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Sheila Alvarez Marsh Date

PEDIATRICIANS' ATTITUDES, PERCEPTIONS, AND BEHAVIORS REGARDING DISCHARGING CHILDREN ON THE BASIS OF PARENTAL VACCINE REFUSAL IN THE STATE OF GEORGIA

BY

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An abstract of
A Thesis submitted to the Faculty of the
Rollins School of Public Health of Emory University
in partial fulfillment of the requirements of the degree of
Master of Public Health in the Career MPH program
2014

Abstract

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One of the greatest public health achievements of the 20th century is the significant decrease in vaccine preventable diseases as a result of vaccine development and mass immunization programs. In the United States, school vaccination requirements have had a dramatic impact in reducing disease morbidity and mortality. However, concerns regarding vaccine preventable diseases have shifted to worries about vaccine safety. Today, many parents worry that vaccines may cause more harm than the very diseases they are intended to prevent. Consequently, parents may be hesitant or refuse to immunize their children. Requests for nonmedical exemptions from vaccination requirements are becoming increasingly common. Research suggests that areas with high concentrations of nonmedical exemptions may be associated with recent outbreaks of vaccine preventable diseases, and as such, pose risks to public health. In an effort to minimize the risk to unvaccinated individuals, some physicians resort to discharging patients who, for nonmedical reasons, refuse vaccination.

In order to understand how public health professionals can address parental vaccination refusal and provide evidence to support physicians in maintaining supportive relationships with parents who express concerns regarding vaccines, a quantitative survey of primary care pediatricians in the state of Georgia was conducted. The goals of this research were to 1) estimate the proportion of primary care pediatricians within the state of Georgia who report discharging patients for vaccine refusal, and 2) understand the characteristics, behaviors, and attitudes regarding parental vaccine refusal of primary care pediatricians within the state of Georgia.

Approximately 46% of responding pediatricians reported they would support discharging a patient over complete vaccine refusal. More than half of responding pediatricians have personally discharged patients because of refusal to immunize. The primary reason for refusal is perceived to be due to concern over vaccine safety. A majority of respondents would willingly agree to an alternative vaccination schedule if a parent requested it. Findings generated from this research and its potential implications provide a foundation for areas of further research, and suggest a need for evaluation of existing practices and policies related to childhood vaccination refusals.

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ACKNOWLEDGEMENTS

I would like to thank my committee chair, Melissa “Moose” Alperin, for her guidance and encouragement throughout this project, and for helping me to realize what was achievable in the timeframe available. Her influence and mentorship made my graduate school journey all the more rewarding. I am grateful to my field advisor, Dr. David Greenberg, for his kindness, and willingness to share his expertise and time with me. Thank you for your valuable critique of my work. In addition, I am grateful to Dr. Harry Keyserling and Mike Chaney, for their input and for their assistance in making this research possible. I am indebted to my colleague and friend, Dr. Kimberly Farris for reviewing my rough draft. To all my colleagues, friends, and family who endured and survived the experience of graduate school with me, I treasure your love, support, and companionship. Finally, and most importantly, I would like to thank my husband Barry. Your unwavering support, patience, encouragement, and love over the past ten years have been, and remain, my source of inspiration. With you, everything is possible.

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CHAPTER ONE: INTRODUCTION

Introduction & Rationale

The development of vaccines to prevent diphtheria, polio, pertussis, measles, mumps and rubella has significantly reduced the incidence and deaths attributable to these diseases in the past century. Because of the relatively low-cost and high-impact in minimizing the risk of vaccine preventable diseases (VPDs) vaccines are considered one the 20th century's greatest public health triumphs (CDC, 1999). In the U.S., robust mass vaccination and the implementation of school vaccination requirements have helped maintain high vaccination coverage rates among children (Plotkin, Orestein, & Offit, 2012a; CDC, 2013a).

However, over the past couple of decades, the number of parents refusing vaccination for their children has increased (Omer, Richards, Ward, & Bednarczyk, 2012). This increase in parental vaccine refusal is largely attributed to misinterpretation or misunderstanding of information presented by the media and on unmonitored and biased websites, which often cause substantial and often unrealistic fears (AAP, 2013). Physicians indicate that parents avoid some or all vaccines recommended for children because of growing concerns over the safety of vaccines. Some parents believe vaccines may be linked to developmental disorders, and that vaccines can cause significant health problems outweighing any benefit (Chatterjee & O'Keefe, 2010). In addition, because most parents and young health care professionals in the U.S. lack any first-hand experience with the devastating effects of VPDs, many are unaware of the serious complications that can result from infection. Ironically, since VPDs are not as common due to the success of vaccines, there is greater scrutiny over vaccine safety over the consequences of serious infections.

While the proportion of parents who choose to delay or refuse vaccines for their children is relatively small, more and more parents are requesting nonmedical exemptions (NMEs) from school vaccination requirements (CDC, 2013b; Omer et al., 2012; Salmon et al., 2005). NMEs are sought by parents on the basis of either religious or philosophical objections to school immunization mandates. But while coverage rates may appear to be high on state-wide levels, on a community level some states are experiencing emerging geographic areas or "clusters" of high numbers of NMEs (Omer et al., 2006; Atwell et al., 2013). These clusters, where exemptions to school vaccination requirements are more common, have experienced outbreaks of VPDs (CDC, 2012; Omer et al., 2008; Atwell et al., 2013). Geographic "pockets" of unvaccinated individuals create areas that are at a greater risk of outbreaks of VPDs because community immunity, or *herd* immunity, may be insufficient to protect unvaccinated individuals (Omer, Salmon, Orenstein, deHart, & Halsey, 2009). Consequently, there is growing concern among health care professionals and public health advocates over the implications of this growing trend.

For some health care providers, the risk to children who may be either too young or medically unfit to receive immunizations is too great, and as such, they have taken the position of dismissing or discharging those who willingly refuse vaccinations from their practice (Flanagan-Klygis, Sharp, & Frader, 2005; Kempe et al., 2011; Leib, Liberatos, & Edwards, 2011). In response, the American Academy of Pediatrics (AAP) has published recommendations for physicians to address parents who refuse vaccinations for their children. In addition to discussing parents' concerns about vaccine safety, and providing parents with reputable references to immunizations and VPDs, the AAP suggests that physicians work to develop relationships with parents over time. With respect to discharging children refusing vaccination, the AAP states:

> In general, pediatricians should avoid discharging patients from their practices solely because a parent refuses to immunize his or her child. However, when a substantial level of distrust develops, significant differences in the philosophy of care can emerge, or poor quality of the communication persists, the pediatrician may encourage the family to find another physician or practice…Such decisions should be unusual and generally made only after attempts have been made to work with the family (Diekema, 2005, p. 1430).

Studies show that many pediatricians regularly discharge patients on the basis of vaccine refusal. This study aims to gain an understanding of the reported incidence of parents' refusal of vaccinations for either safety, religious, or philosophical reasons throughout the state of Georgia. It also aims to identify the proportion of pediatricians who report discharging children from their practices on the basis of vaccine refusal.

Problem Statement

Recent studies and national surveys indicate that anywhere from 25% to 39 % of physicians say that they would discharge families from their practice on the basis of vaccination refusal (For the purposes of this research, vaccine refusal is defined as occurring when a parent willingly refuses to have their child receive one or more recommended vaccines). In the state of Georgia, it is unclear how often patients are discharged as a result of vaccination refusal. This study aims to 1) estimate the proportion of primary care pediatricians within the state of Georgia who report discharging patients for vaccine refusal, and 2) understand the characteristics, behaviors, and attitudes regarding parental vaccine refusal of primary care pediatricians within the state of Georgia.

Research Questions

Specifically, this study will seek to answer the following questions:

- What proportion of primary care pediatricians in Georgia report discharging patients on the basis of parental vaccine refusal?
- What are the current general characteristics of primary care pediatricians in the state of Georgia?
- What are the current characteristics and general policies of pediatric primary care facilities in the state of Georgia?
    - How many primary care pediatric facilities have instituted policies to discharge patients on the basis of vaccine refusal?
    - How many children within the practice are unvaccinated (refused all vaccinations)?
- What are pediatricians' experiences and attitudes with parental vaccine refusals in Georgia?
    - What is the pediatrician-reported frequency of refusals of one or more vaccines?
    - What do pediatricians perceive are the reasons parents refuse vaccines?
- What are pediatricians' behaviors and attitudes regarding parental vaccine refusal, alternative vaccination schedules, and NMEs?
    - How likely are pediatricians to discharge patients on the basis of complete vaccine refusal?
    - How likely are pediatricians to agree with alternative vaccination schedules?

Statement of Significance

Vaccines are considered the safest and most effective public health tools available for preventing disease and death. In order to reap the full benefits of vaccines, the majority of individuals within a community must be immunized against VPDs. The rise of NMEs has rendered some communities vulnerable to VPD outbreaks. In May 2014, the Centers for Disease Control and Prevention (CDC) reported a record number of measles cases reported since measles elimination in 2000 (Gastanaduy et al., 2013). As of this publication date, the number of cases has continued to rise to 539 cases reported in 20 states (CDC, 2014). Most of the individuals who contracted measles were unvaccinated.

Within the state of Georgia, vaccination coverage rates have been relatively high yet VPD outbreaks still occur. VPDs reported in Georgia from 2005 through 2011 are summarized in Table 1.1 below.

Table 1.1. Reported cases of VPDs--Georgia 2005 – 2011

Year	Diphtheria	Measles	Mumps	Pertussis	Polio	Rubella	Tetanus
2005	0	0	11	79	0	0	0
2006	0	0	60	101	0	0	0
2007	0	0	0	37	0	0	0
2008	0	1	4	116	0	0	0
2009	0	1	1	230	0	0	0
2010	0	1	5	247	0	0	0
2011	0	0	5	180	0	0	0

Source: Georgia Department of Health (GDPH), 2011

As seen in Table 1.1, Georgia experienced outbreaks of pertussis in 2009 and 2010. These outbreaks were relatively small compared with pertussis epidemics that occurred in 2010 in states like California, Washington and Arizona, where numbers of cases climbed to more than

9,000. However, the Georgia Department of Public Health warns that decreases in vaccination rates have the potential of contributing to VPD outbreaks (GDPH, 2014a).

Physicians, as parents' trusted sources of health care information, play a crucial role in communicating the value of vaccines. However, physicians who choose to discharge families on the basis of vaccine refusal may end up fracturing the patient-physician relationship, generating feelings of abandonment and mistrust for the family, and diminishing access and continuity to health care for the child. Therefore, understanding physicians' perceptions, attitudes, and behaviors regarding parental vaccine refusal are justifiably important.

This research will help inform public health professionals about the current trends related to parents' increased concerns over vaccine safety and vaccine refusals, and physicians' perceptions, attitudes, and behaviors regarding this issue. Results of this research may facilitate VDP and NME surveillance efforts, policy development, and provision of access to health care within the state of Georgia. Public health agencies and professional organizations may also be able to use results of this research to develop or improve upon communication tools, and clarify current guidelines aimed at health care providers and the general public.

Definition of Terms

Coverage rate – Coverage rate is defined as the estimated proportion of people who receive one or more vaccine(s) of interest in relation to the overall population. CDC specifically defines coverage rate as the percentage of children within a certain geographic area and age group that have been vaccinated, and estimates of the number of people who have received particular vaccines (CDC, 2010; Luman, Worku, Berhane, Martin, & Cairns, 2007).

Discharge – Physician discharge, also referred to as *dismissal* or *firing*, occurs when a physician releases an individual(s) from their practice and/or course of care. Specific to this research, discharge is defined as a pediatrician who ends participation in the care of children whose parent refuses vaccination (Flanagan-Klygis et al., 2005).

Healthy People 2010 & Healthy People 2020 – Healthy People 2010 was a program of nationwide health-promotion and disease-prevention goals set by the United States Department of Health and Human Services based on three previous multi-year national initiatives. Results of Healthy People 2010 helped develop the current Healthy People 2020 initiative aimed at improving health of individuals nationally (HealthyPeople.gov., 2013).

Community immunity – Community immunity, also referred to as *herd* immunity, is an estimation of threshold numbers or proportions of vaccinated persons necessary to induce some degree of immunity against infection among a community, thereby indirectly protecting even non-vaccinated people by the presence and proximity of vaccinated persons (Plotkin, Orenstein, & Offit, 2012b).

Cluster – Depending on the context, a cluster can occur when a larger number of individuals than expected appear to have the same illness within a space-time and/or spatial area. A cluster may

also refer to when a larger number of events (e.g. NMEs) than expected occur in a given space-time and/or spatial area. (Omer et al., 2008).

Immunity - An individual's capacity to respond to foreign pathogens (Offit & DeStefano, 2012). An individual's immunity can be categorized into innate immunity, passive immunity, and acquired immunity. Innate, or *nonspecific*, immunity is the defense system with which one is born. The term passive immunity refers to immunity from antibodies produced from another individual. For example, infants have passive immunity from antibodies transferred through the placenta from their mother. Acquired immunity is immunity that develops with exposure to various antigens such as when individuals receive vaccines (NIH, 2012).

Medical exemptions – A medical exemption frees a person from obligation of receiving one or more vaccines due to having a medical condition that would increase the risk of experiencing an adverse event as a result of receiving a vaccine (Malone & Hinman, 2003). Most states categorize this type of exemption as temporary or permanent, and the definition for each state varies. Some states allow vaccination exemptions for certain diseases if medical documentation shows proof of immunity, including documentation of having had the natural disease (CDC, 2011a).

Nonmedical exemption (NME) – A nonmedical exemption frees a person from obligation to state-required vaccination. It includes exemptions on the basis of personal, philosophical, or religious objections, or for any reason other than for medical reasons (Malone & Hinman, 2003; Omer et al., 2006). In the United States, all states but Mississippi and West Virginia allow non-medical exemptions to state laws requiring vaccination (Johns Hopkins Bloomberg School of Public Health Institute for Vaccine Safety, 2014).

Outbreak – An outbreak is a greater occurrence of cases of disease of what would normally be expected in a defined community, geographical area, or season. An outbreak may occur in a restricted geographical area, or may extend over several countries, and may last for a few days or weeks, or continue over several years (WHO, 2014).

Parental Vaccine Refusal – Parental vaccine refusal occurs when a parent willingly refuses to have their child receive one or more recommended vaccines (Diekema, 2005).

Personal belief exemption – A personal belief exemptions is permitted in some states to differentiate it from limiting nonmedical exemptions due only to religious beliefs. Personal belief exemptions are defined as nonmedical exemptions to vaccine mandates regardless of the nature of the individual's beliefs (religious or philosophical) (Omer et al., 2006).

Philosophical exemption – A philosophical exemption, is sometimes used interchangeably with the term as a *personal belief* exemption in the literature. A philosophical exemption is a nonmedical exemption to vaccine mandates due to an individual's philosophically based beliefs (Salmon & Siegel, 2001). It does not restrict the exemption to purely religious or spiritual beliefs.

Religious exemption – A religious exemption is a nonmedical exemption to vaccine mandates due to an individual's religious principles (Salmon & Siegel, 2001).

Underimmunization – Underimmunization is a term often used to describe a child who is "undervaccinated." It refers to a child that has not received full immunization according to the current schedule recommended by the Advisory Committee on Immunization Practices (ACIP) (Glanz et al., 2013). The terms "undervaccinated" and "unvaccinated" are used to make comparisons between cohorts of children who have received some, but not all, vaccines according to the current ACIP schedule, and children who have received no vaccinations (Smith, Chu, & Barker, 2004).

