

# D1.4

## Report on Vaccine Acceptance/Refusal and Resistance to Vaccination

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WP1 Population Behaviour during epidemics

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## EXECUTIVE SUMMARY

“What’s Past is Prologue.”  
*The Tempest, Act II, Scene 1*

Resistance and opposition to vaccination is not a 21<sup>st</sup> century or a 20<sup>th</sup> century phenomenon. Even prior to the introduction of Edward Jenner’s smallpox vaccine, the practice of variolation was met with significant resistance. Such resistance has persisted over time, evolving in sync with the development and introduction of newer vaccines. Although today’s communication landscape has changed the scope and tactics of vaccine resistance, two overarching themes have remained constant over time. The first of these is the relative merit of the vaccine, questioning whether the overall good of a vaccine outweighs its costs and risks. The second theme challenges compulsory and mandatory administration of vaccines. There is perceived infringement upon individual, religious, and philosophical liberties. Autonomy and individual rights regarding personal healthcare decisions for oneself and one’s family are at the core of this theme. In developing strategies to increase vaccine acceptance, both of these major sources of resistance should be addressed. Appropriate consideration must be given to the strength of convictions held by vaccine resisters, and vaccination programs must address specific concerns expressed by vaccine resistance movements in an open and shared dialogue with those targeted by vaccination campaign efforts (Schwartz, 2012; Offit, 2011).

Such thoughtful consideration and effective dialogue with resisters to vaccination are impossible, however, without an understanding of the composition, beliefs, arguments, cognitive processes, communication platforms, strategies, influences, accessibility, and motivators of vaccine-resistant individuals and their vaccine opposition movements. This is a daunting problem, as vaccine resistance varies considerably between individuals, specific movements, faith and political communities, geographic regions, and generations. Generalizations do not effectively apply to vaccine resisters, as it is not a cohesive movement. Even the language used in discussing and analyzing vaccine resistance thwarts efforts to characterize resistance and learn from past strategies. Many of the terms used to describe resistance, define vaccination rates, and discuss strategies adopted by health officials are ill-defined and inconsistently used. Words such as skeptical, hesitant, resistant, refusing, opposing, fear, risk, perception, anxiety, compulsory, mandatory, required, social protection, and obligation offer a small sampling of the many ambiguous words used throughout the vaccination literature. Without a standard vocabulary, it is difficult to make scientific comparisons; this makes it extremely challenging to evaluate different vaccination strategies or to translate those strategies into effective communications.

These considerations noted, this section of TellMe attempts to cover the many factors and considerations relevant to the vaccine uptake equation. This report first examines vaccine acceptance in the European Union (EU) and the United States (US) with special consideration to pandemic H1N1. Then, the current landscape of vaccination coverage and vaccine acceptance, refusal, and opposition is offered, followed by an examination of factors that influence vaccine decision-making. Historical events and current literature, both scientific and otherwise, inform an in-depth look at the many determinants of vaccine uptake and resistance. Past and current strategies to increase vaccine resistance are also reviewed. Finally, recommendations are offered that apply information presented to potential improvements in future vaccination efforts.

Section 1 introduces an overview of the scope, complexity, and significance of vaccine acceptance and resistance. Offering historical context as well as current insight, the extreme importance of vaccine acceptance is highlighted, and its relevance to the TellMe project and current pandemic strategizing is explained.

The following section, Section 2, provides an epidemiological assessment of both the US and EU populations, including vaccine coverage rates, the incidence of disease, and demographic characteristics of the unvaccinated. Such information can help identify geographical areas with low vaccination rates and begin to tease out any common characteristics of those refusing vaccination. This section also acknowledges the data available outside the peer-review literature, in the so-called “gray literature,” and provides a realistic assessment of the validity and generalizability of existing data.

Section 3 is an analysis of risk, including the acceptable risk, actual risk, perceived risk, and theoretical risk associated with vaccination and vaccine-preventable illness. Risk evaluation must weigh the risks of vaccine-preventable illness against the known and theoretical risks associated with vaccination on both the individual and public health levels. Actual risk for both sides of the equation, while intensely studied and analyzed, is impossible to calculate with precision or certainty, as risk projections rely heavily on historical data, changing biological systems, socioeconomic assumptions, and expert opinion. This analysis is further complicated by the reality that people do not always make decisions based on objective, accurate calculations of actual risk, but rather on perceived risk, an even more elusive concept influenced by cognitive, emotional, behavioral, and social biases. In order to better enable individuals to make sound vaccine acceptance decisions based on actual risk, we must thoroughly understand and be able to communicate true vaccine risk. This means not only offering accurate information regarding vaccines and vaccine-preventable illness, but also recognizing common biases and logical errors in risk calculation and being prepared to affectively demonstrate these biases in a way that constructively allows individuals to better understand the full scope of their vaccination decision.

Risk analysis is only one aspect of vaccine acceptance, and that analysis itself is influenced by many factors. Section 4 examines the literature and explores the most significant influences on individual decision-making regarding vaccination, giving particular attention to the 2009 H1N1 pandemic. Societal responsibility, personal risk perception, cultural and political factors, demographics, trust in the vaccine industry, and trust in medical professionals are identified as factors that influence one’s choice to vaccinate. By identifying and understanding what influences one’s decision to become vaccinated, we can better tailor vaccination messaging and more effectively strategize to increase vaccine uptake.

Section 5 looks at specific case examples from the vaccine opposition movement. Vaccine resistant groups exert their influence through the media, particularly through the press and the Internet, and are very visible in today’s society. This section takes an in-depth look at the goals, tactics, arguments, platforms and reach of a selection of anti-vaccination groups. It assesses the taxonomy of these groups and lobbies, and the communication networks that are used to outreach and influence the general public.

While studying anti-vaccination groups is inherently difficult, the following section, Section 6, identifies trends among the case study examples. It discusses who they are, what they provide, and how they outreach to the public. Perhaps more importantly, it discusses consistencies in the tactics and arguments that are used by such groups and how they play into personal factors of decision-making. A thorough

understanding of the counter-argument can only strengthen the pro-vaccination movement and allow for better communication and messaging efforts.

Section 7 addresses strategies to overcome resistance to vaccination. It reviews important strategies that have been or are currently used, discussing effectiveness, philosophical and political issues, errors, and associated challenges. Recommendations to increase vaccine uptake currently found in the literature are also presented. The important issue of healthcare workers, both healthcare worker vaccination and healthcare professional influence on vaccine uptake, is also examined. Special consideration is also given to specific strategies for optimizing vaccination efforts in the event of an influenza pandemic, taking into consideration lessons learned from past vaccination efforts and epidemiology of the disease.

The document concludes with recommendations and strategies for “the way forward,” with a keen eye to the possibility of the need to elicit behavior change in the instance of a public health emergency.

## 1.0 Introduction

“As flies to wanton boys, are we to the gods; they kill us for their sport”

*King Lear, Act IV, Scene 1*

The enormity, complexity and difficulties inherent in TellMe are matched only by the significance and necessity of accomplishing its goals. Several challenges specific to this work must be acknowledged, as they affect the extent to which this section can be considered a comprehensive review and analysis. First, Work Product 1 identifies risk communication strategies; communication needs of target groups; urban myths surrounding vaccination; stigmatization/discrimination against population behaviors during epidemics; and factors that influence acceptance, refusal, and resistance/opposition to vaccination (the specific focus of this section, WP 1.4) as separate tasks. The interrelationships between these tasks, however, are profound, and the boundaries between them are ill defined, making it difficult to remain focused exclusively on the specific task assigned or to satisfactorily review all pertinent resources. Second, achieving a truly “evidence based” outcome will be difficult in this subject area. While the amount of material published about vaccination is vast, empirical observations are the rule and case-control methodologies the exception, even in the peer-reviewed literature. This problem is confounded by the fact that much of the work done by responsible public health agencies, both in the US and the EU, is not reported in the peer-reviewed literature, but in agency reports and other documents that constitute what has become known as the gray literature. These bodies of work often cannot be found using traditional literature searches, so they can be difficult to identify and access. Finally, with regard to the 2009-2010 H1N1 pandemic, which is a special focus of this project, much valuable work has yet to be reported at all.

Acknowledging these barriers, this section addresses vaccine acceptance/refusal and resistance to vaccination. The multiple factors that influence individual and collective decision making as to accepting or refusing a vaccine will be identified, described in depth, and examined for relative significance, alterability, and possible application to vaccination efforts. These major influences are discussed from different perspectives throughout this section: concepts of responsibility to one’s own health; responsibility to the health of others (social responsibility); perceptions of personal health, vaccine risks and benefits, and disease risk and severity; trust in medical professionals; trust in the pharmaceutical industry; trust in government; trust in official and professional recommendations; trust in the traditional and social media; influences from other people, including advocates, vaccine opponents, and celebrities; philosophical, religious and socio-political beliefs, including responses to mandates; cultural beliefs and influences; demographics; and levels of fear and anxiety. These multiple influences assume greater or lesser importance within and between populations, between different epidemics, and maybe most importantly, over time, both within a given epidemic and between different epidemic events.

These factors that influence vaccine acceptance and refusal are the same factors documented in the voluminous literature on the 1918 H1N1 influenza pandemic. It is important to review some of the historical events and outcomes of that event in order to better understand the importance of TellMe, and the real and potential impacts of time on what we can and cannot do. John Barry’s (2004) *The Great Influenza* is regarded as the outstanding work on the 1918 pandemic and what is presented here is derived from that work.

The first cases of the 1918 H1N1 influenza pandemic were identified in Haskell County, Kansas at the end of January 1918. Cases appeared in Ft. Riley, Kansas by March 4th, and in Queens, NY by mid mid-March. By

May, the flu had spread to Europe, and over the next 16-18 months had reached virtually every corner of the globe. The toll was unimaginable; an estimated one-third of the world's population was infected, with mortality rates of 10-20% resulting in some 50 to 100 million total deaths. These numbers are based on best estimates given the limited and often imprecise data available from those years.

A closer look at more precise mortality data available underscores the importance of the work with which we are involved. From those countries with good vital statistics records, the 1918 pandemic appeared in three waves. In the United Kingdom, the first wave peaked at five deaths per 1,000 per week at the end of June, 1918; the second and most severe wave peaked at 25 deaths per 1,000 per week at the beginning of November, 1918, approximately 5 months after the first reported case in Glasgow; and a third wave peaked at 10 deaths per 1,000 in late February, 1919. Of note, the second wave peaked almost simultaneously in New York, Paris, and Berlin with mortality rates of comparable intensity (Barry, 2004).

Why is this important to TellMe? In the absence of an available vaccine for 1918 H1N1, evaluating parameters of acceptance/refusal and resistance to vaccination is moot. Although, it should be noted that prodigious efforts were expended on developing a vaccine or other medical countermeasures without success, and such an intervention was in great demand (Barry, 2004). Important information can be acquired, however, regarding effectiveness of non-vaccine countermeasures to control the spread and mitigate harm from an influenza pandemic. Without medical countermeasures, non-medical strategies of quarantine, isolation, social-distancing, face masks, respiratory hygiene, and school closings were implemented during the 1918 pandemic; unfortunately, this had very limited effect on the spread of the epidemic within populations and across geographic areas. This does not prove that these measures are unimportant or ineffective; it rather suggests that non-medical strategies may not be sufficient to control an influenza pandemic.

Toner further demonstrates the inadequacy of non-medical interventions to control a pandemic (Toner, 2006). In his research looking into the effectiveness of these measures in 2006, no published evidence of the effectiveness of these non-medical measures can be identified. He concludes that public health disease containment measures could slow but not stop epidemic spread, underscoring the importance of a recommendation by the WHO Writing Group published in 2006, "the need is urgent for additional research on transmission characteristics of influenza viruses and the effectiveness of non-pharmaceutical public health interventions," a largely unheeded recommendation (World Health Organization Writing Group, 2006).

Today, antiviral drugs are available and can be effective to a limited degree. While they might help flatten the pandemic's epidemiological curve, they do not significantly reduce the area under the curve. There is furthermore no sound evidence to document their ability to control viral spread at the population level. The only preventative measure proven effective for controlling a viral epidemic, the gold standard of prevention at the individual and population levels, is vaccination.

This raises two important questions that are extremely cogent to TellMe: (1) Are we any more prepared for an influenza pandemic today than we were in 1918; and (2) What is the primary goal of the vaccine effort? The answers to these questions will help inform the end strategies and recommendations of the project.

We must look at the answer to the first question from two perspectives – that of the infected individual, and that of the population, in other words, the clinical perspective versus the public health perspective.

From the individual patient perspective, we are undoubtedly better able to respond with antiviral medications and advanced supportive care. However, in the absence of a vaccine, we are little better prepared and have no other effective measures to truly control an epidemic. This is a critical consideration when we look at the course of the novel H1N1 pandemic of 2009-2010. There was a 6-month time gap between the initial cases in March 2009 and limited vaccine availability in early October. More general vaccine availability, at least in the US, took another month or two. Had 1918 been replayed in 2009, the vaccine would not have been available for the first wave, and the second, most lethal wave would be approaching its peak. A secondary problem with delayed vaccine availability in the 2009 pandemic was that maximum anxiety level, when public acceptance of a vaccine is greatest, peaked well before the vaccine was generally available (Gidengil, Parker, & Zikmund-Fisher; 2012). Thus, the most recent influenza pandemic experience suggests that we are not prepared to maximize the potential benefits of vaccination in controlling a pandemic.

The second question is one that must be answered in order to be prepared for any epidemic. Is the primary goal of vaccination efforts to prevent individual cases or to protect the public through limiting the spread of infection? The answer to this question can have profound impact on messages and strategies used to achieve the stated goal. Infectivity, virulence, and generation time of the organism in question will likely dictate the vaccination effort's primary goal, as these factors largely determine herd immunity, the percentage of the population that must be non-susceptible in order to break the chain of transmission. The vaccination rate required to achieve herd immunity can significantly influence vaccination program goals, which will in turn determine the strategies that will most effectively accomplish the determined objectives. Many of these considerations will be examined in the final section of this document, which will discuss potential effective strategies and offer recommendations emanating from information and findings presented throughout this work.

## 2.0 Epidemiology of Vaccination and Disease

To better understand discrepancies in vaccination acceptance rates in different populations, we must first understand the profile of those that are and are not getting vaccinated. In other words, we must first understand *who* is unvaccinated before we may begin to understand *why* they have chosen to or been forced to forego vaccination. Working exclusively within the United States (US) and European Union (EU) contexts provides a perspective unique from many other vaccine-related epidemiological assessments in that it assumes a standard of health care, level of access to care, stability of infrastructure, and ability for resource allocation that is more typical of the developed world than of the developing. Traditional vaccination campaigns tend to be focused on areas with underdeveloped healthcare systems, a lack of public infrastructure, or which are in the midst of political, economical, or cultural turmoil. While areas of low coverage in the US and EU may very well be areas that lack the resources and infrastructure of similar jurisdictions, most will be well above the standard found in cities and countries in which vaccination interventions are traditionally focused. As such, it is likely safe to assume that vaccination campaigns targeted to these areas within the developed world should not solely focus on improving access to care and healthcare supplies, but rather should take into consideration a plethora of other factors that may be at play.

Looking beyond barriers associated with infrastructure and supply, it is not always easy to discern the reasons for low vaccination. Looking at the US and EU as large but discrete units is also uniquely challenging, in that both contexts are comprised of many smaller, semi-autonomous units (states in the US



and countries in the EU) which have their own healthcare policies and recommendations, unique healthcare delivery systems, varying levels of governmental support, and differing socioeconomic characteristics. Because a multitude of epidemiological surveillance data on vaccination rates exists for both the US and EU, it is possible to run countless analyses using many units of scale and all of these factors and more. Because the scope of this report precludes such intensive and comprehensive assessments, the intention of this section is instead to present broad and basic trends in vaccine coverage between and across the US and EU contexts. While such data cannot infer correlation or causation, it *can* begin to describe unvaccinated populations and thus provide an essential starting ground for investigating the reasons for vaccine refusal that go beyond issues of access and infrastructure.

This section offers a simple, descriptive epidemiology, which may help lay the groundwork for identifying the places and people that are not currently meeting vaccination goals. It is not meant to derive conclusions regarding the reasons for high or low vaccination coverage, nor does it attempt to draw any statistical significance among variables. These figures have not been controlled for income level, education, insurance status, or any other potential confounding variables. Data are limited to a subset of vaccine-preventable diseases, which have been selected, because the vaccines are relatively ubiquitous in most US and EU populations. Data are represented in their raw form and are purely observational. Time trend data is available elsewhere, as is data on additional vaccinations.

## 2.1 The United States

Tables A through E present coverage levels in the US population at both the national and state levels. Tables A, B, and C display data that addresses US vaccination coverage specifically among different age groups. Special attention is paid to vaccination rates among children since the data is most robust for this population, and because vaccination rates among children are often an indicator of vaccination rates in the American population at-large. Vaccination rates of children ages 19-35 months in the US are used as a case study example of the type of analyses that are available for each age group. Within this population, factors such as socioeconomic status, urbanicity, race, and provider type have been controlled for, with the intention of identifying sub-populations that are less likely to be vaccinated than others.

**Table A. Estimated Vaccination Coverage with Individual Vaccines and Selected Vaccination Series Among Children by State, US 2011**

	3+Polio <sup>1</sup>	1+MMR <sup>2</sup>	3+PCV <sup>3</sup>	4+PCV <sup>4</sup>	3+Hib <sup>5</sup>	Hib-PS <sup>6</sup>	Hib-FS <sup>7</sup>
0-24 months of age	92.6±0.7	89.9±0.8	92.6±0.7	81.7±1.1	91.8±0.8	92.3±0.7	69.6±1.3
19-35 months of age	93.7±0.7	91.7±0.8	93.2±0.7	84.4±1.0	93.1±0.7	93.4±0.7	76.2±1.2

The data in Table A is derived from the US Centers for Disease Control and Prevention National Immunization Survey (Centers for Disease Control and Prevention [CDC], 2011b; CDC, 2011c). As shown,

<sup>1</sup> 3 or more doses of any poliovirus vaccine

<sup>2</sup> 1 or more doses of measles-mumps-rubella vaccine.

<sup>3</sup> 3 or more doses of pneumococcal conjugate vaccine (PCV)

<sup>4</sup> 4 or more doses of PCV.

<sup>5</sup> 3 or more doses of Haemophilus influenzae type b (Hib) vaccine.

<sup>6</sup> Primary series Hib: ≥2 or ≥3 doses of Haemophilus influenzae type b (Hib), depending on brand type.

<sup>7</sup> Full series Hib: ≥3 or ≥4 doses of Hib vaccine depending on product

vaccination coverage rates of 4 typical immunizations in American children meet or exceed the estimated rates of coverage needed in the population to confer herd immunity (see Table H). While rates of Hib vaccine coverage are generally high, rates of the full series are lower than those of the other two categories. As expected, vaccination coverage among children 19-35 months of age is higher than coverage in children 0-24 months.

**Table B. Estimated Vaccination Coverage with Selected Vaccines Among Adolescents Aged 13-17 Years**

							Females Only		
	≥ 1 Td or Tdap <sup>8</sup>	≥ 1 Tdap <sup>9</sup>	≥ 1 MenACWY <sup>10</sup>	≥ 2 MMR <sup>11</sup>	≥ 3 HepB <sup>12</sup>	≥ 1 HPV <sup>13</sup>	≥ 3 HPV	HPV 3 dose <sup>14</sup>	
Age 13-17	81.2 (80.2-82.2)	68.7 (67.5-69.8)	62.7 (61.5-63.9)	90.5 (89.6-91.3)	91.6 (90.8-92.4)	48.7 (46.9-50.5)	32.0 (30.3-33.6)	69.6 (66.8-72.2)	

The data in Table B are derived from the US Centers for Disease Control and Prevention National Immunization Survey Teen<sup>15</sup> (CDC, 2011d). Table B shows coverage levels of 5 commonly recommended or mandated vaccinations for teenagers in the US according to the 2010 NIS-Teen survey. Vaccination rates for the second MMR dose are high, at 90.5%, and exceed the estimates for herd immunity (refer to Table H). Coverage rates for the meningococcal conjugate or meningococcal-unknown type vaccine, however, are relatively low, with just 62.7% of respondents having been vaccinated.

**Table C. Estimated Vaccination Coverage Among US Adults, 2007**

	Influenza, 2006-07	Pneumococcal, ever	Tetanus in past 10 years
18-49	37.3% (29.6, 45.7)	32.8% (27.1, 39.0)	57.2% (54.0, 60.5)
50-64	42.2% (39.0, 45.)	-----	57.2% (53.8, 60.5)
65+	68.8% (65.9, 71.6)	65.6% (62.6, 68.6)	44.1% (40.7, 47.6)

Recommended vaccinations for adults are different than those for the younger age ranges (CDC, 2008). However, in general, vaccination rates for recommended vaccines among adults are much lower than among children and rates are higher among older adults than their younger counterparts.

As shown in Table C, the 65+ population has higher levels of influenza and pneumococcal vaccination than the 50-64 year old and 18-49 year old age groups. Pneumococcal vaccine coverage was twice as high for the over 65 group than for the 18-49 year olds, but the pneumococcal vaccination rates for adults aged 50-64 years old were unavailable. Influenza vaccinations were underutilized in all age groups, especially in the younger groups, with vaccination coverage being almost twice as high among 65+ group than the 18-49 group. In contrast, adults age 65 and older had fewer tetanus vaccinations in the last 10 years than the other two groups.

<sup>8</sup> ≥1 dose of tetanus toxoid-diphtheria vaccine (Td) or tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis (Tdap) since the age of ten years.

<sup>9</sup> ≥1 dose of tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis (Tdap) since the age of ten years.

<sup>10</sup> ≥1 dose of meningococcal conjugate vaccine or meningococcal –unknown type vaccine.

<sup>11</sup> ≥ 2 doses of measles-mumps-rubella vaccine.

<sup>12</sup> ≥3 doses of hepatitis B vaccine.

<sup>13</sup> ≥1 dose of human papillomavirus vaccine, either quadrivalent or bivalent. Percentages reported among females only (n=9,220).

<sup>14</sup> Percent of females who received three doses among those who had at least one HPV dose and at least 24 weeks between the first dose and the interview date.

<sup>15</sup> Adolescents in this population were born during January 1992 – February 1998. Vaccination coverage estimates include only adolescents who had adequately complete provider-reported immunization records, which limits the generalizability of the data to the greater population, as they may be more likely to have been vaccinated than other children.

**Table D. Estimated Vaccination Coverage Among Children Ages 19-35 Months, by Select Demographic Factors**

	3+Polio	1+MMR	3+PCV	4+PCV	3+Hib	Hib-PS	Hib-FS
TOTAL	93.7±0.7	91.7±0.8	93.2±0.7	84.4±1.0	93.1±0.7	93.4±0.7	76.2±1.2
WIC Participants	93.7±1.0	92.5±1.0	92.9±1.1	82.7±1.5	92.0±1.1	92.3±1.1	72.3±1.8
Non-WIC Participants	93.7±0.9	90.8±1.1	93.5±0.9	86.5±1.4	94.4±0.8	94.6±0.8	80.8±1.4
Poverty level or above	94.1±0.8	91.7±0.9	94.1±0.8	86.7±1.2	94.5±0.7	94.7±0.7	79.3±1.3
Below poverty level	92.9±1.4	91.6±1.4	92.0±1.4	80.2±2.2	90.7±1.5	91.0±1.5	70.9±2.4
MSA Central City	93.8±1.0	93.0±0.9	93.4±1.1	84.8±1.6	92.8±1.1	93.1±1.1	76.6±1.8
MSA, not Central City	93.7±1.1	90.8±1.4	93.4±1.1	84.5±1.7	93.6±1.1	93.8±1.1	76.8±1.9
Non-MSA	93.4±1.4	90.8±1.6	92.2±1.5	82.9±2.1	92.5±1.5	93.0±1.5	73.4±2.5
Racial/Ethnic Group							
White, Non-Hispanic	93.7±0.8	91.0±0.9	93.3±0.8	85.1±1.2	93.6±0.8	93.8±0.8	77.0±1.4
Black, Non-Hispanic	93.4±2.1	90.7±3.1	92.5±2.3	81.5±3.5	91.2±2.5	91.3±2.5	72.3±3.3
Hispanic	93.7±1.6	93.2±1.4	93.4±1.7	83.9±2.4	93.4±1.5	93.5±1.5	74.8±2.7
American Indian or Alaska Native only, non-Hispanic	94.5±3.9	92.1±6.2	93.6±3.9	82.1±7.4	92.4±5.1	95.3±3.5	80.2±7.9
Asian only, non-Hispanic	96.0±2.1	94.2±2.2	94.1±2.1	87.1±3.4	93.3±2.5	94.0±2.4	80.8±5.5
Native Hawaiian or other Pacific Islander only, non-Hispanic	98.7±2.6	96.9±3.8	97.8±3.1	94.0±5.3	98.0±2.8	98.0±2.8	90.6±6.3
Multiple Race, non-Hispanic	92.3±3.2	91.3±3.3	91.9±3.4	85.7±3.9	92.0±3.3	92.4±3.3	81.0±4.4
Provider Type							
Public	93.8±1.6	93.0±1.8	92.2±1.8	79.9±3.1	93.1±1.7	93.4±1.6	70.7±3.8
Private	95.1±0.8	92.5±1.0	94.7±0.9	86.6±1.3	95.0±0.9	95.2±0.8	79.6±1.4
Mixed	97.2±1.0	95.1±1.3	96.5±1.1	86.3±2.8	96.7±1.1	96.8±1.1	76.8±3.3
Other	90.9±1.7	90.3±1.7	91.0±1.7	82.5±2.5	89.1±1.9	89.4±1.9	71.6±2.9

Children ages 19-35 months are used in Table D as an example to display the many ways that vaccination coverage by demographic variables can be displayed (CDC, 2011c). Because this age group has a high number of recommended vaccinations, it is a fitting group to examine in order to identify trends in vaccination acceptance. WIC (Women Infants Children) is a national program in the US that provides assistance to pregnant women and caregivers of young children with poor financial resources.

With the exception of the MMR vaccine, rates of vaccination were higher among non-WIC participants than among WIC participants. In general, vaccination rates were higher among people at or above the poverty line than for those below the poverty level; however, there are notably lower levels of 4+PCV and Hib-FS, which may indicate trouble completing vaccination series in low-income populations. Persons living in a non-medically served area (MSA) generally had lower vaccination rates than those living in an MSA. There was no notable difference in vaccination rates among those living in an MSA Central City and those living in an MSA but not in a Central City location. Children aged 19-35 months with private or mixed insurance coverage had higher average estimated vaccination rates than did those with public providers.

