The Promise and Potential of Immunization Information Systems

by Megan Patricia Jordan

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Date
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Abstract

INTRODUCTION: Immunization information systems (IIS) are confidential, population-based, computerized information systems that consolidate vaccination data. The Childhood Immunization Initiative (CII) of 1993 was the impetus for the development of the 56 state and local registries currently in operation. The CII also provided for an overarching national IIS that does not currently exist.

HYPOTHESIS: I hypothesize that the decision of the NVAC and NVP to have the CDC serve as a grant-funding agency to the states rather than to establish a national registry was motivated by several prevailing stakeholder perspectives, including concerns about the privacy of health information and the appropriate scope of the federal government in delivering public health services, the lack of consensus on EHR in the burgeoning internet age, and by a desire to build on the existing public health infrastructure of local health departments.

SIGNIFICANCE: Despite improvements in public health outreach, the lack of interoperability of state-based IIS and lack of a unifying national IIS may make maintaining high levels of pre-school-age immunization difficult.

DATA AND METHODS: This is a qualitative study that triangulates medical and public health literature and elite interviews with policymakers to generate data. Interviewees included the former Director of the U.S. Department of Health and Human Services, the current and former directors of the National Immunization Program, the director of the National Vaccine Program Office, consultants to the CII from the UNC Sheps Center, among others.

CONCLUSIONS: Several themes emerged as explanations for the structure of immunization information systems. Concerns about privacy were paramount. Stakeholder resistance to new federal government programs and an emphasis on state solutions figured highly. Changes were propelled in advance of internet technology by the need for an ad hoc solution to the measles outbreak of 1989-91. Priorities for national immunization policy should include enforcement of functional standards for IIS and developing the technology needed to seamlessly integrate IIS data between states and at a national level.
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Preface

During my outpatient pediatrics rotation of medical school, I was struck by the presence, in each patient’s chart, of a single sheet of paper bearing the state seal. This was a printout of the child’s immunization history from the North Carolina Immunization Registry, and it enabled the care team to see what immunizations had been delivered and what was still needed. The system seemed an eloquent improvement over the wrinkled, yellow pamphlet my parents carried along with me to my pediatric appointments. As a medical student I had experience with patients whose immunization history was incomplete, and I could imagine the economic implications and health risks of either over- or under-vaccination for both individual patients and populations.

My original question was how the existence of the North Carolina Immunization Registry had affected the rates of children receiving the ACIP-recommended primary series of immunizations. But not only was the NCIR unable to provide this information, I discovered that at a national level the CDC was not able to use state registry data to assess vaccination coverage levels. With further study it became clear that while the Childhood Immunization Initiative of 1993 was very successful in increasing rates of pediatric immunization, the framework it created for state-based immunization information systems (IIS) may now pose significant challenges to the collection and communication of immunization data.

My perspective as a future pediatrician is that it is incumbent on the U.S. public health system to provide both political and financial support to the implementation of effective IIS. IIS are shown to improve immunization rates and decrease the rates of vaccine-preventable diseases, which are a frequently used metric for measuring the quality of a nation’s health care system. The purpose of this study is to examine the development of immunization registries, in the context of the formative Childhood Immunization Initiative. My hope was to elucidate the formative relationships and interests that led the CDC to serve as a grant-funding rather than an administrative body in developing IIS, and to better understand where the vision for a unifying national system fell short.
Background

Few advances in modern medicine have reduced global morbidity and mortality as much as has immunization. The simple act of introducing into a well person a small amount of killed or inactive pathogen to evoke an immune response has prevented millions of deaths from infectious disease and has extended the life expectancy of developed nations by decades. Over the last century in the United States, immunization combined with sanitation has resulted in a dramatic decrease in mortality (figure 1) and immunization has caused a shift in child morbidity from infectious diseases to chronic diseases and injuries. Vaccines have proven to be a safe, convenient, effective and cost-effective public health intervention that has gained broad acceptance globally.

Yet one consequence of this dramatic biomedical success is that we are moving into an era in which few parents or health care providers have any recollection of the scourge of polio or measles, or the rapidity with which Haemophilus influenzae can claim a young child’s life. Complacency about the early childhood vaccine schedule on the part of both providers and parents poses a real risk of reemergence of highly virulent diseases such as pertussis and measles.