Vaccination mandate – In the United States, vaccination mandates are state requirements for children to receive a series of vaccinations as a condition of attending public school or state-licensed day-care facilities. According to the Center for Law and the Public's Health at Johns Hopkins and Georgetown Universities,

> Subject to exceptions, including individual medical, religious, and philosophical objections, modern state school vaccination laws mandate that children be vaccinated prior to being allowed to attend public or private schools. Failure to vaccinate children can result in children being denied from attending school, civil fines and criminal penalties (although rarely employed) against their parents or guardians, and other measures (e.g., the closure of a school) (Hodge & Gostin, 2001, p. 5).

CHAPTER TWO: REVIEW OF THE LITERATURE

Introduction

A review of the current, available literature was conducted in order to better understand the current trends of parental concerns regarding vaccines, and consequently, health care professionals who opt to discharge patients on the basis of parental vaccine refusal. This chapter will begin by providing a historical context of the development of vaccines and its impact on human disease. Next, a brief history of vaccination policies in the United States will be presented leading to the current state laws, and allowable exemptions from vaccination requirements. With an appreciation of the history and current status of vaccination policies, the current trends of vaccine exemptions will be highlighted. Vaccine exemptions due to parental refusal are often associated with concerns over the safety of vaccines. Therefore, common reasons for parental vaccine refusal and the impact of such refusals on a national level and within the state of Georgia will be highlighted. This chapter will also describe research conducted within the past decade to investigate the prevalence of health care professionals who discharge families on the basis of vaccination refusal. The final two sections of this chapter will describe the current AAP recommendations for physicians facing parents who express hesitancy or objections to childhood immunizations, and factors that contribute to parents' decision-making.

Historical Development of Vaccines and Impact on Human Disease

"The most dangerous epidemic is the smallpox...

which sweeps at times like a storm of death over the land."

Richard Burton, 1860

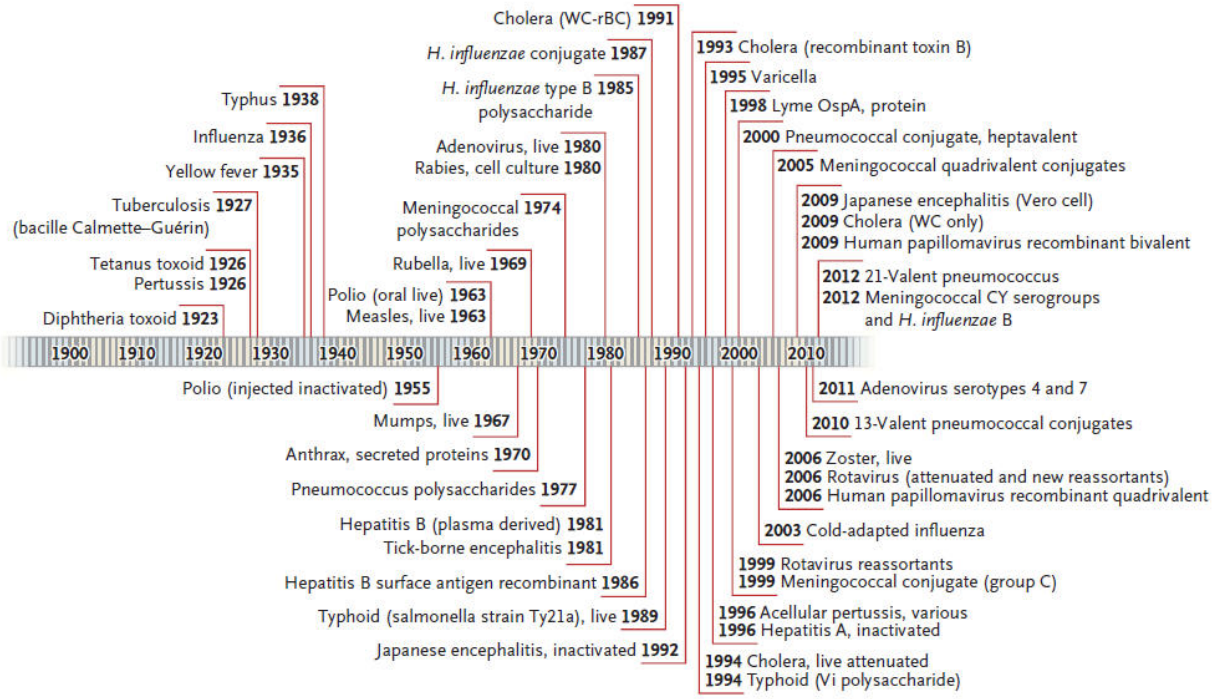
The history of vaccination is seeded in the history of communicable diseases, and above all diseases, smallpox. During the 1400s, Europe experienced rapid urbanization with people

crowding into cities (Hodge & Gostin, 2001). With more people living and working near each other, the epidemic spread of smallpox afflicted the landscape. As the world's population grew and travel increased, so did the scourge of smallpox. As early as the 16th century, practitioners were already providing people with immunity from smallpox disease by blowing dried smallpox scabs into the nose—a practice referred to as variolation. The precise origin of variolation is unknown. However, it seems to have developed somewhere in Central Asia in the early part of the second millennium and then spread east to China and west to Turkey, Africa, and Europe (Plotkin & Plotkin, 2012c). Variolation reduced the chances of a person dying from smallpox from 30% to just 1-2% (U.S. National Library of Medicine National Institutes of Health, 2013).

On May 14, 1796, English physician, Edward Jenner, completed an experiment to investigate the effect of cowpox as a vaccine to prevent smallpox disease. Often labeled the "Father of Vaccination," Jenner took cowpox pus from the hand of an infected woman and placed it in an incision on an 8-year old's arm (Hodge & Gostin, 2001). Fortunately, the experiment proved to be successful at providing the boy protection from subsequent exposure to smallpox. Jenner's findings were published in 1798, and he made history as having developed the first ever vaccine (Jennermuseum.com, 2013).

It would be another 87 years after Jenner's first experiment until the development of the next human vaccine for rabies which was introduced in 1885 by Louis Pasteur. Jenner and Pasteur had both used live attenuated (or weakened) viruses for the smallpox and rabies vaccines. Later, vaccines for typhoid, cholera, and plague were made with killed bacteria. Eventually, the technological advancement of cell culture further refined the development of vaccines (Plotkin & Plotkin, 2012c). Figure 2.1 highlights advancements in vaccine development in the 20th and 21st centuries.

Figure 2.1. Timeline of Vaccine Development



Source: Nabel, 2013

Routine vaccination in large populations increasingly became common practice during the 20th century significantly reducing disease in humans to the extent that smallpox, claiming an estimated 300 million people in the 20th century alone, was declared eradicated in 1979 (WHO, 2013; The College of Physicians of Philadelphia, 2013). Vaccination has reduced 99% of poliomyelitis cases, making it the next disease targeted for eradication. Today, vaccines are manufactured to help prevent over 17 VPDs across the lifespan including smallpox, diphtheria, tetanus, yellow fever, pertussis, *Haemophilus influenzae* type b disease, poliomyelitis, measles, mumps, rubella, typhoid, rabies, rotavirus, and hepatitis B (Plotkin & Plotkin, 2012c).

Indeed the introduction and large-scale use of vaccines has significantly curtailed the occurrence of VPDs globally. Not surprisingly, in the U.S., the impact of vaccination policies

and programs has resulted in a dramatic reduction of disease morbidity. Table 2.1 compares annual morbidity before the introduction of vaccines with annual morbidity in 2000.

Table 2.1. Comparison of Twentieth Century Annual Morbidity* and Current Morbidity of Vaccine-Preventable Diseases[a]

Disease	20th Century Annual Morbidity[b]	2012c	% Decrease
Smallpox	29,005	0	100
Diphtheria	21,053	1	>99
Measles	530,217	55	>99
Mumps	162,344	229	>99
Pertussis	200,752	48,277	76
Polio (paralytic)	16,316	0	100
Rubella	47,745	5	>99
Congenital rubella syndrome	152	3	>99
Tetanus	580	37	>99
Haemophilus influenzae type b and unknown serotype (<5 years)	20,000	240[d]	>99

*Typical average during the 3 years before vaccine licensure.
[a]Source: Whitney, Zhou, Singleton, & Schuchat, 2014
[b]Source : Roush & Murphy, 2007
[c]Source : CDC, 2013a.
[d]30 type b and 210 unknown serotype (<5 years of age).

According to the CDC, today VPD levels in the U.S. are at or near record lows (CDC, 2009). However, outbreaks of VPDs such as measles, mumps, whooping cough, and chickenpox still occur. Most cases occur in people who are unvaccinated, potentially placing themselves and their communities at risk (Salmon et al., 1999; Feiken et al., 2000; CDC, 2014).

Vaccination Policies in the United States

> [T]he rise of small pox coincided with the enactment of compulsory school attendance laws and the subsequent rapid growth in the number of public schools. Since the bringing together of large numbers of children clearly facilitated the spread of smallpox, and since vaccination provided a relatively safe preventive, it was natural that compulsory school attendance laws should lead to a movement for compulsory vaccination (Duffy, 1978, p. 345).

The earliest compulsory vaccination laws were enacted in response to smallpox outbreaks in the U.S. in the early 1800s. However, the first U.S. mandates were met with resistance from some individuals opposed to population-based vaccination requirements on legal, ethical, social, and epidemiological grounds. While some presented valid arguments regarding the effectiveness of vaccines, others claimed vaccines caused harm to humans, and that diseases such as syphilis could be caused by vaccines. Some viewed mandatory vaccination as a government infringement on human autonomy and personal liberty (Hodge & Gostin, 2001). An opponent of compulsory vaccination, Henning Jacobson, alleged that vaccination was a "pagan" rite, and thus refused to be vaccinated. Furthermore, his refusal to pay the $5 fine for failure to comply resulted in him being tried in a district court. Eventually, Jacobson took his case to the U.S. Supreme Court citing that the vaccination mandate violated his civil rights. However, in 1905, the Supreme Court ruled that the right to refuse vaccination was not guaranteed by the U.S. Constitution. *Jacobson v. Massachusetts* established that public health and societal good trumped individual freedom. *Jacobson v Massachusetts* is considered by some to be "the most important Supreme Court case in the history of American public health" (Offit, 2011, p. 127). To fully understand

why this case holds such significance for public health, one must understand that vaccines provide protection for both the individual and the public.

Most VPDs are spread from one individual to another. When a sufficiently large proportion of individuals within a community are immunized, those who are immunized provide protection against the spread of the disease among the community as a whole. As such, those within the community who receive vaccination as well as those who do not receive vaccination are protected. The proportion of individuals within the community that need to receive vaccination in order to achieve protection for the community, referred to as *community* or *herd* immunity, depends on the infectiousness of the disease (Plotkin et al., 2012b). In the case of poliomyelitis, the proportion is approximately 80%. The proportion for measles is approximately 90% (Malone & Hinman, 2003). Mandatory vaccination policies ensure high vaccination coverage rates among the public in order to help achieve community immunity and prevent outbreaks of VPDs.

Although there is no *federal* mandatory child care or school vaccination law, the U.S. Supreme Court upholds the constitutionality for states to pass their own laws requiring proof of vaccination prior to child care or school entry (Salmon et. al., 1999). Today, all states, Puerto Rico, the District of Columbia, and other U.S. Territories have some form of mandatory vaccination requirements prior to child care and school entry (Malone & Hinman, 2003). The required vaccination types and/or doses needed prior to child care or school entry varies among states, and failure to adhere to mandatory vaccination requirements can result in children being denied school or child care admittance. Other consequences can include civil fines and criminal penalties to parents who refuse to comply, although these are rarely enforced (Hodge & Gostin, 2001).

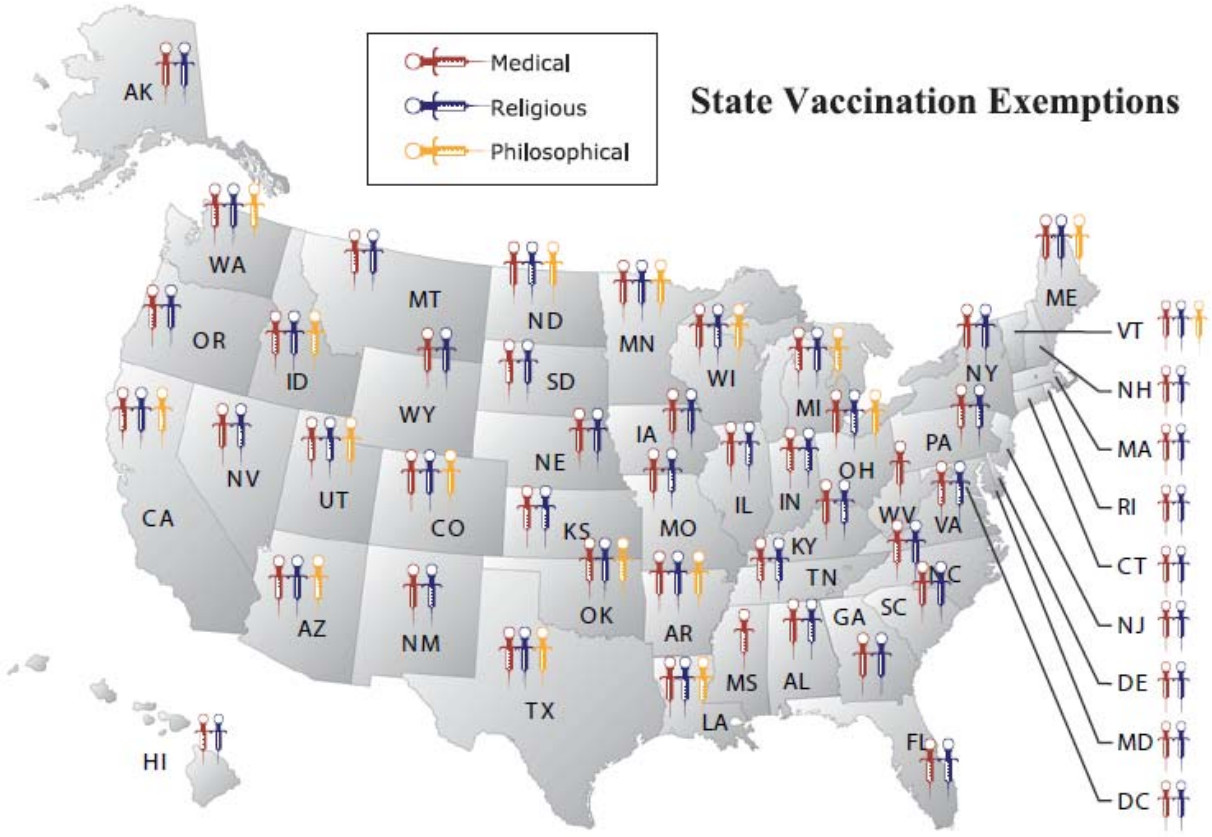
Despite inconsistencies between state vaccination and reporting laws, the impact of mandatory state child care and school vaccination policies are clear. According to Offit and DeStefano in the 6th edition of *Vaccines*,

> The number of children in the United States killed by pertussis decreased from 8,000 each year in the early 20th century to fewer than 20; the number paralyzed by polio from 15,000 to 0; the number killed by measles from 3,000 to 0; the number with severe birth defects caused by rubella from 20,000 to 0; and the number with meningitis and bloodstream infections caused by Hib from 20,000 to fewer than 300 (Offit & DeStefano, 2012, p. 1464).