When divided by ethnic groups, differences were most apparent for certain vaccines rather than among racial/ethnic groups. Black, non-Hispanic children ages 19-35 months had lower rates of vaccination coverage for 4+PCV, 3+Hib, and Hib-FS than all other ethnic groups. American Indian and Alaska Natives also had relatively low rates of 4+PCV coverage, despite having relatively high rates for the other vaccines.

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The Hib-FS has lower overall coverage rates than the other vaccines in each of the ethnic groups, with rates among Blacks, Whites, and Hispanics in the seventieth percentile range.

When comparing racial/ethnic groups to one another, there were some differences. American Indian or Alaska Native, Asian non-Hispanic, Native Hawaiian or other Pacific Islander, and Multiple Race non-Hispanic populations had marginally higher vaccination rate estimates than did White, non-Hispanic children. Native Hawaiian or other Pacific Islanders had higher overall coverage rates than other racial/ethnic groups, followed by Asian and American Indian or Alaska Natives.

**Table E. Estimated Vaccination Coverage with Individual Vaccines and Selected Vaccination Series Among Children 19-35 Months of Age by US State**

	3+Polio	1+MMR	3+PCV	4+PCV	3+Hib	Hib-PS	Hib-FS
US National	93.7±0.7	91.7±0.8	93.2±0.7	84.4±1.0	93.1±0.7	93.4±0.7	76.2±1.2
Alabama	94.5±2.9	94.4±2.5	95.7±2.4	87.0±4.2	94.5±2.9	96.5±2.2	78.4±5.2
Alaska	91.6±3.8	89.7±4.0	91.1±4.0	78.1±5.6	88.8±4.3	93.5±3.4	80.9±5.2
Arizona	94.4±2.8	89.2±4.7	93.6±3.1	82.8±5.3	93.9±3.2	94.8±2.8	76.5±6.4
Arkansas	96.0±2.2	93.5±3.2	92.9±4.3	77.4±6.5	93.6±4.1	93.9±4.1	70.9±7.1
California	92.4±3.4	90.9±3.9	92.8±3.4	82.0±5.4	92.9±3.3	92.9±3.3	76.7±5.5
Colorado	93.3±2.8	89.9±3.5	90.6±4.3	82.5±5.5	92.7±3.4	92.9±3.3	78.1±5.7
Connecticut	95.6±3.1	95.0±2.9	95.6±2.8	87.8±4.6	94.4±3.3	94.4±3.3	82.0±5.3
Delaware	93.2±3.9	91.7±4.2	95.0±3.3	87.2±5.0	94.9±3.4	94.9±3.4	79.5±5.5
Dist. of Columbia	93.8±3.6	92.3±4.9	96.8±2.2	90.5±4.4	94.9±3.5	94.9±3.5	84.5±5.9
Florida	97.8±1.5	96.3±2.2	96.1±3.0	88.7±4.6	94.7±3.6	94.9±3.6	81.8±5.8
Georgia	96.0±2.9	91.3±4.3	95.7±3.1	88.2±5.1	92.8±3.9	93.2±3.9	66.1±7.1
Hawaii	94.7±2.8	91.7±3.7	93.0±4.4	83.8±5.8	91.7±4.6	92.6±4.5	78.9±5.8
Idaho	89.6±4.8	86.7±5.3	87.2±5.1	78.9±6.0	85.8±5.3	85.8±5.3	59.0±7.4
Illinois	95.0±2.4	90.5±3.3	93.5±2.7	86.0±3.9	93.8±2.7	94.1±2.7	77.5±4.7
Indiana	95.1±2.7	93.7±2.9	94.6±2.8	84.2±5.1	94.2±3.2	94.2±3.2	77.7±5.7
Iowa	92.7±4.4	89.4±5.0	93.2±4.2	86.8±5.7	92.0±4.5	92.5±4.5	76.6±7.0
Kansas	92.1±4.2	85.8±5.4	90.9±4.4	82.5±5.9	91.7±4.2	91.7±4.2	75.1±6.4
Kentucky	96.1±2.8	92.1±3.9	95.1±2.9	89.3±4.2	94.7±3.1	95.0±3.1	78.3±5.8
Louisiana	95.7±2.8	90.0±4.1	93.1±3.9	83.1±5.8	94.1±3.5	95.0±3.3	75.7±6.4
Maine	94.7±3.2	92.5±3.6	94.0±3.3	88.8±4.5	93.0±3.7	93.9±3.4	71.4±6.3
Maryland	95.0±3.2	92.2±3.7	91.4±4.3	86.9±4.8	94.7±3.1	94.8±3.1	79.3±5.6
Massachusetts	94.1±3.9	93.3±4.1	95.3±3.6	88.5±5.2	94.9±3.8	94.9±3.8	84.2±6.0
Michigan	93.3±3.9	88.4±4.6	90.8±4.5	84.1±5.6	91.0±4.5	91.4±4.4	72.0±6.7
Minnesota	94.0±4.7	93.5±4.9	96.4±3.9	89.7±5.7	94.6±4.4	94.6±4.4	77.9±6.8
Mississippi	93.8±3.4	91.2±3.7	94.0±3.4	82.3±5.4	93.6±3.4	94.2±3.2	75.0±5.9
Missouri	91.8±3.6	89.7±4.1	88.7±4.3	78.4±5.6	90.8±3.8	90.8±3.8	73.2±6.0
Montana	88.7±4.5	90.6±3.8	87.4±4.6	79.8±5.4	87.5±4.6	88.7±4.1	73.7±5.9
Nebraska	94.0±3.3	94.4±2.9	94.1±4.3	89.4±5.1	90.2±5.1	90.7±5.1	81.9±5.8
Nevada	91.0±4.1	89.1±4.5	90.5±4.4	77.6±6.1	90.7±4.3	90.7±4.3	72.5±6.6
New Hampshire	97.2±2.4	92.9±4.1	97.1±2.5	93.8±3.8	97.8±2.3	97.8±2.3	86.6±5.5
New Jersey	92.3±3.6	91.8±3.9	94.7±3.1	87.7±4.5	95.5±3.3	95.5±3.3	79.4±5.6
New Mexico	93.1±3.1	89.0±4.0	90.6±4.0	81.5±5.2	93.1±3.2	93.9±3.0	73.4±6.0
New York	91.8±3.1	91.0±3.1	90.9±3.2	80.0±4.3	90.8±3.2	90.8±3.2	70.2±5.0
North Carolina	93.3±4.4	91.1±4.7	93.0±4.4	83.9±5.6	91.1±4.8	92.4±4.5	66.6±7.1
North Dakota	95.2±2.9	92.7±3.4	95.9±2.7	88.0±4.4	92.4±3.5	92.4±3.5	79.4±5.4
Ohio	93.4±3.7	92.0±4.0	91.2±4.5	80.2±6.5	93.9±3.6	93.9±3.6	79.6±6.3
Oklahoma	92.4±3.9	92.5±3.7	90.9±4.0	76.9±5.8	91.0±4.1	91.2±4.1	72.4±6.1
Oregon	93.5±3.5	92.4±3.3	95.7±2.5	87.5±5.2	93.0±3.7	94.3±3.2	71.4±6.9
Pennsylvania	95.1±2.3	91.6±3.0	94.4±2.3	85.9±3.7	95.5±1.9	95.6±1.9	79.6±4.3
Rhode Island	98.4±1.6	97.5±2.0	96.9±2.5	92.1±3.9	96.5±2.7	98.4±1.5	76.4±6.8
South Carolina	94.9±2.7	94.0±2.8	94.0±3.1	86.7±4.8	93.3±3.2	93.3±3.2	72.0±6.2
South Dakota	95.5±3.0	90.0±5.2	90.9±4.5	76.8±6.7	89.8±5.0	90.4±4.9	70.9±7.1
Tennessee	94.7±3.3	91.9±3.8	93.2±3.7	83.8±5.2	92.5±4.6	92.5±4.6	82.4±5.8
Texas	93.1±2.4	93.9±2.1	93.4±2.4	85.8±3.2	93.3±2.3	93.4±2.3	77.0±4.0

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Utah	90.2±4.9	88.5±4.5	90.7±4.3	75.5±6.8	91.9±4.0	91.9±4.0	76.1±6.4
Vermont	98.3±1.3	95.6±2.3	94.7±3.1	87.8±4.5	96.9±2.0	96.9±2.0	73.8±6.4
Virginia	91.6±4.8	88.8±5.0	91.6±4.9	83.0±5.8	91.7±5.2	91.7±5.2	72.8±6.8
Washington	91.5±3.5	90.4±3.6	94.0±2.9	88.8±3.9	92.8±3.2	92.8±3.2	78.3±5.1
West Virginia	92.0±3.5	90.1±3.6	90.5±3.6	78.8±5.2	92.0±3.4	92.0±3.4	70.4±5.6
Wisconsin	94.0±3.5	92.9±3.5	95.3±3.0	91.6±4.1	95.8±2.9	95.8±2.9	84.7±5.2
Wyoming	93.9±3.0	92.9±3.4	93.8±3.2	76.0±6.9	94.3±4.3	94.7±4.2	77.2±6.7

Vaccination coverage varies by both state and vaccine (CDC, 2011c). As shown in Table E, Hib-FS and 4+PCV have some of the lowest coverage rates across all states, while 3+Polio, Hib-PS, and MMR have some of the highest. Interestingly, Alaska has high coverage rates of Hib-FS and relatively low coverage of 1+MMR and 4+PCV, which have high coverage rates in most other states.

States with the lowest vaccination coverage include Idaho, Montana, Missouri, Utah, Alaska, and South Dakota. States with the highest vaccination rates include New Hampshire, Rhode Island, Florida, Wisconsin, Vermont, Pennsylvania, New Jersey, Massachusetts, Louisiana, Kentucky, Indiana, DC, Delaware, and Alabama.

For each vaccine, coverage ranges are as follows:

- 3+Polio: 98.4% in Rhode Island, 88.7% in Montana
- 1+MMR: 97.5% in Rhode Island, 85.8% in Kansas
- 3+PCV: 97.1% in New Hampshire, 87.2% in Idaho
- 4+PCV: 93.8% in New Hampshire, 75.5% in Utah
- 3+Hib: 97.8% in New Hampshire, 85.8% in Idaho
- Hib-PS: 98.4% in Rhode Island, 85.8% in Idaho
- Hib-FS: 86.6% in New Hampshire, 59.0% in Idaho

## 2.2 The European Union

Tables F and G illustrate vaccination coverage in the EU context. Data is presented both by country (where data were available) and by particular disease. Data in Table F was drawn from the World Health Organization (WHO)/UNICEF estimates of National Vaccination Coverage (World Health Organization [WHO]/UNICEF, 2012). In most countries, administrative coverage data monitor the number of vaccine doses administered to the target population. This number is divided by the total estimated target population, which is used as an estimate of the percentage immunization coverage. WHO and UNICEF request from countries their best estimate of coverage (administrative or survey data) and this figure is reported as the official coverage estimate. Based on the data available, consideration of potential biases, and contributions from local experts, WHO and UNICEF have attempted to determine the most likely true level of immunization coverage.

**Table F. WHO and UNICEF estimates of national vaccination coverage percentage by country, European Union 2011**

	3+Polio	MCV	MCV2	HepB3	3+Hib	DTP3	PCV3
Total Average	89	88	91	88	88	89	73
Albania	99	99		99	99	99	

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Andorra	99	99	82	99	99	95	
Armenia	96	97	98	95	95	83	
Austria	83	76		83	83	74	
Azerbaijan	80	67	98	48	38	98	
Belarus	98	99	99	98	21	98	
Belgium	98	95	83	97	98	88	
Bosnia and Herzegovina	89	89	88	88	85	95	
Bulgaria	95	95		96	95	96	94
Croatia	96	96	98	97	96	99	
Cyprus	99	87		96	96	99	
Czech Republic (the)	99	98	98	99	99	91	
Denmark	91	87	86	94	91	93	90
Estonia	93	94	95	65	93	99	
Finland	99	97		92	99	99	
France	99	89		93	97	94	89
Georgia	90	94	77	95	92	99	
Germany	95	99	92	95	93	99	15
Greece	99	99	77	99	83	99	
Hungary	99	99	99	96	99	96	84
Iceland	96	93		99	96	95	
Ireland	95	92		96	95	94	90
Israel	94	98	88	91	93	96	
Italy	96	90		95	96	99	
Kazakhstan	99	99	99	95	95	96	
Kyrgyzstan	94	97	98	82	96	94	
Latvia	94	99	91	99	93	92	78
Lithuania	92	94	94	91	92	99	
Luxembourg	99	96		98	99	96	86
Malta	96	84	85	97	96	99	
Monaco	99	99		96	99	95	
Montenegro	95	91	97	96	90	97	
Netherlands (the)	97	96	93	97	97	94	96
Norway	94	93	94	86	95	99	92
Poland	96	98		89	99	98	
Portugal	97	96	96	99	97	93	
Republic of Moldova	96	91	97		78	89	
Romania	89	93	91	97	89	97	
Russian Federation (the)	97	98	97	96	85	86	
San Marino	86	83	84	90	91	91	
Serbia	91	95		96	99	99	
Slovakia	99	98	99	97	96	96	99
Slovenia	96	95		21	97	97	
Spain	97	95		99	98	98	
Sweden	98	96	95	99	95	95	60
Switzerland	95	92	82	99	96	96	
Tajikistan	97	98	96	95	89	95	
The former Yugoslav Republic of Macedonia	95	98		83	97	97	
Turkey	97	97		48	71	97	93
Turkmenistan	97	99	99	98	26	50	

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Ukraine	58	67	56	97	95	95	
United Kingdom & Northern Ireland	95	90	88	88	99	99	90
Uzbekistan	99	99	99	96	99	99	

Like the US, vaccination coverage within the EU varies by country and by immunization. However, whereas in the US there are states which clearly have higher rates of all vaccinations, in the EU it is much more common to see countries with high levels of one vaccination and low levels of another. The following are examples:

- Azerbaijan has very low vaccination rates for polio, MCV, Hepatitis B, and 3+Hib, but very good rates of coverage for DTP3 and MCV2
- Belarus has generally good vaccine coverage, with the exception of a very low coverage rate for the Hib vaccine
- Greece and Georgia have relatively high vaccination rates for all except the MCV2 classification
- Estonia, Kyrgyzstan, and Slovenia have relatively high vaccination rates for all except the Hepatitis B vaccination
- Turkmenistan has generally good vaccination coverage for all except the Hib and DTP vaccines
- Ukraine and Azerbaijan have consistently low vaccination rates

In terms of each vaccine, polio coverage is fairly ubiquitous, with the exception of the countries of Ukraine (58%), Azerbaijan (80%), Austria (83%), San Marino (86%), and Romania and Bosnia and Herzegovina (89%), which fall below the 90% estimated coverage rate for herd immunity. Hib vaccination coverage is generally above the 70% estimated threshold for herd immunity, with the exception of Azerbaijan (38%), Belarus (21%), and Turkmenistan (26%). Measles vaccination coverage is generally above the 83-94% threshold, with the exception of Azerbaijan (76%) and Austria (76%). Andorra (82%), Georgia (77%), Greece (77%) and Switzerland (82%) have the lowest rates of MCV2. .

Data in Table G is derived from the HEIDI (Health in Europe: Information and Data Interface) data tool; health services indicators, vaccination coverage in children (European Commission, 2012). Childhood coverage rates are defined as the percentage of infants reaching their first birthday in the given calendar year who have been fully vaccinated against diphtheria (3 doses of DPT or DT), tetanus, pertussis, poliomyelitis (3 doses), haemophilus influenza type b or Hepatitis B and those reaching their second birthday in the given calendar year who have been fully vaccinated against measles (1 dose), mumps and rubella.

**Table G. Childhood coverage rates of vaccine-preventable disease in the European Union, 2008-2009**

	Diphtheria	Tetanus	Pertussis	Poliomyelitis	Haemophilus B	Hepatitis B	Rubella	Measles
Maximum	99.8	99.8	99.8	99.8	99.9	99.0	99.0	99.8
Average	95.4	95.4	95.4	95.1	92.1	87.6	91.8	93.2
Minimum	73.0	73.0	73.0	73.0	48.9	15.7	76.0	76.0

As shown in Table G, for each vaccine, there are countries that have very high coverage levels, with the maximum for each vaccine at or above 99.0%. Across all countries, the average coverage is highest for

diphtheria, tetanus, and pertussis (95.4%) and lowest for haemophilus B (92.1%), rubella (91.8%), and hepatitis B (87.6%).

For some vaccines, there is shockingly low coverage in certain countries. Hepatitis B coverage falls as low as 15.7%, and haemophilus B coverage falls as low as 48.9%.

Countries falling at the high and low ends of coverage are as follows:

- Diphtheria: Hungary is on the high end (99.8%) and Malta is on the low end (73%), 2009.
- Tetanus: Hungary is on the high end (99.8%) and Malta is on low end (73%), 2009.
- Pertussis: Hungary is on the high end (99.8%) and Malta is on the low end (73%), 2009.
- Poliomyelitis: Hungary is on high end (99.8%) and Malta is on low end (73%), 2009.
- Haemophilus B: Hungary is on the high end (99.9%) and Macedonia is on the low end (48.9%), 2008.
- Hepatitis B: Slovakia is on the high end (99%) and Sweden is on the low end (15.7%), 2008.
- Rubella: Slovakia and Finland are on the high end (99%) and Austria is on the low end (76%), 2009.
- Measles: Hungary is on high end (99.8%) and Austria is on low end (76%), 2009.

## 2.3 Assessment of Risk

Tables H and I begin to paint a picture of the risk associated with each disease. Incidence of vaccine-preventable disease in different populations can help to identify areas at greater risk and furthermore provide a starting point for investigating social and societal influences that may decrease vaccine acceptance. Data on herd immunity also helps to identify areas of higher risk and provides a rough benchmark for populations to aim to achieve.

Herd immunity is defined as “resistance to the spread of infectious disease in a group because susceptible members are few, making transmission from an infected member unlikely.” This number is estimated based on the virulence of the disease, the efficacy of the vaccine, and the contact parameter for the population.

**Table H. Percentage of the population needing immunity, either vaccinated or natural, to confer herd immunity**

Disease	Percentage of Population Needing Immunity
Influenza	13-100%
Chickenpox	80%
Diphtheria	85%
Measles	83-94%
Mumps	75-86%
Rubella	83-85%
Polio	90-95%
Pneumococcal meningitis	75%
Haemophilis Influenzae	70%
Pertussis	94%
Smallpox	85%



This table displays estimated coverage levels needed to confer herd immunity in the population (Fine, 1993; Kung, 2008; Luman et al., 2001; Moulton, Chung, Croll, Reid, & Weatherholtz, 2000; National Network for Immunization Information, 2006; Plans-Rubio, 2012). While we often hear of the “90% rule”, this is actually a conservative estimate for most communicable diseases. The estimates presented here reflect more accurate measures based on the virulence of the disease and the conferred immunity in the population. Whereas these estimates generally range from 70% - 95%, evidence supports that much lower coverage rates can reduce incidence of disease.

Table I shows the incidence of vaccine-preventable disease in the US and countries in the European Union, as reported by the World Health Organization’s immunization and surveillance monitoring program (World Health Organization [WHO], 2012). Incidence of select vaccine-preventable diseases has been increasing in recent years. The data displayed is from the 2010-2011 year, and focuses on the 6 specific vaccine-preventable diseases listed in the coverage rates tables for the US and the EU.

**Table I. Incidence rates of select disease, United States and European Union, 2011**

	Total Population	Mumps	Measles	Hib-M	Diphtheria	Pertussis	Polio
United States	311,591,917	2311	63	8	0	27410	0
Albania	3,544,841	-	-	-	-	-	0
Andorra	68,403	0	0	0	0	4	0
Armenia	3,262,200	15	0	0	0	1	0
Austria	8,169,929	-	68	3	0	309	0
Azerbaijan	9,493,600	101	0	4	0	27	0
Belarus	10,335,382	48	50	2	0	151	0
Belgium	11,007,020	15	576	-	0	103	0
Bosnia and Herzegovina	3,964,388	8209	10	0	0	30	0
Bulgaria	7,621,337	-	-	-	-	-	0
Croatia	4,490,751	86	12	1	0	103	0
Cyprus	803,147	0	0	0	0	2	0
Czech Republic (the)	10,674,947	2885	17	4	0	324	0
Denmark	5,368,854	13	84	1	0	71	0
Estonia	1,294,236	8	7	2	0	478	0
Finland	5,302,545	2	27		0	555	0
France	63,601,002	-	14949	-	-	-	0
Georgia	4,960,951	44	64	2	1	33	0
Germany	81,799,600	-	1607	21	4	-	0
Greece	11,606,813	1	40	6	0	3	0
Hungary	10,075,034	5	5	8	0	9	0
Iceland	312,384	-	-	-	-	-	0
Ireland	4,234,925	177	285	0	0	229	0
Israel	7,765,700	301	70	7	0	2345	0
Italy	59,715,625	-	-	-	-	-	0
Kazakhstan	16,558,459	51	127	0	0	66	0
Kyrgyzstan	5,507,000	300	222	-	0	77	0
Latvia	2,220,000	10	1	0	6	10	0
Lithuania	3,601,138	64	7	3	1	30	0
Luxembourg	512,000	0	6	0	0	4	0
Malta	397,499	0	3	0	0	8	0
Monaco	31,987	-	-	-	-	-	0
Montenegro	626,000	57	5	0	0	8	-
Netherlands (the)	16,798,800	610	51	3	1	6726	0
Norway	4,942,700	16	39	1	0	3695	0
Poland	38,625,478						0
Portugal	10,617,192	134	2	2	0	32	0
Republic of Moldova	3,559,000	143	0	2	0	102	0
Romania	22,303,552	195	4189	5	0	86	0

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Russian Federation (the)	142,008,838	406	629	-	5	4733	0
San Marino	27,730	1	0	0	-	0	0
Serbia	7,498,001						
Slovakia	5,422,366	2	0	0	0	936	0
Slovenia	2,048,847	-	-	-	-	-	0
Spain	46,777,373	-	-	-	-	-	0
Sweden	9,076,744	38	26	-	2	177	0
Switzerland	7,301,994	-	621	4	-	-	0
Tajikistan	6,976,958	1441	1	-	0	56	0
The former Yugoslav Republic of Macedonia	2,063,893	-	-	-	-	-	-
Turkey	70,000,987	-	-	-	-	-	0
Turkmenistan		31	0	-	2	0	0
Ukraine	45,396,470	955	1333	4	8	2937	0
United Kingdom of Great Britain and Northern Ireland (the)	62,262,000	2716	1112	2	2	1243	0
Uzbekistan	29,341,200	1160	476	-	0	36	0

In terms of straight count data, the United States, Bosnia and Herzegovina, the Czech Republic, Tajikistan, Ukraine, the United Kingdom and Northern Ireland, and Uzbekistan have the highest number of mumps cases. Interestingly, the US had a low count of measles (63), but a relatively high count of mumps (2,311), despite the prevalent administration of a combination vaccine.

Measles accounted for a very high disease burden in 2011. France, Germany, Romania, Ukraine, and the United Kingdom and Northern Ireland have the highest number of measles cases. France's measles cases (14,949) far outnumber that of any other nation. While data was unavailable in the WHO/UNICEF database for some countries, news reports indicate that measles outbreaks have also been identified in Spain, Macedonia, and Uzbekistan.

Pertussis also accounted for a significant proportion of the disease burden. Pertussis counts are highest in the US (27,410), Israel (2,345), the Netherlands (6,726), Norway (3695), the Russian Federation (4,733), Slovakia (936), Ukraine (2,937), and the United Kingdom and Northern Ireland (1,243).

Hib meningitis counts are generally low, with the highest number of cases seen in Germany (21). Diphtheria counts are generally low, with the highest number of cases seen in Germany (4), the Russian Federation (5), and Ukraine (8).

There were no cases of polio seen in the US or EU in 2011.

### 2.4 Trends: Vaccination Coverage in the United States compared to the European Union

Rates of whole population vaccination in the US are slightly higher than those in the EU, with both maintaining relatively high overall rates of vaccination for most vaccines. There is a greater discrepancy in vaccination rates from vaccine-to-vaccine in the US than there is in the EU. Average coverage rates in the EU were similar across the board (with the exception of PCV3), whereas in the US, coverage rates for the full series of PCV and Hib were much lower than for other vaccines; this may indicate difficulty in fulfilling multi-visit vaccinations in the US.

Rates of childhood vaccination in the EU were more variable than were their overall population rates, perhaps due to the recent decrease in vaccine acceptance. The lowest rates of childhood coverage were for rubella and Hepatitis B.

In the United States, vaccination coverage varied significantly from state to state. While some states had very low vaccination rates for some vaccines and high rates for others, others had consistently high coverage rates for all vaccines. This observation was mirrored in the EU context, where some countries had particular vaccination rates as low as 15%, and others had high rates across the board.

## 2.5 Trends: Disease Incidence Rates in the US and EU

Disease incidence rates vary from state-to-state and country-to-country, with some vaccine-preventable diseases more prevalent than others. The data substantiates the many news reports regarding increased incidence of measles. France was the hardest hit, with about 15,000 cases. Germany, Romania, Ukraine, and the UK also saw over 1,000 cases. In the US, pertussis accounted for more of the disease burden, with over 27,000 cases. Israel, Norway, Poland, San Marino, Ireland and Ukraine also experienced a relatively large number of measles cases.

Interestingly, the incidence of mumps was relatively high in the US in 2011, despite the fact that most people in the US get a combination vaccine that protects against both measles and mumps. Incidence of mumps was also high in Bosnia and Herzegovina, Ukraine, Uzbekistan, the UK, the Czech Republic, and Tajikistan.

The data indicate that it is difficult to make “blanket” conclusions regarding who is and is not getting vaccinated in the US and EU. In both contexts, rates vary based on geographical location, particular vaccines, and demographics; this variation may support the notion that there are a wide variety of factors that are likely to influence population and individual decisions on whether to vaccinate.

The epidemiological approach is essential in helping to identify populations and areas which may need additional attention in order to improve vaccination rates. It does not, however, provide much information as to *why* these areas and individuals in particular do not meet vaccination levels of other places and people. Because epidemiology is a population-based science, it also does not lend to drawing conclusions at the level of the individual. In order to make better sense of the epidemiological landscape presented here, it is essential to take into consideration individual risk-benefit decision-making processes and understand that exploration must go beyond that which is predominantly quantitative and derived by surveillance and statistics.

