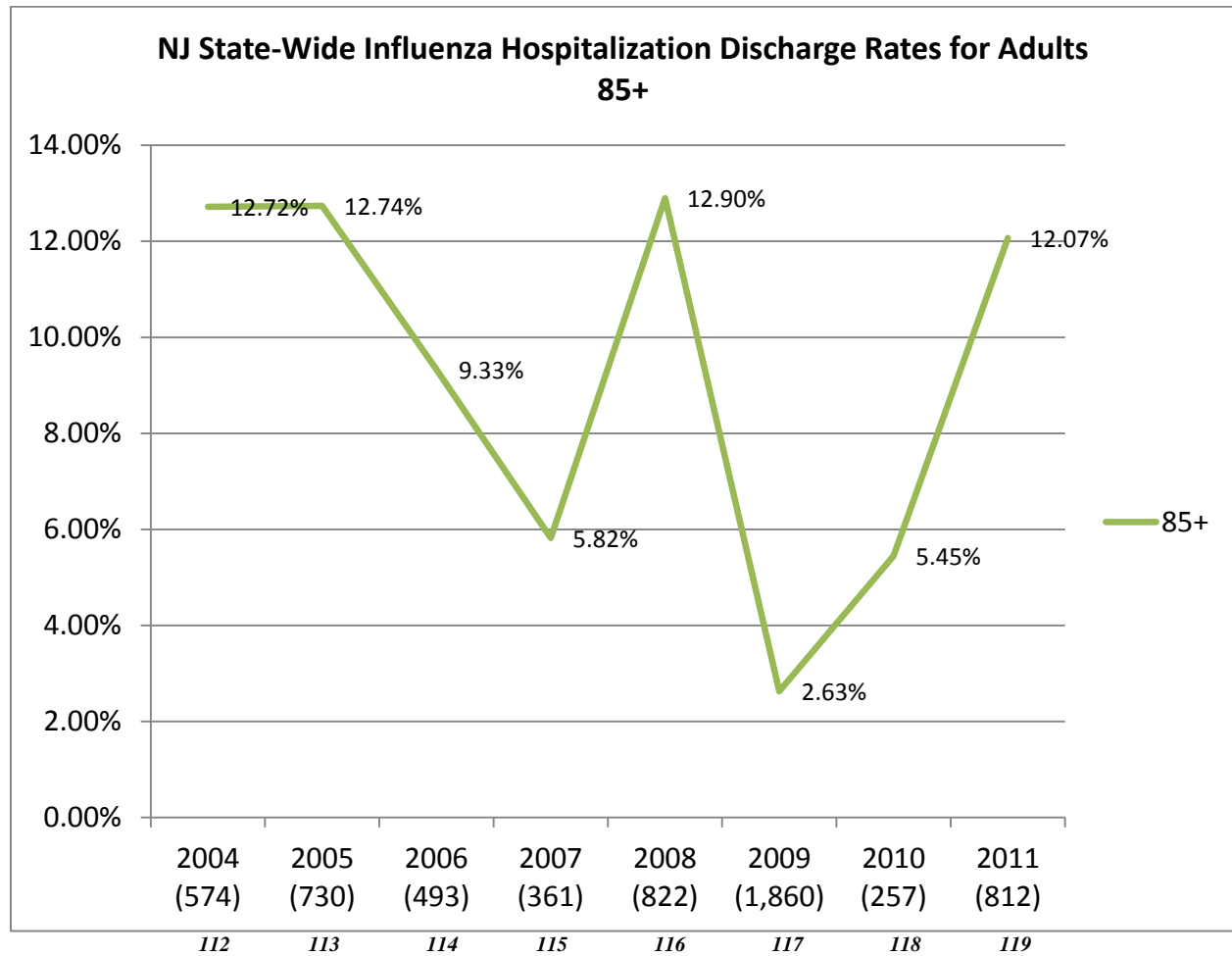
¹⁰⁸ *Id.* at (2008).

¹⁰⁹ *Id.* at (2009).

¹¹⁰ *Id.* at (2010).

¹¹¹ *Id.* at (2011).

Table 4.



¹¹² Agency for Healthcare Research and Quality, *Outcomes by patient and Hospital Characteristics for CCS Principal Diagnosis Category Influenza/State Statistics – 2004 New Jersey – Principal Diagnosis Only*, HCUP State Inpatient Databases (2004) <http://hcupnet.ahrq.gov>

¹¹³ *Id.* at (2005).

¹¹⁴ *Id.* at (2006).

¹¹⁵ *Id.* at (2007).

¹¹⁶ *Id.* at (2008).

¹¹⁷ *Id.* at (2009).

¹¹⁸ *Id.* at (2010).

¹¹⁹ *Id.* at (2011).

Table 5.