Although mandatory state vaccination policies are credited with reductions of VPDs within states, in any population, there are individuals who may be unable to receive vaccinations due to medical reasons.

Every state makes provisions for individuals for whom vaccinations are contraindicated by allowing medical exemptions to school vaccination requirements. Medical exemptions are granted by physicians for individuals who are immunocompromised, have allergic reactions to vaccine components, or who have moderate or severe illness (Salmon et al., 1999). In addition to medical exemptions, 48 states (with the exception of Mississippi and West Virginia) allow NMEs. NMEs may be based on either philosophical, personal belief, or religious grounds, and the distinction between the types of NMEs varies between states (Rota et al., 2001). As of 2010, 21 states have statutes in place for philosophical exemption to vaccination (Offit, 2011). States are also increasingly making provisions for personal belief exemptions, and philosophical exemptions (Salmon & Siegel, 2001). Figure 2.2 illustrates the types of state vaccination exemptions allowed in each state.

Figure 2.2. Types of state vaccination exemptions



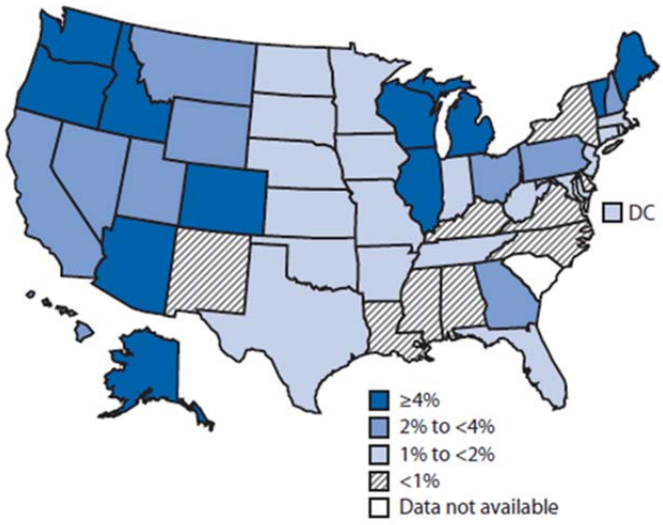
Source: National Vaccination Information Center, 2014

The drastic decline in the incidence of VPDs has resulted in a lack of appreciation for the severity of such diseases. Some groups have focused on efforts to weaken state legislation regarding immunization laws, and to actively encourage the public to use exemptions to circumvent laws. This has prompted some states to modify existing policies to either limit the types NMEs or increase the effort to obtain them (Rota et al., 2001). Consequently, some state NMEs clauses may only require a parental signature on a standard form available at the child's school, while other states are more stringent in requiring that parents go to the state health department or require that requests be made via notarized letter (Omer et al., 2006).

Current Trends of NMEs and Reasons for Vaccine Refusal

On the surface, vaccination coverage rates of American children entering school may appear to be universally high, and not cause for alarm. Coverage rates are at or near national *Healthy People 2020* targets whereby an estimated 95% of children entering school have received 2 doses of MMR vaccine, 4 doses of DTaP vaccine, and 2 doses of varicella vaccine (CDC, 2006; 2007; 2011a; 2013b). Moreover, a recent CDC report indicates that exemption rates among school children (including medical and NMEs) in 49 reporting states and the District of Columbia, ranged from less than 1% to 6.5%. That translates to a median total exemption level of about 1.7% (CDC, 2013b). Figure 2.3 highlights estimated percentages of U.S. children exemptions from one or more vaccines. However, national and state aggregate figures fail to pinpoint geographic areas at the community level that may have significantly higher exemption rates.

Figure 2.3. Estimated percentage of children enrolled in kindergarten who have been exempted* from receiving one or more vaccines United States, 2012–13 school year



*Note: Exemptions might not reflect a child's vaccination status. Children with an exemption who did not receive any vaccines are indistinguishable from those who have an exemption but are up-to-date for one or more vaccines.
Source: CDC, 2013b

Reports indicate the number of NME requests to school immunization requirements has been growing over the past decade (Associated Press, 2007; Omer et al., 2006; Salmon et al., 2005). In addition, an analysis of NME rates from 2005 to 2011 suggests that the trend of increasing NMEs is accelerating (Omer et al., 2012). Furthermore, studies show that the level of complexity for obtaining exemptions may affect NME rates. For example, states that easily grant NMEs have higher overall exemption rates. The *type* of NMEs that states allow (e.g., personal belief versus religious) can influence the rates of exemptions. States that allow personal belief exemptions have been shown to have NME rates that are 2.5 times higher on average than states that only offer religious exemptions (Omer et al., 2006).

Studies that have examined the knowledge, attitudes, and beliefs of parents regarding vaccination issues are typically conducted among parents of preschool aged children. Interestingly, some investigators have found no association between parental beliefs and vaccination. Others studies have found that general distrust in the health care system also contributes to underimmunization. Besides safety concerns, parents may oppose vaccination mandates for moral and religious reasons. Some individuals disapprove of vaccines that may be manufactured from animal products or from cell lines acquired from aborted fetuses (Salmon et al., 2005).

Meanwhile, some parents may have philosophical objections to vaccination. Some may perceive compulsory vaccination as paternalistic and an infringement on individual rights (Hodge & Gostin, 2001). The utilitarian approach (the basis for vaccination policies and mandates) achieves the greatest welfare for the public as a whole as opposed to the individual (Steinbock & Beauchamp, 1999). As a result, the benefits of mass vaccination programs cannot make assurances or guarantee benefits to each and every individual. Therefore parents, who do

not perceive vaccination programs as providing personal benefit, or who fear injury (whether actual or perceived) may become distrustful of institutions and professionals who advocate for vaccination mandates in order to increase vaccination rates. In addition, parents tend to perceive the risks to each individual child from vaccination as greater than the collective risks to the population for failing to vaccinate (Hodge & Gostin, 2001).

By their own admission, some parents claim religious exemptions to avoid vaccinating their children. Citing skepticism of vaccine efficacy and concerns over vaccine safety, parents sometimes lie about their religious beliefs in order to circumvent state laws requiring vaccination for school entry. Moreover, health care professionals are not always in agreement on the actions parents should take when facing the dilemma over state laws requiring vaccination and their own concerns for the safety of their children. Prominent physicians have dismissed parents' resistance to vaccination as "an irrational, fear-based decision" and justification for discharging families from care. Meanwhile, some pediatricians have come forward admitting that they advise parents to pursue a religious exemption regardless of their actual beliefs, if they have concerns regarding vaccines causing harm to their children (Associated Press, 2007).While some parents may seek NMEs for religious or philosophical objections, lack of knowledge about disease risk or susceptibility, along with the increased attention given to mild or rare reactions from vaccination, may also be the cause for the trend of increasing NMEs. Results from a 2009 HealthStyles survey conducted by the CDC showed that approximately one in five of the parents surveyed (n=475) were not fully confident in the safety or importance of vaccines (Kennedy, Basket, & Sheedy, 2011). More alarming, a 2008 survey of pediatricians and family practitioners, assumed to be champions for childhood vaccination, showed that 11% (n=1,251) of them did not recommend to parents that children receive all available vaccines (Gust et al., 2008). A more

recent study concluded that recent medical school graduates had 15% decreased odds of believing vaccines are efficacious compared to graduates from a previous 5 year period; had lower odds of believing that many commonly used childhood vaccines were safe; and 3.7% of recent graduates believed that immunizations do more harm than good (Mergler et al., 2013).

In the past decade, concerns regarding VPDs among parents - and some health care professionals - have shifted from diseases to the safety of vaccines. A recent review of the most prevalent controversies surrounding vaccine safety include, 1) worries of a proposed causal relationship between the measles-mumps-rubella vaccine and autism, 2) thimerosal as a potential link for autism, 3) a purported association between pertussis vaccination and adverse neurological events, and 4) concerns over the damage or weakening caused to an infant's immune system by receiving too many vaccines in a short period of time (Chatterjee & O'Keefe, 2010). Another recent review also found that common concerns regarding vaccines include suspicion that they can cause autoimmune disorders and claims that vaccines provide immunity that is "less safe" than natural infection (Poland & Jacobson, 2012).

Autism

The most contentious vaccine controversies to date began during the mid-1990s over the safety of the MMR vaccine and a supposed link to autism spectrum disorders (ASD) (Chatterjee & O'Keefe, 2010). A theory posited by Andrew Wakefield, and published in the *Lancet* in 1998, proposed a causal relationship between MMR vaccine and autism. Wakefield, a gastroenterologist in the U.K., proposed an "autistic enterocolitis" hypothesis also known as the "leaky gut" theory supposedly supported by studies that identified measles virus nucleic acid sequences in the blood cells and intestinal tissue in a sample of vaccinated children who had experienced behavioral regression.

Following Wakefield's publication, a large, retrospective, cohort study on more than half a million children in Denmark (including 100,000 who had not received the MMR vaccine) was conducted to evaluate the hypothesized association with autism. The results, published in 2002, found that the relative risk associated with MMR was 0.92 (95% confidence interval [CI], 0.68-1.24) for autism disorder and 0.83 (CI, 0.65-1.07) for other ASDs (Madsen et al., 2002). Due to its large sample size and narrow CIs, this study provided convincing evidence that the MMR vaccine did not increase the risk of autism due to its large sample size and narrow CIs (DeStefano & Thompson, 2004). In 2001, the Institute of Medicine (IOM) Immunization Review committee concluded that, "the evidence favors the rejection of a causal relationship at the population level between the MMR vaccine and ASD (Meadows, 2004, p. 19). In 2003, one of the original co-authors of the "autistic enterocolitis" hypothesis rejected a causal relationship between MMR vaccine and ASD (Murch, 2003). Furthermore, since the original publication of the "autistic entercolitis" hypothesis, approximately 20 epidemiological studies (including one conducted in the U.S. by the CDC) have failed to find an association between MMR vaccine and autism or any particular subtypes of ASDs (DeStefano & Thompson, 2004). In 2010, the *Lancet* retracted Wakefield's article due to the determination that several elements of the original paper were proven to be false (Dyer, 2010). However, Wakefield's article is believed to be largely responsible for worldwide decrease in public confidence of the safety of the vaccines (particularly the MMR vaccine) over the past couple of decades. It is believed that the impact of the discredited article has resulted in falling vaccination coverage levels that has led to measles outbreaks (Poland, 2011).

Thimerosal

Around the same time as Wakefield's article, worries began over the possible causal relationship of mercury exposure from a preservative used in vaccines, thimerosal, and autism. As more vaccines that contained thimerosal were added to the immunization schedule, the cumulative exposure to mercury was suspected to negatively affect neurodevelopment in children. Mercury exposure among the general population became a concern in the late 1990s when the Environmental Protection Agency (EPA) published standards of safe limits of methylmercury exposure (Chatterjee & O'Keefe, 2010). Methylmercury exposure in the womb can result from a mother's consumption of fish and shellfish. Methylmercury is a known neurotoxin that can adversely affect a baby's growing brain and nervous system (EPA, 2013). Although thimerosal contains 49.6% mercury by weight, it is metabolized into ethylmercury and thiosalicylate (DeStefano, 2007). Studies comparing ethylmercury and methylmercury suggest that they are processed differently in the human body (Chatterjee & O'Keefe, 2010). Ethylmercury is broken down and excreted much more rapidly than methylmercury. Ethylmercury is much less likely than methylmercury (the type of mercury in the environment) to accumulate in the body and cause harm (CDC, 2011b). However, in 1999, the American Academy of Pediatrics (AAP) and the U.S. Public Health Service (USPHS) issued a joint statement calling for the removal of thimerosal from pediatric vaccines as a precaution. Today, routinely recommended pediatric vaccines do not contain thimerosal even though studies have shown that the properties of thimerosal are distinct from the environmental neurotoxin in mercury. Nevertheless, the impact of showing overt caution by reputable professional organizations like the AAP and the USPHS further hampered general public's trust in the safety

of vaccines, and perhaps increased public doubt regarding the process of scientific research (Chatterjee & O'Keefe, 2010).

Neurological Disorders

Prior to concerns over the safety of vaccines that emerged in the late 1990s, there was debate of the safety of the whole-cell pertussis vaccine. During the 1970s, increased reports of post-vaccination febrile seizures sparked concerns over the vaccine's safety. In 1974, a study was published suggesting neurological complications "identified as convulsions, hemiparesis, and cranial nerve palsies" with whole-cell pertussis vaccine (Kulenkampff, Schwartzman, & Wilson, 1974). Pertussis vaccination coverage rates around the world plummeted with some countries going as far as lifting national immunization mandates. Some countries, including the U.S., U.K., Sweden, and Japan experienced pertussis outbreaks (Chatterjee & O'Keefe, 2010). In 1981, a national case-controlled study in the U.K. concluded that the risk of permanent brain injury from the whole-cell pertussis vaccine was extremely low (1 in 300,000) (Miller, Ross, Alderslade, Bellman, & Rawson, 1981). Worries about the safety of the whole-cell pertussis vaccine prompted the development of more purified (acellular) pertussis vaccines. Acellular pertussis vaccines are associated with a lower frequency of adverse events, but are still effective in preventing pertussis disease (CDC, 1997). Immunization rates eventually began to recover. Subsequent studies have shown no evidence of an association between the whole-cell pertussis vaccine and encephalopathy (Nakayama & Onoda, 2007; Ray et al., 2006).

Antigenic Overload

With the increase of recommended childhood vaccines, parents have expressed concerns about the effects that too many vaccines have on their child's immune system (Chatterjee & O'Keefe, 2010; Freed, Clark, Hibbs, & Santoli, 2004; Offit et al., 2002; Poland & Jacobson,

2012). Parents question whether too many vaccines can cause an “antigenic” overload. Antigenic overload is alleged to occur when individuals (especially infants and young children) receive a “large” number of antigens through vaccines for which the human body cannot safely respond. The immune system of the individual becomes “overloaded.” This concept gained popularity with support from Robert W. Sears, MD, a pediatrician who recommends alternatives to the current Advisory Committee on Immunization Practices (ACIP), AAP, and the American Academy of Family Physicians (AAFP) vaccine schedule in his best-selling book titled, “The Vaccine Book: Making the Right Decision for Your Child” as well as on numerous appearances in popular television programs, websites, and blogs (Offit & Moser, 2009). Research has shown that alternative vaccine schedules with recommendations of administering vaccines over a longer period may exacerbate health inequities, since parents with high socioeconomic status are more likely to make the extra visits required under the alternative schedules than parents with low socioeconomic status (Omer, et al., 2009). The concept of antigenic overload is rooted in the false belief that vaccines trigger a ‘‘cytokine storm’’ or ‘‘immune cascade’’ which result in adverse health events (Poland & Jacobson, 2012). Because of the higher number of vaccines that are given as part of the recommended immunization schedule today (often in combination), some may assume that childhood vaccines contain massive amounts of antigens. While the number of injections has indeed increased up to 26 in total, in reality by the age of two, children today receive fewer antigens since vaccines today are more purified than in the past (Chatterjee & O'Keefe, 2010; Offit et al., 2002). Previously, children received approximately 200 antigenic proteins in a single smallpox vaccine. Today, the 11 routinely recommended vaccines contain fewer than 130 antigenic proteins in total. Furthermore, large-scale population-based studies

have failed to support the hypothesis that too many vaccines overload or weaken a child's immune system (Offit et al., 2002).