## 2.6 Validity of Available Datasets

Investigators who administer large public health surveys, such as those referenced in this report, invest much effort and expense to ensure the survey results are valid, representative, and with minimal sampling error (Luman, Sablan, Stokley, McCuley, & Shaw, 2008). Data presented in Section 2 were primarily derived from two sources, the US Centers for Disease Control and Prevention National Immunization Survey (NIS), and the World Health Organization’s Expanded Program on Immunization (EPI).

It has been suggested that results of the NIS may be subject to bias, since it is a telephonic survey, which would exclude children from non-telephonic households. The sampling design and statistical methods used in the survey, however, attempt to mitigate the effects of sampling error and bias by introducing sampling weights to account for the selection of a random sample of telephone numbers and by instituting quality assurance by monitoring a percentage of household surveys and following up with the children's healthcare providers when possible (Smith, et al., 2001a). At least one examination of the findings determined survey results to be consistent with those from another national, large-scale in-person interview sampling designed to reduce coverage bias (Bartlett, Ezatti-Rice, Stokley, & Zhou, et al., 2001). Another examination of the statistical methods supports the weighting methodology (Smith, et al., 2001b).

Results of one study found that the survey methodology used in the EPI provided consistently higher immunization coverage estimates than an alternative systematic random sampling method. The systematic random sampling method additionally surveyed a somewhat different cohort, reaching a wider variety of socioeconomic levels, somewhat older mothers, and a greater percentage of persons practicing orthodox religion than the Expanded Program on Immunization (Luman, Worku, Berhane, Martin, & Cairns, 2007). Another assessment of the survey strategy using computer models found that within particular population clusters, more traditional sampling methods gave more accurate and less variable results; it was indicated, however, that the goal of the EPI methodology, to provide estimates within 10 percent of true population levels, was supported (Lemeshow, et al., 1985).

## 2.7 Investigating the Gray Literature

Numerous agencies have performed analyses of population subsets to better determine which individuals are likely to be vaccinated and which are not. Many of these analyses can be found in the peer-reviewed literature, but some are published as reports or white papers and can only be found in sources that lack traditional bibliographic control. In an effort to investigate what type of vaccination information is available in this so-called "gray literature," the research team worked with the US National Library of Medicine's Disaster Management Information Resource Center to review sources found in their online Resource Guide (2012). The exercise proved to be challenging for the resource librarians as well as the researchers, as both were largely unfamiliar with non-scientific repositories of information, and the quantity of non-peer reviewed reports and white papers on this topic was relatively small. As such, the search was expanded to include news reports and webpages of academic institutions and legitimate health organizations. While a thorough review of these sources yielded little by way of population-based epidemiology, it did lend additional insight into two potential vaccination strategies to increase vaccination: using fear or scare tactics in messaging, and using incentives to elicit behavior change.

Whether to use graphic images, dramatic language, or other fear-inducing material in pro-vaccination advertising is a topic of debate. While some see "fighting fire with fire" as a perfectly legitimate tactic, others are skeptical of its efficacy. According to a report issued by the US Association of State and Territorial Health Officials, positive messaging may be more effective than scare tactics or negative imagery (Association of State and Territorial Health Officials, 2010). According to this report, positive messages regarding pediatric vaccination were rated as much more convincing and believable than negative messages by the parents and guardians in the study. This same argument was supported in an article by Gary Finnegan (2010) of the EU's publication *Vaccines Today*, in which he indicates that "fear appeals in a context of vaccination campaigns may backfire." He cites successful campaigns that relied on more positive

messages, such as a poster aimed at young women that says “Protect against cervical cancer. I did,” and another which read “Healthy thanks to MMR.” In a separate study, another set of researchers also showed that messages strongly indicating that there is “no risk” involved in vaccination led to a *higher* perceived vaccination risk than weak negations of risk (Betsch, & Sachse, 2012).

Using incentives as a means to increase vaccination rates is also being explored in various populations. A lot of work in this area is not scientific in nature or is not far enough along to produce definitive results. For example, private insurance companies are beginning to use incentive programs to increase vaccination rates among their patients. San Francisco Health Plan has implemented a program which awards \$50 gift cards to all clients whose children complete all vaccinations needed by age two<sup>16</sup>. The Australian government offers a tax incentive for families whose children receive all recommended vaccinations, and to families who conscientiously opt out.<sup>17</sup> A school district in Orange County, CA has entered children who get vaccinated for meningitis into a drawing for an iPod or laptop.<sup>18</sup> Massachusetts General Hospital employees and professional staff who record that they have received or declined the vaccine receive a \$50 bonus, and if 90 percent of MGH employees and professional staff document their flu vaccination status, those who have done so will receive another \$50.<sup>19</sup> While the body of evidence to suggest that these tactics actually improve vaccination rates is limited, it is worth noting that the strategy is currently being explored in a wide variety of target populations.

### 3.0 Risk Analysis: Real, Perceived, and Theoretical Risk

Vaccine risk and risk perception play significant roles in vaccination acceptance by health organizations, government policy makers, health practitioners and individuals. Attempting to determine acceptable risks for the individual versus society is an ethical challenge complicated by the elusive nature of risk conferred by vaccines and vaccine preventable diseases. The actual risks are continuously changing and very difficult to calculate. Additional theoretical risks are nearly limitless and almost impossible to prove or disprove with certainty. Finally, the interpretation of and understanding of risk – perceived risk – varies widely, as it is an individual or organization’s composite risk assessment affected by information, background, environmental and social influences, personal experience and individual personality traits. It is vital that perceived vaccination risk be better understood, as it is this interpretation of risk that is used in determining vaccine acceptance; and it can be corrupted by misinformation, reasoning flaws, social influences and mistrust, potentially leading to poor risk assessment and decision making.

Acceptable risk varies among groups and individuals, and there is no standardized definition or universal threshold for acceptable risk levels in vaccination. Some tenets, however, are consistent within the risk/benefit analysis.

The most widely agreed upon requirement for immunizations given to otherwise healthy individuals is that they must infer minimal risk of serious adverse effects, including death, and they must be effective at

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<sup>16</sup> San Francisco Health Plan. Immunize your child.

[http://www.sfhp.org/files/PDF/providers/incentives/6013\\_Immunization\\_\\$50incentive\\_English.pdf](http://www.sfhp.org/files/PDF/providers/incentives/6013_Immunization_$50incentive_English.pdf). Retrieved August 20, 2012.

<sup>17</sup> Byrne, James. (December 2011). Australian government provides incentive for vaccination. Scientific American. Blogs. Retrieved August 21, 2012. <http://blogs.scientificamerican.com/disease-prone/2011/12/02/aust-government-provides-incentive-for-vaccination/>

<sup>18</sup> Micheals, Will. North Carolina Public Radio. (May 2011) Vaccination incentive program draws fire. Retrieved August 21, 2012.

<sup>19</sup> Massachusetts General Hospital. (November 5, 2010). Incentive for flu shot documentation. News. <http://www.massgeneral.org/about/newsarticle.aspx?id=2417>. Retrieved August 21, 2012.

reducing risk imposed by the targeted disease (Grabenstein, & Wilson, 1999; Calreus, 2010). Acceptable risk for routine vaccinations relative to other medical interventions is very low, as they are prophylactic, not therapeutic measures. Also, it is recognized that there is a lower threshold for acceptable risk in acts of commission rather than omission. On the organizational and personal levels, active intervention confers greater responsibility and therefore greater accountability than not intervening to prevent an undesirable outcome (Jacobson, 2007; & Meszaros, et al., 1996). Therefore, the vaccine-associated risks must be considerably lower than the predicted risk of not vaccinating for one to choose vaccination.

The level of risk one is willing to accept from vaccination increases with (1) increasing severity of risk associated with the correlating vaccine preventable disease; (2) one's susceptibility to that disease; and (3) vaccine efficacy (van der Weerd, Timmermans, Beaujean, Oudhoff, & van Steenberg, 2011; Kok, Jonkers, Gelissen, Meertens, Schaalma, & de Zwart; 2010; Brewer, et al., 2007; & Bults, et al., 2011). For a common and severe disease, a higher rate and severity of vaccine-associated side effects will be tolerated. For a rare or typically mild disease, fewer side effects or even theoretical threats are tolerated. As several vaccine preventable diseases have been drastically reduced via successful immunization programs, many individuals, including a significant number of healthcare workers, have deemed even minuscule risk of serious vaccine induced adverse events as unacceptable, as they perceive little to no risk of incurring the infectious disease (Maldonado, 2002).

Because serious adverse events caused by currently recommended immunizations are so rare from an epidemiological perspective, morbidity and mortality resulting from vaccine-preventable diseases will remain higher than that caused by vaccines until virtual eradication of the infectious agent is achieved. Therefore, even if an individual's risk from vaccine preventable disease – whether perceived or actual – is negligible, making the risks of vaccination appear unacceptable to that individual, this small individual risk would be acceptable in the broader societal context, as it significantly lowers risk for the population by preventing spread of potentially dangerous diseases to those who are susceptible and more vulnerable (Diekema & Committee on Bioethics, 2005).

This apparent conflict in acceptable risk as determined from an individual versus a societal perspective appears to be the source of much of the disagreement concerning acceptable risk, as providers and lay individuals focus their risk analysis on individual outcomes, whereas governing and public health organizations analyze risk according to population trends and the greater common good. This conflict, however, is exaggerated. Both personal and societal risk from vaccination is very low, and protection offered is substantial, which should result in similar risk considerations for the individual and society. However, much of the personal decision-making regarding acceptable risk is based on perceived risk rather than actual risk, which can be biased by many factors. The risk that individuals perceive from vaccine-preventable diseases is often underestimated, and the risk of vaccine harm is often overestimated (Maldonado, 2002). This can cause individuals to assess vaccine risk as unacceptable based on perceived risks that do not accurately reflect actual risks. Furthermore, allowing an individual to calculate acceptable risk without considering the potentially harmful consequences to others allows them to negate an important factor in vaccine risk analysis.

While the risk associated with vaccine injury is personal, the other side of the balance should weigh disease severity and susceptibility for the individual as well as others in society, including those at high risk of increased morbidity and mortality from infectious diseases (Diekema, and Committee on Bioethics, 2005). It has been suggested, however, that rational parental decision making according to social norms focuses

decisions primarily on protecting one's children from perceived harm, and therefore relying on herd immunity for the child's protection without regard to social responsibility is an act consistent with protective parenting rather than selfish "free riding" (Bellaby, 2003).

When addressing risk of less severe side effects from vaccines, acceptable risk is higher, particularly for diseases perceived as severe or relatively common and associated with extended morbidity. This applies particularly to acceptable risk as determined by caregivers for their children (Wischnack, et al., 1995). In making decisions regarding one's own vaccinations, perceived risk from disease is often underestimated or even dismissed in healthy individuals (Grabenstein, & Wilson, 1999). With this bias, even mild side effects from vaccines are less acceptable. This low risk acceptance is demonstrated among low vaccination rates of healthy children and adults to seasonal influenza, even among those for whom health authorities recommend vaccination, such as healthcare workers in most countries (Tosh, Jacobson, & Poland, 2010). Those with a higher perceived risk from influenza, including those with chronic medical problems and older adults, find the common mild side effects an acceptable risk, which likely explains the higher influenza vaccine uptake in the US and Europe among these groups (Loerbroks, Stock, Bosch, Litaker, & Apfelbacher, 2012; Blank, Freiburghaus, Schwenkglens, & Szucs, 2008; de Andres, et al., 2007, Foster, & Nevin-Woods, 2011).

Acceptable risk for vaccinations produced and distributed in the event of a pandemic is similarly predicated on vaccine efficacy and safety and perceived severity and susceptibility to the targeted disease (Rubin, Amlot, & Wessely, 2009; Kok, et al., 2010; & Bults, et al., 2011). At least one study suggests, however, that more attention is given to potential disease risk in a pandemic event than to vaccine risk (Liao, Cowling, Lam, & Fielding, 2011). This supports the historical pattern of increased vaccine uptake corresponding to increased disease incidence.

In the modern milieu of safer vaccines, lower infectious disease rates and improved medical management of diseases, the acceptable risk for routine vaccines demands almost no serious adverse events, relatively few or mild side effects, and low cost of vaccination in terms of money and time. In order for healthcare providers, caregivers and individuals to accept vaccination, this extremely low level of acceptable risk also has to be effectively demonstrated and communicated, ensuring that perceived risk corresponds to actual risk as much as possible.

There is overwhelming data to support the general safety of routinely recommended immunizations. The vast majority of vaccine adverse reactions are considered mild. These include local reactions that can manifest as pain, redness, or swelling at the injection site. These reactions occur in approximately 50% of those vaccinated. Mild systemic reactions such as low grade fever, soreness, fussiness, fatigue and transient influenza-like illnesses are vaccine-specific, ranging from almost nonexistent with the inactivated polio vaccine to over 30% risk of fever and fussiness in infants given the pneumococcal conjugate vaccine. These risks do not generally affect the perceived safety of a vaccine, as they do not induce long-term harm and rarely require intervention (Maldonado, 2002).

Moderate to severe reactions do rarely occur and must be considered in an evaluation of vaccine risk. Anaphylactic reactions occur in approximately 1/1,000,000 vaccine doses administered (CDC, 2012). In a retrospective review of anaphylactic reactions associated with 7,644,049 vaccine doses administered, anaphylactic incidence was calculated to be 0.65-1.53/1,000,000 doses. There were no associated deaths (Bohlke, et al., 2003).



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There are also vaccine-specific risks that must be considered. There is a documented risk of idiopathic thrombocytopenic purpura (ITP) associated with MMR vaccination, with 0.087-4 cases of ITP per 100,000 vaccine doses. Cases have spontaneously resolved within 6 months and there has been no documented recurrence of ITP with additional vaccine doses (Mantadakis, Farmaki, & Buchanan, 2010). Encephalitis has also been documented with MMR vaccination at a rate of 1 case per 1,000,000 vaccine doses (CDC, 2012). DTaP immunization is associated with seizures in 1/14,000 doses administered and fever of 40.5 degrees C or higher in 1/16,000 doses. The occurrence of permanent brain damage has been suggested but remains unproven (CDC, 2012). Inactivated influenza vaccine might cause Guillian Barre Syndrome at a rate of 1-2/1,000,000 vaccine doses administered. This risk has not been definitively established, but if actual, it appears to affect vaccine recipients over 50 years old and is associated with particular variants of the H1N1 influenza vaccine (DeWals, 2012). There is even some evidence to suggest that risk of Guillian Barre Syndrome is higher following influenza infection than following influenza vaccination (Tosh, et al., 2010).

The actual risks assumed by declining vaccination are more difficult to quantify, as disease prevalence changes in response to natural cycles, vaccination rates, global interconnectedness, cyclical variation, and environmental changes. With extremely low incidence of vaccine preventable illnesses in developed nations, specific disease risk is also unclear, as more advanced medical practices could conceivably result in lower morbidity and mortality rates than documented historical outcomes would predict.

There is, however, plenty of evidence to indicate significantly lower individual and societal risk with higher levels of vaccine acceptance. Globally, pediatric vaccinations alone account for an estimated 3 million lives saved annually (Maldonado, 2002). Comparing 13 vaccine-preventable illnesses prior to and following vaccine programs in the US shows a greater than 92% decrease in cases of the examined vaccine-preventable illnesses and a greater than 99% decrease in deaths due to the specified vaccine preventable illnesses (Roush, 2007).

More recently, even in areas with previously high vaccination rates and the accompanying benefit of herd immunity, there have been many outbreaks of vaccine preventable illnesses that have been directly correlated with decreased vaccination. For example, Omer has correlated several clusters of pertussis outbreaks in the United States with increased rates of non-medical exemptions from pertussis vaccination (Omer, et al., 2008). There have been a number of measles outbreaks in Europe, including Switzerland, associated with lower vaccination rates, and the United Kingdom experienced a nearly 20 fold increase in the incidence of measles in the 9 years following the published suggested link between MMR vaccination and autism (Callreus, 2010). One study also demonstrates an increased risk of pertussis in children with parents who refuse vaccination (Glanz, et al., 2009).

The risks associated with declining vaccination for more common infections such as influenza are also evident. Approximately 10% of adults experience influenza illness each year. Although only 2-4/10,000 healthy young adults will be hospitalized with influenza, approximately 1/3 of adults with influenza will visit their doctor and many more will miss work. In addition to the increased personal risk of influenza when declining vaccination, one imposes increased risk on society. Although the influenza vaccination is only 60-90% efficacious, immunization programs targeting children, high risk individuals with chronic medical problems, the elderly and medical staff working with the elderly have all effectively reduced hospital admissions, outpatient visits, missed work/school days, antibiotic use and mortality among high risk populations during outbreaks of influenza (Neuzil, Griffin, & Shaffner, 2001). Vaccinating children against influenza has been associated with a 42-80% reduction in illness among household contacts; 70% reduction



in missed school days; and a decrease in influenza like illnesses in community dwelling elderly (Tosh, et al., 2010). A recent trial also suggests that influenza vaccination of children in rural communities can protect unimmunized individuals (Loeb, et al., 2010). As children tend to acquire influenza more readily and shed viral particles for a longer period, failing to immunize them imposes increased risk of influenza contraction on household and social contacts, including medically fragile individuals.

In addition to known risks from vaccine refusal and vaccine acceptance, one must acknowledge additional, yet unidentified actual risk. This introduces the problem of theoretical risk into assessing vaccine safety. Due to the pervasiveness and frequency of vaccinations, unrelated events temporally linked to vaccination times can suggest causal relationships that can be very difficult, time consuming, and costly to definitively disprove (Chen, et al., 2001). Plausible explanations of potential mechanisms of vaccine-induced pathology can also be readily theorized, but disproving a theory can be difficult, particularly when the theorized harm is immeasurable due to normal variance in development and disease expression.

There have been several theoretical vaccine risks that garnered a significant amount of public concern and caused persistent skepticism regarding vaccine safety even after extensive scrutiny that revealed no evidence for an actual threat. The best recognized of these proposed vaccine risks that have failed to be substantiated are the suggested link between MMR vaccination and autism; the assertion that immunizations can cause autoimmune disorders such as diabetes mellitus, asthma and atopic dermatitis; and the proposed causal relationship between hepatitis B vaccination and multiple sclerosis. Studies have failed to support any of these associations (Chen, et al., 2001).

Additional theoretical vaccine risks entail extrapolating potential harm from vaccine ingredients that can be toxic in large quantities. Basing concern on the fact that some components of immunizations are toxic in very high levels, some have questioned the toxicity of the vaccines themselves. No such toxicity has ever been demonstrated by the tiny amounts of ingredients such as aluminum and formaldehyde in vaccines, but the idea of trace toxins causing some insidious level of harm remains popular (Chen, et al., 2001).

Finally, there are theoretical epidemiological risks that have been proposed with particular vaccinations. Some researchers have expressed concern about selecting more virulent strains of pneumococcus by inhibiting the most common, possibly less severe strains. This could theoretically predispose for infections with more virulent organisms, thus increasing morbidity and mortality (Weinberger, Malley, & Lisitch, 2011.) Two concerns have also been expressed regarding influenza vaccination. One theory proposes that lower vaccine efficacy rates might increase the frequency of mild influenza infections in vaccine recipients, encouraging increased transmission due to a lack of isolation and prolonged transmission (Bemejo-Martin, 2009). Another concern is that children immunized against current strains of influenza will not develop heterosubtypic immunity and therefore will be more vulnerable to new pandemic strains (Heikkinen, & Peltola, 2009). This was not described with the H1N1 pandemic strain.

Analysis of the actual risks from vaccination versus the benefits, or risks of not vaccinating, clearly indicates that vaccination provides the lowest risk option. However, this conclusion does not take into account perceived risk, or the risk that individuals believe they incur with a particular choice. When perceived risk becomes distorted and no longer reflects actual risk, reasonable analysis can lead to poor decisions due to invalid premises. Exaggerated perceived risk from vaccination or diminished perceived risk from vaccine preventable illness can lead to decreased acceptance of vaccination.

Much research has been done to try to elucidate why perceived risk is often inconsistent with actual risk. A number of behavioral theories and common reasoning errors that affect one's perceived risk have been explored. Robert Jacobson and colleagues used a literature survey to identify common misconceptions within the anti-vaccine movement, and then classified the most common reasoning errors according to Thomas Gilovich's taxonomy of common reasoning flaws seen in contemporary society. This taxonomy divides common reasoning flaws into cognitive determinants and motivational/social determinants. Each of the commonly held misconceptions regarding vaccination risk is explained according to these recognized reasoning flaws (Jacobson, Targonski, & Poland, 2007).

The first flaw, one's natural desire to find order and predictability in random data, can explain the erroneously held belief that DTaP vaccination causes sudden infant death syndrome (SIDS). SIDS is the most common cause of death in infants older than 1 month. This relatively common event will occur at a random time, sometimes soon after DTaP vaccination, another common event. It is a common error to impose a causal relationship in an attempt to create order from randomly occurring events.

The second common reasoning flaw, difficulty in detecting and correcting biases in incomplete and unrepresentative data, applies to two common anti-vaccine movement misconceptions resulting in underestimation of perceived risk: diseases against which we vaccinate were already declining before immunizations, and vaccine-preventable diseases are no longer threats. The current low rates of vaccine-preventable diseases do not indicate viral or bacterial eradication or diminished threat from these infections when contracted, but an inability to account for the bias imposed by successful vaccination; people interpret low incidence to mean low risk.

The third cognitive flaw is an eagerness to interpret ambiguous and inconsistent data to fit theories and expectations. Anti-vaccine movements ascribe the fact that many of those who get vaccine-preventable illnesses are immunized to low vaccine efficacy. However, in a universally, or even highly vaccinated population, everyone would be likely to be immunized. A very low vaccine failure rate would allow some low incidence of disease among vaccinated individuals when introduced into a community. The fact that the majority of those who contract the illness have been vaccinated only indicates a high vaccination rate. It does not indicate similar risk of disease among vaccinated and unvaccinated individuals. Unvaccinated individuals in a highly vaccinated community are rare, therefore absolute number of disease cases will be lower among unvaccinated individuals, even though relative risk is higher.

The first common reasoning flaw arising from motivational and social determinants is wishful thinking and a self-serving distortion of reality. This reasoning flaw can explain the anti-vaccine movement's eager acceptance of the suggested link between autism and MMR vaccination. Humans desire to find causes for bad outcomes; they desire to link an act of commission to bad outcomes rather than chance; and they desire to find a blameworthy cause for bad events outside of their control. The suggested conspiracy among medicine, industry and government offered an etiologic explanation for a seeming epidemic that created a blameworthy culprit and engendered the potential to control future negative events. The disproven but still propagated causal link between MMR vaccination and autism creates not only increased perceived risk regarding vaccinations, but in following public health recommendations and cooperating with public health initiatives.

This same behavioral/social reasoning flaw allows parents to believe the commonly held notion that children receive too many vaccinations at once, and these vaccinations interfere with natural development.

This serves the parent's natural desire to avoid painful and harmful interventions. Bringing in a vaguely defined ideal of natural development allows parents to identify potential vaccine risks that cannot be substantiated or refused, thereby allowing them to rationalize a decision that appeals to their desire to avoid painful experiences.

Gilovich identifies the second common reasoning flaw stemming from motivational/social determinants as pit-falls of second-hand information and miscommunication including mass communication. Jacobson, Targonski, & Poland (2007) ascribe the thimerosal scare to this reasoning flaw. The voluntary removal of thimerosal by manufacturers from the hepatitis B vaccination due to theoretical potential risks to low birth weight infants resulted in the miscommunication to vaccine providers that the thimerosal was a dangerous component of that vaccine and should be avoided. Although no harm was ever demonstrated by the presence of thimerosal in vaccinations, the message was received as designating thimerosal a potentially toxic vaccine additive.

The final reasoning flaw described by Gilovich is exaggerated impressions of social support. Individuals who decline vaccination find validation in this decision through identifying with others who forego vaccination. This relieves one of further risk analysis, as one can assume that these like-minded, reasonable people are making rational decisions. Within this context, actual risk becomes less relevant. In the age of globally expanding social media, this social support is readily available and made to seem deceptively more common than numbers indicate. Although vaccine hesitancy is becoming an increasing problem, the majority of parents still comply with recommended immunizations.

Other reasoning problems have also been cited for the often-skewed perception of vaccine risk. A recurrent concern is innumeracy among lay people and healthcare providers, including physicians. Particular difficulty has been described with understanding relative risks and conditional probabilities. When vaccine and disease risks are communicated using these statistics, underestimation and overestimation of actual risk can result in perceived risk from vaccination that is much higher than the actual risk (Gigerenzer, & Edwards, 2003). It has also been noted that people have a difficult time conceptualizing likelihood of very rare events. There is even a tendency to give disproportionate consideration to extremely rare events, especially if they are very frightening or very good, making the more relevant considerations of common risks less significant. This allows one to overemphasize a 2/1,000,000 risk of developing GBS after influenza vaccination while disregarding the significantly higher number of influenza related hospitalizations and deaths (Edwards, Elwyn, & Mulley, 2002).

Recent looks at behavior and perceptions during the H1N1 pandemic of 2009 support the risk assessment considerations of vaccine risk, disease risk and susceptibility, and vaccine efficacy. However, surveys regarding the H1N1 pandemic identify additional factors that influence risk assessment during a pandemic. Significant anxiety was associated with increased intentions to comply with public health recommendations such as immunization, as were perceived vulnerability, self-efficacy and government trust (Rubin, et al., 2009, Raude, & Setbon, 2009, & Kok, et al., 2009). This suggests that perceived disease risk is higher during a pandemic. Interestingly, the perceived increase in risk relates to perceived severity more than susceptibility (Raude, & Setbon, 2009). Early in the 2009 pandemic, when disease risk perceptions were high, expressed willingness to comply with health recommendations was also high. As perceived disease risk diminished, so did individuals' willingness to comply with protective measures and intervention (Bults, et al., 2011). Cited reasons for maladaptive behaviors and noncompliance with recommendations during pandemic influenza were: underestimation of disease risk due to the belief that the government and media

exaggerated risks; diminished perception of potential efficacy of intervention in the form of fatalism, which is characterized by the belief that a pandemic and its consequences simply need to be accepted as a reality; and avoidance, characterized by staying inside and avoiding any contact (Raude, & Setbon, 2009).

Vaccine risk is a complicated but crucial issue. In order to maintain and increase vaccine acceptance, vaccine manufacturers, governing bodies, public health authorities, and medical providers must work to continuously reduce actual risk associated with vaccination; align perceived risk with actual risk; and be ready to demonstrate and counter common cognitive and behavioral biases that lead to potentially harmful decisions to avoid vaccination.