Autoimmune Disorders

In a survey of factors associated with refusal of childhood vaccines among parents of school-aged children, the most common reasons stated for not vaccinating were related to perceived vaccine safety, including that vaccines might cause harm (n=190, 68.6%) and that they might overload the immune system (n=136; 49.1%; not mutually exclusive) (Salmon et al., 2005). The survey results support current concerns regarding vaccines, and also highlight another common belief that vaccines may trigger autoimmune disorders. The claim that vaccines can cause autoimmune disorders such as Type 1 diabetes mellitus, multiple sclerosis, and Guillain-Barre syndrome (GBS) is based on the hypothesis that a vaccine component "mimics" a human protein or cellular component, and hence antibodies produced against the vaccine may also bind to its human analog, and cause damage from either autoantibodies or T cells reactive to self-antigens (Poland & Jacobson, 2012). Vaccines are not 100% safe, and while rare, temporal associations with certain adverse events are possible. For example, studies show a temporal association between and idiopathic thrombocytopenic purpura (ITP) and the MMR vaccine (Mantadakis, Farmaki, & Buchanan, 2010). There is also strong evidence of a temporal association between febrile seizures and the MMR vaccine (Maglione et al., 2014). However, systematic reviews of the literature repeatedly show that adverse events associated with vaccines are extremely rare, and data across all licensed vaccines and across all age groups indicate that vaccines are overwhelmingly safe among the majority of people for whom they are recommended (Maglione et al., 2014, Poland & Jacobson, 2012).

Natural Immunity

Poland and Jacobson (2012) add that another prevailing reason why some parents refuse vaccination which is the belief that vaccines provide a "less safe" immunity than natural infections. The notion that "natural" immunity is safer than immunity from a vaccine is inconsistent with the actual risk of death from a VPD outweighing the risk of an adverse outcome from a vaccine. For example, "natural" measles infection can provide life-long immunity, but it also carries the risk of debilitating sequelae and death in 1 out of 3000 cases. The licensed MMR vaccine, despite billions of doses of vaccine having been administered, is not linked with a greater risk of death detectable by statistical methods (Poland & Jacobson, 2012).

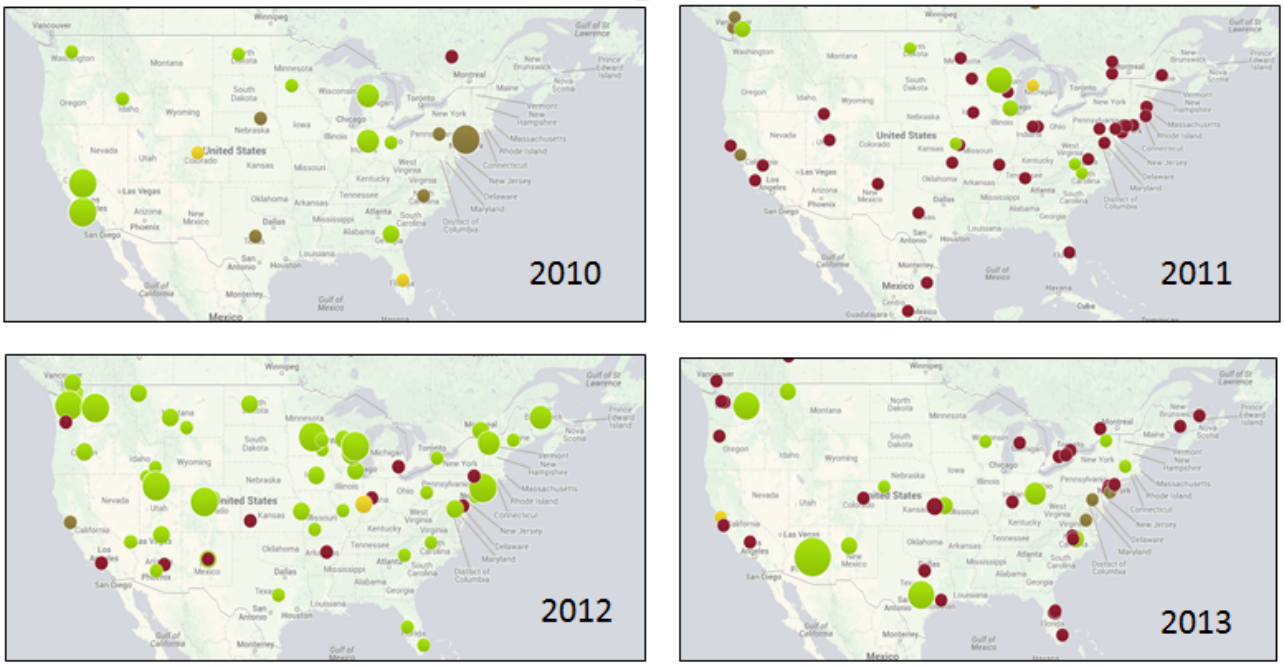
Impact of NMEs

NMEs and coverage rates may directly influence disease rates disease rates on both national and local levels.

National impact

Vaccination exemptions have been shown to cluster geographically and result in outbreaks among the unvaccinated persons at local levels in schools and communities (CDC, 2012; Omer et. al., 2008). High exemption levels in a school or community could mean that the number of unvaccinated children might be sufficient to decrease community immunity and permit transmission of VPDs (CDC, 2012; Glanz et al., 2009). Despite national school and child care mandates and relatively high, state-level coverage rates in the U.S., a number of VPD outbreaks have occurred within recent years. Figure 2.3 shows recent outbreaks of VPDs in North America.

Figure 2.3. Vaccine-Preventable Outbreaks in North America—2010 through 2013

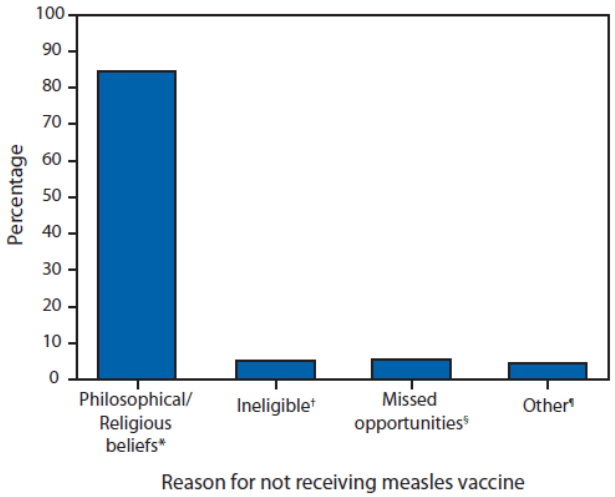


Source: Council on Foreign Relations, 2014

Results of a study, which analyzed all reported measles and pertussis cases among children aged 3 to 18 years in Colorado during 1987-1998, suggested that when mixing of NME and vaccinated populations occurs in a county, in a school, or during an outbreak, "exemptors" can transmit disease to vaccinated individuals (Feiken et al., 2000). In 2010, California reported 9120 cases of pertussis, more than in any year since 1947. The resurgence of pertussis in California and other parts of the country was widely attributed to waning immunity from acellular pertussis vaccines. However, a recent analysis also concluded that clustering of NMEs may have also been a contributing factor in the 2010 California pertussis resurgence (Atwell et al., 2013). Another study that included school-children in Michigan, a state with relatively high NMEs and ease for granting exemptions, showed considerable overlap between the clusters of NMEs and pertussis (Omer et al., 2008). Moreover, the current record number of measles cases reported during January 1–May 23, 2014, including an ongoing outbreak involving 138 persons in Ohio, represents the highest number of measles cases reported for that period since 1994. Most

of the cases occurred in individuals who were unvaccinated and had declined vaccination because of religious, philosophical, or personal objections (n=165, 85%) (Gastanaduy et al., 2013). Figure 2.4 shows the percentage of U.S. residents during the current measles outbreak who were unvaccinated, by reason for not receiving measles vaccine.

Figure 2.4. Percentage of U.S. residents with measles who were unvaccinated (N = 195), by reason for not receiving measles vaccine — United States, January 1–May 23, 2014



Source: Gastanaduy, et al., 2014

Local impact

On a local level, Georgia allows exemptions from school vaccination requirements for medical and religious belief reasons only. In addition, Georgia is considered a state where it is relatively easy to obtain a NME on the basis of religious beliefs. For a child to be exempt from immunizations on religious grounds, the parent or guardian must furnish the school or facility with a notarized affidavit stating that immunization conflicts with his or her religious beliefs. Georgia does not provide a standard form for religious exemptions. Despite the relative ease of obtaining religious exemptions in Georgia, it ranks lower than many states in estimated NMEs among children in kindergarten. During the 2012-2013 school year, there were only 77 NMEs reported in Georgia among children in kindergarten (CDC, 2013b). However, Georgia had a

pertussis outbreak in 2010 with 247 total cases (GDPH, 2010). Coincidentally, between 2011-12 and 2012-13, Georgia reported one of the highest increases in vaccine exemptions in its history (CDC, 2013b).

Prevalence of Discharge Due to Vaccine Refusal

The proportion of children who receive a NME from school immunization requirements is the current, primary measure of vaccine refusal. Between 1991 and 2004, there was an increase from 0.98 to 1.48% in the mean state-level rate of NMEs (Omer et al., 2009). In 2010, an internet-based survey of a nationally representative sample of parents of children 6 months to 6 years of age (n= 748) revealed that 17% respondents reported refusing all vaccines. Most refused only certain vaccines (53%) and/or delayed some vaccines until the child was older (55%) (Dempsey et al., 2010). By contrast, pediatricians surveyed in 2002 in a nationwide study (n=302) conducted by the AAP showed that 54% reported encountering a parent who refused all vaccines in the previous 12 months. Eighty-five percent of sampled pediatricians reported encountering parents refusing at least one vaccine in the previous 12 months (Flanagan-Klygis et al., 2005).

Public health agencies and professional organizations acknowledge the dilemma that health care professionals face when dealing with parents worried about the safety of vaccines. Parents may express apprehension to vaccinate the child during a well-child visit, but clinician time is often at a premium, and finding the time to adequately communicate with parents about the benefits of immunization and allay concerns may pose a challenge. To help health care professionals address parents who refuse vaccination, public health agencies and professional organizations have developed guidelines and toolkits (CDC, 2013b). However, despite these

efforts some health care providers respond to vaccine refusals by "discharging" patients, or ending their participation in the care of children whose parents refuse immunizations.

Flanagan-Klygis et al. (2005) showed that 39% percent of the responding pediatricians would discharge a child whose parent refused all vaccinations, while 28% said they would discharge a child if the parent refused only vaccines categorized as "traditional" vaccines. Additionally, survey results showed that pediatricians cited the number one reason for parental refusal was over the safety of vaccines. More recently, a national survey conducted in 2011 included a group of pediatricians and family medicine physicians recruited from the AAP and AAFP who had previously agreed to respond to several surveys a year. This study yielded a high response rate of 88% (366/416) and 78% (330/423) for family medicine (FM) physicians. Results showed that 25% pediatricians would discharge families from their practice "always," "often," or "sometimes" if they refused vaccines in the primary series, but only 3% of family medicine physicians would do so (Kempe et al., 2011).

On a state level, a 2011 survey of pediatricians (n=113) in the state of Connecticut showed that over 31% of physicians had discharged families as a result of refusing vaccinations. The survey showed that about half of physicians were permitted to personally decide whether or not to discharge, and about half of physicians were part of a practice with policies requiring all physicians to discharge families who refuse all vaccines. However, over 50% of physicians "agreed" or "strongly agreed" with discharging families who refused all vaccines. Results of the Leib et al. study also showed that suburban physicians caring for wealthier, better educated families, experienced 1) more vaccine concerns, 2) more vaccine refusals, and 3) are more likely to discharge patients on the basis of parental vaccine refusal (Leib et al., 2011).

In Arizona, the public health department conducted an online survey of physicians listed in the Arizona State Immunization System (ASIIS). A total of 1125 clinicians in the ASIIS database listed email addresses and were asked to participate. The response rate of the survey was 11.6%. Survey results (n=131) showed that nearly 9% of them would discharge a child from their practice if a parent requested a NME. The primary reasons clinicians reported for parental refusal were over concerns that their child would suffer long-term complications from the vaccine, and that their child would develop autism as a result of a vaccine (Ernst, Haenchen, Pinyerd, & Jacobs, 2013).

Another online study recruiting from among nine AAP chapters in the Midwest were presented at the 2011 annual Infectious Disease Society of America (IDSA) conference in Boston. Complete or near-complete responses were available for 695 participants. Respondents indicated that parents most often refused the MMR vaccine over others. The most frequent reasons for refusal given were parents' perceived, 1) "fear of autism," 2) "too many shots," and 3) "serious side effects" associated with vaccines. Overall, 21% of respondents indicated they would discharge for refusal of all vaccines. Minnesota ranked lowest at 0.9%, and Iowa ranked highest at 38% (Tryon, Neilan, Bartlett, & Harrison, 2011).

AAP Recommendations

The AAP Committee on Bioethics advises clinicians against discontinuing their provider relationship with parents who refuse vaccines. Rather than discharging the family, the AAP recommends that clinicians listen to parents' concerns, honestly discuss the risks and benefits of vaccination, refer parents to reputable sources for information about vaccines and VPDs, and explore any underlying reasons for refusal, such as cost (Diekema, 2005). Furthermore, the AAP advocates for a "Patient- and Family-Centered Care" approach recognizing the vital role that

families play in ensuring the health and well-being of children, and acknowledges that emotional, social, and developmental support are integral components of health care (AAP, 2012). The approach is based on respecting each child's and family's "innate strengths and cultural values" and the role of the physician to provide support to families in their caregiving and decision-making roles. A caveat to this recommendation is the provider's responsibility to make health care decisions after consulting with the patient and the family, and if there are "major differences of opinion between physicians and families in the care of the child that cannot be resolved with consultation and further medical opinions, consultation with an ethics committee would be prudent" (Diekema, 2005, p. 399).

Specifically addressing vaccination refusals, however, the AAP suggests physicians establish a risk management strategy by, providing parents (or guardians) with an opportunity to ask questions about their concerns regarding recommended childhood immunizations, attempting to understand parents' reasons for refusing one or more vaccines, and maintaining a supportive relationship with the family (AAP, 2013). The AAP also encourages that physicians provide documentation of vaccine refusals. In addition to establishing a risk management strategy, the AAP also encourages physicians to do the following:

- Document discussions with parents about the serious risks of what could happen to an unimmunized or under-immunized child.
- Provide the appropriate vaccination information sheet (VIS) for each vaccine at each immunization visit and to answer parents' questions.
- Document vaccine refusal, the conversation with the parent, and the provision of the VIS(s).

- Have the parent sign a Refusal to Vaccinate form, and keep the form in the patient's medical record. If a parent refuses to sign a refusal form, it should be documented, along with the name of a witness to the refusal, in the medical record.
- Revisit the risks and benefits of foregoing immunization discussion at each subsequent appointment and carefully document the discussion (AAP, 2013).

In special circumstances, the AAP acknowledges that clinicians may need to take stronger actions. For example, the AAP states that clinicians may need to involve state agencies to override parental discretion on the basis of medical neglect in special circumstances such as during epidemics. In rare circumstances, the AAP also advises that pediatricians may discharge families provided that they give sufficient advance notice so that the family may establish and continue care with another health care professional (Diekema, 2005).

Parents' Decision-making Process

In light of the frequency with which some physicians' opt to discharge patients over vaccine refusal, it is worthwhile to consider parents' decision-making process. With the volume of information available about vaccines, parents can be overwhelmed when required to make vaccine decisions. Choosing whether or not to immunize their child is considered to be a complex process, both psychologically and computationally (Connolly & Reb, 2012). Parents are confronted with information about vaccine safety from public health organizations, physicians, and non-health professional sources such as celebrities and internet sites. Sources of health information can have varying credibility, and with certain segments of the population, can impact the acceptance of information, the degree to which it is trusted, and on which it is acted. The way vaccine safety information is disseminated also varies. Dissemination methods include

the conventional physician-parent discussions at office visits, as well as mass-distribution such as public safety announcements, advocacy websites and blogs, and television drama and talk shows (Freed, Clark, Butchart, Singer, & Davis, 2011).

Still, a recent survey of a nationally-representative sample investigating parents' trust of vaccine health information sources (n=1,552), found that 76% reported trusting their child's doctor "a lot", which is consistent with results of several previous studies. However, the study also found that mothers differed from fathers in that they were more likely to place "some" or "a lot" of trust regarding vaccine safety on nonprofessional sources such as parents who claim their child was harmed by vaccines, celebrities, television shows, and magazine articles. Ethnic/racial differences were also found. For example, the study showed that Caucasian and Hispanic parents were more likely than African American parents to trust family and friends, and Hispanic parents were more likely to place "some" or "a lot" of trust on celebrities (Freed et al., 2011).

While studies show that parents are likely to report their child's health care provider as the top-trusted source of vaccine safety information, some parents may feel under-informed and lacking in relevant vaccine knowledge. As a result, parents may turn to the internet for more information (Haase & Betsch, 2012). In 2001, Poland and Jacobson (2001) identified well over 300 "anti-vaccine" websites from a single search. This is particularly relevant because a study conducted in Germany on the impact that the internet has on parents' vaccine risk perception, revealed that even brief 5- to 10-minute searches on vaccine-critical websites can lead to an increased belief that vaccines are risky and that omitting vaccination is less risky. The study found that parents exposed to internet searches of vaccine-critical websites had a high-risk perception of vaccines, and were more likely to either under-vaccinate their children or refuse vaccination all together (Betsch, 2011).

Research conducted in the U.K. following the publication of the Wakefield article revealed that emphasizing the seriousness of VPDs is most likely to influence vaccination decisions, as opposed to other arguments for vaccination such as social responsibility, the right of the child to be protected, the value of prevention, or even anecdotal assertions regarding the health care provider's own decision to immunize her/his own child. Interviews with parents wary of vaccines revealed that parents want more information than what is usually provided, and that they prefer two-way conversations with providers regarding risks and opinions about vaccines. Decision aides and "balanced" information that is not framed in a biased way based on the practitioner's predetermined goals for vaccination are also preferred by parents (Betsch, 2011).

Current communication and educational efforts developed by public health agencies about vaccines tend to use a unimodal, fact-based, left-brain cognitive style (Poland, 2011). A common expectation of public health and health care professionals is that a 30-second presentation of facts will suffice in convincing a parent of the value of vaccines. However, the findings presented suggest that communication should be customized to its intended audience in order to increase awareness, knowledge, and behavior of vaccine acceptance. In order to improve popular perceptions about vaccines, increase vaccination rates, and ultimately prevent the incidence of VPDs, public health professionals suggest expanding current vaccine education efforts. Consideration for diverse audiences, different modes of communication, and understanding vaccine psychology and decision-making are critical to making improvements to commonly used communication strategies regarding vaccines. Utilizing a variety of ways to communicate and educate diverse audiences is important because vaccine acceptance is not just based on rational analysis of facts, but is driven by biases and heuristics among other factors. For example, a parent may make a decision regarding whether or not to have their child receive a

vaccine based on fear, coercion, or bandwagoning. Communication and education efforts should not only be directed to parents of children who may be at higher risk for a VPD, but also involve key influencers such as providers (e.g. physicians, nurses), payers, policy makers, and the general public. Each audience group will have different educational needs, prefer different modes or styles of education, have differing levels of cognitive ability, and have varying emotional baseline characteristics. Incorporating theoretical behavior science models to current public health messaging may empower some audiences to make positive health decisions (Poland, 2011).

Summary

The significant decrease in VPD morbidity and mortality as a result of vaccines and mass immunization programs during the 20th century is considered one of the greatest public health achievements. In the U.S. there is no federal law regarding required childhood vaccination; however, all states have mandatory child care and school vaccination laws that ensure that coverage rates among school children remain high.

During the past decade, parents and some health care providers have shifted their focus from concerns regarding the consequences of VPDs to worries about the safety of the vaccines used to prevent them. As a result, studies show that rates of NMEs to school immunization requirements have been increasing over the past, and exemptions rates are accelerating. In areas where NMEs are high, clusters of VPD outbreaks have been reported.

Because of the risks to public health associated with NMEs, some doctors choose to discharge families who refuse to immunize their children, even though the practice is discouraged by the AAP and other medical professional organizations. The AAP recommends specific guidelines for physicians facing parents who refuse vaccination, and encourages

physicians to establish a risk management strategy to provide parents (or guardians) with an opportunity to ask questions about their concerns regarding recommended childhood immunizations, attempt to understand parents' reasons for refusing one or more vaccines, and maintain a supportive relationship with the family.

As the number of parental refusals continues to escalate, and consequently, some physicians continue to stand firm on discharging patients on the basis of vaccine refusal it is valuable to understand parents' decision-making process. Parents may become overwhelmed sifting through extensive vaccine safety information from various different sources. Most parents claim that their child's doctor is the most trusted source of vaccine-related information. However, differences in gender and racial and ethnic background are associated with differences in parents' trusted sources of information and can impact 1) the acceptance of information, and 2) the degree to which it is trusted, and on which it is acted. Some parents may search the internet for additional information regarding vaccines, but the number of vaccine-critical websites parents encounter may increase their perception of risk and influence vaccination refusal.

To avoid fracturing the patient-physician relationship and improve public acceptance of vaccines, evidence-based information must be made available to families, physicians, and public health professionals. Public health professionals must understand the issues physicians face in dealing with parental concerns regarding vaccines, and recognize that different strategies may be required to communicate the value of vaccines to the general public. This research will investigate the characteristics, attitudes, perceptions, and behaviors of physicians regarding vaccination delays and refusals, and in deciding to discharge families on the basis of vaccine refusal in the state of Georgia.

CHAPTER THREE: METHODOLOGY

Introduction

This chapter will describe the methods and procedures used to understand how public health professionals can address parental vaccination refusal and provide evidence to support physicians in maintaining supportive relationships with parents who express concerns regarding vaccines. A thorough description of the study population and sample, research design, survey instrument, procedures, plans for data analysis, limitations, and delimitations will be presented.

Population and Sample

Study participants were drawn from the membership of the Georgia Chapter of the AAP (GAAAP) with the organization's permission. The GAAAP was established from the national AAP organization. The AAP, founded in 1930, is a professional membership organization of primary care pediatricians, pediatric medical sub-specialists and pediatric surgical specialists dedicated to the health, safety, and wellbeing of infants, children, adolescents and young adults. Today the national AAP is comprised of over 62,000 general pediatricians and pediatric medical and surgical sub-specialists (AAP, 2014). In May 1954, the GAAAP held its first meeting as a separate chapter of the national AAP. The mission of the GAAP is, 1) to improve the health and welfare of all infants, children, adolescents and young adults in the state of Georgia, and 2) to unite qualified pediatricians of the state into a representative organization for the advancement of the practice of pediatrics (GAAAP, 2014a). Currently, the GAAAP is comprised of approximately 1,600 members, approximately 1,200 of whom are primary care pediatricians (Chaney, 2014).

A 22-item questionnaire was developed and entered into the web-based application Survey Monkey®. An invitation to participate was sent to 1,247 primary care pediatricians who

were included in the GAAAPs electronic mailing list. The inclusion criteria limited participation to current members of the GAAAP who were primary care pediatricians and who administer vaccines in their practice. Physicians who were not primary care pediatricians and non-members of the GAAAP were excluded from participation. No other screening criteria were applied to this research. A completion rate of approximately 35%, based on previous similar research, was expected.

Research Design

This research consisted of a cross-sectional, quantitative, web-based survey of primary care pediatricians within the state of Georgia. A cross sectional research design was selected for this research based on previous similar research conducted by the national AAP organization and other public health agencies (Ernst et al., 2013; Flanagan-Klygis et al., 2005; Kempe et al., 2011; Leib et al., 2011). This cross-sectional design is limited to data collection at a single point in time and can only be used to measure frequencies and differences among participants. As such, this design utilizes a passive approach to inferences based on findings.

The primary observational objective of this research was to estimate the proportion of pediatricians who report discharging patients for vaccine refusal within the state of Georgia. The secondary observational objective of this research was to understand the characteristics, behaviors, and attitudes regarding parental vaccine refusal of primary care pediatricians in Georgia. The primary variables included the reported number of primary care pediatricians who report having discharged one or more patients on the basis of parental vaccine refusal, and the number of pediatricians who report being likely to discharge one or more patients on the basis of parental vaccine refusal. Secondary variables included the respondents' demographic characteristics; practice characteristics and current policies; perceived number of parental

vaccine refusals due to safety concerns, and religious or philosophical objections; willingness to discharge patients for refusing one or more vaccinations; willingness to agree to an alternative immunization schedule; willingness to agree to a NME; reasons for discharging a patient on the basis of parental vaccine refusal; methods of documenting vaccine refusals; attitudes regarding the value of maintain a vaccine refusal registry; and attitudes regarding their available time and resources to address parents' concerns regarding vaccines.

Instruments

A questionnaire comprised of 22 items was developed with input from Dr. Harry Keyserling, MD, Chair of the GAAAP Committee on Infectious Diseases, and 2014 recipient of CDC's Childhood Immunization Champion for Georgia (GAAP, 2014b). Dr. Keyserling is also a liaison member of the federal ACIP (Emory University, 2014). The final version of the questionnaire used is provided in Appendix A.

Questionnaire items were based on prior research conducted by AAP, CDC, and state public health departments to similar topics related to parental vaccine refusals and pediatricians' decisions to discharge. Most items limited responses to categorical variables to facilitate data analysis. However free-text fields were also included so that participants could further elaborate on responses. Based on the number of items and time required to respond to each item it was estimated that respondents would take 10 to 20 minutes to complete the entire survey.

No prior validation of the survey instrument or pilot study was conducted was conducted prior to its use due to cost and time limitations. A "Research Study Information" document, included in Appendix B, was also developed using a question and answer format for the purpose of providing participants additional information regarding the study.

Procedures

A research protocol was developed and submitted for review to Emory University's Institutional Review Board (IRB) along with the survey instrument and supplementary documents on January 29, 2014. On March 23, 2014, this research study received exemption from further review from the IRB. Documentation of the IRB's exemption letter is included in Appendix C.

The survey, "Pediatricians' Characteristics, Attitudes, Perceptions, and Behaviors Regarding Discharging Families on the Basis of Vaccine Delays or Refusal in the State of Georgia, 2014" was launched and emailed to potential participants on May 1, 2014. All eligible recipients were invited via email to participate. The email recruitment letter is provided in Appendix D. A reminder email was sent to potential study participants approximately two weeks before the survey closed.

Participants were informed that consent to participate was implied with the completion of the survey which was strictly voluntary. No hardcopies of informed consent were collected for this study due to the web-based method of data collection. Participants were also informed that the research would not collect names, addresses, email addresses, or IP addresses, and as such, no personal information would be collected, disclosed, or published. No direct benefits or compensation was provided to respondents for their participation. However, participants were reminded that their input would add to the current literature available on the subject of parent vaccine refusals and physicians' decision to discharge.

Data Collection and Analysis

A convenience sample of primary care pediatricians in the state of Georgia was used. Data were collected from May 1, 2014 through June 9, 2014. Most participants took between

five and eight minutes to complete the questionnaire. The survey allowed participants to skip questions with the exception of the following questions:

- **How many children have you seen whose parent refused at least one vaccine in the past 12 months due to safety concerns?**
- **How many children have you seen whose parent refused at least one vaccine in the past 12 months for religious/philosophical reasons?**
- **How many children have you personally discharged due to vaccine refusal?**

Participants' responses were collected in aggregate using the Survey Monkey® web-based application. No hypotheses were tested in this study. This research was intended to provide descriptive frequencies and statistics only. Responses were examined to reveal the relationships, patterns, and trends by comparing frequencies of select variables to similar research results in the available literature using Microsoft Excel®, version 14.0. Missing data, were applicable, were highlighted in the results provided in the following chapter.

Limitations and Delimitations

As indicated earlier, this research design was based on previous similar research conducted by public health agencies. The use of a web-based survey has advantages in that it is a relatively inexpensive and less time-consuming method to conduct research. Another advantage is that responses can remain anonymous, which may result in more sincere responses to items that may be considered highly sensitive to respondents.

There are also disadvantages of this type of research. These include selection bias and response rate bias. Selection bias and response rate bias have the potential to significantly impact the generalizability of research findings. The selection bias of this research is due to using a convenience sample of primary care pediatricians selected from the GAAP, meaning findings

may not be generalizable to all pediatricians within the state. Given that the GAAP is one of the largest medical professional organizations within the state, it was selected as the source from which to recruit study participants. Another limitation of this type of research is the potential for low response rate bias—responses that may differ from participants than those who do not participate, and may not be representative of the group as a whole. To reduce the potential for low response bias, the survey was designed to take between 10 to 20 minutes to complete, and a reminder email was sent to participants two weeks before closing the survey to encourage recruitment.

Another limitation to this research is the necessity of participants to recall past events or experiences, or recall bias. Because this research fundamentally requires pediatricians to remember encounters with parents who refuse vaccines, the reasons parents give for refusing vaccines, and instances when they may have discharged patients, it is subject to recall bias. Recall bias is a threat to the internal validity of this study. There is no way to estimate the level of systematic errors due to differences in accuracy or completeness as a result of recall bias.

Finally, this research is also subject to question and questionnaire design bias. Question design bias may occur, for example, if any question(s) within the survey is ambiguous or complex so that it leads respondents to understand the question differently than was intended (Choi & Pak, 2005). Consideration was taken in designing survey questions to reduce complexity and ambiguity. For example, questions identified a defined period of time (e.g., In the past 12 months……?). Attempts were also made to avoid the use of jargon and vague wording. Questionnaire design bias may occur if, for example, the questionnaire is too long as it can induce fatigue among respondents, and affect overall response rate (Choi & Pak, 2005). Additionally, formatting problems may also introduce questionnaire design bias. In an attempt to

reduce questionnaire design bias, a minimal number of items were included in the survey. In addition the survey was conducted using a commonly used web-based application with which participants would likely be familiar.

CHAPTER FOUR: RESULTS

Introduction

This chapter describes the findings and results of the survey "Pediatricians' Attitudes, Perceptions, and Behaviors Regarding Discharging Children on the Basis of Vaccine Refusal in the State of Georgia, 2014." Key study questions addressed are:

Research Questions

Specifically, this study will seek to answer the following questions:

- What proportion of primary care pediatricians in Georgia report discharging patients on the basis of parental vaccine refusal?
- What are the current general characteristics of primary care pediatricians in the state of Georgia?
- What are the current characteristics and general policies of pediatric primary care facilities in the state of Georgia?
    - How many primary care pediatric facilities have instituted policies to discharge patients on the basis of vaccine refusal?
    - How many children within the practice are unvaccinated (refused all vaccinations)?
- What are pediatricians' experiences and attitudes with parental vaccine refusals in Georgia?
    - What is the pediatrician-reported frequency of refusals of one or more vaccines?
    - What do pediatricians perceive are the reasons parents refuse vaccines?