## 4.0 Influences on Vaccination

Concerns about vaccination initiatives are not new. Anti-vaccination movements began in the United Kingdom with the passage of compulsory vaccination acts between 1840 and 1867. In 1898, a clause was introduced that allowed parents an exemption to a compulsory vaccine based on conscience, thus introducing the notion of “conscientious objector.” The anti-vaccination movement subsequently spread to the United States in reaction to the smallpox vaccination effort. A comparison of the current anti-vaccination movements with those of the late 19<sup>th</sup> century reveals remarkable similarities and common themes (Wolfe, & Sharp, 2002).

In this section, some of the contemporary influences on vaccine uptake are examined, focusing especially on experience from the 2009-2010 H1N1 influenza pandemic, in an effort to better understand how they might inform strategies to advance vaccine uptake during a future pandemic or public health emergency. Review of the literature indicates that the most commonly recognized general influences on vaccine acceptance or refusal include personal health and risk perception, perception of vaccine efficacy, trust in medical professionals, trust in the vaccine industry, cultural and political factors, and media communication, and societal responsibility.

The social responsibility to avoid harming others by spreading vaccine preventable illnesses to vulnerable individuals is the justification used for vaccine mandates. Mandates requiring vaccination for school attendance have had significant impact on vaccine uptake in the United States and Europe, increasing vaccine uptake to levels commensurate with community herd immunity for many vaccine preventable illnesses. Although most states and countries allow for medical, religious and philosophical exemptions that permit varying levels of vaccine refusal, vaccine mandates have been and remain a powerful influence on vaccine acceptance.

Work place mandates, such as mandated seasonal influenza vaccine for healthcare workers, have had variable success, but overall they remain much less effective in increasing vaccine uptake than mandates for childhood vaccination. Using mandates as a strategy for increased vaccine uptake will be more closely examined in Section 7.

While mandates and compulsory vaccination justified by societal responsibility are major influences on vaccine uptake, societal responsibility as a factor in personal decision making comes up rarely in studies and surveys looking at vaccine acceptance, particularly regarding adult and seasonal vaccinations. More commonly cited factors include vaccine efficacy and safety, disease susceptibility and severity, and

recommendations from health care professionals. A 2008 US national vaccine poll did find, however, that 80% of Americans feel that vaccines are important to the health of their society, and 51% think that parents who choose not to vaccinate their children are putting their communities at risk (Research!America, 2009). It remains unclear how strongly these beliefs influence personal decision making in vaccine acceptance or refusal.

Personal risk perception, as discussed earlier, is recurrently cited as a major influence on vaccine acceptance or refusal. While it is generally accepted that the risk of vaccine-preventable diseases is greater than the risk of vaccines, perceived disease severity, perceived personal health/vulnerability to disease, perceived vaccine-specific side effects and efficacy, and personal levels of anxiety greatly affect vaccine risk interpretation and therefore affect acceptance and refusal.

Perceived disease severity plays an important role in vaccine acceptance. There is evidence that persons who perceive a disease to be severe rather than mild, and who also perceive they and their families are at risk for the disease, will make an effort to protect both themselves and their families (Stanton, 2004). Additional studies further demonstrate the importance of personal risk from disease as an important determinant in vaccine acceptance. One report of baseline and follow-up surveys among 896 subjects studying intent and receipt of the pandemic H1N1 vaccine demonstrates low intention to vaccinate and even lower uptake of the vaccine. Perceptions of low H1N1 risk (60%) and vaccine concerns (37%) were the main drivers for not receiving the vaccine (Liao, et al., 2011). Interestingly, at least in this study, perception of disease risk was a stronger motivator than risk of vaccine.

Studies of the general population in the UK, Australia and the USA also found a lower intention to be vaccinated associated with those who perceived H1N1 influenza to be mild. In the UK, Greece, Turkey and Australia, a greater intention to be vaccinated and to have children vaccinated was associated with the perception that H1N1 influenza was severe; and studies of Canadian healthcare workers found a lower intention to be vaccinated among those who perceived the severity of the pandemic to be mild (Bish, Yardley, Nicoll, & Michie, 2011).

A comprehensive review of data from 20 telephonic national public opinion polls conducted between April 2009 and January 2010 reports that 60 to 70 percent of parents initially expected to have their children vaccinated, but that in July and October people were roughly evenly divided as to taking or not taking the vaccine. Although vaccine risk was the most frequently cited reason to decline vaccination, over 60% of those who intended not to become vaccinated said they would change their mind if people in the community were sick and dying. As public perception of H1N1 severity declined, the percentage of those concerned with getting sick dropped from 60% to 40%. These findings further substantiate the significant influence of perceived severity of disease on vaccine uptake (Steel Fisher, Blendon, Bekheit, & Lubell, 2010).

Perceived susceptibility to a disease also significantly influences vaccine acceptance. Lower perceived susceptibility can lead to the belief that vaccination against that disease is unnecessary. This perception of insusceptibility is particularly important in determining overall vaccine acceptance among healthy adults (Trust for America's Health, 2010). The same review of telephonic polls discussed above also demonstrates the influence of perceived vulnerability or risk of disease on vaccine acceptance. In this study regarding pandemic H1N1 vaccination, many felt that the vaccine was not needed. Fully 50% of adults were not concerned that they or a family member would contract H1N1 influenza, and they felt comfortable that if they did, medication would be available (Steel Fisher, 2010). Among the general population, reduced

vaccination uptake for H1N1 influenza has been found to be associated with those who perceived themselves to be at low risk for infection. During the 2009 H1N1 pandemic, some countries experienced lower than expected uptake of the H1N1 vaccine among both healthcare workers and the general population. Studies in the UK, Greece, Spain and Turkey found reduced intentions to be vaccinated associated with healthcare workers who did not perceive themselves to be at risk during the 2009 H1N1 pandemic (Bish, et al., 2011).

Concerns about the safety and efficacy of vaccines also heavily influence vaccine acceptance. A 2008 US national vaccine poll found that 90% Americans think that vaccines are safe, but only 76% think that the risk of vaccine-preventable diseases is greater than the risk of the vaccines (Research!America, 2009). The success of vaccination programs in high-income countries has left the general population with a lack of familiarity with vaccine-preventable diseases and their consequences, resulting in a low tolerance for any adverse effects of vaccines, either real or suggested. Many studies site vaccine safety concerns as the primary reason for vaccine refusal.

In a report on AH1N1 vaccination policies and coverage in Europe, authors address potential factors influencing vaccination rates (Mereckiene, et al., 2012). Data and information collected by a standardized survey show that a number of public perception factors may have negatively impacted uptake rates, including concerns about vaccine safety, confidence regarding need for vaccines, concerns regarding thimerosal and/or adjuvants and the accelerated licensing process.

A review of surveys from the H1N1 pandemic on intention to vaccinate and personal risk perception found that persons who were concerned about harmful effects from the vaccine were less likely to accept the vaccine (Steel Fisher, et al., 2010). Studies show that barriers to acceptance of the H1N1 vaccine by healthcare workers also include concerns about vaccine safety and side effects, resulting in reduced vaccine utilization. The studies further indicate that these perceived barriers among healthcare workers in the UK, Greece, Turkey, Spain, Morocco, Australia and Canada are similar to those of the general population studied in France, Greece, Australia and the USA; and studies among healthcare workers in UK, Greece, Turkey, Spain, Morocco, Australia and Canada indicate that those with concerns about the H1N1 vaccine safety and side effects were also associated with refusing the vaccine for their children (Bish, et al., 2011).

Another cited reason for decreased vaccine acceptance is a perceived lack of vaccine efficacy. The perceived lack of efficacy of vaccines such as the seasonal influenza vaccine is strengthened by conflicting reports in the scientific literature and "personal experience". Studies reveal that during the 2009 H1N1 pandemic, healthcare workers in the UK, Turkey and Australia had a lower intention to be vaccinated associated with a belief that the vaccine did not confer immunity. And, a study of healthcare workers in Turkey found that during the 2009 H1N1 pandemic, a lack of confidence in the vaccine's efficacy was associated with refusing the vaccine for their children (Bish, et al., 2011). Conversely, various studies of the general population in South Korea, Turkey, Australia, Malaysia and the UK indicate that a perception that the H1N1 vaccine was effective was associated with an intention to be vaccinated, further delineating perceived vaccine efficacy as an important factor in vaccine acceptance (Bish, et al., 2011).

Acceptance of vaccine during a pandemic is additionally influenced by anxiety level and fear. Persons who had higher levels of worry about catching H1N1 influenza were more likely to accept the vaccine (Nguyen, Henningsen, Brehaut, Hoe, & Wilson, 2011). Two studies from the Netherlands also cite increased fear and anxiety as motivators to accept vaccination and to comply with other protective strategies (Bults, 2011; &



van der Weerd, et al., 2011); and a phone survey regarding the swine flu outbreak further supports a positive association between anxiety and following recommended behaviors (Rubin, et al., 2009).

In addition to perceptions and concerns regarding personal health risk, cultural values and beliefs about vaccination can also influence vaccine uptake. In lower-income countries where vaccine-preventable diseases are prevalent, resistance to vaccines may be dependent on cultural, religious, political and economic factors (Larson, Cooper, Eskola, Katz, & Ratzan, 2001). Also, cultural perceptions about health and disease based on traditional or indigenous health practices can influence receptiveness to vaccines.

A study to determine factors influencing influenza vaccine uptake of older adults included focus groups from nine countries with diverse cultures, healthcare financing systems and a range of vaccination rates. It included China, Indonesia, Turkey, Korea, Greece, Canada, Brazil, Nigeria and the United Kingdom. The vaccinated focus group participants generally believed in the protective value of influenza vaccine for themselves and their families. However, the unvaccinated participants tended to question the efficacy of influenza vaccine. Instead, they trusted indigenous health practices for protection from disease, believed in naturalism, or believed in personal choice regarding vaccination. This suggests that efforts should be made to use indigenous health practices to complement influenza vaccination efforts (Kwong, Pang, Choi, & Wong, 2010).

The 2003 response to the Global Polio Eradication Initiative in northern Nigeria clearly illustrates how political and cultural factors can influence vaccine uptake. Muslim leaders boycotted the oral polio vaccine, claiming it was contaminated with anti-fertility agents and the HIV virus. Leaders asserted that this was a scheme by Western governments against the Muslim population. This resulted in poor vaccine uptake and a resultant increase in polio cases in Nigeria. Outbreaks were soon reported across other sub-Saharan African nations. Cultural factors affecting healthcare beliefs and practices offered additional challenges to vaccination. Among the Hausa people in northern Nigeria, Shan-inna is the name for polio, which they believe is an ailment of the spiritual world. The Hausa call upon traditional healers to fight the disease, and in many remote communities, these healers are the only form of healthcare (Yahya, 2006).

Demographic factors associated with vaccine acceptance and resistance are also important to identify, as they can assist in targeted messaging in vaccination efforts. These factors can be difficult to identify, however, because they are less consistent in the literature. This might be due to variability in the demographic make-up of different communities and regions as well as varied influences on similar demographic groups in different areas. Although difficult to generalize many demographic characterizations regarding vaccine acceptance, some associations are worth noting. Studies from the 2009 H1N1 pandemic reveal mixed results related to the influence of age on intention to be vaccinated, but studies suggest an association between increased age (>65) and vaccination. Some data from the USA and Australia indicate persons over 65 were more likely to be vaccinated against H1N1 influenza than those in a younger age group. And studies in France, Greece and Canada found an association between older healthcare workers and their intention to be vaccinated against H1N1 influenza (Bish, et al., 2011). Surveys related to H1N1 pandemic responses from the Netherlands report increased intention to comply with recommendations to be associated with increased age (Bults, 2011).

Data from other studies from the 2009 H1N1 pandemic reveal a relationship between ethnicity and intention to be vaccinated in countries with many ethnic groups represented, e.g. the US and Canada. In these countries, persons in the general population who did not have a Caucasian background were more

likely to intend to be vaccinated (Nguyen, et al, 2011). A review of articles on factors associated with uptake of vaccine against pandemic influenza reports increased vaccine uptake to be associated with older age, male gender, ethnic minority, and for health professionals, being a doctor (Bish, et al., 2011).

Among healthcare workers in the US, higher vaccination rates are associated with employer requirements for influenza vaccination; working in a hospital; being a physician, dentist, nurse practitioner, or physician assistant; and age 60 years or older. No significant differences in influenza vaccination rates by race and ethnicity are evident in this survey (CDC, 2011a).

One of the most significant influences on vaccine uptake is recommendation from a healthcare professional. Physicians play an important role in family decisions to either refuse or accept vaccinations for their children. Clinicians have a unique opportunity to listen to concerns of parents and also to educate parents about the importance of establishing herd immunity in their community to protect very young children and those for whom vaccination poses a medical threat (Berlinger, 2006). Studies have found that physicians are valuable and trusted sources of information about vaccines, even for parents who refuse to vaccinate their children (Fredrickson, et al, 2004). Some findings also suggest that physicians' attitudes toward vaccination may help protect against negative media coverage of vaccine controversies (Smith, Ellenberg, Bell, & Rubin, 2008).

Numerous studies indicate that recommendation from a health provider greatly influences influenza vaccine acceptance. Advice from medical professionals is reported the most significant positive predictor of influenza vaccination in a survey of 65 year olds living with others (Burns, 2005). A study of influenza vaccination coverage rates in 11 European countries deems the advice from a family doctor or a nurse as the main encouraging factor for vaccination (Blank, Schwenkglens, & Szucs, 2009). In a study of influenza vaccination coverage in the Germany, offer of vaccination by a physician is shown to be associated with a high likelihood for vaccination (Wiese-Posselt, et al., 2006). Yet another study on vaccination rates in 5 European countries also cites receiving advice from a family doctor as an important reason for being vaccinated; and individuals in the study who had not been vaccinated offer not having received a recommendation for vaccination from a family doctor as a reason for not being vaccinated (Muller, 2007).

The significant influence health professionals have on vaccine acceptance and resistance is further demonstrated by instances of declining vaccination in response to erroneous claims and vaccine opposition from physicians. The following examples of such influences are taken from Dr. Offit's book, *Deadly Choices*.

Dr. John Wilson, in October 1973, presented to the Royal Society of Medicine in London his finding that DTP (specifically the Pertussis component) was directly responsible for causing brain damage. This led to a significant decrease in vaccine uptake and resulted in one of the largest epidemics of whooping cough over the last century. Likewise, Dr. David Miller was commissioned to do a comprehensive study of the relationships of vaccine and neurological effect. He concluded that DTP caused permanent brain damage in one hundred thousand children. Again, the negative impact on vaccination rates was profound. Over time neither of these studies could be replicated and others showed no connection between Pertussis vaccine antigen and brain damage. Large population studies with a true "control" show conclusively the lack of a relationship. However, the damage was done. The court of public opinion, spurred on by media sensationalism, led to inestimable morbidity and mortality from a disease for which a safe and effective vaccine was available.



A similar incident was triggered in 1998, after Dr. Andrew Wakefield published a paper asserting an association between MMR vaccine and autism. This claim was eventually shown to be without merit, but not before resulting in decreased uptake of MMR vaccine, leading to global measles outbreaks. What sets this example apart is the international scientific misconduct in conducting and reporting his findings and having those published in the most reputable of peer-review publications. When such sensational studies are published in trusted medical journals, the media and public responses are virtually instantaneous, whereas the scientific study needed to refute the claims is a multi-year endeavor. During that window of time the human damage that can be inflicted is staggering. Unfortunately, the only initial defense against such actions is a rigid, closely monitored peer review system.

Yet another example of trust in physicians that can lead to decreased vaccination due to scientifically unsupported theory comes from well-intended, well-trained practitioners. These health professionals command a great deal of public confidence, as their approaches are both logically and psychologically attractive, often based on intellectually plausible elements. Robert Sears, MD (2011), or “Dr. Bob” as he prefers, incorporates alternative and traditional medical care in his practice. His beliefs in healthy natural living, limiting antibiotic usage and good nutrition are commendable. He is well published and has a large number of followers across the US. One of his books, *The Vaccine Book, Making the Right Decision for your Child*, is the source of controversy in the vaccine scientific community. Dr. Bob, in short, offers an “alternative” vaccine schedule, a schedule that results in full vaccination but does so in a way that he claims minimizes risk. In actuality, he recommends an immunization schedule that delays protective immunity for his patients and requires more office visits, making missed immunizations more likely. Dr. Offit’s rejoinder: “rather than calming patients with science. He caters to their fears by offering a schedule that has no chance of making vaccines safer and will only increase the time during which children are susceptible to infections that can kill them.” This is certainly true, but even truer is the fact that Dr. Bob influences thousands of parents around the globe.

In addition to trusting health care professionals, vaccine acceptance also demands a level of trust in vaccine manufacturers and policy makers. When questions are raised about hidden agendas, profit from immunizations, and lack of due concern for vaccine harm by pharmaceutical companies, public acceptance of vaccination can be affected. Recent controversies and public concern about the HPV vaccine illustrate the importance of maintaining public trust in vaccine manufacturers and those who recommend vaccines.

In the US, the human papilloma virus (HPV) vaccine became the target of a political controversy on several fronts. The HPV vaccine is most effective for younger individuals, both women and men, who are not yet sexually active. The American Academy of Pediatrics HPV vaccine recommendations include routine immunization of both girls and boys 11 – 12 years of age (American Academy of Pediatrics, 2012). This created concerns among socially conservative parents who felt the HPV vaccine might either interfere with their parental rights to educate their children about sexual activity or contribute to promiscuous behavior of adolescents (Intelkofer, et al, 2012). Despite a proven safety record for the HPV vaccine there was a perception that the vaccine manufacturers rushed the vaccine to market without adequately testing for safety and clearly identifying deployment strategies. This was fueled by an award-winning marketing campaign that appeared to create a sense of urgency for parents to get the vaccine for their children. In some states, there were legislative efforts to mandate the HPV vaccine. The HPV vaccines also carried a high price when compared to other childhood vaccines and created burdensome costs for both parents and state health systems. The 2008 sales figures for the HPV vaccine were in excess of \$1.4 billion in the US and Europe for one of the manufacturers. In the US, physicians and nurses were paid as much as \$4,500 to give

informational talks about one of the vaccines. Grant funding was provided to a US college health association to promote HPV vaccination on college campuses (Rosenthal, 2008). The HPV vaccine was further politicized in 2011 during a Republican presidential debate. In an effort to criticize an opponent, a candidate used a false claim that a constituent's daughter had suffered from mental retardation after receiving the HPV vaccine. Such controversies about vaccines can contribute not only to distrust of the vaccine industry and its influence on the public health agencies responsible for setting vaccination policy, but also to the public misconception that the vaccine is unsafe, and thus to be avoided (Intelkofer, 2012).

Along this line, a final, yet increasingly important, influence on vaccine acceptance is media communication and sensationalism. It is generally believed the media can amplify public risk concerns around a particular vaccine issue. The United Kingdom media response to the alleged potential link between the MMR vaccine and autism coincided with a decline in MMR uptake from around 91% to below 86%, although, it is recognized that media is but one of many factors that influences risk perception within the general population (Smith, et al, 2008).

In a recent Medscape segment, Eric Topol, author of *The Creative Destruction of Medicine* pointed out that the Facebook user community is approaching 1 billion registrants. He goes on to point out that patients are turning to on-line health social networking, and virtual peers are an increasingly used source of medical information. He further notes that he uses twitter as his most important source of information in the digital health arena (Topol, 2012). There is no way to measure just how influential the media is in vaccine acceptance, but the regular patterns of heavy media interface in Europe and the US suggest that media at the very least has the potential to influence health care decisions such as vaccine acceptance or refusal. In one study, viewing a vaccine-critical website for 5-10 minutes increased study participants' perceived risk of vaccinating and decreased perceptions of risk for omitting vaccination (Betsch, Renkewitz, Betsch, & Ulshofer, 2010).

## 5.0 Case Examples from the Anti-vaccination Campaign

The Internet is the fastest growing source of consumer health information. The anti-vaccination movement has utilized the Internet and its ability to reach consumers seeking information pertaining to vaccine and vaccine safety. The instance of anti-vaccination Web sites identified in systematic scientific reviews has grown from 51 sites in 1999 to 78 sites in 2004 (Zimmerman, et al, 2005). A systematic review performed in 2010 found the following themes on anti-vaccination sites (Kata, 2012):

1. Safety and effectiveness
2. Alternative medicine
3. Civil liberties
4. Conspiracy theories
5. Morality, religion, and ideology
6. Misinformation and falsehoods
7. Emotive appeals
8. Content aspects

When entered as a Google.com search term, "vaccination" reveals the following anti-vaccination organizations appearing in the top ten results:

#4: The Vaccination Conspiracy and Holocaust ([www.whale.to/vaccines.html](http://www.whale.to/vaccines.html))

#5: National Vaccine Information Center ([www.nvic.org](http://www.nvic.org))

#6: Vaccination Liberation ([www.vaclib.org](http://www.vaclib.org))

#8: Natural News – Vaccination ([www.naturalnews.com/vaccination.html](http://www.naturalnews.com/vaccination.html))

For the purposes of this analysis of “opponents to vaccines and their communication networks, contents of their Web sites, and arguments,” a selected sample of major international opponents in English were selected, summarized, and analyzed, with additional sites reviewed.

### National Vaccine Information Center<sup>20</sup>

The National Vaccine Information Center (NVIC) is a national, charitable, not-for-profit organization advocating for the institution of vaccine safety and informed consent protections in the public health system. According to its mission, the NVIC is “dedicated to the prevention of vaccine injuries and deaths through public education and to defending the informed consent ethic in medicine.” The NVIC maintains that it is an “independent clearinghouse” for information on diseases and vaccines.

The NVIC was established in 1982 by parents who believe their children experienced injury or death following administration of the DPT vaccine. The NVIC monitors vaccine research, development, policymaking, and legislation while advocating that scientific studies must be conducted to (1) define various biological mechanisms involved in vaccine injury and death, (2) identify genetic and other biological high risk factors for suffering chronic brain and immune system dysfunction after vaccination, and (3) evaluate short and long-term health outcomes of vaccinated and unvaccinated individuals to determine the health effects of vaccination.

The NVIC is a 501(c)3 organization that declines funding from the pharmaceutical industry or government entities and instead receives support by private donations. The NVIC has received grants from the Albert and Claire Dvoskin Foundation (2008) and Logos Fund (2011) as well as in-kind donations from Mercola.com. The NVIC describes itself as “the leading consumer voice in the vaccine safety and informed consent debate, providing clear, consistent, and responsible framing of the most critical issues involved in the science, policy, law, and ethics of mass vaccination.”

The NVIC maintains an extensive Website hosted by Mercola.com ([www.nvic.org](http://www.nvic.org)) and describes its site as “the oldest and most influential consumer-operated vaccine information Website.” Translation for the Website is available in twelve languages. The Website is organized by the following categories (1) Vaccines, (2) Law and Policy, and (3) News and Events, and includes an assortment of tools, detailed in Table J.

**Table J. NVIC Website**

1. VACCINES	
<b>Ask Eight</b>	An NVIC campaign encouraging individuals to be fully informed about the risks of disease and vaccine, <i>Ask Eight</i> provides consumers with a list of questions to speak with a trusted health care professional about regarding the decision to vaccinate.
<b>Diseases and Vaccines</b>	The NVIC maintains an independent clearinghouse for information “from peer-reviewed science, resources, and federal agencies” on both vaccination and disease for nineteen infectious diseases. In this clearinghouse, each infectious disease includes quick facts about the disease and vaccine, links to federal organizations, search for vaccine reactions, and frequently asked questions.
<b>Vaccine Ingredient Calculator</b>	The VIC “enables [sic] the public to make informed vaccination decisions for themselves and their children” and encourages consumers to create a Vaccination Plan prior to visiting a health care professional. The VIC requires age and weight, vaccine selection, and provides vaccine ingredient

<sup>20</sup> National Vaccine Information Center. <http://www.nvic.org/>. Accessed July 15, 2012.

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	chart. Sixteen ingredients included in the vaccines recommended by the Centers for Disease Control and Prevention (CDC) immunization schedule are included.
<b>Barbara Loe Fisher Speaks Out</b>	Barbara Loe Fisher, cofounder and president of the NVIC, maintains a written and audio commentary dating back to 1997. Ms. Fisher has “researched, analyzed, and publicly articulated the major issues involving the science, policy, law, ethics, and politics of vaccination to become one of the world’s leading non-medical, consumer advocacy experts on the subject.”
<b>Ask Nurse Vicky</b>	Vicky Debold, RN, PhD, hosts the online video health education program produced by the NVIC. Ms. Debold responds to letters from consumers with questions about vaccinations.
<b>Report a Reaction</b>	The NVIC operates a Vaccine Reaction Registry, serving as a “watchdog” on reports submitted to the Vaccine Adverse Events Reporting Systems (VAERS) operated by the US Government. MedAlerts, a VAERS database search engine, is available to search for adverse events following vaccination.
<b>Vaccine Memorial</b>	The NVIC hosts a memorial to “honor(ing) those whose lives have been lost or forever changed by vaccination.” Over 1,700 “vaccine victims” are honored in this memorial that includes name, birth and death date, state, country, age, vaccine, reaction, and description to that reaction.
<b>Searchable Reaction Database</b>	The NVIC operates MedAlerts, a VAERS database search engine, to search for adverse events following vaccination and is an “alternative to CDC Wonder” that “contains the same information” but “this site offers a better user interface, more powerful search capabilities, and more extensive reporting, making it the best VAERS search facility on the Web.”
<b>2. LAW AND POLICY</b>	
<b>Current Advocacy and Action Alerts</b>	The NVIC Advocacy Portal (NVICAP) “helps you, our members, to organize and make a difference in your home state right where you live to protect and expand vaccine exemptions.” The NVICAP lists, by state, Bills to Watch, Action Needed Now, and Announcements. Registration to become an NVIC Advocacy Team Member – calculating elected officials and direct links to connect – provides advocacy alert e-mails when action is needed to support state efforts. The NVICAP provides “the steps, tools, and connection to leaders and organizations to help you make a positive impact on your rights to exercise informed consent in the vaccination decision making process.”
<b>Federal</b>	1986 Vaccine Injury Law: The NVIC provides detailed information pertaining to the National Childhood Vaccine Injury Act of 1986, maintaining that the law “acknowledged that vaccine injuries and deaths are real and that the vaccine injured and their families should be financially supported and that vaccine safety protections were needed in the mass vaccination system.”
<b>State</b>	State laws and exemptions: The NVIC provides a listing state by state on the medical, religious, and philosophical exemptions for vaccinations, with information on how to achieve such exemptions.
<b>Institutes of Medicine (IOM)</b>	The NVIC maintains selected statements from the organization to the IOM on the accomplishment of NVIC advocacy goals. Ten statements, dating from 1995, are included.
<b>3. NEWS AND EVENTS</b>	
<b>Media room</b>	The NVIC provides up-to-date news and announcements related to vaccines and vaccine policy in the United States, as well as media appearances of the NVIC.
<b>NVIC newsletters and archives</b>	The NVIC provides a weekly free newsletter via e-mail to subscribers containing news and announcements related to vaccines and vaccine policy.
<b>NVIC conferences</b>	The NVIC held a number of conferences since 1989, including an International Scientific Workshop (1989), and International Public Conference on Vaccination (1997, 2000, 2002, and 2009), to present new scientific data about vaccines and diseases and discuss biological mechanisms of vaccine-induced injury, death, and chronic illness.
<b>NVIC video briefs</b>	The NVIC has produced a number of public service announcements and video briefs related to their advocacy goals.