- What are pediatricians' behaviors and attitudes regarding parental vaccine refusal, alternative vaccination schedules, and NMEs?
    - How likely are pediatricians to discharge patients on the basis of complete vaccine refusal?
    - How likely are pediatricians to agree with alternative vaccination schedules?

Findings

Demographic Composition

Study participants were recruited from the Georgia Chapter of the AAP. The survey was emailed to 1,247 primary care pediatricians. A reminder was sent approximately two weeks after the initial email. A total of 66 complete or near-complete surveys were received for a response rate of 5%. The response rate was lower than expected, as similar surveys have yielded response rates between, 12% and 45% (Flanagan-Klygis et al., 2005; Ernst et al., 2013; Leib et al., 2011). The lower response rate may be attributed to differences in recruitment strategy, and the unimodality of the web survey. The majority of survey respondents were female (64.1%, n=41) and between 40 and 49 years of age (41.3%, n=26). Approximately three-quarters of respondents (76.6%, n=49) reported having practiced as pediatricians for over ten years. The demographic composition of the respondents is summarized in Table 4.1.

Table 4.1. Respondents' Demographic Characteristics

Characteristic	Number[a]	Percent[b]
Gender		
Female	41	64.1%
Male	23	35.9%
Total	64	100%
Age		
≤ 20	0	0.0%
21 – 29	2	3.1%
30 – 39	5	7.9%
40 – 49	26	41.3%
50 – 59	16	25.4%
60 – 69	14	22.2%
≥ 70	0	0.0%
Total	63	99.9%
Race		
Caucasian	49	79.0%
African American/Black	8	12.9%
Asian	5	8.1%
Other	0	0.0%
Total	62	100%
Ethnicity		
Hispanic/Latino	4	6.5%
Non-Hispanic/Latino	58	93.6%
Total	62	100%
Number of years in practice		
<5	4	6.3%
5 – 10	11	17.2%
11 – 20	18	28.1%
21 – 30	18	28.1%
>30	13	20.3%
Total	64	100.0%

a Totals showing n<66 indicate missing data.
b Percentages based on number of responses to each question.

Practice Characteristics and General Policies

Table 4.2 below summarizes the type of practice of survey respondents. Most respondents indicated that their practice is comprised of either one or two pediatricians (23.1%, n=15) or a group practice (67.7%, n=44).

Table 4.2. Respondents' Practice Type

Characteristic	Number	Percent
Practice Type		
Solo or two pediatricians	15	23.1%
Group practice (> 2 pediatricians)	44	67.7%
Community health center	3	4.6%
Hospital- or university-based	3	4.6%

a Totals showing n<66 indicate missing data.
b Percentages based on number of responses to each question.

Survey respondents were also asked to provide the county where the majority of their patients are seen. The geographic coverage was concentrated to the Atlanta metropolitan area, which includes Cherokee, Cobb, DeKalb, Douglas, Fayette, Forsyth, Fulton, Gwinnett, Henry, Rockdale, and Spalding counties. No responses were received from pediatricians representing Clayton county even though it borders Fulton county and is considered part of the Atlanta metropolitan area. Few responses were received from other counties within the state. Table 4.3 shows the counties were respondents said they see the majority of their patients.

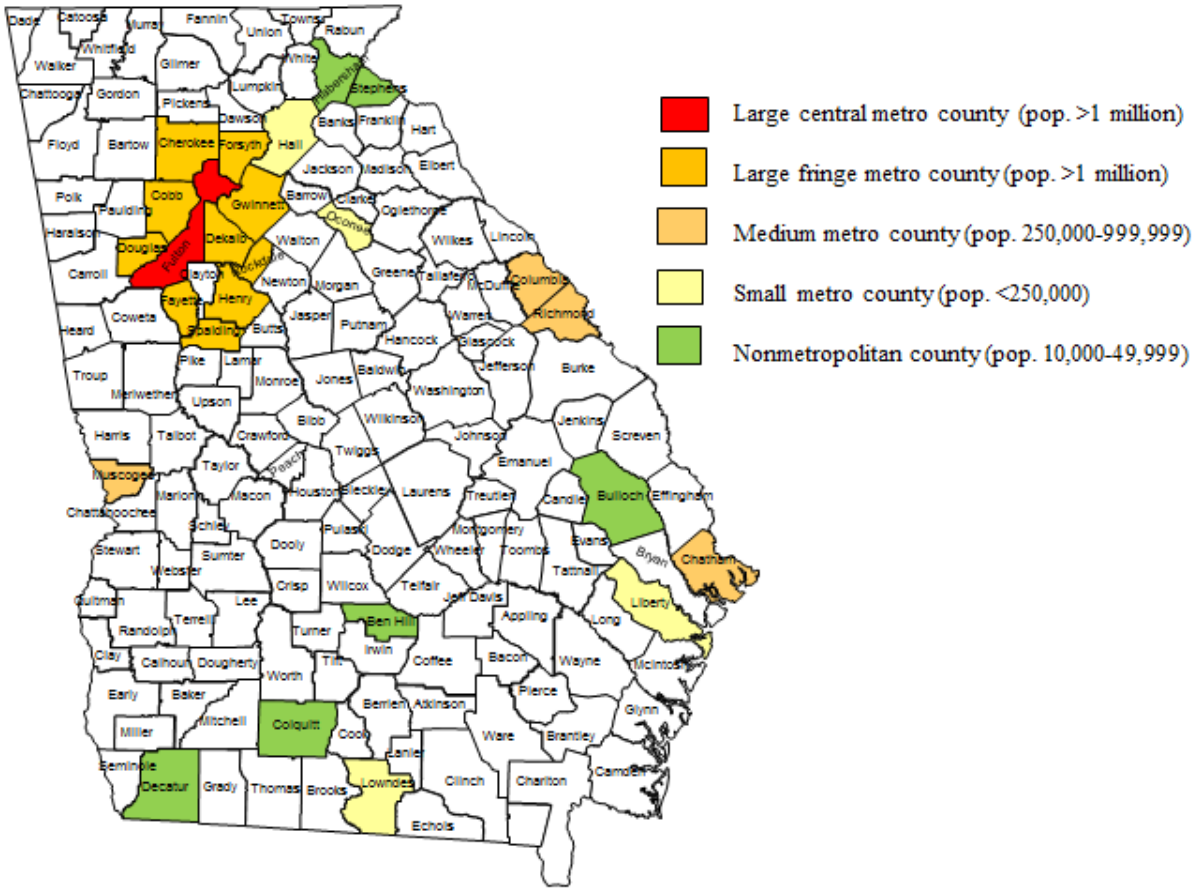
Table 4.3. Respondents' Practice Location

Characteristic	Number	Percent
County [c]		
Ben Hill	1	1.5%
Bulloch	1	1.5%
Chatham	2	3.1%
Cherokee*	3	4.6%
Cobb*	7	10.8%
Colquitt	1	1.5%
Columbia	1	1.5%
Decatur	1	1.5%
DeKalb*	5	7.7%
Douglas*	1	1.5%
Fayette*	2	3.1%
Forsyth*	2	3.1%
Fulton*	12	18.5%
Gwinnett*	12	18.5%
Habersham	1	1.5%
Hall	1	1.5%
Henry*	2	3.1%
Liberty	1	1.5%
Lowndes	2	3.1%
Muscogee	1	1.5%
Oconee	1	1.5%
Richmond	2	3.1%
Rockdale*	1	1.5%
Spalding*	1	1.5%
Stephens	1	1.5%
Total	65	99.7%

a Totals showing n<66 indicate missing data.
b Percentages based on number of responses to each question.
c Counties not listed were not reported by any respondents as being the primary county of practice.
* Represents county within the Atlanta metropolitan area.

Reported counties were categorized according to urbanization levels defined using the 2013 National Center for Health Statistics (NCHS) Urban–Rural Classification Scheme for Counties (Ingram & Franco, 2014). The purpose of classifying counties of practice was to more easily identify the urbanization category of each county represented in the sample. Figure 4.2 highlights the counties respondents identified as where the majority of patients are seen.

Figure 4.1. Counties Represented by Survey Respondents



Most respondents were located in suburban areas, more than half (64.1%, n=41) of respondents indicated that their practice does not have a standard policy to discharge children due to vaccination refusal (Table 4.4). Generally, respondents indicated that their practices have fewer than 50 children in their practice who have refused all vaccines. It is difficult to interpret these findings because the categorical response choices included a large range of numbers, and pediatricians were not asked to provide the total number of children within the practice.

Table 4.4. Respondents' Practice Policies

Characteristic	Number	Percent
Children who have refused all vaccinations		
None	24	36.4%
5 to 10	22	33.3%
11 to 50	15	22.7%
51 to 100	3	4.5%
101 to 500	2	3.0%
>500	0	0.0%
Total	66	99.9%
Discharge for vaccine refusal policy		
Yes	23	35.94%
No	41	64.06%
Total	64	100.0%

[a] Totals showing n<66 indicate missing data.
[b] Percentages based on number of responses to each question.

Perceptions Regarding Parental Vaccine Refusal

Almost all pediatricians reported at least one vaccination refusal due to safety concerns within the past 12 months (Table 4.5). Study findings also show that pediatricians perceived that a greater number of parental refusals due to vaccine safety concerns over philosophical or religious objections. However, these results are based on pediatricians' perceived reasons for refusal. Within the scope of this study, no attempt was made to confirm parents' true reason for refusal.

Table 4.5. Respondents' Experience with Parental Vaccine Refusal

Responses	Number	Percent
Parental refusal due to safety		
None	3	4.5%
1 to 5	17	25.8%
6 to 10	19	28.8%
11 to 20	6	9.1%
More than 20	21	31.8%
Total	66	100.0%
Parental refusal due to philosophical/religious		
None	23	34.8%
1 to 5	30	45.5%
6 to 10	5	7.6%
11 to 20	4	6.1%
More than 20	4	6.1%
Total	66	100.0%

a Totals showing n<66 indicate missing data.
b Percentages based on number of responses to each question.

Behaviors and Attitudes Regarding Vaccine Refusals

Over half (63.6%, n=42) of responding pediatricians indicated that they had not discharged children due to vaccine refusal (Table 4.6). Interestingly, respondents appeared to be almost evenly divided in reporting to be either "very likely" or "very unlikely" to discharge children on the basis of vaccine refusal. These findings suggest that pediatricians have strong opinions on whether physicians should discharge patients on the basis of vaccine refusal. Furthermore, results may indicate that there may be no general consensus among pediatricians.

While findings in this study suggest that few pediatricians would discharge if a parent refused "at least one vaccine," nearly half reported they would be "very likely" to discharge if a parent refused all vaccines (45.5%, n=30). Respondents seemed to be more willing to continue the care of children whose parents refused selected vaccines than children whose parents refused

all vaccines. This study found that the percentage of pediatricians in Georgia who reported being likely to discharge children for complete vaccine refusal are slightly higher in comparison to other similar studies.

Table 4.6. Respondents' Behaviors and Attitudes Regarding Discharge and Vaccine Refusal

Responses	Number[a]	Percent[b]
Number of personal discharges		
None	42	63.6%
5 to 10	15	22.7%
11 to 50	7	10.6%
51 to 100	1	1.5%
101 to 500	0	0.0%
>500	1	1.5%
Total	66	99.9%
Would discharge for refusing at least one vaccine		
Very likely	7	10.8%
Somewhat likely	9	13.8%
Somewhat unlikely	13	20.0%
Very unlikely	36	55.4%
Total	65	100.0%
Would discharge for refusing ALL vaccines		
Very likely	30	45.5%
Somewhat likely	5	7.6%
Somewhat unlikely	9	13.6%
Very unlikely	22	33.3%
Total	66	100.0%

a Totals showing n<66 indicate missing data.
b Percentages based on number of responses to each question.

Findings showed most pediatricians are "somewhat" or "very" likely to agree to an alternative vaccination schedule if a parent requested it. This finding may have greater public health implications. As mentioned in Chapter 2, alternative vaccine schedules may contribute to

the worsening of health disparities, since parents with high SESs are more likely to make the extra visits required under alternative schedules than parents with low SESs.

The greater proportion of respondents (83.3%, n=54) were "very unlikely" to grant a non-medical exemption from school immunization requirements if a parent requested it (Table 4.7). As stated in Chapter 2, obtaining an NME in the state of Georgia considered relatively easy. No formal documentation from a child's pediatrician is required in order for a parent to obtain an exemption from school immunization requirement. The study findings also suggest that pediatricians are willing to compromise with parents and agree to an alternative vaccination schedule provided they are willing to continue immunizing their child. However, pediatricians are unwilling to support waivers for school immunization requirements, perhaps out of concerns for the welfare of other children and the general public's health.

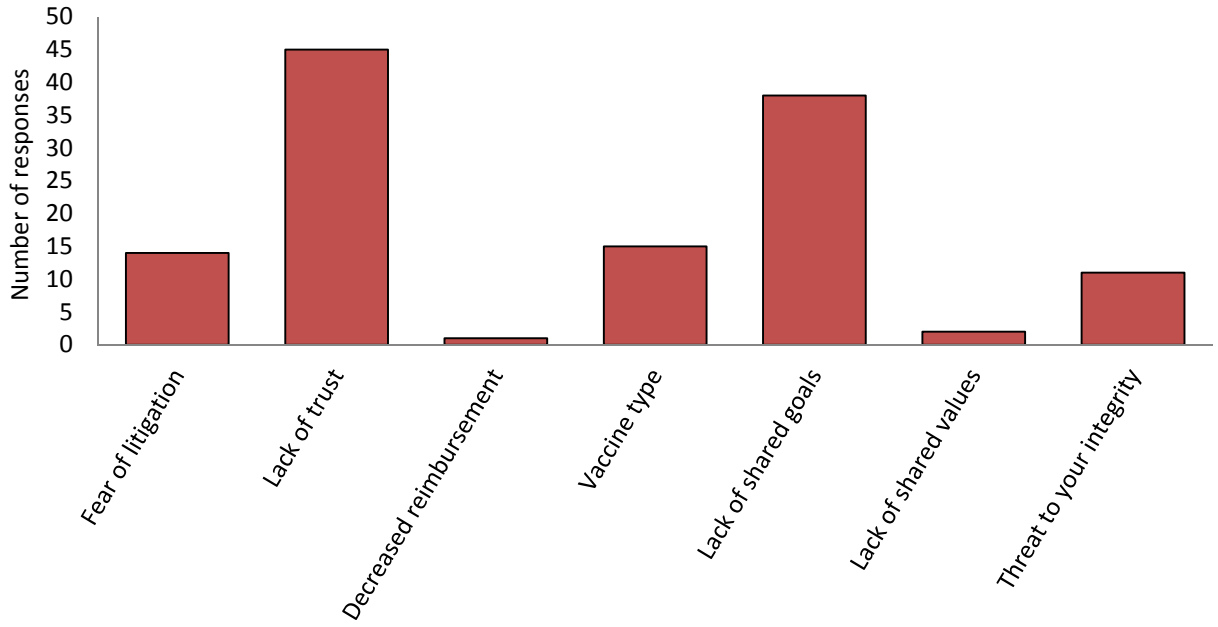
Table 4.7. Respondents' Attitudes Regarding Alternative Schedules and NMEs

Responses	Number[a]	Percent[b]
Agree with an alternative vaccination schedule?		
Very likely	25	38.5%
Somewhat likely	26	40.0%
Somewhat unlikely	4	6.2%
Very unlikely	10	15.4%
Total	65	100.0%
Agree with granting a NME?		
Very likely	1	1.5%
Somewhat likely	3	4.6%
Somewhat unlikely	7	10.8%
Very unlikely	54	83.1%
Total	65	100.0%

a Totals showing n<66 indicate missing data.
b Percentages based on number of responses to each question.

When respondents were asked about the reasons they would hypothetically discharge a child based on parents' vaccine refusal, the primary reasons included "lack of trust between the patient and doctor," and "lack of shared goals for the child's care." Almost 25% (n=15) of respondents indicated that discharging a child over vaccine refusal would depend on the type of vaccine being refused. Decreased reimbursement and lack of shared values did not appear to be important with regard to discharging children. Figure 4.2 summarizes survey findings.

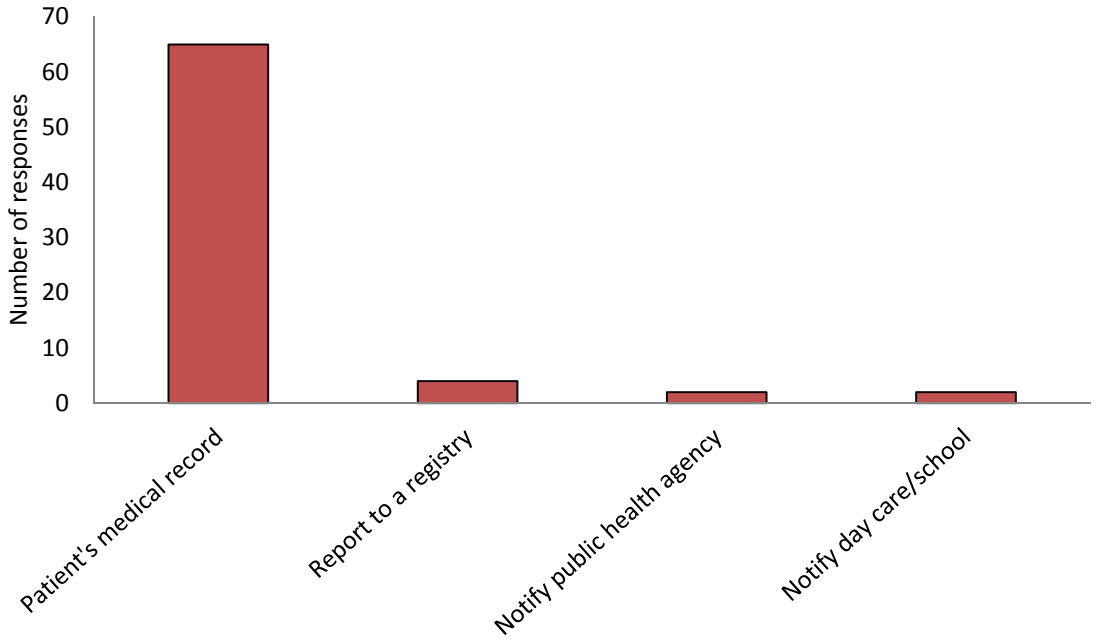
Figure 4.2. Respondents' Reasons for Hypothetical Discharge



The previous survey question allowed respondents to provide further comments. A number of comments further asserted that they would not discharge children on the basis of vaccine refusal, yet other responses stressed concern for the welfare of other children. One respondent wrote, "Non-vaccinators put the other children present in my office at risk by not adhering to herd-immunity." Another wrote that children who are not vaccinated pose a, "…threat to other children in practice who are susceptible to vaccine-preventable diseases."

All respondents indicated that they would document vaccine refusals in the patient's medical records. Figure 4.3 highlights documentation behaviors of survey respondents. Only 6% (n=4) stated that they would report the refusal to a registry such as the Georgia Immunization Registry (GRITS). According to the Georgia Registry Law, any immunization administered in the State of Georgia must be reported to GRITS. However, reporting vaccine refusals is not a requirement (GDPH, 2014b).

Figure 4.3. Respondents' Vaccine Refusal Documentation



The previous question allowed respondents to provide comments. A few respondents suggested they would be in favor of a vaccine refusal registry. One respondent expressed privacy concerns in maintaining a vaccine refusal registry. When asked specifically, approximately 83% of respondents (n= 54) either "very much" agreed or "somewhat" agreed in the value of maintaining a vaccine refusal registry (Table 4.8).

Table 4.8. Respondents' Attitudes Regarding the Value of a Vaccine Refusal Registry

Responses	Number[a]	Percent[b]
Value in maintaining a vaccine refusal registry?		
Very much agree	31	47.7%
Somewhat agree	23	35.4%
Somewhat disagree	6	9.2%
Very much disagree	5	7.7%
Total	65	100.0%

[a] Totals showing n<66 indicate missing data.
[b] Percentages based on number of responses to each question.

When asked about educational resources, the majority of respondents agree in that they have enough resources available to address families who have concerns about vaccines (Table 4.9). In addition, the greater majority of pediatricians surveyed reported that too much time is required in communicating the value of vaccines with parents who express vaccine concerns.

Table 4.9. Respondents' Attitudes Regarding Available Time and Resources

Responses	Number[a]	Percent[b]
Enough resources for parents with vaccine concerns?		
Very much agree	35	54.7%
Somewhat agree	20	31.3%
Somewhat disagree	7	10.9%
Very much disagree	2	3.1%
Total	64	100.0%
Too much time required for parents with vaccine concerns?		
Very much agree	29	44.6%
Somewhat agree	30	46.2%
Somewhat disagree	5	7.7%
Very much disagree	1	1.5%
Total	65	100.0%

[a] Totals showing n<66 indicate missing data.
[b] Percentages based on number of responses to each question.

Other Findings

Comments provided by respondents

Survey respondents were allowed to provide additional comments in an open-text field. Comments suggest that the pediatricians who responded appear to be polarized on the topic of discharging children due to vaccine refusal. Some commented, "We keep non vaccinators because we will slowly get them vaccinated which is better than completely non vaccinated"; "It is a regular occurrence [*sic*] to have parents question the safety and even refuse to have vaccines given to their children. However, when the time is taken to answer their concerns, I have never had a family continue to refuse vaccines. Some will still want a modified schedule, giving one vaccine at a time, which seems like a reasonable compromise, despite the lack of evidence that there is any benefit"; and "We are not the medical police. Families have a right to decline anything unless imminent danger to the child." Others clearly support discharging those who

refuse vaccines. One pediatrician wrote, “Will not see a new patient if doesn't vaccinate [*sic*].” Another wrote, “Parents who do not want to have their children vaccinated either leave on their own or if coming into the practice we screen and let them know up front that I will work with them but will not accept a parent who refuses all vaccines.”

A common theme stemmed from questions about AAP vaccine refusal guidelines. One pediatrician wrote, “AAP needs to have a stronger voice in the media about this issue. I hear more from celebrities than I do you all.” Another wrote, “We need to revisit the AAP policy on vaccine refusal guidelines.”

Finally, some respondents commented about vaccine refusal registries. One stated, “I think that it is a good idea to have a registry and to require parents to state their reason for denial.” Another said, “I am unaware of a registry to document vaccine refusals -- I will have to check GRITS and see if it is capable.”

Limitations

It is important to consider that survey results yielded a low response rate of 5%. The geographic coverage of this research was concentrated to the Atlanta metropolitan area. Estimates presented in this chapter are subject to non-response bias because differences between respondents and non-respondents are unknown. No hypotheses were tested in this study, and only descriptive statistics of frequency were reported and analyzed. Some responses, such as the perceived reasons for parental refusal, are based on respondents’ recall and perception and confirmation of responses is outside the scope of this study. Therefore, findings identified in this study may not be representative of primary care pediatricians in Georgia and are not presumed to be generalizable to all primary care pediatricians in the state.

Summary

In order to better understand physicians' perceptions, attitudes, and behaviors regarding parental vaccine refusal in the state of Georgia, primary care pediatricians from the Georgia chapter of the AAP were invited to participate in a cross-sectional, quantitative, web-based survey. The findings from this study suggest that most pediatricians in Georgia perceive more parental refusals over vaccine safety concerns than due to philosophical or religious objections. While over half of pediatricians denied personally discharging children due to vaccine refusal, 46% would do so if a parent refused all vaccines. Pediatricians appeared to be almost evenly divided on whether they support discharging children on the basis of parental vaccine refusal. While most pediatricians would support an alternative vaccine schedule, most said they would not grant an NME if a parent requested it. The primary reasons pediatricians cited for discharging children would be lack of trust and lack of shared health care goals. Most pediatricians indicated that too much time is required to address parents with concerns regarding vaccines. However, the majority agree that there are enough resources available to help physicians address parents' concerns. All pediatricians document vaccine refusals in the patient's medical records and findings suggest that this may be the only current method of reporting vaccine refusals in Georgia. However, most respondents agreed in the value of tracking refusals in a registry.

CHAPTER FIVE: CONCLUSIONS, IMPLICATIONS, AND RECOMMENDATIONS

Introduction

This chapter will present a brief summary of the current study problem, methodology, results, discussion, and conclusion. Major findings will be highlighted and observed support or distinction to comparable research will be discussed. Implications of current study findings will be explored. Finally, recommendations as a result of this study will be described.

Summary of Study

A cross-sectional, quantitative survey of pediatricians was conducted to gain understanding of current practices and decisions to discharge families on the basis of vaccine refusals. The primary observational objectives of the study were to investigate pediatricians' characteristics, attitudes, perceptions, and behaviors regarding discharging children on the basis of vaccine refusal in the state of Georgia. A 22-item survey instrument was developed and made available online via SurveyMonkey.com® to primary care pediatricians recruited from the Georgia chapter of the AAP. The survey remained available during a 4-week period of time in May 2014.

Sixty-six pediatricians completed the questionnaire for a response rate of 5%. Variables examined included number of parental vaccine refusals, pediatrician-reported discharges as a result of vaccine refusals, level of agreement with alternative vaccine schedules and NMEs, and refusal documentation practices. Descriptive statistics of frequency were reported and analyzed.

Almost all pediatricians reported at least one vaccination refusal due to safety concerns within the past 12 months. Responding pediatricians perceived the majority of parental refusals are attributed to vaccine safety concerns. Half of pediatricians denied personally discharging children due to vaccine refusal, but 46% claim they would do so if a parent refused all vaccines.

Approximately 80% would agree to an alternative vaccination schedule. Too much time is required of physicians to address parents with concerns about vaccines according to almost all respondents.

Discussion

Findings from the current study also suggest that some pediatricians may be willing to negotiate with concerned parents rather than resorting to discharge. A majority of respondents would willingly agree to an alternative vaccination schedule if a parent requested it. Some of the open-text comments entered by respondents suggest that pediatricians may sometimes agree to alternative vaccination schedules because they believe parents will continue immunizing their children even if they do not complete immunization according to the recommended schedule. On the surface, pediatricians' cooperative approach may appear beneficial in promoting immunization. However, it is important to note that alternative vaccination schedules may in fact lead to decreased coverage among some populations. Alternative vaccine schedules may exacerbate health inequities among lower SES due to the additional health care visits required for alternative immunization schedules.

In today's busy world it is not surprising that responding pediatricians reported that a great amount of time is required to address parents' concerns regarding vaccines. Nevertheless, 86% (n=55) "very much agree" or "somewhat agree" that there have enough educational resources to help address parents who are express hesitancy or object to immunizing their child.

Finally, the most responding pediatricians indicated that they document vaccine refusals in the patients' medical records only. Based on the responses received in this study, it appears that responding pediatricians typically take no further action when reporting a vaccine refusal. However, most respondents did agree that there is value in maintaining a vaccine refusal registry.

Comments provided by a few respondents seem to suggest that pediatricians would be interested in knowing more about the capabilities of a vaccine refusal registry.

Implications

The threat of VPDs is relatively low in the U.S. thanks to the availability of vaccines and mass vaccination policies. Nevertheless, reports indicate the number of vaccine refusals and NMEs has been growing over the past decade. The full public health implications pediatricians who take the position to discontinue care for families refusing some or all vaccines are yet to be determined. However, short-term implications may be inferred. When physicians discharge patients on the basis of vaccine refusal, they willingly end participation from the patient's care and any opportunities to promote the value of vaccines. As a direct result, discharged families may feel their concerns are undermined, and/or generate feelings of abandonment and mistrust of health care professionals. Such consequences may reduce access to care. Families who have been discharged may be less likely to seek preventive or acute health care services. Long-term implications may also impact vaccination rates.

Recommendations

The results and findings generated from this research and its implications provide a foundation for areas of further research and suggest a need for evaluation of existing practices and policies related to childhood vaccination refusals.

Conduct additional quantitative research.

Additional quantitative research is recommended to evaluate pediatricians' experiences, attitudes, perceptions, and behaviors regarding parental vaccine refusal. Ideally, quantitative research should yield a larger response rate to reduce response rate bias and non-response bias. Large response rates may be achieved with a more robust recruitment strategy developed in

collaboration with AAP Georgia Chapter. Future quantitative research should also include weighted data with broad geographic and demographic representation so that research results are generalizable to the target populations (e.g., parents and pediatricians) within Georgia. The current survey instrument may be used or revised to conduct further research. Surveys may be piloted on a small sample to test for validity. Furthermore, it is recommended that prospective research define hypotheses and supporting statistical methods and analyses to compare against current study findings. For example, chi-square analyses may be used to determine the significance of associations of outcome variables of interest, and multivariate logistic regression analyses may be performed to predict outcomes while controlling for demographic variables.

Conduct qualitative research.

Supportive qualitative research is recommended in order to 1) triangulate current study findings, 2) gain a more in-depth understanding of how parents and pediatricians make decisions, what influences the decisions, and to determine the kinds of information and educational resources that may be helpful, and 3) further explore pediatricians' attitudes and perceptions leading to discharge on the basis of refusal. In the same manner that greater geographic and demographic representation is recommended for future quantitative research, a similar approach is suggested for qualitative research. Qualitative research may be conducted on samples of pediatricians and/or parents. Research designs may include case studies or random sampling to reveal range of behavior and perceptions and support the construction of hypotheses. A longitudinal case study of families who have been discharged for vaccine refusal may reveal useful insights to health care providers about the effects of such behaviors.

Evaluate current state school vaccination laws and exemption policies.

As a result of state vaccination requirements, Georgia maintains relatively high vaccination coverage among school-aged children. Limiting NMEs to allow only religious exemptions may be a contributing factor in maintaining high coverage rates. However, unlike other states, Georgia requires minimal effort to obtain a religious exemption. Evaluation of exemption policies may be justified if recent trends of increased NMEs and outbreaks of VPDs continue within the state.

Evaluate current recommendations for health care providers, and resources for parents.

The AAP recommends specific guidelines for physicians facing parents who refuse vaccination, and encourages physicians to establish a risk management strategy. This risk management strategy aims to encourage discussions between physicians and parents with concerns regarding vaccines to better understand reasons for vaccine refusal. The goal is to maintain a supportive relationship with the family. Additionally public health agencies and professional medical organizations regularly develop resources for parents about childhood immunizations. However, the rise in NMEs within the state of Georgia (and nationally) suggests there may be strategy gaps or inefficiencies. Evaluation of current AAP recommendations may provide insights to ensure that such recommendations remain effective in reassuring parents of the safety and value of vaccines. Moreover, current study findings suggest that pediatricians believe the AAP and public health agencies need to project a stronger voice in social media to provide support at the front lines of the current vaccine debates. This may be an under-utilized means of communicating the value of vaccines, especially since research shows that even minimal exposure to vaccine-critical websites may result in parents having a higher risk-

perception regarding vaccines, and are more likely to either under-vaccinate or refuse vaccination all together.