The NVIC endorses “the right to informed consent as an overarching ethical principle in the practice of medicine for which vaccination should be no vaccination” and maintains that “vaccination is a medical intervention performed on a healthy person that has the inherent ability to result in the injury or death of that healthy person. The NVIC provides an overview of each communicable disease well as the corresponding vaccination. The NVIC asserts that it is “dedicated to the prevention of vaccine injuries and deaths through public education.”

**World Association for Vaccine Education<sup>21</sup>**

The World Association for Vaccine Education (WAVE) is a “globally focused, non-profit, educational institution advocating reformation of the mass vaccination systems.” WAVE “provides an avenue for a public exchange of non-medical vaccine information, ideas, and a continuously updated database of documents that concern vaccine risk and uselessness.” WAVE’s intent is to provide a balance of information available to the public regarding vaccination, acknowledge vaccine reactions, and advocate and maintain freedom of choice. WAVE is guided by an international board of directors of ten individuals with the mission to: “promote independent thinking, personal responsibility, and social evolution” and is “dedicated to the prevention of vaccine injuries and deaths through public education and awareness.”

WAVE is a non-profit, globally focused, educational institution. WAVE directors, authors, and assistants contribute on a volunteer basis and are not reimbursed for time, efforts, or materials. Monetary donations are accepted and allocate to Website maintenance and promotional expenses.

WAVE describes itself as “the most complete vaccine research resource” and encourages the public to “study vaccine data from a non-medical point of view.” WAVE maintains an extensive Website ([www.novaccine.com](http://www.novaccine.com)) organized within Table K.

**Table K. WAVE Website**

<p><b>Specific Vaccinations</b></p> <p>WAVE provides 43 conditions by vaccination, and identifies, by manufacturer, the microorganism, license date, recommendations, ingredients, and product descriptions (package insert). Each condition includes a “Vaccine Risks” as well as “Vaccine Ineffectiveness,” citing both peer-reviewed published literature and “gray” literature. An option is available to view scientific literature only.</p>
<p><b>Reactions/Conditions</b></p> <p>WAVE lists seven subcategories of reactions including: neurological conditions, autoimmune disease, development disorders, local/acute reactions, systematic disease, and organ dysfunction, with specific conditions that includes the history of such reaction and documentation citing both peer-reviewed published literature and “gray” literature.</p>
<p><b>Vaccine Ingredients</b></p> <p>WAVE provides the ingredients in 43 vaccinations and chemical analysis of over 100 chemicals, including description and toxicity.</p>
<p><b>Vaccine Risks</b></p> <p>WAVE admits that vaccine risk is “a difficult thing to precisely assess, but undeniably each vaccine includes a significant risk worth considering and investigating” and identify the following vaccine safety considerations: (1) underreporting of adverse effects, (2) faulty methods use to examine safety, (3) lack of long-term safety studies, (4) elusiveness of risk assessment, and (5) emergency of new diseases resulting from vaccines.</p>
<p><b>How? Why?</b></p> <p>WAVE explores the arguments for vaccinations and provides the “psychological dynamics, social tendencies, and historical facts” for the acceptance of vaccination, to include: responsibility, independent thinking, history, and corruption.</p>
<p><b>Authorities Speak Out</b></p> <p>WAVE cites 44 instances of the “thousands of doctors, historians, researchers, and government authorities who have not hesitated to voice the truth.”</p>
<p><b>Laws/Exemptions</b></p> <p>By state, WAVE lists the law and exemptions for vaccinations and points to the “legal loopholes” that the Declaration of Independence, First Amendment, and Four Amendment provides. Further, because “mass vaccination appears to have been largely neglected by modern biomedical ethicists,” WAVE provides ethical guidelines of utilitarianism, “one big flaw,” precedents, crimes of omission, “where does it stop?” and errors in judgment.</p>
<p><b>Communication</b></p> <p>WAVE provides several outdated means of communication mechanisms, including: BlogVax (last updated in November 2009) and a newsletter (last updated in February 2007).</p>

WAVE maintains “vaccines contributed little to the eradication of diseases like smallpox, tetanus, or polio” and “drug companies conduct studies and determine effectiveness by merely measuring antibody response.” WAVE states “vaccine risk may be a difficult thing to precisely assess, but undeniably each

<sup>21</sup> World Association for Vaccine Education. <http://www.novaccine.com/>. Accessed July 15, 2012.

vaccine includes a significant risk worth considering” and question vaccine safety, including underreporting, faulty methods, no long-term safety studies, elusiveness of risk assessment, and emergence of new diseases. In addition, WAVE asserts “some of the [vaccine] ingredients are extremely toxic and have detrimental effects on human health.”

**Think Twice Global Vaccine Institute<sup>22</sup>**

The Think Twice Global Vaccine Institute is a clearinghouse for information on vaccine risks with a collection of books and other informational resources on vaccination. The Think Twice Global Vaccine Institute, established in 1996, “provide[s] parents and other concerned people with educational resources enabling them to make more informed vaccine decisions,” encouraging “an uncensored exchange of vaccine information and supports every family’s right to accept or reject vaccines.” It denies affiliation with any religious, political, or government organization. Neil Z. Miller, author of the books and articles promoted by the site, oversees the Think Twice Global Vaccine Institute; his self-identified credentials include a bachelor’s degree in psychology and membership in MENSA. The Think Twice Global Vaccine Institute is affiliated with the *New Atlantean Press*, a publisher and distributor of holistic books. It includes links to purchase a variety of anti-vaccination books.

The organization maintains, “Parents are entitled to a full disclosure of *all* pertinent data and the freedom to choose whether or not to vaccinate their children.” The Think Twice Global Vaccine Institute maintains a Web site ([www.thinktwice.com](http://www.thinktwice.com)) that provides “uncensored information about vaccines and how they affect our children” detailed in Table L.

**Table L. Think Twice Global Vaccine Institute Website**

<p><b>Frequently asked questions</b></p> <p>The Think Twice Global Vaccine Institute answers frequently asked questions and offers responses from e-mails and telephone calls. In response to one question from a reader regarding their pediatrician who terminated their relationship because of refusal to vaccinate, the organization responded, “You should be thankful that this dysfunctional relationship with your health practitioner has been terminated.”</p>
<p><b>Individual vaccines</b></p> <p>The Think Twice Global Vaccine Institute lists, by vaccination, the description, disease danger, and safety of the vaccine. For some vaccinations, the Web site advises the reader that “the most up-to-date information may be found in the book <u>Vaccine Safety Manual</u>” available for purchase through the Institute.</p>
<p><b>Articles</b></p> <p>The Think Twice Global Vaccine Institute provides links to read “important vaccine information that you won’t find in the mainstream media,” including: (1) Secret government database of vaccine-damaged children (VAERS Database), (2) CDC fraud (letter to the publisher of Elsevier), and (3) Are vaccine studies truly scientific (article in the Atlantic).</p>
<p><b>Studies</b></p> <p>The Think Twice Global Vaccine Institute provides links “to discover a small percentage of the many scientific studies that document hazards associated with vaccines.” Each condition includes an extensive bibliography of articles from peer-reviewed articles – most dated twenty or more years old.</p>
<p><b>Personal stories</b></p> <p>The Think Twice Global Vaccine Institute provides four “unsolicited personal stories of vaccine damage and death received” from vaccination.</p>
<p><b>Support groups</b></p> <p>The Think Twice Global Vaccine Institute provides links to “groups throughout the world that promote an uncensored exchange of vaccine information and support the right to accept or reject immunizations.”</p>
<p><b>Immunization laws</b></p> <p>The Think Twice Global Vaccine Institute maintains that “many people are opposed to vaccines yet are unaware of their legal rights” and provides advice for readers on how to avoid immunizations in one of seven categories: young child, public institution, private institution, employer, foreign travel, US entry, and military. Resources are available for purchase, including a sample affidavit and vaccine state laws.</p>
<p><b>Bookstore</b></p>

<sup>22</sup> Think Twice Global Vaccine Institute. <http://www.thinktwice.com/>. Accessed July 15, 2012.



## D1.4 Report on Vaccine Acceptance/Refusal and Resistance to Vaccination TELLME project – GA: 278723

The Think Twice Global Vaccine Institute is affiliated with the New Atlantean Books and Holistic Products, and includes a link to the bookstore.

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### Emotional response

The Think Twice Global Vaccine admits “our website elicits strong responses” and includes excerpts from “love letters and supportive e-mail” and “angry letters and contrasting perspectives” with responses.

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The Think Twice Global Vaccine Institute asserts, “It’s the vaccinated children who spread disease. Many of the disease outbreaks that we are warned about today, are caused by, and occur in, recently vaccinated children.” Furthermore, “recently vaccinated children do carry the disease germ and are able to spread it to other children.” The group additionally recommends to “consider homeopathic alternatives or to do nothing and contend with disease if and when it occurs. Breastfeeding and natural foods work for many families.”

The Think Twice Global Vaccine Institute states “many children (and adults) receive vaccines and shortly thereafter have a serious reaction, often requiring emergency hospitalization. Such reactions include seizures, autism, immunological damage, neurological damage, sudden infant death syndrome, and/or a number of other rare and elaborately named “new” diseases.” It asserts, “Often, the doctor, nurse, or hospital personnel will try to convince you that the reaction is “normal” and nothing to worry about. Other times they will claim your child contracted a simple virus, or is screaming uncontrollably (nonstop for hours!) because she didn’t like the needle prick. These are all lies. Doctors almost NEVER admit a correlation between vaccines and serious reactions.”

### European Forum on Vaccine Vigilance<sup>23</sup>

The European Forum for Vaccine Vigilance is a coalition of groups in Europe that inform the general public, the politicians, and the press about the adverse effects of vaccinations. The European Forum on Vaccine Vigilance is a “forum of European organizations [sic] which are dedicated to the investigation and prevention of such health derangements, under the presidency of ALIS (France) and the LIGA (Spain).”

The goals of the European Forum on Vaccine Vigilance are as follows: (1) provide information about vaccine adverse effects and their consequences for society in terms of financial, social and psychological cost; (2) promote freedom of choice as to vaccination in all European countries; (3) provide a discussion forum for European groups, and to support the exchange of information; (4) enable common political viewpoints; and (5) prepare common action.

An extensive list of contacts from the following countries is included: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Italy, Luxembourg, Netherlands, Norway, Romania, Slovenia, Spain, Sweden, Switzerland, and United Kingdom. No identified funding source was determined based on review of the European Forum for Vaccine Vigilance online resources.

The European Forum for Vaccine Vigilance aims to: inform all individuals about the possible risks and side effects of vaccines, network people and organizations with an interest in area, make vaccination issue one of public interest which must be discussed openly, help victims of vaccine damage to help them defend their rights, put more pressure upon politicians to increase freedom of choice and balanced information, and demand financial compensation for those victims of the vaccination policy.

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<sup>23</sup> European Forum on Vaccine Vigilance. <http://www.vaccinatieschade.be/efvvwebsite/e1.html>. Accessed July 15, 2012.

The European Forum on Vaccine Vigilance maintains a Website in multiple languages. <http://users.telenet.be/vaccine.damage.prevention/englishhomepage?68,10> (Chart L)

**Table L. European Forum on Vaccine Vigilance Website**

Report	<p>The European Forum on Vaccine Vigilance publishes the overall conclusions of an extensive report of their findings from a six-year period, providing the following description of the study: <i>Our research was based on approximately 1000 cases of individuals ranging from birth to 75 years of age and, for the Belgian, British, French and Dutch components, covered a six-year period (from 1999 to 2004). The Spanish research covered 12 years (1987-2004). Most of the pathologies testified by the respondents had not been recognized or acknowledged as post-vicinal complications and had consequently not been reported to the pharmacovigilance services.</i></p> <p>Only the overall conclusions and proposals of the report are available on the Web site, with the remaining report available via a national chapter of the European Forum on Vaccine Vigilance. The conclusions are as follows (1) assume constitutional equality, (2) that everyone be fully informed of the adverse effects of vaccinations, (3) that an effective and independent vaccinovigilance unit be created, and (4) compensation for all vaccine damages.</p>
Links	<p>The European Forum on Vaccine Vigilance contains links to various vaccination sites, including: critical sites (assorted languages – 29), official sites (3) and pro-vaccination sites (1).</p>
Agenda	<p>The agenda for <i>International Vaccine Victim Week</i> – held every year “as a tribute to and commemoration of all vaccine victims worldwide” – is published from October 4 – 9, 2010.</p>

## Additional Groups

### Vaccination News<sup>24</sup>

Vaccination News, a non-profit entity, is “published in order to provide a wide range of news and views on vaccination policy.” It asserts that through providing all sides of the vaccination controversy, “the public/consumer will be best equipped to make reasoned decisions regarding vaccination use, decisions which will have profound implications for them and their family’s health” and “readers will recognize both the complexity of the controversy and the dearth of good information available to them.”

Vaccination News maintains a Web site ([www.vaccinationnews.com](http://www.vaccinationnews.com)) primarily dedicated to news links from a variety of sources on vaccination and other related topics primarily from popular media and other sources, and appears to serve primarily as a clearinghouse of information pertaining to the vaccination debate, including links to various tools, blogs, medical journals, state laws, and important notices.

### Vaccine Resistance Movement<sup>25</sup>

The Vaccine Resistance Movement (VRM) founded by Joel Lord is a “grass-roots, non-profit organization striving for safe alternatives to vaccines.” Specifically, the VRM – located in Canada with an international reach – empowers global citizens with “the means of self-sufficiency while determined to expose vaccine fraud and pharmaceutical industry malfeasance.” The VRM mission statement has four primary goals: (1) expose vaccine fraud and industry, media, and government malfeasance, (2) provide the most complete source of safe alternatives to vaccines available, (3) prepare for multiple class action lawsuits to be served to our respective health agencies around the world, and (4) identify the real cause and cure for autism. The VRM hosts a Website ([www.vaccineresistancemovement.com](http://www.vaccineresistancemovement.com)) that contains dozens of articles based on the premise “the ENTIRE Vaccine Industry is a fraud, period.” The VRM hosts an online petition, organizes rallies, and provides numerous articles pertaining to the vaccine industry.

<sup>24</sup> Vaccination News. <http://www.vaccinationnews.com>. Accessed July 25, 2012.

<sup>25</sup> Vaccine Resistance Movement. <http://www.vaccineresistancemovement.com>. Accessed July 25, 2012.



### **Vaccine Liberation**

Vaccine Liberations ([www.vaclib.com](http://www.vaclib.com)) is “part of a national grassroots network dedicated to providing information on vaccinations not often made available to the public so that one can make the only informed choice, complete avoidance and refusal. According to its Website, “many consider Vaclib to be the premier grassroots anti-vaccine association in the United States.” The Vaccine Liberation mission statement includes (1) reveal the myth that vaccines are necessary, safe, and effective, (2) expand our awareness of alternatives in healthcare, (3) preserve our right to abstain, and (4) repeal all compulsory vaccination laws nationwide.

### **The Informed Parent<sup>26</sup>**

According to its Web site ([www.informedparent.co.uk](http://www.informedparent.co.uk)) TheInformed Parent, a United Kingdom group, was “set up to counter frustration and isolation experienced by parents in their efforts to seek information about immunization, following uncertainty about its safety and effectiveness.” The Informed Parent annual subscription provides a newsletter and “voice for subscribers” as well as a reading list and notice of any local talks or meetings. The Informed Parent maintains “we cannot give medical advice, and we neither recommend nor advise against vaccination, but we can help parents inform themselves and make the right decision for their child.”

Its aims and objectives include (1) promote awareness and understanding about vaccinations in order to preserve the freedom of an informed choice, (2) offer support to parents regardless of the decisions they make (3) inform parents of the alternatives to vaccinations, (4) accumulate historical and current information about vaccination and to make it available to subscribers and interested parties, (5) arrange and facilitate local talks, discussions and seminars on vaccinations and preventative medicine for childhood illnesses, (6) establish a nationwide support network and register (subject to subscribers permission), (7) publish a newsletter three times a year, and (8) obtain, collect and receive money funds by way of contributions, donations, subscriptions, legacies, grants or any other lawful methods; to accept and receive any gift of property; to administer such funds and property and to devote the income, assets or property of the organization in or towards fulfillment of the objectives of the organization.

### **Vaccine Injury<sup>27</sup>**

Vaccineinjury.info ([www.vaccineinjury.info](http://www.vaccineinjury.info)) was begun by Andreas Bachmair of Germany ten years ago. The founder was working as a homeopath and “was confronted again and again with patients who were injured through vaccination.” The Web site contains vaccine-critical information, and references a study that visiting the site “for only five to ten minutes increases the perception of risk regarding vaccinations and decreases the perception of risk regarding the omission of vaccinations as compared to visiting a control site.”

### **International Medical Council on Vaccination<sup>28</sup>**

The International Medical Council on Vaccination (<http://www.vaccinationcouncil.org/>) is an association of medical doctors, registered nurses and other qualified medical professionals whose purpose is to counter the messages asserted by pharmaceutical companies, the government and medical agencies that vaccines are safe, effective and harmless.

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<sup>26</sup> The Informed Parent. <http://www.informedparent.co.uk>. Accessed July 25, 2012.

<sup>27</sup> About vaccineinjury.info. <http://www.vaccineinjury.info/about.html>. Accessed July 27, 2012.

<sup>28</sup> International Medical Council on Vaccination. <http://www.vaccinationcouncil.org>. Accessed July 27, 2012.

Its principles and findings include (1) We are profoundly critical of the practice of vaccination. Vaccination is an unacceptable risk to every member of society, regardless of age, (2) As medical professionals, Council members have observed first-hand the health of vaccinated vs. the unvaccinated. We find the latter group to be robust, healthy and drug-free compared to the former group, (3) We have reviewed published studies in support of vaccines and have found them wanting in both substance and science, (4) We have brought out into the open hundreds of peer-reviewed, published medical articles that document the damage and the diseases caused by vaccines, (5) We find the premise of herd immunity to be a faulty theory, (6) We encourage intelligent debate about vaccination, (7) We expect individuals to take responsibility for their health and the health of their children by investigating the problems due to vaccination prior to subjecting their children, or themselves, to this medical procedure, and (8) We believe that refusing vaccination is a personal right that should be legislatively guaranteed.

### **The Vaccination Conspiracy and Holocaust<sup>29</sup>**

The Vaccination Conspiracy and Holocaust (<http://www.whale.to/vaccines.html>) is a compilation of numerous articles and links against vaccinations and maintains, “vaccination is the longest running hoax perpetrated by allopathy, the most pernicious, and the most dangerous thing that your children will ever face.”

### **Vaccine Awareness Network<sup>30</sup>**

The Vaccine Awareness Network (<http://www.vaccineriskawareness.com/>) is a collection of articles and links regarding vaccination, developed by a woman who attributes her various nervous system disorders to vaccination.

### **Natural News – Vaccination news, articles, and information<sup>31</sup>**

Natural News (<http://www.naturalnews.com/vaccination.html>), a non-profit collection of public education websites, provides information on topics that “empower individuals to make positive changes in their health, environmental sensitivity, consumer choices and informed skepticism.”

### **The Role of Social Media/Web 2.0**

As defined by Betsch, et al., (2010), Web 2.0 or social media is “Internet applications that enable users to create and upload new content, comment on existing content and share content with other users, eg. discussion boards, web blogs and social media websites such as Facebook, Twitter, Wikipedia, LinkedIn and YouTube. That is, while ‘Web 1.0’ Internet websites typically allowed for one-way communication from the creator of the site to the user (eg static health portals), Web 2.0 enables two-way and multi-way communication.”

Facebook is used “to stay connected with friends and family, to discover what’s going on in the world, and to share and express what matters to them.”<sup>32</sup> Users can “friend” other users, or “like” public figures and organizations which then allows them to follow their up-to-date information.

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<sup>29</sup> The Vaccination Conspiracy and Holocaust. <http://www.whale.to/vaccines.html>. Accessed July 27, 2012.

<sup>30</sup> Vaccine Awareness Network. <http://www.vaccineriskawareness.com>. Accessed July 27, 2012.

<sup>31</sup> Natural News. <http://www.naturalnews.com/vaccination.html>. Accessed July 27, 2012.

<sup>32</sup> Facebook – Key Facts. <http://newsroom.fb.com/content/default.aspx?NewsAreaId=22>. Accessed July 27, 2012.

According to its Web site, Twitter is a “real-time information network that connects you to the latest stories, ideas, opinions, and news about what you find interesting.”<sup>33</sup> Users can follow a variety of organizations, public figures, and friends to stay up-to-date on news via “Tweets.”

YouTube “provides a forum for people to connect, inform, and inspire others across the globe and acts as a distribution platform for original content creators and advertisers large and small.”<sup>34</sup> Users are able to upload videos for public viewing on this social media platform.

### **Benefits of Social Media**

In contrast to traditional Web sites, which only allow communication of information to the public, social media allow not only the ability to provide information to the public, but also for the public to share information with the source. Users can create and disseminate information themselves, thus becoming more involved. An example of this interaction is demonstrated by a statement shared by the Centers for Disease Control and Prevention (CDC) on their Facebook page regarding vaccination on July 5, 2012:

*“When was your last tetanus shot? Tetanus vaccines can prevent this disease in children, teens and adults. Without the vaccine, you can get tetanus (“lockjaw”) just by getting cuts, especially puncture wounds, that become infected with the bacteria.”*

This statement received 100 “likes” and elicited both supportive statements such as “Mine was only a couple years ago, but it's good to know what it helps prevent. I've had this done twice already” as well as dissenting statements with links to other information.

Social media also allows individuals to provide public support for organizations, individuals, and causes by “liking” on Facebook or “following” on Twitter. For example, the CDC has over 200,000 “likes” as compared to NVIC with 35,000. This is a simple way for an organization to draw attention to itself or to a cause.

It also enables the sharing of information with a large audience. A link shared by an organization, individual, or cause, can be “shared” or “retweeted” to an individual’s friends or followers, which can, in turn, lead to even greater shares or retweets. In this day and age, “going viral” is one of the fastest ways to facilitate the spread of information. One major advantage of social media is that it can share “real-time” information regarding a public health crisis or other emergency scenario. For example, not only could a user receive information from an organization (eg, CDC), a public figure, but also their friends and associates.

Because the individual self-selects the source of their own information, they are able to determine the sources that they most trust (CDC vs. NVIC), or alternatively like or know (eg, friend or celebrity). Such sources are likely to shape beliefs, attitudes, and behaviors. While this is great for sharing information, it can also be challenging, since people will be getting their information from the same types of places, which may not be reputable. They may also receive conflicting information, which can lead to mistrust and confusion. Furthermore, individuals can easily receive information from “friends” or “followers.” Simply sharing or tweeting “Should I vaccinate my child?” could provide an array of responses – both positive and negative – which could potentially influence an individual’s decision making process.

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<sup>33</sup> Twitter – About. <http://twitter.com/about>. Accessed July 27, 2012.

<sup>34</sup> YouTube – <http://youtube.com>. Accessed July 27, 2012.

### **Challenges of social media**

It is relatively easy for messages to get distorted or used out of context. For example, for each “retweet” or “share,” the original message can potentially be modified or added to by the user. While the initial source of information (eg, Web site) will remain the same, the commentary/interpretation on such initial source of information can be altered drastically. Because of this, misinformation can rapidly spread amongst social media sources, leading to such sources as Snopes ([www.snopes.com](http://www.snopes.com)), a well-known resource for validating and debunking “social media legends.” Frighteningly, social media users can “share” or “retweet” misinformation just as quickly and easily as accurate information. For example, an image shared on the NVIC page on July 1, 2012 stating “*If you caused a 6,000% increase in autism wouldn’t you try to cover it up, too?*” which was shared 94 times by followers.

Two-way communication, while listed as a strength of social media, can also be used negatively to further perpetuate misinformation. For example, the National Vaccine Information Center recently shared the article *Another Fabricated Pandemic like the Swine Flu?* (<http://articles.mercola.com/sites/articles/archive/2012/07/07/pandemic-swine-flu-vaccines.aspx>) on July 8, 2012. Fifty one people “liked” this article, with the following selected comment: “*Of course but they will wait a couple of years before the next one so that maybe we will forget how H1N1 was not the threat they said it was. . .except from the vaccine itself.*”

While social media avenues are great for getting information out quickly, they are not always well-suited to sharing complex or substantial amounts of information. Most social media outlets only allow limited lengths of communication. For example, “tweets” are limited to less than 140 characters, which often precludes sufficient evidence or explanation being provided.

### **Recommendations in a pandemic or other public health emergency**

**Release accurate information quickly:** Accurate information should be released via Twitter and Facebook as quickly – if not quicker – than traditional means as many individuals now receive news via social media. One strategy of the anti-vaccination movement is to be able to quickly share information without lengthy public relation reviews.

**Be alert for misinformation:** Frequently scan anti-vaccination organizations for inaccurate information regarding vaccination or disease in a pandemic and be prepared to release correct information via these channels.

**Consider targeting advertising to anti-vaccine individuals:** One unique feature of Facebook is that a specific audience can be targeted via advertisements to receive public health messages. For example, Ads can target only users who “like” a certain anti-vaccination group.

**Reach out to public figures:** Public health agencies should establish relationships with public figures with large public followings (e.g., President Barack Obama has 27,556,856 followers) to release messages that support vaccinations and countermeasures.

## 6.0 Trends in the Anti-vaccination Campaigns

Thorough review of the anti-vaccination campaigns brings to light the specific tactics used by such organizations to influence decision-making of the general population. These tactics play on human behavior, psychology, societal pressure, and prevailing cultural belief. This section discusses the myriad of different tactics used by the anti-vaccination groups that were reviewed. In understanding the techniques used by the opposing viewpoint, we may better understand how to counter the argument and integrate similar techniques into the pro-vaccination movement.

One technique used by nearly all of the anti-vaccination groups reviewed was to promote “informed decision-making”. Many of the websites said they were aiding parents to make more informed decisions. This gives parents a sense of empowerment rather than a sentiment of being directed or mandated. This is likely more palatable to some parents than simply being told that their child needs a vaccination based on requirements or recommendations rather than fully informed decisions considering the risks and benefits of each particular vaccine. It is a strong technique in that it communicates to parents that someone within the group will really take the time to answer questions and act as a trusted partner or friend. Because research supports that many physicians are not talking about the risks/benefits of immunizations with their patients (Currie, 2008) and because we know that average time spent per patient has gone down (Collins, Schoen, & Sandman, 1997) we may infer that health care providers are perhaps not sufficiently helping the parents to make informed decisions (Dugdale, Epstein, & Pantilat, 1999).

While the anti-vaccination movement promotes “informed” decision-making, it is unclear whether the information they are relaying is always accurate or reliable. Often, groups cite data that is outdated, misrepresented, or not actually supported by scientific data. It is also often presented from an individual perspective, rather than from a population-based one. For example, in each of the campaign examples in the previous section, there is little discussion of the concept that while a vaccine may pose a small risk for the individual, it could have the potential to confer benefits to the greater population. One potential counterstrategy to this technique is to encourage physicians and other health care professionals to spend time explaining the risks and benefits of vaccination to their patients. Alternatively, other forums where parents meet and interact with trusted authorities (e.g., parent teacher associations, church groups) may be used by medical or public health professionals to explain in simple terms the information a parent would need to make an informed decision regarding vaccination for their children. Particularly important in a pandemic or other emergency situation, risk messaging should empower individuals to make good choices for their own health and safety, and for that of their families, friends, and communities.

A second tactic used in many of the anti-vaccination campaigns was citing or using testimony from “trusted” health professionals. This is likely effective because parents are left feeling as though they have unlimited and reliable access to medical professionals who are willing and able to answer their every question. If a person's regular provider is less responsive or available, the anti-immunization group is able to fill the information void. This technique is particularly problematic in that, often, those giving health advice for these groups do not actually have the credentials and experience to be reliable sources. Furthermore, advocates that do have the appropriate education and credentials often do not represent the majority opinion of healthcare providers.

A potential counter to this technique would be better advertising for pro-vaccination information from trusted health professionals. It may also be useful to include in large campaigns an explanation of individual versus population-based risk analyses. Physicians and other health professionals who spend appreciable amounts of time with patients (nurses, allied health) should be trained and encouraged to spend time explaining vaccinations and why they are helpful and important. It is also a possibility to increase visibility of trusted

medical professionals that are already in the public eye and ask them to speak out in favor of immunizing by providing facts. During an outbreak or pandemic situation, it may also be useful to establish hotlines, infomercials, and consistent ads so that the public feels like they have access to health professionals that can answer their questions and allay their fears.

The third technique that is particularly common in the anti-vaccination campaigns is the use of “scientific” data regarding vaccine safety. Anti-vaccination organizations utilize selected scientific data – often from peer-reviewed journals and other reputable sources – to support their argument that vaccines are unsafe. Through careful selection of scientific studies that support their position, and by taking data out of context or using inadequately unsubstantiated data, organizations are able to build credibility with their audience by maintaining the guise that all data provided is built upon the best evidence. Because the average layperson does not likely have the scientific background to critically review and decipher the vast amount of medical data surrounding the efficacy of vaccinations, and there is evidence that numerical literacy in the general population is low (Gigerenzer, & Edwards, 2003), anti-vaccination campaigns can pass a wide variety of questionable data as legitimate.

One solution to this issue is for anti-vaccination literature to be acknowledged and analyzed by an independent third party alongside the scientific literature supporting vaccination. The failure to acknowledge and analyze the anti-vaccination studies – critique of method, inaccurate conclusions – may further lead consumers to distrust the medical establishments that support vaccinations. Also, additional education on how to read and interpret scientific data may be valuable, particularly as data suggests that many of those that are anti-vaccines are college-educated. In an outbreak or emergency scenario, the best scientific evidence should be disseminated broadly via non-traditional means and displayed in ways that people can easily interpret and relate to. It may not be realistic to expect the lay public to understand and apply scientific and mathematical data to their own lives.

Yet another very commonly used strategy by anti-vaccination organizations is to utilize first-hand stories of harm caused by vaccinations. These stories – based on anecdote – provide supporters with “evidence” of the dangerous nature of vaccinations. This approach provides readers with “faces” to the harm that vaccination has caused, rather than dehumanizing the issue with facts and numbers. Compelling, sensationalized stories of children with terrible, even life threatening conditions – including autism and SIDS – provide some parents with the evidence necessary for them to forgo immunization for their children. With all of the scientific and often difficult to understand data available on vaccination, the true-life stories can be easier for parents to identify with. Additionally, they appeal to human emotion, which tends to make a more lasting impression than simple rhetoric.

Unfortunately, while this technique is very effective, it only takes into account anecdotal evidence, which cannot be generalized to others or directly correlated to a cause. No scientific evidence is available from the anecdotes to confirm or deny that the damages or diseases may indeed be caused by vaccinations. In creating informal risk messaging, consideration should be given to provide personal scenarios from those who weren’t vaccinated and experienced adverse effects. For example, one anti-vaccination Web site posted a very angry letter from a mother who did not have her child vaccinated. The child then succumbed to the disease that would have been easily preventable. Stories such as these should be made public to better show both sides of the story.

The anti-vaccination movement also maintains that the pharmaceutical industries that develop vaccinations are motivated by profit and greed. Of particular concern to the movement is the “for-profit”



status of the pharmaceutical industry, and the perception that the pharmaceutical industry stands to profit enormously from vaccine acceptance. In addition, the vaccine industry is also the entity that often tests a certain vaccination for safety. Using this approach in anti-vaccination campaigns, introduces an element of mistrust in consumers. That is, how can a company manufacturing and distributing – and thus profiting – from vaccination, also reliably test for safety?

Consumers often do not realize the extensive costs of vaccine development, including research and safety. In some cases, individuals may not realize that vaccinations are not profiting the companies that develop, test, and distribute vaccinations. To counteract this concern, vaccinations should be very inexpensive for the consumer, and vaccine manufacturers should maintain low profit margins or reinvest profits into research and development in order to build public trust of vaccinations. Vaccine manufacturers could also avoid advertising to consumers (e.g., Gardasil) in order to avoid a profit-driven image. Additionally, independent, third parties would ideally perform all studies regarding the safety and efficacy of vaccinations. In an outbreak or emergency scenario, the vaccine manufacturers should offer vaccination at-cost or even free. This may help to promote trust by allaying some fears that the vaccination industry is profiting from the emergency scenario.

Along similar lines, the anti-vaccination movement uses a handful of additional strategies to promote trust from the public. They use non-inflammatory and often scientific-sounding titles which convey an air of authority and credibility. Many campaigns also maintain non-profit status, which both promotes an image of philanthropy and allows for tax-exempt deductions to be made to the organizations. By maintaining non-profit status, the anti-vaccination organization is able to favorably contrast itself to the for-profit pharmaceutical industry. They are able to present the image that their mission is to preserve the health and well-being of consumers. To counter this strategy, it is essential that pro-vaccination messaging come from trusted, non-partisan sources. Trusted philanthropic groups and medical professionals should be recruited to help disseminate information both on a public and grassroots level.

This tactic is paired with using celebrities as spokespeople for the movement. Many anti-vaccination campaigns are led or endorsed by well-known performers, actors, writers, or others in pop culture. This serves to draw attention to the issue, capture a wide audience, and popularize an issue that may not otherwise enter the public eye. Because people often idolize celebrities, or at the very least stay abreast of the issues they speak about and the activities they are involved in, these individuals are the perfect vehicle for spouting rhetoric. They additionally command media attention, and are very visible in the public sphere. In attempts to garner maximum public sympathy, the most vocal of celebrities often use personal anecdotes that play on human emotion and resonate with personal fears and experiences. It is important when attempting to counter such activity to remember the power held by the media and popular culture. Celebrities are able to influence the opinion of a great many people regardless of their credentialing or expertise, and can also be used as vaccination advocates. Take the ASPCA commercials featuring Sarah McLachlan, for example. Since the launch of the Sarah McLachlan campaign in 2003, fundraising revenues have more than doubled, while fundraising ratio has remained constant.<sup>35</sup> Imagine what strong celebrity presence has the potential to do for vaccination education and awareness.

Another approach used by the anti-vaccination movement is to disseminate information to the public by taking advantage of a wide variety of multimedia strategies, such as the Internet, social media (e.g., Twitter and Facebook), blogs, and other strategies that consumers are comfortable with and use frequently. The

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<sup>35</sup> ASPCA Response to Sarah McLachlan Campaign Criticism. Retrieved August 25, 2012: <http://cats.about.com/b/2010/01/04/aspca-response-to-sarah-mclachlan-commercial-criticism.htm>



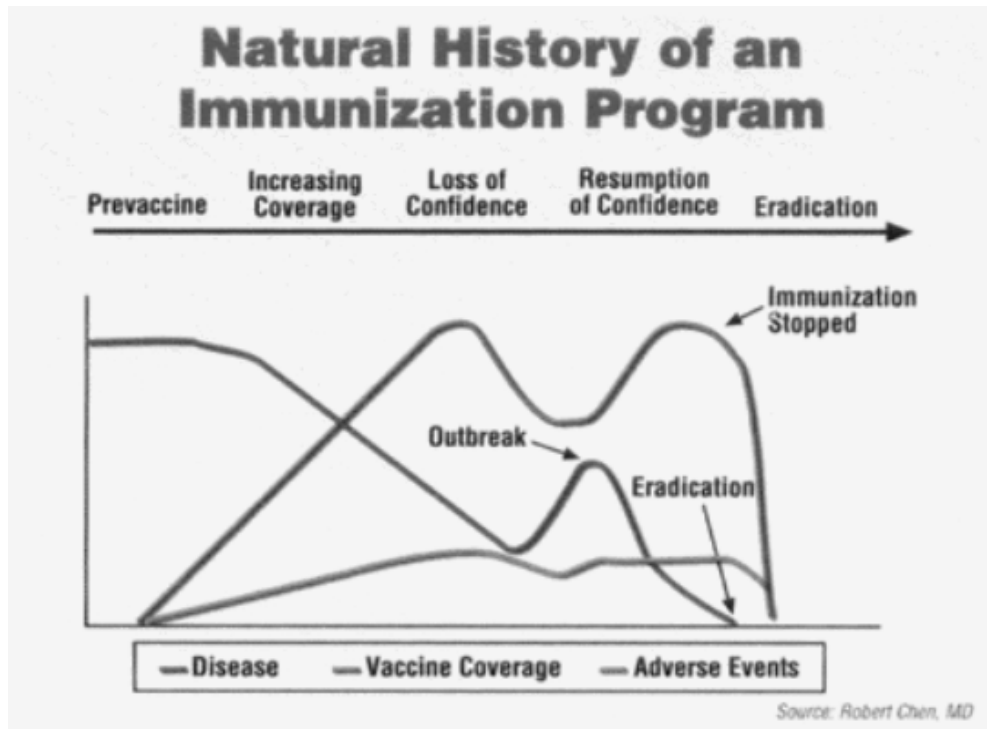
anti-vaccination movement – with its grassroots network – utilizes low cost, high return mechanisms to communicate with the public. The advantage of this strategy is that consumers already frequently utilize the various mechanisms that the anti-vaccination movement employs. The anti-vaccination movement is able to frequently initiate interaction with the public, providing timely links, information, and notices to the public. This approach has been a strength for the anti-vaccination movement, and government and other entities have likewise been quick to utilize social media (e.g., Facebook and Twitter) and other outlets (e.g., blogs) as a mechanism to communicate with the public. Government, health, and other organizations supporting vaccinations should extensively and widely utilize multimedia to interact with consumers, especially in the midst of an emergency when the public is looking for fast and reliable information.

Finally, many of the case studies use the argument that they are seeking the truth from the medical establishments, government, and the pharmaceutical industry. Because the pharmaceutical industry and many government entities have long been criticized and questioned by individuals in society, this tactic is able to play on individual and societal mistrust of the organizations that provide and promote vaccinations. As such, it is essential to maintain an honest and forthright image in the public eye. When possible, it may make sense for local organizations and healthcare providers to deliver vaccine messaging and advocate for community health and preparedness.

While a brief analysis of the anti-vaccination campaign strategies is very informative, it should not be taken out of the context of the larger picture. Influences on the decision to or not to vaccinate will depend on the global political and cultural climate, burden of disease, attitudes of trust, quantity and quality of risk messaging, comprehension and retention of the message, prevailing myths and beliefs regarding safety and efficacy of vaccines, current individual and group decision-making dynamics, and the context in which one is making a decision. While understanding the counterargument can strengthen messaging approaches, particularly when needed most, the counterstrategies mentioned here should occur in tandem with those completely unrelated to anti-vaccinationist group response. A more detailed review of specific strategies to overcome vaccination resistance is discussed at length in the following section.

## 7.0 Strategies to Increase Vaccination

In a broad sense, there are three approaches to increasing the uptake of vaccines in a population (Offit, 2011). The first is taken from a graph prepared in 1998 by Robert Chen (Figure) at CDC that demonstrates the natural cycle of increased vaccine uptake → decreased incidence of disease → decreased vaccine uptake → increased incidence of disease and finally increased vaccine uptake to start the cycle over (Infectious Diseases in Children Specialty Forums, 1999). Vaccine uptake is motivated by an increase in disease morbidity and mortality. The effectiveness of this strategy is amply demonstrated in Dr. Offit's work for many vaccine disease entities, most markedly for smallpox and pertussis, both in England and the United States. However, the magnitude of the resultant consequences of decreased vaccine uptake in terms of morbidity and mortality make this an unacceptable medical and/or public health strategy.



The second general solution is to enforce mandated vaccination requirements. Vaccination mandates have played an important role in increased vaccination uptake in the US and EU, however, religious and philosophical exemptions exist to some extent in all 50 states in the US and in most countries in Europe. Elimination of non-medical exemptions is one strategy that could increase vaccination uptake. Dr. Offit sums up his estimate as to the viability of this strategy in these words: “the notion that US courts would eliminate religious exemptions to vaccination, when they haven’t eliminated religious exemptions to lifesaving medicines, is fanciful” (Offit, 2011). This sentiment might be overly pessimistic, however, especially in light of the United States Supreme Court’s 1944 ruling in *Prince vs. Commonwealth of Massachusetts*, which states, “the right to practice religion freely does not include liberty to expose the community or the child to communicable disease or the latter to ill health or death” (*Prince v. Massachusetts*, 1944). While individual and religious liberties are held as sacrosanct in the US and E.U., even more so are the rights of the public, and our children in particular, to enjoy the state’s protection from preventable disease and loss of life.

The “police power” of the states within the US to mandate vaccination was established by the 1905 US Supreme Court case *Jacobson v. Massachusetts*, which upheld the validity of an ordinance of the board of health of Cambridge, Massachusetts to vaccinate all its citizens against smallpox based on the premise that “There are manifold restraints to which every person is necessarily subject for the common good” (*Jacobson v. Massachusetts*, 1905). The right of states to require vaccination has since been repeatedly upheld in the US, and most European nations maintain the right to mandate and enforce vaccination. Throughout the history of vaccination, however, enforced mandates have been met with passionate opposition and resistance, even rioting and violence. Philosophical and political objections to mandated and compulsory vaccination warrant careful deliberation regarding individual and state rights.

First, the distinction between mandatory and compulsory vaccination must be made. Compulsory vaccination allows the enforcement of a legal requirement to vaccinate that can result in individuals being vaccinated by force. There is a long history of compulsory vaccination, especially associated with smallpox;

unfortunately, the first anti-vaccine movement also resulted from these programs. These movements have evolved and strengthened over the years, and, as detailed elsewhere in this report, they are a potent, virulent force to be contended with in our efforts to promote vaccination programs. The very notion of compulsion can be perceived as antithetical to the basic liberties of free peoples, and the use of compulsion will predictably lead to a significant backlash, providing ammunition to vaccine opposition movements.

In recent times, one only need to look at the compulsory vaccination policy for anthrax vaccine that was adopted by the US prior to the first Gulf War for an illustration of the predictably negative reactions to compulsory vaccination. The media frenzy surrounding service members who refused vaccination and the subsequent attacks of the anti-vaccine forces led to distrust and negativity regarding the anthrax vaccine that still remains. To this day, anthrax vaccine is looked upon with such great suspicion and apprehension by policy makers, that it has been virtually ignored by those charged with medical counter measures (J. James, personal communication, August 18, 2012).

In contrast to this, a mandated vaccination program is one in which an individual can refuse vaccination, but refusal entails a penalty, usually the denial of a social privilege such as attending school or working in a hospital. Vaccine mandates have tended to elicit strong negative reactions from subsets of the population, and, over time, the concerns of these groups have led to the allowance of medical, religious and philosophical exemptions to vaccine mandates, eroding their effectiveness. Mandates have, however, been responsible for improved vaccine uptake in many instances, conferring significant benefit to the public, or population good. Slovenia has one of the world's most aggressive vaccination programs, mandating vaccination against nine designated diseases under threat of heavy financial penalty, allowing only for committee reviewed medical exemptions. Slovenia also boasts a greater than 95% compliance rate for mandated vaccines (Walkinshaw, 2011). While the demonstrated effectiveness of vaccine mandates demands their consideration for strategies to improve vaccine uptake, there are profound and complex ethical, philosophical, political and practical challenges inherent to mandates that are difficult to resolve with social "equity."

The World Health Organization (2007) has no official policy on mandatory vaccinations, but Alison Brunier, communications officer for Immunizations, Vaccines, and Biologicals at the WHO has recently written: "While it is preferable that high community demand and acceptance make community vaccination programmes unnecessary, WHO understands that some countries may wish to move in that direction when faced with declining vaccination rates and outbreaks of disease" (Walkinshaw, 2011). This stance underscores the great problem with vaccine mandates: they are an imperfect solution to a very serious problem. One possible approach to making mandates more acceptable would be the formation of a multi-national commission to better delineate individual vs. societal rights and propose model legislative remedies to better address this complicated, multi-faceted issue.

Particularly pertinent to TellMe is the question of mandating an annual and/or pandemic influenza vaccine for healthcare workers. Commentary from an ethical perspective by Miller and Ross will be used as a framework to introduce the dilemma of mandating influenza vaccination for healthcare workers, with inserted critical observations, as appropriate (Miller, & Ross, 2010).

The commentary relates to the International and US guidelines recommending influenza vaccination for healthcare workers. This recommendation is based on a general acceptance that this practice reduces nosocomial infection and reduces staff illness and absenteeism, even though there is no good scientific

evidence demonstrating decreased nosocomial spread. On this basis, the ethical physician imperatives of non-maleficence (do no harm) and beneficence (act in the patient's best interest) certainly support mandated HCW vaccination. The most compelling counter-argument is grounded in the ethical principals of respect for an individual's rights and autonomy. Competent adults have the right to make their health care decisions, and in absence of posing imminent and serious danger to others (e.g. TB, Smallpox), they cannot be compelled to receive medical intervention. Absent infection, a HCW not immunized against influenza poses no imminent danger. This is particularly true in light of overall population vaccination rates and an inability to contribute to herd immunity (further discussed below).

This conclusion is further supported by the WHO report on ethical public health responses to influenza pandemic: "measures that limit individual rights and civil liberties must be necessary, reasonable, proportional, equitable, non-discriminatory, and in full compliance with national and international laws" (WHO, 2007). These principles, especially necessity and reasonableness, cannot be satisfied scientifically or ethically in mandating HCW influenza vaccination. Based on these considerations, mandated programs, by generating individual and collective anger, hostility and alienation, may, as with compulsory programs, feed and support the anti-vaccination forces without any measurable clinical or public health benefit.

On a practical level, penalties to the individual HCW and the institution imposing the mandate must also be considered. The institution must consider "exclusions" and be prepared to assume liabilities for vaccine related side effects. The individual HCW is threatened by loss of job, stigmatization and career disruption. Both the individual HCW and the institution issuing the mandate face the legal quagmire attendant to actions and policies that may or may not be legal. And, as history has illustrated, although mandates are very effective when first implemented, over time they can breed resistance, legal battles, exclusions, and eventually decreased vaccine uptake rates. Such challenges are demonstrated by attempted mandates for healthcare workers to receive influenza vaccination in the US (Buppert, 2010).

Driven by the Healthy People 2020 objective of 90% influenza vaccination among healthcare workers, aiming to double the 2008 vaccination level of 45% (Healthy People 2020, 2012), a number of hospitals instituted vaccination requirements during the H1N1 pandemic. In one state, New York, the State Health Department adopted an emergency requirement that healthcare workers in hospitals, home health agencies and hospice care receive both the seasonal and the H1N1 influenza vaccine. However, the mandate was met with opposition from New York's health care unions. Ultimately, a group of nurses filed a lawsuit that successfully halted enforcement of the requirement. The state subsequently suspended the mandate due to a well-documented shortage of H1N1 vaccine. New York was unsupported in its initiative. It was the only state to adopt a vaccination mandate, and neither the World Health Organization (WHO) nor the Centers for Disease Control and Prevention (CDC) recommended mandatory H1N1 vaccinations for healthcare workers at that time (Hartocollis, & Chan, 2009).

In spite of their numerous challenges, however, mandated HCW vaccination continues to be supported by many official health organizations and professional medical associations, and many hospitals and health care systems continue to use vaccination mandates for healthcare workers. Just recently, the state board of health in Colorado voted to adopt a seasonal influenza vaccination mandate that will require certain health care settings such as hospitals and nursing homes to ensure 90% of their healthcare workers are vaccinated (Booth, 2012).

The National Vaccine Advisory Committee (NVAC), under direction from the US Department of Health and Human Services (HHS) Assistant Secretary for Health (ASH), established the Health Care Personnel Influenza Vaccination Subgroup (HCPIVS) to prepare recommendations and strategies to achieve the Healthy People 2020 annual goal for seasonal influenza vaccination coverage. The NVAC approved four recommendations based on the premise that healthcare workers “who are committed to promoting the welfare of patients and the health of the public, and to safeguarding their own and their colleagues’ well-being, have an ethical responsibility to take appropriate measures including vaccination, to prevent the spread of influenza infections in health care settings.” (U.S. Department of Health and Human Services, 2012) The four recommendations presented:

- Health care employers should institute comprehensive influenza infection prevention programs to reach the Healthy People goal of 90% of healthcare workers vaccinated.
- Health care employers should integrate seasonal influenza vaccination programs into existing infection prevention and occupational health programs.
- HHS should work with the CDC and the Centers for Medicare and Medicaid Services to standardize tools for measuring healthcare workers’ vaccination rates across all healthcare settings.
- If health care employers have implemented the above three recommendations and still have not achieved the Healthy People goal of 90% of healthcare workers vaccinated, then they should consider an influenza vaccination requirement that allows medical exemptions and they should also consider allowing other exemptions.
- HHS should continue to encourage ongoing research and development efforts toward new and improved influenza vaccines and vaccine technologies (U. S. Department of Health and Human Services, 2012).

The American Medical Association also offers support to mandated HCW vaccination in its Code of Medical Ethics, which asserts that physicians have an ethical obligation to:

- (a) Accept immunization absent a recognized medical, religious, or philosophic reason to not be immunized.
- (b) Accept a decision of the medical staff leadership or health care institution, or other appropriate authority to adjust practice activities if not immunized (e.g., wear masks or refrain from direct patient care). It may be appropriate in some circumstances to inform patients about immunization status. (American Medical Association, 2011).

Healthcare workers are mixed in their support for mandated health care worker vaccination. In a standardized survey to identify common barriers and facilitators for accepting H1N1 Pandemic vaccine in healthcare workers across Hong Kong, Singapore and Leicester, UK. 25%, 42% and 75.3% of respondents in Hong Kong, United Kingdom, and Singapore, respectively supported the concept of mandatory pandemic influenza vaccination of healthcare workers (Chor, et al, 2011). In a recent study based on a questionnaire mailed to 1600 physicians and nurses (69% response rate) in Minnesota, only 58% of physicians and 47% of nurses felt that legal mandates were acceptable even when “all other means have been exhausted” (Henriksen Hellyer et al., 2011).

Finally, it should be remembered that mandates are initially very effective. In the TellMe project, we are preparing for the next novel bio-event; if required, a vaccine mandated program could affect rapid uptake

of a vaccine and potentially curtail the propagation of disease. A mandate approach would likely be maximally effective in areas not already burdened by mandates for adult vaccinations.

Clearly, vaccination mandates bring with them significant challenges and consequences. Health care worker vaccination, however, remains an important public health goal. Additionally, support from health care professionals for vaccination in general and as active participants in vaccination efforts is critical for vaccine acceptance among the general population, as demonstrated in Section 4 of this work. This is the basis of Dr. Offit's third general strategy in increasing the uptake of a vaccine in a population.

Dr. Offit's third strategy involves the health professions becoming more actively involved in this issue of vaccination acceptance. He proposes that health care professionals improve vaccine acceptance by becoming better informed, influencing behaviors on the part of both care providers and the general population and finally engendering an increased "trust" with regard to the knowledge, motivations, abilities and commitments of those involved in developing, producing, approving, distributing, administering and monitoring vaccines. This strategy, while the least clearly defined, is the basis of vaccination efforts that target individual vaccine reluctance and resistance. While philosophically and politically based vaccine opposition can be difficult to change, vaccine resistance based on personal and societal health decisions and risk analysis is believed to be less rigid and more open to influence. Within this group, trusted health professionals can improve vaccine acceptance through personal example; unequivocal vaccination recommendations based on scientific evidence; accurate and clearly explained information with a preparedness to counter common misconceptions and cognitive errors; and using effective timing strategies to take advantage of heightened vaccine acceptance in various settings and emotional states.

Dr. Offit (2011) fully recognizes the inherent difficulties in achieving such a level of trust in medical professionals, especially given the virulence of anti-vaccine groups globally and their liberal and deliberate use of misinformation, disinformation and outright falsifications, delivered through hostile and personally demeaning attacks from popular media platforms and expanding Web 2.0 outlets. However, strategies to improve health professional support and delivery of vaccinations have the potential to significantly improve vaccine uptake, especially within the context of highly vaccinated communities that are trending towards greater vaccine resistance.

Medical professionals play a crucial role in vaccine efforts that attempt to avoid relying on coercion or increased disease morbidity and mortality to motivate vaccine uptake. It is therefore important to look at current beliefs, knowledge, practices, participation and recommendations of health care professionals regarding vaccination and vaccine efforts.

As with so many of the other areas addressed in TellMe, the peer-reviewed and gray literature published on influenza vaccination of healthcare workers is too voluminous to thoroughly review. Furthermore, most of what is published relates to narrative descriptions, professional opinions, and empirical reports. Reports that are supported by data driven methodologies rely on distributed telephonic and web-based surveys of varying scope. Although the gold standard case-control methodology defies application in the area of interest, useful retrospective and prospective cohort studies have been reported. Unfortunately, even when good data are available, they defy comparisons across populations due to varying demographics, socio-economic factors, political structures and health systems between and within populations.