Evaluate current surveillance practices.

Georgia Registry Law requires that health care professionals report the administration of vaccines GRITS, Georgia's current immunization registry. However because no standard surveillance exists for vaccine refusals, it is difficult to estimate actual figures. Current study findings suggest that, although it is not standard practice to report refusals to a centralized registry, the majority of pediatricians agree there is value in maintaining collecting these data. Therefore, an evaluation of current surveillance practices and investigation into the utilization of existing systems such as GRITS is recommended.

Conclusion

Although Georgia's NME rates rank among the lowest in the country, high exemption levels can cluster within communities, increasing the risk for disease outbreaks. VPDs continue to be transmitted despite high levels of vaccination at the state levels. Furthermore, in 2013, Georgia experienced one of the highest increases in total vaccination exemptions in its history. How individual health care professionals and public health agencies respond to the problem of parental vaccine refusal may affect the health and welfare of local communities. This research highlights the attitudes, perceptions, and actions taken by pediatricians when confronted with parental vaccine refusal at local levels within the state of Georgia. Data presented in this thesis provide a basis for further study and recommendations in order to create evidence-based health communication strategies to help parents understand the risks for VPDs and the benefits of vaccinations.

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APPENDIX A. Survey Instrument

Thank you in advance for agreeing to participate in this important research study and for sharing your opinions. Your input is very valuable. If you have questions, please do not hesitate to contact me at sheila.marsh@emory.edu.

First, I would like to get some information about your background.

1. What is your gender?
2. What is your age?
3. Please specify your racial origin:
    a. White
    b. African American
    c. Asian/Asian American
    d. Multiracial
    e. Other: Please specify
4. Do you identify yourself as a Latino/Hispanic?
    a. Yes
    b. No
5. How many years have you been in practice?
    a. <5
    b. 5–10
    c. 11–20
    d. 21–30
    e. >30
6. In what county do you see most of your patients?

Appling	Bryan	Cobb
Athens-Clarke	Bulloch	Coffee
Atkinson	Burke	Colquitt
Augusta-Richmond	Butts	Columbia
Bacon	Calhoun	Columbus-Muscogee
Baker	Camden	Cook
Baldwin	Candler	Coweta
Banks	Carroll	Crawford
Barrow	Catoosa	Crisp
Bartow	Charlton	Cusseta-Chattahoochee
Ben Hill	Chatham	Dade
Berrien	Chattooga	Dawson
Bibb	Cherokee	Decatur
Bleckley	Clay	DeKalb
Brantley	Clayton	
Brooks	Clinch	

Dodge
Dooly
Dougherty
Douglas
Early
Echols
Effingham
Elbert
Emanuel
Evans
Fannin
Fayette
Floyd
Forsyth
Franklin
Fulton
Georgetown-Quitman
Gilmer
Glascock
Glynn
Gordon
Grady
Greene
Gwinnett
Habersham
Hall
Hancock
Haralson
Harris
Hart
Heard
Henry
Houston
Irwin
Jackson
Jasper
Jeff Davis
Jefferson
Jenkins
Johnson
Jones
Lamar
Lanier
Laurens
Lee
Liberty
Lincoln
Long
Lowndes
Lumpkin
Macon
Madison
Marion
McDuffie
McIntosh
Meriwether
Miller
Mitchell
Monroe
Montgomery
Morgan
Murray
Newton
Oconee
Oglethorpe
Paulding
Peach
Pickens
Pierce
Pike
Polk
Pulaski
Putnam
Rabun
Randolph
Rockdale
Schley
Screven
Seminole
Spalding
Stephens
Stewart
Sumter
Talbot
Taliaferro
Tattnall
Taylor
Telfair
Terrell
Thomas
Tift
Toombs
Towns
Treutlen
Troup
Turner
Twiggs
Union

7. Please select the type of practice where you work.
    a. Solo or two pediatricians
    b. Group practice (> 2 pediatricians)

    Community health center

    c. Hospital- or university- based
8. Please specify your specialty.
    a. Pediatric primary care
    b. Adolescent medicine
    c. Pediatric cardiology
    d. Critical care
    e. Child abuse pediatrics
    f. Developmental pediatrics
    g. Pediatric emergency medicine
    h. Pediatric endocrinology
    i. Pediatric gastroenterology
    j. Pediatric hematology/oncology
    k. Pediatric infectious diseases
    l. Neonatal medicine
    m. Pediatric nephrology
    n. Pediatric pulmonology
    o. Pediatric rheumatology
    p. Other

Next, I would like to solicit your feedback regarding your experience with parents who refuse childhood vaccination. A parent can include one or both parents, caregiver, or legal guardian of a child under the age of 18 years.

9. How many children have you seen whose parent refused **at least one** vaccine in the past 12 months due to **safety** concerns?
    a. None
    b. 1 to 5
    c. 6 to 10
    d. 11 to 20
    e. More than 20
10. How many children have you seen whose parent refused **at least one** vaccine in the past 12 months for **religious/philosophical reasons**?
    a. None
    b. 1 to 5
    c. 6 to 10
    d. 11 to 20
    e. More than 20

I would like to know your current practices regarding parents who refuse childhood vaccination. A parent can include one or both parents, caregiver, or legal guardian of a child under the age of 18 years.

11. How many children have you personally discharged due to vaccine refusal?
    a. None
    b. 5 to 10
    c. 11 to 50
    d. 51 to 100
    e. 101 to 500
    f. Over 500

12. Approximately how many children are currently being seen at your practice whose parents have refused all vaccines?
    a. None
    b. 5 to 10
    c. 11 to 50
    d. 51 to 100
    e. 101 to 500
    f. Over 500

13. Does your practice have a standard policy to discharge children whose parents refuse vaccinations?
    a. Yes
    b. No

14. Regardless of whether your practice has a standard policy to discharge children over vaccine refusal, how likely are **you** to discharge a child whose parent refuses **at least one** vaccine?
    a. Very likely
    b. Somewhat likely
    c. Somewhat unlikely
    d. Very unlikely

15. Regardless of whether your practice has a standard policy to discharge children over vaccine delay or refusal, how likely are **you** to discharge a child whose parent refuses **all** vaccines?
    a. Very likely
    b. Somewhat likely
    c. Somewhat unlikely
    d. Very unlikely

16. How likely are you to agree to a flexible vaccination schedule (ie, delaying at least one vaccination) if a parent requests it?
    a. Very likely
    b. Somewhat likely
    c. Somewhat unlikely
    d. Very unlikely

17. How likely are you to grant a child a non-medical exemption from school immunization requirements if a parent requests it?
    a. Very likely
    b. Somewhat likely
    c. Somewhat unlikely
    d. Very unlikely

18. How do you document vaccine refusals: (Check Yes or No)
    a. Document in patient's medical record Y/N
    b. Report to registry Y/N
    c. Notify public health agency Y/N
    d. Notify child's day care/school Y/N
    e. I do not document vaccine refusals Y/N
    f. Other: Please specify (no character limit)

19. Do you agree there are enough resources available to you to address parents who express concerns about vaccines?
    a. Very much agree
    b. Somewhat agree
    c. Somewhat disagree
    d. Very much disagree

20. Do you agree that too much time is required to communicate the value of vaccines with parents who express concerns about vaccines?
    a. Very much agree
    b. Somewhat agree
    c. Somewhat disagree
    d. Very much disagree

21. Do you agree that there is value in maintaining a vaccine refusal registry?
    a. Very much agree
    b. Somewhat agree
    c. Somewhat disagree

d. Very much disagree

22. What would be your reasons for discharging a child who delays or refuses vaccines? Check all that apply.
    a. Fear of litigation
    b. Lack of trust between the patient and doctor
    c. Decreased reimbursement
    d. Type of vaccine delayed or refused
    e. Lack of shared goals for the child's care
    f. Lack of shared religious/cultural values
    g. Threat to your integrity
    h. Other: Please comment. (no character limit)

23. Please use this area to comment or provide feedback regarding this research topic/survey. (no character limit)

Thank you for your participation. Your feedback is very valuable and appreciated.

APPENDIX B. Research Study Information Document

Research Study Information

Pediatricians' Characteristics, Attitudes, Perceptions, and Behaviors Regarding Discharging Families on the Basis of Vaccine Refusal in the State of Georgia

What is the research about?

Many parents today have concerns about the safety of vaccines. Some of these concerns are real (but rare) or unsubstantiated. As a result, parents may wish to delay or forego vaccines for their children. In response, some clinicians are making the decision to discharge families who refuse vaccination from their practices. The goal of this research is to better understand the characteristics, attitudes, and current practices of pediatricians dealing with parents' concerns regarding vaccine safety.

What is the purpose of this research?

Research like this enables public health professionals better understand and address increasing rates of childhood vaccination refusals and develop strategies for assisting physicians to improve communication and patient-doctor relationships with families who have vaccine safety concerns.

What is involved in participating in this research?

Your participation will involve completing a brief (approximately10 minutes) online survey to assess your experiences with vaccine refusals. Participation in this study is strictly voluntary. You may choose not to participate in this study.

If I agree to participate, what will I be consenting to?

During the online survey, you will be asked to provide you opinions and input to a series of questions regarding discharging families on the basis of vaccine delay or refusal. Data will be collected in aggregate. No personal identifiable information will be collected. Your participation is voluntary.

Will participating in the study cost me anything?

No. There is no cost to participate. The survey will take only 10minutes of your time to complete.

Will I receive compensation for my participation?

No financial compensation will be provided. However, you can take confidence in knowing that your feedback is very valuable to furthering scientific research to help parents understand the value of childhood vaccines, and contributing to improving public health.

Confidentiality / how is my personal information protected?

The investigator, Sheila Marsh, attests that the survey is not configured to capture your IP address and/or email address. Furthermore, the investigator assures you that this research study does not intend to collect any personal identifiable information. Names/ identities, addresses, or information that could link survey responses to an individual study participant will NOT be collected or used in any study results.

For information regarding Survey Monkey® privacy policy please follow the link below.

http://help.surveymonkey.com/articles/en_US/kb/Are-my-survey-responses-anonymous-and-secure?

Who is conducting/sponsoring this research?

This research is being conducted by Sheila Marsh, BS, BA, a graduate student at Rollins School of Public Health at Emory University. Ms. Marsh intends to author and present a thesis paper as a partial fulfillment of the requirements for a Master of Public Health (MPH) degree from the Rollins School of Public Health at Emory University. Ms. Marsh is currently a full-time Regional Clinical Trial Manager at Sanofi Pasteur, a global vaccine manufacturer.

Ms. Marsh will be consulting with a Thesis Committee during the study. The Thesis Committee consists of a Thesis Chair and a Field Advisor. The Committee Chair is Melissa Alperin, MPH, CHES, and is a faculty member at Rollins School of Public Health at Emory University. The Field Advisor is David P. Greenberg, MD. Dr. Greenberg is Vice President of Scientific and Medical Affairs at Sanofi Pasteur, U.S.. Dr. Greenberg is also Adjunct Associate Professor of Pediatrics at University of Pittsburgh School of Medicine and Pediatric Infectious Diseases at Children's Hospital of Pittsburgh.

This research study received approval from Emory University's Institutional Review Board on **XX/XX/2014**. The study reference number is XXXXX.

APPENDIX C. IRB Exemption Letter

EMORY UNIVERSITY

Institutional Review Board

March 12, 2014

Sheila Marsh
Principal Investigator
Public Health

RE: **Exemption of Human Subjects Research**
IRB00072527
Pediatricians' Characteristics, Attitudes, Perceptions, and Behaviors Regarding Discharging Families on the Basis of Vaccine Delays or Refusal in the State of Georgia

A cross-sectional, quantitative survey of pediatricians in the state of Georgia will be conducted to gain understanding of current practices and decisions to discharge families on the basis of vaccination delays or refusals

Dear Principal Investigator:

Thank you for submitting an application to the Emory IRB for the above-referenced project. Based on the information you have provided, we have determined on **3/12/2014** that although it is human subjects research, it is exempt from further IRB review and approval.

This determination is good indefinitely unless substantive revisions to the study design (e.g., population or type of data to be obtained) occur which alter our analysis. Please consult the Emory IRB for clarification in case of such a change. Exempt projects do not require continuing renewal applications.

This project meets the criteria for exemption under 45 CFR 46.101(b)(2). Specifically, you will administer online surveys regarding attitudes and practices towards discharge of patients associated with vaccine refusal and vaccine schedule delays. These surveys will be administered to Pediatricians who are members of the Georgia Chapter of the American Academy of Pediatrics. The survey content is of a non-sensitive nature, and

no identifiers will be collected. The following document is approved for use:

- Study Protocol v2.0, version date 3/12/2014

Please note that the Belmont Report principles apply to this research: respect for persons, beneficence, and justice. You should use the informed consent materials reviewed by the IRB unless a waiver of consent was granted. Similarly, if HIPAA applies to this project, you should use the HIPAA patient authorization and revocation materials reviewed by the IRB unless a waiver was granted. CITI certification is required of all personnel conducting this research.

Unanticipated problems involving risk to subjects or others or violations of the HIPAA Privacy Rule must be reported promptly to the Emory IRB and the sponsoring agency (if any).

In future correspondence about this matter, please refer to the study ID shown above. Thank you.

Sincerely,

Sam Roberts, BA CIP
Senior Research Protocol Analyst
This letter has been digitally signed

CC: Alperin Melissa Behavioral Science

Emory University
1599 Clifton Road, 5th Floor - Atlanta, Georgia 30322
Tel: 404.712.0720 - Fax: 404.727.1358 - Email: irb@emory.edu - Web: http://www.irb.emory.edu/
An equal opportunity, affirmative action university

APPENDIX D. Email Recruitment Letter

If you're having trouble viewing this email, you may see it online.

Share this:

Re: Survey of Georgia Chapter Members Regarding Vaccine Delays or Parental Refusals of Vaccines

Estimated Time to Complete: Less than 10 minutes

Dear Colleague:

The Georgia Chapter has been working with Ms. Sheila Marsh on a research study entitled, "Pediatricians' Characteristics, Attitudes, Perceptions, and Behaviors Regarding Discharging Children on the Basis of Vaccine Delays or Refusal in the State of Georgia". The study will examine pediatricians' current practices regarding decisions to discharge families on the basis of vaccination delays or refusals.

The survey is directed at pediatricians who administer vaccines in their practice.

This research study received approval from Emory University's Institutional Review Board and is open to pediatricians of all specialties who are members of the Georgia Chapter of the American Academy of Pediatrics.

The intent of this research is to help pediatricians deal with parents who want to delay or refuse vaccines. Your input and opinions will be collected via a brief, 10 minute online survey. No personal identifying information is requested, the data will be collected anonymously, and data will be aggregated to maintain complete confidentiality. Please click on the link below to access the survey.

Your input is very valuable. If you have questions, please do not hesitate to contact Ms. Marsh at sheila.marsh@emory.edu.

https://www.surveymonkey.com/s/vaccrefuse

Harry Keyserling, M.D.
Chair, Infectious Disease Committee

Georgia Chapter of the American Academy of Pediatrics
1330 West Peachtree Street, NW | Suite 500 | Atlanta, GA 30309
phone: 404-881-5020 | fax: 404-249-9503 | www.gaaap.org

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