An additional problem in comparing the literature on healthcare workers is the lack of a consistent definition as to who is and who is not included. Most publications tend to consider healthcare workers caregivers, such as doctors and nurses. Others include all personnel, including support staff, who work in a health care facility, or they focus on some other discrete group such as student nurses or medical students. Some address only inpatient or outpatient environments and others include both. This is important, because many of the observations, concerns and strategies may, in different countries, be applicable to particular health professions to a greater or lesser degree. For example, in the US, nursing and pharmacy professions play an increasingly significant role in influencing vaccine uptake in the population, and it is important to know whether they are included in studies that examine HCW vaccination. It should be noted that from a global perspective, it is the perceptions, behaviors and practices of medical professionals that are consistently of paramount importance (Hansebout, 2012).

The difficulties inherent in review of this area are well illustrated by a study that sought to identify and assess evidence for the effect of vaccinating HCWs on vulnerable patient groups (Dolan, 2012). The study identified 12,352 citations from health care databases (10,713) and other sources. Of these, only 17 met the inclusion criteria, and only 4 were randomized controlled trials, each of which exhibited some degree of bias. The overall finding was that evidence is limited in supporting vaccination as a protective factor for respiratory disease. Accepting this conclusion as fact, however, demonstrates a common fallacy, utilizing a clinical outcome standard to measure a public health outcome. The attempt is made to quantify that which has not occurred. The rationale for vaccinating Healthcare workers is epidemiologically sound, and it needs to be one of our core strategies in minimizing influenza related morbidity and mortality. Studies such as this one, however, demonstrate how the type and breadth of research concerning HCW vaccination can lead to conclusions that are not scientifically sound, and important health strategies can fall victim to not heeding the old philosophical adage, the absence of proof is not the proof of absence.

In another review article it is noted: “health care workers are particularly exposed to influenza infection in both the general community... and the work place. Close proximity to patients, and a constant flow of visitors and co-workers may increase the infection risk.” It is that interaction between healthcare workers and patients that forms the basis for necessitating vaccination of healthcare workers in terms both of occupational safety and health and patient safety (Hofmann, Ferracin, Marsh, & Dumas 2006). In spite of this, overall, influenza immunization rates among HCW’s were found to be unacceptably low. Reasons for low vaccination were: 1) a misperception of influenza versus vaccine risks and the HCW’s role in transmission, and 2) a real or perceived lack of accessible, free vaccine (Hofmann, et al., 2006). Weingarten, Riedinger, Bolton, Miles, & Ault (1989) published the results of a survey administered in a Medical Center with no formal annual immunization plan. Only 5.3% of the healthcare workers surveyed received vaccination prior to the 1986 – 1987 influenza season. Subsequently, 35.3% of hospital employees developed a flu-like illness, 76.6% of whom cared for patients while ill. Fear of adverse reactions, avoidance of medications and inconvenience were the primary reasons cited for not receiving the vaccine.

Against this backdrop of documented low seasonal influenza vaccination among healthcare workers, it is interesting to note that for the 2009-10 pandemic vaccine, as of January 2010, only 37% of HCW in the US had accepted pandemic H1N1 vaccination, whereas 64% had taken the annual influenza vaccine (CDC, 2011a). In comparison, across 27 countries, the VENICE (Vaccine European New Integrated Collaboration Effort) reported that all 27 EU countries recommended vaccination of some, if not all, healthcare workers. Thirteen countries reported uptake rates ranging from a low of 3 (Slovakia) to a high of 68 (Hungary) (Mereckiene, et al., 2012).



A survey was reported from Canada on attitudes and practices of family practitioners (FPs) regarding Pandemic H1N1 vaccine. A mail-based questionnaire was sent to a sample of 1182 FP's and all 1852 Canadian pediatricians with return rates of 18 and 39 percent respectively. The survey was conducted prior to availability of vaccine and demonstrated that at that time 80% intended to be vaccinated, and the majority believed that H1N1 was potentially serious and that the vaccine was safe. The most trusted source of information was that from professional associations, and interestingly, 47% of FP's and 37% of pediatricians felt their knowledge was insufficient. Of particular note is the finding that physician intention to receive the vaccine and acceptability of the vaccine among vaccinators were the most significant factors influencing recommendation of vaccination to their patients (Dube, et al., 2010).

The importance of vaccinator support of the vaccination strategy is paramount to insuring program success (Offit, 2011). Studies clearly indicate the importance of recommendation by a trusted person, in particular one's physician, as essential to ensuring success in influenza vaccine uptake (Hansebout, 2012). Unfortunately, studies have shown surprisingly low uptake of influenza vaccine among physicians, prompting one to legitimately question why we would expect a patient population not to be influenced by their physicians' behavior. An IOM report sums up this clear barrier to uptake of influenza vaccination in the general public: "only 30 percent of healthcare workers were vaccinated as of January 2010.... This is problematic.... Because healthcare provider support is critical in increasing vaccine uptake" (Institute of Medicine, 2010).

Among Dutch general practitioners, the seasonal influenza vaccination rate was 36% for 2007-8. Following active recommendation and government urging as to the importance of vaccination, a questionnaire survey was mailed to 810 GP's and 300 GP-trainees in February of 2010 with overall response rates of 83% and 90% respectively. Vaccination uptake rates were reported to be 63% and 85% among GP's and 47% and 77% among trainees for seasonal and pandemic H1N1 immunizations, respectively. Reducing the risk of infecting patients and personal protection were the strongest motivators of increased vaccine uptake, suggesting that government encouragement was effective in improving vaccine uptake among physicians and medical students. (Opstelten, van Essen, Heijnen, Ballieux, & Goudswaard, A., 2010)

In a study by Chor, et al., (2011) 6318 questionnaires were distributed with response rates of 27%, 95% and 75% for Hong Kong, Singapore, and Leicester respectively. The single most common factor associated with vaccine acceptance was having received 2009 seasonal vaccine. Side effects was the strongest negative correlate. Fear of infection and health authority advice were the main reasons for accepting vaccinations, but uptake rates only ranged from 25% (Hong Kong) → 42% (UK). Of particular importance to TellMe, the survey demonstrated among this group of respondents that the media, not scientific publications, served as the primary source of information on vaccination.

A recent study based on a questionnaire mailed to 1600 physicians and nurses (69% response rate) in Minnesota brought out some interesting contrasts in the attitudes and behaviors between these professions. Both physicians and nurses had above average self-reported vaccine (H1N1 Pandemic) uptake rates (85% and 62% respectively), but physician compliance was significantly higher. Physician vaccine acceptors cited "worry about transmission" as their primary impetus, while nurse acceptors cited "following advice from health authorities." The high overall vaccine uptake rate was attributed to a best-case scenario of a perceived extraordinary threat leading to high demand for a vaccine in limited supply. However, the survey does reinforce both the efficacy of educating health care professionals about their

responsibility to employ every reasonably available strategy to prevent transmission of communicable disease to patients, as well as the importance of communication through trusted health authorities (Henriksen Hellyer, 2011).

A literature review of 32 primary articles addressing HCWs' attitudes towards influenza vaccination indicates that vaccination campaigns with free vaccine and educational programs seem to lead to higher vaccine uptakes, especially in the US. In this study, misperceptions regarding the risk of influenza, the risk of vaccination, and the role of healthcare workers in transmitting infection; and lack of easily accessible vaccine were found to be the main barriers to vaccinations. At the time the review was performed, annual vaccination of healthcare workers was highly recommended in the US and in most European countries, yet uptake rates were universally low across the US and Europe with a median uptake of about 30%. An interesting contrast found in one of the reviewed studies from Germany found that 44% of homeopathic physicians considered vaccination unnecessary as opposed to only 21% of allopaths. The original article comments that homeopaths do not dismiss vaccines, rather they tend to assess them as separate entities and support the "classic" vaccines at the same level as their allopathic counterparts. The authors of this literature review also make note of the lack of consistency in the definition of health care worker found throughout the reviewed studies (Hoffman, 2006).

Further evidence of unacceptably low influenza vaccine acceptance among healthcare workers is found in a study regarding Italian healthcare workers. Two hundred forty-nine physicians and 1,711 nurses responded to a survey administered to Italian healthcare workers on preventative measures against Pandemic H1N1 in October 2009. Among surveyed healthcare workers, 67% of physicians and 31% of nurses would accept H1N1 Pandemic vaccine; 70% of females and 51% of males would not (La Torre, Di Thiene, Cadeddu, Ricciardi, & Bocca, 2009).

Although healthcare workers are at increased risk of infection, can place patients at risk, and play a vital role in an overburdened care system, the numerous studies cited above demonstrate that intended and actual influenza vaccination rates across the US and EU remain unacceptably low. This is in spite of official policies recommending vaccination in the US and most European nations. An evaluation of such policies among European nations showed that 27 EU countries as well as Norway, Switzerland and Russia had established policies promoting vaccination for healthcare workers, especially for Hepatitis B and influenza (Maltezou, et al., 2011). Thus, HCW behavior does not correspond to established ethical imperatives and existing vaccination policies in the US and across Europe.

Another important behavioral aspect of healthcare workers is their attitudes toward vaccinating their children. Among 389 responding healthcare workers in Turkey with children between 6 months and 18 years, 66% had decided to not vaccinate their children, and another 13% were undecided with possible vaccine side effects being the primary concern, followed by questions of vaccine efficacy (Torun, Torun, & Catak, 2011)). This contrasts with findings from a Canadian study of 684 healthcare workers in which high vaccine acceptance was associated with concerns for personal and family safety. Although this study is not published, the author was very involved with health care subject matter experts and policy/communications personnel from the Centers for Disease Control in addressing best communication strategies during the 09-10 H1N1 pandemic. Among these expert groups, there was general and significant consensus that one of the most powerful motivational messages was one that underscored self-vaccination as a means of protecting both one's family and one's community.

The professional lives of physicians and nurses begin in medical and nursing schools. If we are to be successful in affecting positive vaccination behaviors in practitioners, we need to look at influencing their development during the periods of professional education. In one study looking at influenza vaccination behavior among 430 student nurses in England, only 12% of students had received regular annual vaccination and only 28% had ever received seasonal and/or pandemic H1N1. The positive influences on vaccination were perception of being at risk and free vaccination; the primary negative factor was the perception that it wasn't needed. Reasons for accepting vaccination were risk of disease outweighing risk of vaccine and a recommendation to be vaccinated. An indirect driver was level of knowledge (average correct score on knowledge questions was 68%), but source of knowledge was often e-health websites (Hunt, & Arthur, 2012). An analysis of such websites has shown only 10% to be actual public health websites (Betsch, & Wicker, 2012).

Considering the importance of these future professionals on vaccine practices, there are few studies addressing the training of doctors and nurses, or, more importantly, assessing interventions, curricular and/or behavioral, that will lead to improved vaccination and vaccine knowledge. The need for knowledge improvement is well demonstrated in a medical online assessment of 10,626 participants, 90% of whom were physicians and nurses. The results were quite variable, but overall knowledge scores were far too low to expect these practitioners to make informed decisions for themselves or their patients.

Along these lines, the problem of health professionals who disseminate bad information to the public must be considered in developing strategies to overcome vaccine resistance. Seemingly qualified health professionals, considered authoritative experts by the public, have been known to publish erroneous information based on unproven, scientifically unsupported theories, and rarely, intentionally falsify data and conclusions published in peer-reviewed literature. Examples of such cases were described in section 4 in the discussions of Dr. Wilson's and Dr. Miller's erroneous conclusions as to deleterious effects caused by pertussis vaccine; Dr. Wakefield's more recent misconduct in publishing an unsubstantiated association between MMR vaccination and autism; and current celebrity physicians who offer vaccination recommendations not supported by official health organizations or valid scientific data, such as Dr. Bob Sears. Each of these instances of physician communicated misinformation led to decreased vaccination uptake or delayed vaccination. Regarding the latter example of Dr. Bob, it should be noted that vaccine acceptance might have been improved in some cases, due to his willingness to partially immunize and work with vaccine hesitant parents. Trust in celebrity physicians like Dr. Bob can have a meaningful positive influence on vaccine acceptance within some contexts.

The importance and effectiveness of the physician's role cannot be overemphasized. An IOM report comparing the drop in immunization rates for DPT in the US and England in response to the widely published alleged association between pertussis vaccine and severe neurological sequelae showed that vaccination rates fell slightly in the US, and in England they dropped precipitously, ushering in one of the worst epidemics of whooping cough in modern history. Dr. James Cherry, actively studying pertussis at the London School of Hygiene and Tropical Medicine found that "it wasn't the public, it was the doctors. Family physicians (in England) stopped vaccinating." A subsequent survey published in the London Sunday Times found that 47% of general practitioners would not recommend pertussis vaccine (Offit, 2011). Physicians, like the public, are influenced by information coming from other health professionals, especially when published in trusted medical journals. These physicians directly and indirectly affect vaccination levels by way of their recommendations, examples and practices (Omer, Salmon, Orenstein, deHart, & Halsey, 2009).

Another secondary, if unintentional, effect of publications that gain broad notoriety is the predictable spate of studies that will be influenced by the initial publication. A recent report found a relationship between increasing autism rates and vaccination in children with a conclusion that there is a possible link between vaccines and autism (DeLong, 2011). This is another example of association, not cause and effect. While these types of studies are certainly necessary to support further study efforts, it cannot be ignored that a myriad number of other environmental factors might also demonstrate some degree of association and need to be studied as well. Publishing studies with inflammatory conclusions as yet unsubstantiated by evidence offers significant opportunities for physicians and the general public to misinterpret information and form negative opinions about vaccines without any scientific basis. The readiness of the anti-vaccination groups and the media to report association as causation further jeopardizes vaccination efforts. To effectively manage this, we must be proactive in delivering our message utilizing the full array of communication platforms. Messaging content and platforms specifically targeting health professionals should also be considered. As demonstrated, physicians exert great influence on vaccine uptake, and they are not always influenced by the same factors and sources as the general public.

Targeted messaging as a strategy for improved vaccine acceptance warrants consideration. An Institute of Medicine Workshop Summary on pandemic influenza recommends categorizing Americans into three groups with regard to vaccine uptake. Based on experience of the Center of Disease Control, groups identified were: 1) individuals who routinely receive the influenza vaccine – this group is more accepting of vaccines and includes a majority of those above 65; 2) individuals who sometimes receive an annual immunization – these individuals, who comprise the largest population segment, make an active decision based on various inputs such as perceived risk of disease versus risk of exposure and perceived severity of disease; and 3) those who do not get and do not intend to get the influenza vaccine--this group tends to feel that the vaccine is ineffective, unwarranted, or even dangerous (Nowak, 2005).

This population break down has many shortcomings. It does not consider variances across or within populations, is defined only in the context of the influenza vaccine, and perhaps most importantly, for the third or resistant group, it does not differentiate between those who are reluctant, versus resistant, versus opposed. These distinctions are important, because the stated purpose of defining different groups is to enable tailoring of specific messages to reach them. Cultural, ethnic, social and linguistic differences within various governmental and national health systems will further complicate attempts to stratify the population for targeted messaging. While daunting, the significant public health impacts of infectious disease necessitate developing strategies that will improve vaccine acceptance, and these strategies must particularly target segments of the population who are vaccine reluctant or resistant. While deficiencies will be inherent in any given model of categorization, Nowak's core strategy cannot be dismissed. If messages are to be effective, they must be targeted.

A useful approach to targeting vaccination efforts might be to apply Pareto's Principle, also known as the "law of the vital few," or, more universally, the 80-20 rule. Within the context of vaccination strategies, this would translate into focusing efforts on the sub-group(s) that would potentially give the greatest yield. Referring back to Nowak's groupings, fewer scarce resources would be expended on the first group, and a much greater percentage would be directed to the second group, which would potentially provide the greatest yield. The third group is a special case in that it needs to be subdivided between those who are passive resisters, for whom messaging will probably have limited effect, and the activist opponents, whose counter-messages must be addressed in order to successfully improve vaccine acceptance.

In order to communicate effective targeted messages to any of these groups, we need to better understand the makeup and demographic characteristics of the target population. This is particularly important when dealing with the anti-vaccination groups. An understanding of who comprises the extremist groups will enable the development of more affective strategies to blunt their rhetoric and address the perceived and/or real concerns expressed by the broader, less extreme, grass-roots elements. For example, within the United States, the anti-vaccination advocate tends to be a Caucasian, married mother with a college degree, an annual household income greater than \$75,000, and one who makes her own vaccination decisions (Smith, Chu and Barker, 2004). This information could be used not only to target appropriate audiences with messaging that refutes extremist claims, but also to discredit sources of inaccurate, inflammatory anti-vaccination assertions.

Many additional strategies have been recommended and implemented in an effort to increase vaccine uptake. There are literally thousands of reports documenting vaccination efforts by individual practitioners and researchers as well as by institutions and government agencies from the local to the national level. Some of the reports can be found in the traditional peer-reviewed literature, but more are documented in what is termed the gray literature, which includes agency reports and articles taken from the popular, non-peer reviewed literature. Web 2.0 modalities and web sites such as Wikipedia serve as important resources for information outside of the peer-reviewed literature that is relevant to vaccination efforts. The quality of the data covers the spectrum from anecdote through empiricism and descriptive epidemiology through analytical and case control methodologies. Unfortunately, but of necessity, the anecdotal and empirical far outweigh the analytical and outcome reports. Further complicating the review are the unreported data, those data derived but for a multitude of reasons, not reported.

Given the admixture and volume of inputs a complete review of vaccine uptake strategies would be impossible without unlimited resources, and a cogent meta-analysis would yield little in terms of useful information due to a lack of uniformity across reports. However, the data and information that are available are valuable; a great deal of fine work has been done across the US and the E.U. in regards to developing effective vaccination strategies. What follows is a review of a representative number of reports that recommend strategies for improved vaccine uptake, roughly in chronological order.

The first report offers the 10 strategies defined by the CDC convened “Task Force on Community Preventative Services” (CDC, 2010). The strategies derived were:

- 1) Standing orders – pre-prepared written orders with appropriate criteria for use in multiple practice settings. This has been found to be the single most effective tool for increasing vaccination uptake. Multiple studies document this, including one that demonstrated that 40% of in-patients with standing orders received a flu shot versus 10% without.
- 2) Computerized record reminder – computer generated vaccination reminders linked to patient records. This strategy is effective for those with medical contacts but misses others. In one practice, vaccination rates increased from 29% to 86% for pneumococcal vaccine.
- 3) Chart reminders – can use a variety of formats but is again linked to medical records and does not reach the general population. One report showed an increase in influenza vaccination from 18% to 40% using this approach.

- 4) Performance feedback – retrospective evaluation of provider performance compared to a set goal or standard with built-in incentive to attain a goal. One report documented achieving an overall influenza vaccination rate of 66% (6% higher than the national goal) versus 34% in a control group.
- 5) Home visits – this approach can range from mail and telephonic contacts to the actual delivery of vaccination services to the home environment. This can be well targeted to higher risk groups but can be resource intensive. Several studies have shown a modest overall benefit to include one that showed an increase in influenza vaccination of 20% comparing older immobile individuals in the U.K.
- 6) Mailed/telephone reminders – best adapted to stable, managed care practices that have electronic medical record capabilities. A study showed an influenza vaccine uptake of 37% in the reminders group versus only 9.8% in a randomized control group (McDowell, 1986). Mailed and telephone reminders have been found to be equally effective.
- 7) Expanding access – multiple possible approaches such as expanded hours, setting up more convenient vaccination sites, reducing administrative barriers, etc. This strategy can broaden target population to include higher risk individuals but at increased levels or resource requirements. A doubling in overall vaccination rates was accomplished by increasing availability of vaccine plus a telephone reminder.
- 8) Patient education – this strategy was narrowly defined to educational material being given to individuals during a clinical contact. In the limited context defined this can be a very effective intervention. Pneumococcal and influenza vaccine uptake rates of 75% and 78% were reported utilizing a hospital pre-discharge educational program as compared to a control group with 0% uptake.
- 9) Personal Health Records (PHRs) – PHRs, not official medical records, that contain recommended vaccination information are issued to patients. This, unfortunately, can be a complex intervention as it is dependent on the adoption and creation of a PHR within a practice unit. However, when used, it has been shown to be an effective strategy, with one report showing an increase in pneumococcal vaccination rates from 4.8% to 20.5% with provision PHRs.
- 10) Measuring and Tracking Rates for Most Strategies – Two approaches are recommended to assist in standardizing the measures used to evaluate the effectiveness of a given vaccination strategy.

These are:

- Compare vaccination rates pre- and post-implementation of the strategy, and
- Set a vaccination goal prior to implementing the intervention and track the immunization level over time.

At first glance one might question the apparent omission of a case/control methodology; however, the task force was addressing measures, and the first measure above can be used to support a case/control methodology.

Numerous other interventional strategies to promote increased vaccine uptake have been recommended based on information from studies looking at factors and influences associated with vaccine uptake. One such report on H1N1 vaccination policies and coverage in Europe, documents coverage rates for 22 of 26 EU/EEA countries. As with state level data in the US, the rates showed a very wide variance between countries, although the ranges were somewhat comparable. The authors address potential factors



influencing vaccination rates and go on to suggest a strategy to improve effectiveness of vaccine programs. The authors recommend implementation of better vaccination monitoring systems and call for clearer delineating of the overall vaccine strategy – protecting the vulnerable vs. reducing transmission (Mereckiene, et al., 2012).

Another recommended strategy to increase influenza vaccine uptake comes from the previously cited review of 37 articles on factors associated with uptake of vaccine against pandemic influenza using a framework of Protection Motivation Theory. Based on their findings, authors recommend highlighting risks of pandemic influenza, demonstrating efforts to ameliorate vaccine risk, and countering the perception that inaction is safer than action (getting vaccinated) (Betsch, & Sachse, 2012). What is not well addressed is the relative timing factor as to the public's peak perception of risk and availability of vaccine. This effect is well documented for the 2009-2010 H1N1 pandemic, showing higher demand for vaccine prior to its availability with a significant lessening of demand as the perception of risk declined over time (Gidengil, et al., 2012).

The potential effectiveness of a strategy that targets children in vaccination efforts is illustrated by the success of a statewide influenza program involving a school based initiative, as reported by Effler et al., (2010). Following the 2008 recommendation by the US Advisory Committee on Immunization Practices to expand the target population for annual influenza immunization to include children between 6 months and 18 years of age, influenza vaccine was offered on a free and voluntary basis to 132, 775 children through a network of 627 clinics at 340 schools statewide, beginning in 2007-08 and continued yearly. Overall student participation averaged approximately 46%. A signed parental consent was required for immunization. Unfortunately, no data were presented on the parents who did not participate.

One of the great advantages evolving from the program was having a ready infrastructure to support and administer the H1N1 pandemic vaccine (Effler, et al., 2010). On an epidemiological level, another important argument to support this strategy of targeting children, is that depending on the  $R_0$ -value (to be addressed later) of the infecting organism, vaccination of 50% of school age children might significantly contribute to achieving a protective level of herd immunity.

Further support for this strategy comes from the success of a vaccination program in Japan. The mandated influenza vaccination of school children in 1987 was thought to prevent almost 50,000 deaths per year, possibly due to achieving herd-immunity. With discontinuance of the mandated program in 1994 all cause mortality significantly increased (Reichert, et al., 2001). The Japanese experience also illustrates the potential effectiveness of a mandate to improve vaccine uptake.

Although national and cultural differences were apparent in individual responses to a survey regarding the 2009-10 H1N1 pandemic, vaccine uptake rates were low across most nations and among healthcare workers. This was attributed to a lack of individual concern and an unwillingness to be vaccinated. In response, timelier, appropriate data-driven health information, especially in open societies where trust in government might be an issue is recommended (Poland, 2010). Supporting this recommendation is a study on messaging impact on vaccine uptake among 311 individuals in Italy aged 65 or older. The group was divided into three sets, which received no health communication, didactic health communication, or narrative communication. Compared to both no and didactic communication, narrative communication was related to perceiving both higher risk from disease and efficacy of vaccine, although, no differences in intent to be vaccinated were shown (Prati, Pietrantonio, & Zani, 2012)



Younger children are often the targets of vaccination campaigns, but without the existence of a mandate, the parent(s) will be the primary decision maker and will exert the strongest influence on vaccine uptake. It is therefore important to address parental acceptance in strategies for vaccination efforts. Parental attitudes regarding the pandemic H1N1 vaccine were studied among 611 Turkish parents with children between 6 months and 5 years of age, who completed a survey. Of these, 226 (37%) had their children vaccinated. Decreased acceptance was most strongly associated with education levels less than 12 years, no immediate relative in health care, having a child less than 36 months of age, and influences from friends and the media. Factors most strongly associated with vaccine refusal were believing other preventative measures were more effective and perception that the pandemic itself was exaggerated. Conclusions were that national health authorities, health care providers and the media need to better keep the public informed and improve risk/benefit communications on vaccines (Akis, Velipasaoglu, Camurdan, Beyazova, & Sahn, 2011).

Regarding the 2009 pandemic influenza vaccination effort, another strategy that warrants closer examination is prioritizing high-risk groups. The perception of many involved with the program was that the overall effect was a negative one, and prioritizing as a strategy needs careful evaluation. The comprehensive review of data from 20 telephonic national public opinion polls conducted between April 2009 and January 2010 discussed earlier in this paper demonstrates potentially lowered vaccine uptake overall when priority is given to particular groups. When vaccine was available in limited supply and earmarked for priority groups, 70% of adults seeking vaccination were unable to get it and 66% of high priority adults and children seeking vaccination had the same experience. In terms of actual vaccination, a substantially greater proportion of parents had their children vaccinated, but not themselves (Steel Fisher, et al., 2010). This experience suggests that prioritizing distribution of a vaccine may lead to an overall decrease in vaccine uptake, as individuals who might initially accept vaccination later refuse it when anxiety levels are lower.

When considering communication strategies to improve vaccine uptake, another strategy that warrants consideration is expanding the message. The majority of communication efforts target the benefits (individual and population) of the particular vaccine. They describe the true impact of the disease prevented and demonstrate the overall safety of the vaccine itself. However, there are a number of reports that demonstrate additional benefits from individual vaccines and vaccination in general beyond the intended prevention of the targeted disease. A review of 13 million new cases of cancer worldwide estimated that approximately 2 million (15%) were the result of earlier preventable bacterial, viral and parasitic diseases. One notable example is chronic hepatitis B infection and subsequent liver cancer (de Martel, et al., 2012). A Scientific American podcast addressed a study that showed a possible protective effect of smallpox vaccination against HIV (Weinstein, 2010; & Mirsky, 2010). Another study demonstrated slightly better performance in particular neuropsychological outcomes in children who had received all recommended infant vaccinations according to the recommended schedule (Smith, & Woods, 2010). Important population dynamics such as resilience can also be positively impacted by vaccination in populations and sub-populations. Also, health responders in multiple reports have expressed an increased willingness to respond during an anthrax event given prior vaccination. These added benefits of vaccination provide us additional persuasive material to use in our messaging to increase vaccine uptake.

The use of incentives is another strategy that demonstrates potential to improve vaccine uptake. Incentives can take many forms, from deductions on health insurance premiums, tax benefits, and public recognition,

to small incentives such as lunch passes, etc. In Australia, these incentives have been successful in childhood immunization programs using tax credit incentives for meeting childhood immunization requirements. At the local level, multiple initiatives, e.g. entering a vaccinated child into a drawing for an iPod, are also being tried. There is little available data at this time, but studies looking at the effectiveness of such programs would be useful.

In developing and evaluating strategies for vaccination programs, it is imperative to identify the purpose of the vaccination program – to control the spread of an epidemic/pandemic or to prevent individual cases of a given infectious disease. This is critical within the context of TellMe, because depending on the individual disease/vaccine parameters for a given event, the approach might be significantly different when approached from individual case reduction vs. control of epidemic/pandemic spread. Clearly defining the vaccination program goal at the outset is essential to developing appropriate, effective strategies. If we don't accomplish this, we will continue to foster the uncertainties and programmatic conflicts that crippled the pandemic H1N1 campaign.

It must also be taken into consideration that available literature about vaccination efforts and resistance is largely comprised of historical data and studies looking at traditional, fairly universal pediatric immunization programs, seasonal influenza vaccination, and 2009 – 2010 pandemic influenza experiences. Lessons learned from this information may not be directly applicable to attempts to control the pandemic or epidemic spread of an emergent infectious agent. The decision of a caregiver to accept vaccination on behalf of her child, under no perception of immediate threat, is likely motivated by very different factors than an individual's decision to protect himself and others when faced with outbreak of a dangerous disease. Likewise, a different level of intervention would likely be required in order to motivate individuals to accept a vaccine for an apparently mild disease versus vaccine for a highly virulent disease actively spreading within the community. Therefore, the extent to which information presented can be applied to preparing for a novel organism that may well be potent and able to cause widespread fear and concern must be considered. In this scenario, if a vaccine is available, it will likely be in high demand, as with the smallpox experience of the past. Considering vaccination strategies and programs that lead to the successful eradication of smallpox would likely be more applicable to the formation of a plan aimed at preparedness to control an emergent epidemic or pandemic using vaccination.

Variolation and subsequent smallpox vaccination efforts brought with them the earliest anti-vaccination sentiments and movements. The perceived risk of smallpox was extremely high, and the vaccine was highly effective. However, the vaccine also caused well-documented side effects, and the new medical intervention was received with much skepticism. In spite of anti-vaccination movements, however, smallpox vaccination programs were so effective that the naturally occurring disease was eradicated. All of these elements came together in a highly effective vaccination campaign that took place in New York City in 1947 in response to a smallpox outbreak. Without compulsion or mandate, but rather using strong encouragement by health authorities through the media, 6.35 million New Yorkers were vaccinated over a 29 day period (Thorpe, et al., 2004). Remarkably, this represented approximately 80% of the target population.

On a global basis, the Smallpox Eradication Unit was established in 1965 at the World Health Organization, and through its efforts, the World Health Assembly was able to announce in May of 1980 that smallpox was the first disease in history to be eradicated. The Center for Global Development in a case study on eradicating smallpox noted that, "no two national campaigns were alike...vaccination programs had to be

adapted to different administrative, socio-cultural, and geographical situations.” Another observation in the report was that for the United States, the largest single donor to the eradication campaign, the total contributed amount was returned every 26 days in the form of vaccinations no longer needed and disease not treated (Seymour, 2012).

In vaccine efforts aimed at stopping the spread of disease, goals must include the achievement of reaching herd immunity. It is therefore important that those who are developing strategies for preparedness for an emergent pandemic have a good understanding of this concept.

Considering herd immunity and the basic reproductive number  $R_0$  for a given epidemic is important, as it facilitates a more objective, quantitative decision. As we are herein so dependent on the pandemic H1N1 experience, we will use that as a working example. The  $R_0$  is the average number of new cases generated by each infected individual, and herd immunity is the percentage of non-susceptible members of the population needed to effectively prevent further transmission. There is a relationship between these two parameters in that the level of herd immunity needed for community protection (a proxy for the level of vaccine uptake needed) is equal to  $1-1/R_0$ . Thus for an  $R_0$  of 2, herd immunity is reached at a level of 50% non-susceptibles (this would be with 100% vaccine efficacy but is counter balanced by those with natural or induced immunity already infected). When this rate is over 90% as for measles and pertussis, for example, the individual versus population approaches converge, requiring almost universal immunization for either individual or community protection. However, for pathogens requiring lower levels of herd immunity, the alternatives can lead to divergent paths, and vaccination strategies targeting individuals can provide adequate control.

One of the realities of dealing with influenza is that the  $R_0$  is not a constant, as it derives from the virulence and other genetically driven characteristics of the specific influenza sub-type. This becomes especially problematic with influenza, because it means that the required level of herd immunity varies with individual strains. That limitation in mind, the  $R_0$  can be estimated mathematically and the estimate refined as an outbreak continues over time. In the case of influenza, a great deal of study has gone into estimating the  $R_0$  for the H1N1 genotype for both the 1918 and 2009 pandemic, and in each case the most likely estimate is in the range of 1.5 to 2, yielding a herd immunity rate of 50%. (Mikolajczyk, et al., 2009, & Winner, 2009). This fact, plus the given rapid accumulation of previously infected individuals in a community, means that fewer individuals should require vaccination in order to interrupt transmission relative to trying to achieve universal protection.

The very real implications and impacts of programs designed to protect individuals versus limiting transmissions was well articulated in a commentary on the distribution of vaccine in the 2004 – 2005 influenza season. Quoting from this abstract summarizes the situation well:

Despite evidence that vaccinating schoolchildren against influenza is effective in limiting community-level transmission, the United States has had a long-standing government strategy of recommending that vaccine be concentrated primarily in high-risk groups and distributed to those people who keep the health system and social infrastructure operating. Because of this year’s influenza vaccine shortage, a plan was enacted to distribute the limited vaccine stock to these groups first. This vaccination strategy, based on direct protection of those most at risk, has not been very effective in reducing influenza morbidity and mortality. Although it is too late to make changes this year, the current influenza vaccine crisis affords the opportunity to examine an alternative for future years. (Longini, Jr., & Halloran, 2005)

The 2004 – 2005 influenza season was marked by vaccine shortages compounded by marked confusion in the program regarding who should be vaccinated, resulting in a relatively ineffective vaccination effort aimed at protecting individuals. The alternative strategy would have been to develop a program aimed at achieving herd immunity and thus limiting disease transmission. This goal could likely have been achieved through vaccination of school children, a strategy supported by field studies, population experiences and mathematical models.

Unfortunately, the same individual-based strategy of prioritizing vaccine distribution was used in the 2009 – 2010 H1N1 pandemic; and again, vaccine delays and shortages resulted in poor overall vaccine coverage. The alternate program goal of achieving population protection during the H1N1 pandemic (09-10) would have required achieving herd immunity by vaccinating 50% of the population. Considering the reproduction and transmission characteristics of the influenza virus, attaining a goal of preventing individual infection would necessitate closer to a 100% vaccine requirement, an ambitious goal for any vaccine program. The ineffectiveness of past influenza vaccination programs likely resulted from setting the wrong objective, demonstrating the importance of considering overall goals of vaccination programs when developing strategies (Fukuda, & Kieny, 2006).

## 8.0 Conclusions and Recommendations

“Better three hours too soon than a minute too late.”  
*The Merry Wives of Windsor, Act II, Scene 2*

Increasing vaccine resistance is a problem throughout the European Union and the United States. Poor vaccine uptake of influenza vaccine among the general population and healthcare workers in the E.U. and US is also concerning, as is the documented poor uptake of pandemic H1N1 vaccine during the 2009 influenza pandemic. Utilizing information and experience from almost 200 years of vaccination efforts and accompanying vaccine resistance does, however, afford the possibility of developing informed strategies to achieve various vaccination objectives relating to the aforementioned areas of concern, i.e., the increasing resistance to childhood vaccinations; universally poor uptake of seasonal influenza vaccination; and preparedness to use vaccination as an effective intervention to curb potential epidemic and pandemic events. Strategies will vary according to the specified goals of the different vaccination efforts. Recommendations are therefore divided into three different sections, providing proposed strategies based on findings presented in this document.

First, however, there are two highly effective strategies that will apply to each of the vaccine efforts. The first strategy concerns targeted messaging and interventions. Applying Pareto’s principle, the population groups for which resources and interventions would be the most effectively and efficiently applied must be specified for each vaccination effort. Influences on vaccination acceptance vary among population groups. Identifying a specific subset of the population on which to concentrate efforts enables consideration of influences, information resources, and other important characteristics unique to that group. This will result in targeted messaging and interventions that are highly effective for the key strategic groups most likely to impact overall vaccination success.

The second strategy universally applicable to all vaccine efforts is improved health care provider support and participation. This is crucial for many reasons. The literature clearly indicates that recommendation

from a healthcare professional is one of the strongest influences on vaccine acceptance. Healthcare providers also play a role in the delivery of vaccines and can affect vaccine accessibility, convenience, quality of experience and proper distribution. Furthermore, healthcare workers who accept vaccination for themselves play a critical role in reducing disease transmission and influencing patient vaccine acceptance. For these reasons, it is strongly recommended that health care professionals' knowledge of vaccines be improved, and that measures be taken to improve support of vaccine efforts by all healthcare workers. Healthcare workers should actively promote vaccinations in all healthcare settings, as currently modeled within pediatrics.

Possible strategies include:

- Vaccine education and promotion should begin in training. Curricula of all medical professional and medical support schools should include immunization education. Physician and nursing schools should require demonstration of a sound understanding of vaccination and all of its personal and public health implications.
- Target vaccine-promoting literature to professional association publications and newsletters.
- Increase partnership between public health organizations and clinicians. This would encourage and better enable clinicians to understand and act on a population level; and it would involve clinicians in public health messaging, offering insight into individual patient decision-making.
- Make updated vaccination information a part of continuing medical education training and provider licensing requirements.
- Consider the creation of a WHO endorsed “vaccination supporter” emblem that can be used on identification tags, office signs, practice advertisements, etc. The emblem could serve as public promotion for vaccination as well as induce some peer pressure on individual healthcare workers and medical practices to comply with recommended vaccinations and demonstrate public support of vaccines overall.
- Develop multi-pronged programs to address misinformed, erroneous vaccination recommendations from health care professionals. Clear explanations of the errors, misinformation and inherent risks must be targeted to medical professionals as well as public audiences, using the appropriate technical levels and media outlets for each. Do not demonize misinformed celebrity health professionals, but rather express understanding of their positions and offer nonjudgmental explanations to counter scientifically unsupported advice.
- Enforce high standards for acceptance to peer-reviewed literature, requiring more rigorous review of reported data, methods and conclusions.

### **Improving acceptance of childhood immunizations**

In the case of overall increasing resistance to routine vaccination, evidence suggests that the area most amenable to intervention is the vaccine hesitant decision maker. Vaccine hesitant individuals comprise the majority of vaccine refusers, and relative to vaccine opponents, they are influenced to a greater extent by risk perceptions and recommendations from health professionals. There is also evidence that a proportion of parents of under-vaccinated children (children who have some but not all of the recommended vaccines) are not resistant to vaccination; rather, they often have issues with vaccine accessibility related to

economic, social, and in some regions, geographical barriers. Focusing vaccination efforts on these groups would likely have the greatest impact on reducing vaccine refusal and delays.

Mandates requiring vaccination for school entry have been and remain effective, but overly harsh enforcement of mandates and compulsory immunizations have historically led to hostile opposition. Furthermore, current low rates of vaccine preventable disease in Europe and America make it ethically problematic to use overly aggressive mandates and compulsions, as imminent risk is difficult to substantiate. For these reasons, increasing mandates or strengthening their enforcement by eliminating philosophical and religious exemptions are likely not the best strategies to reverse the current trend of increasing resistance to vaccination. Incentives can also be effective in achieving high immunization rates, but they do little to influence the growing concerns regarding vaccine safety and necessity, or to alter the situations of children with poor healthcare access.

Understanding that caregivers are responsible for routine vaccine acceptance, efforts need to be directed toward caregivers using communication platforms routinely used by this section of the population. It was found that consistent influences on vaccine decision-making by hesitant individuals include recommendation from a health professional, perceived vaccine safety, perceived risk from and severity of disease, and vaccine effectiveness. It was further found that emotional influences, such as trust in health providers and the vaccine industry, and desiring to avoid traumatic and painful experiences for their children affect vaccine acceptance.

These findings are the basis for the following recommended strategies to decrease resistance to childhood immunizations:

- Local and national governments should take whatever actions are necessary to ensure that all children have equal access to routine immunizations.
- Health providers should include the positive aspects of vaccination in informed consent papers and in obtaining informed consent. Informed consent should not only focus on risks from vaccination, but on risks of not vaccinating as well.
- Efforts should be made to minimize discomfort during and after vaccination using measures such as ice, analgesics, massage and distraction.
- Health care providers should work with vaccine resistant caregivers, avoiding strategies that will alienate them. Aim for incremental success if full vaccination cannot be persuaded. Acknowledge concerns and be prepared to address them using accurate information. Do not abandon vaccine resistant patients; continue to provide care, and take advantage of every opportunity to further educate about the benefits of vaccination.
- Provide health care providers with suggested counter-arguments to common misconceptions and fears regarding vaccines. Consider creating a handout for vaccine resistant parents discussing the benefits of vaccines and addressing the most common information and reasoning biases and errors that lead to vaccine reluctance.
- Give positive feedback to caregivers praising their efforts to protect their children and community.
- Use positive messaging utilizing cartoon figures, celebrities and trusted authority figures, easy to understand and accurate information, and guidance within the context of informed decision-making.



- Avoid the use of difficult-to-interpret statistics such as relative risks and probabilities that involve very large or small numbers.
- Encourage individuals and civic groups within pro-vaccination efforts and outreaches to enlist the support of celebrity spokespersons.
- Utilize the same communication outlets as vaccine opponents.
- Monitor common Internet search engine results for key terms, and look into ways to ensure that the top results are not anti-vaccination web sites.
- Consider an official endorsement emblem of WHO-approved web sites, so that caregivers seeking information on vaccination can feel confident about the information on those sites and potentially avoid biased anti-vaccine sites.
- Increase public awareness of the continued reality of vaccine preventable illnesses. Consider fundraising campaigns to fight vaccine preventable illnesses in countries where they remain a problem, potentially increasing visibility of the diseases and aiding in vaccine programs around the world.
- Encourage vaccine manufacturers to avoid advertising and to keep vaccine costs as low as possible.
- Encourage vaccine developers to try, when possible, to avoid using highly controversial ingredients such as aluminum, mercury, formaldehyde, and cells derived from human stem cells.
- Advocate for federally/nationally funded vaccination development and administration. If vaccines can be mandated on the premise of public protection, then governing bodies have the obligation to ensure that such public protection is available and provided.

### **Improving seasonal influenza vaccination programs**

In the case of poor seasonal influenza vaccine uptake, it is recommended that the entire current approach be reconsidered. Today's programs rely on targeted vaccination of groups with higher morbidity and mortality associated with the disease and healthcare workers, in order to protect the high-risk groups from healthcare worker transmission of the virus. This individual-based approach is clearly not effective at interrupting transmission or protecting individuals at increased risk, as demonstrated earlier in this paper. The viral characteristics of influenza make the success of vaccinating for personal protection from disease almost impossible. The  $R_0$  value for various influenza strains, which is between 1.5 and 3 (approximately 2 in the case of H1N1), would require nearly universal vaccination to achieve this goal. In contrast, a program that aims for population protection would only need to vaccinate approximately 50% of the population in order to accomplish its goal. Achievement of this objective would not only protect medically vulnerable individuals, but the entire population would benefit from decreased morbidity, meaning fewer lost work and school days, decreased financial loss, reduced need for antibiotics associated with secondary bacterial infections, and less strain on health systems that, in many areas, are already overburdened.

There is some historical evidence as well as mathematical modeling that predict achieving herd immunity from influenza by targeted vaccination of children. Even in the absence of herd immunity, evidence suggests that immunizing children is an effective way to reduce influenza morbidity and mortality in the community. School-based vaccination programs have been very successful at achieving high vaccination rates in children. It is strongly recommended, therefore, that seasonal influenza vaccination efforts target children using school programs.



Some suggestions for this targeted approach are listed:

- Employ local, state, national, and regional health authorities to enlist the cooperation of schools and childcare centers.
- Attempt to use the fact that individuals prefer to commit acts of omission. When obtaining informed consent from caregivers for in-school vaccination, require that parents who do not want their children vaccinated sign a declination form stating that they understand the risks to their child and community by refusing vaccination.
- Consider using intranasal vaccine to avoid a traumatic experience at school and eliminate the possibility of unintentional needle sticks and bleeding.
- Consider incentives for receiving vaccination. For example, all children who are vaccinated could receive a coupon for an excused absence; this could be justified on the basis that accepting vaccination likely eliminated multiple sick days for the school as a whole. Or young children could be allowed a “bring a buddy to school day,” permitting the child to bring a stuffed animal or doll.
- Educate the children prior to vaccination using age-appropriate material, so that they will more likely be supportive of the program.

It is further recommended that healthcare workers continue to be targeted in seasonal influenza vaccination efforts. Herd immunity does not confer individual immunity, and due to imperfect vaccine efficacy, even vaccinated patients could remain susceptible to influenza. Healthcare workers frequently care for individuals from outside of their community as well as individuals within the community who have recently traveled or been exposed to a traveler. Therefore, even within the context of local herd immunity, healthcare workers can still be exposed to the influenza virus. They have an ethical obligation to take reasonable actions to protect themselves from influenza, thus attempting to ensure that they do no harm to influenza susceptible patients under their care. In fact, it can be argued that healthcare workers have an increased obligation to be vaccinated in the presence of community herd immunity, as the risk of community acquired illness in this setting would be low, making it more likely that a patient who contracts influenza from a health care worker would not have been otherwise likely to be exposed. Additionally, healthcare workers have a responsibility to protect themselves in order to be available to care for others.

Seasonal influenza vaccination efforts have as yet failed to achieve desired levels of vaccination among healthcare workers, even though most programs specifically recommend health care worker vaccination. As this is in itself a target group, it is uncertain that one group is more or less important to target in terms of influenza vaccine uptake. Consideration should be taken, however, to use targeted messaging approaches among the various medical professions as well as other healthcare facility workers involved with patient care. Regarding the best approach to improve influenza vaccination uptake among healthcare workers, proactive programs including targeted education should be developed. While mandates have been shown to be initially effective, they predictably spawn legal challenges and are gradually eroded by an ever-expanding list of exemptions. Incentives, on the other hand, have demonstrated notable success among healthcare workers. Universal compliance will not be reached using incentives, but a vaccination program does not require that every person become vaccinated in order to be effective. Incentives should therefore be considered as a promising strategy to increase influenza vaccination of healthcare workers.

Based on these general findings, some recommendations and suggestions to improve seasonal influenza uptake among healthcare workers follow:

- Encourage healthcare facilities and organizations to offer free influenza vaccinations to employees. An economic approach pointing out reduced sick days and improved productivity could be used as a persuasive argument.
- Solicit professional organizations to issue statements of support for health care professional vaccination, including ethical, medical, and practical reasons for their support.
- Make influenza vaccination easily accessible at work.
- Offer a choice between injection and intranasal spray.
- Encourage healthcare facilities to use incentive programs to encourage health care worker vaccination. Incentives could include financial benefits, such as bonuses, time off, dress down days, meal coupons, etc.
- Consider using peer tactics such as inter-departmental competitions, or rewards based on reaching various goals for vaccine coverage rates. A sign indicating influenza vaccination, such as a sticker on name badges, could be used to demonstrate support and possibly influence other workers.
- Ask insurance companies to consider offering incentives for influenza vaccination of healthcare workers.
- Require healthcare workers and medical and nursing students who refuse influenza vaccination to sign declination statements.

#### **Preparedness for a novel epidemic or pandemic event**

From the perspective of TellMe, the most important set of strategies and derivative messages are those that will be used in the face of an outbreak resulting from a novel pathogen, one for which a vaccine is not available and must be developed. In the event of such an outbreak, messaging must not only address vaccine uptake strategies, but also strategies to help ensure that population behaviors are positively influenced to optimize the balance of adopting protective efforts and minimizing those that enhance transmissions and/or exposure prior to the availability of an effective vaccine.

Clearly, accomplishing this is a challenge of great complexity and magnitude. Effective messaging and exerting a positive influence on protective population behaviors depend on an aggressive, global epidemiological surveillance system with public health assessment and communication capabilities. The governments of all nations, through the World Health Organization, must be continuously encouraged to support in spirit and deed the global efforts needed to isolate, identify and fully characterize, both genetically and epidemiologically, an infectious agent in as short a time as possible. Only then will we be able to identify needed medical countermeasures, and, in the absence of such medical interventions, implement effective, nonmedical public health countermeasures.

The above-noted activities take considerable effort and time and must be accomplished against a background of actual or impending pandemic. Public health messaging will not only be critical, it will have to change and adapt as the outbreak and our understanding of its epidemiological characteristics expand. Finally, the criticality of appropriate, internationally consistent messaging will become more urgent, and thus more difficult with agents of increased virulence and/or lethality.

Regarding vaccination strategies for epidemic and pandemic events caused by novel pathogens, the specific characteristics of the novel pathogen, particularly its  $R_0$  value and transmission mechanisms, must be described before it can be determined whether to take an individual protection vs. population protection approach. Historically, most pandemic threats stem from highly communicable and rapidly reproducing pathogens. Such a pathogen would require achieving herd immunity to effectively minimize morbidity and mortality, thus necessitating mass vaccination programs rather than risk group targeted initiatives. It makes sense, therefore, to have a plan in place that would facilitate mass vaccination in the event of a new pandemic or epidemic event. Tentative plans to target risk groups would be more difficult to have in place, as the risk groups for a new pathogen are unknown.

It has been demonstrated that vaccine resistance, while present, is not a significant barrier in an epidemic or pandemic situation in which the disease is perceived as severe and exposure as likely. More significant are communication and timing issues. Vaccination uptake is greatest when vaccine availability coincides with high levels of public anxiety and awareness. This suggests that clear, consistent, synchronized media communications must accurately inform the public of ongoing disease threat as vaccine is made available and throughout the vaccination effort, until desired goals are reached. This will be easier to facilitate in nations with nationalized broadcasting; it will likely require greater advanced planning in nations with privatized media control.

In addition to synchronized communication, capitalizing on public anxiety and maximizing vaccination benefits require rapid synthesis and distribution of effective vaccine. Efforts should be made to coordinate global efforts in vaccine development and manufacturing in order make discovery, synthesis and distribution as efficient and rapid as possible.

Recommendations for implementing these strategies follow:

- Development and maintenance of an effective global health surveillance system is critical.
- With identification of a potential pandemic agent, aggressive genetic and epidemiological assessment must be made.
- In an initiative coordinated through the WHO, nations should be divided according to particular strengths and capabilities regarding vaccine development and manufacturing. Specific tasks required for vaccine development and distribution should be assigned to nations or groups of nations according to capabilities. This would save time in vaccine development by minimizing redundant efforts between countries. It would also allow nations to allot appropriate funding and resources to maintain expertise and readiness in their assigned tasks, potentially providing an overall improvement in global capabilities.
- Messages must be coordinated and consistent. Consideration should be given to an agreement among nations to provide multi-media public communications disseminated by the WHO with a frequency warranted by the pandemic or epidemic.
- Messages should be factual. They must address both what is known and what is unknown.
- When possible, messages should give people something proactive to do, such as frequent hand washing.
- Messages must be current, and therefore updated frequently.

- Messages must be attuned to changes overtime, especially as to changing risks, perceived and real, as well as to projections for availability of medical countermeasures.
- Messages should be communicated through all available media.
- Have a communication system, including networks in place. If possible, build on a system already in place. If communicators, outlets, and spokespersons have to be identified and incorporated de novo, consistent message communication within a political unit is unlikely, and virtually impossible globally.
- Special emphasis needs to be given to stigmatization issues in characterizing and naming infectious agents. For example, labeling by place of geographic origin will promote defensiveness and be counterproductive to achieving the global openness required by the circumstance.
- As soon as enough information about the infective agent is learned, define a strategic goal identifying personal disease prevention or community protection, and develop a plan accordingly.
- Incorporate all stakeholders as early as possible. Eventual policies and programs may be scientifically informed, but they must be politically supported and publicly acceptable.

The complexities involved in vaccination strategies, policies and resistance are well characterized by the “wicked problem” concept described in a treatise by Horst Rittel and Melvin M. Webber. A wicked problem generally derives from complex areas involving the intersection of politics, policy and science, such as climate change or nuclear energy. It is characterized by having: no definitive formulation; no true-false answer, only better or worse; neither an immediate nor an ultimate test of a solution; no opportunity to learn by trial and error; every attempt at solution counts significantly; uniqueness; and the imperative that the planner has no right to be wrong, incurring full liability for the consequences of his decisions and the actions they generate (Wikipedia, 2012). The application of this concept to designing and implementing vaccination strategies is clear, and the recognized approaches to dealing with wicked problems translate well to vaccine efforts.

Rittel and Webber discuss three available strategies for coping with wicked problems--authoritative, competitive and collaborative. In open societies, confronting contentious issues with an authoritarian approach is ineffective and often offensive; and for any endeavor requiring the cooperation, knowledge and abilities of multiple adverse entities, a competitive approach would almost certainly lead to suboptimal results. Collaboration, on the other hand, provides an opportunity to find the overall best solution for all stakeholders. According to Rittel, the collaborative approach is “to make those people who are affected into participants of the planning process. They are not merely asked but actively involved in the planning process” (Wikipedia, 2012).

The collaborative approach, recognizing that the results will be imperfect to some degree for everyone involved, provides the best means of reaching a strategy that maximizes the overall benefits for all stakeholders. In order to achieve the necessary support of the adverse groups involved in and affected by vaccine programs, all of these groups must participate in developing the messaging, communication and implementation of strategies entailed.

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