The re-emergence of measles in the early 1990’s may have been the first sign that U.S. immunization practices were weaker than publicly perceived. Pediatric measles cases rose from less than 3000 cases per year in 1998 to almost 30,000 cases in 1990, with outbreaks occurring mostly among preschool children in under-immunized areas. The outbreak resulted in 1100 hospitalizations and 123 deaths, and forced the federal government to reevaluate its immunization delivery and surveillance system (Orenstein 2006.)

In 1993, President Clinton launched the Childhood Immunization Initiative, which doubled the budget of the CDC’s immunization program and earmarked $300 million for immunization infrastructure in particular. Through an expanded Vaccines For Children program, the government would provide all recommended vaccines free of charge to uninsured children, Native American children, and those
insured by Medicaid (Gostin, Lazzarini, 1995.) Recognizing that financial barriers are only one impediment to immunization, the Childhood Immunization Act went further – Clinton charged Secretary of Health and Human Services Donna Shalala “to start working with the states on an integrated immunization registry system” (Hinman, Urquhart, Strikas, 2007.) The CDC set a goal for Healthy People 2010 that 95% of children aged 0-6 would be enrolled in an immunization registry (Linkins 2001.) And in answer to the lack of surveillance, the CII reinstated the National Immunization Survey (formerly the United States Immunization Survey, which had been discontinued under President Reagan.) The NIS would provide an annual surveillance report of immunization coverage levels, with particular attention to pre-school-age children.

Immunization Information Systems (IIS) are computerized, population-based, confidential registry systems for immunization data (Linkins, 2001.) Well-designed IIS have the potential not only to keep track of an individual’s immunization history, but also to help practices monitor vaccine inventory, and help public health officials track and improve the delivery of immunization services.

Although the federal government’s active support of IIS began formally in 1993, the precedent and potential for effective registries had long since been established by the private sector. Progressive health systems such as Group Health of Puget Sound in Washington state had been developing prototype systems since the early 1980’s (Wood, Saarlas, Inkelas, 1999.) Seeking to expand the successes of the Group Health registry to other states, the Robert Wood Johnson Foundation established its All Kids Count (AKC) program in 1991. AKC provided grants for the development of 24 additional community-based IIS, and asked consultants at the Sheps Center at the University of North Carolina at Chapel Hill to develop an evaluation plan for the new registries (Faherty, Waller, DeFries, 1996.)

Rather than establishing a centralized, national immunization registry run by the CDC, the federal government chose a “local solutions to local problems” approach that would build on the
successes of community-based registries and the RWJF’s All Kids Count program. At the time, local health departments were responsible for the delivery of greater than 60% of all pediatric immunizations; thus, it seemed logical to give state and local health systems the opportunity to develop IIS that best suited their needs. In 1993, the federal government funded grants for IIS development in 23 states and the District of Columbia (Gostin, Lazzarini, 1995.) By 1998, all 50 states had developed some type of immunization registry (Wood, Saarlas, Inkelas, 1999.)

Over the years since 1996 when the primary pediatric immunization series was standardized, vaccines have been developed, reengineered and combined to provide the safest, most effective coverage at the optimal times in the fewest doses. The schedule is far from simple – the Advisory Committee on Immunization Practices currently recommends 26 doses of vaccine by age two (Figure 2) (CDC, 2011.) The mobility of the U.S. population makes immunization surveillance even more difficult. More than 20% of children will have seen multiple health care providers by age two, and incomplete immunization data for these children results in costly over- and underimmunization (Linkins, 2001.) A centralized repository for immunization data would help mitigate the challenges to modern vaccine delivery.

Despite the goal of Healthy People 2000 to “increase to 90% the number of children receiving the recommended vaccines by age 2” (Freed, Bordley, DeFriese, 1993,) in 2007, only 47% of U.S. 3-year olds had completed the series (Urquhart, Rasulnia, Kelly, 2008.) Although school requirements bring that number close to 100% by the time children enter kindergarten, this leaves a window during which young children are vulnerable to re-emerging vaccine-preventable diseases such as measles and pertussis (Freed, Bordley, DeFriese, 1993.) This points to a persistent system-based failure to provide immunization coverage to young children, most of whom will visit a pediatrician more times by age 2 than in the balance of their childhood.
By 2008, 75% of U.S. children under age 6 were registered in some form of electronic immunization information system (IIS) (Kelly, Heboyan, Rasulnia, 2010.) Registry systems are independently operated in all 50 states and in six large metropolitan areas. However, registries have proven resource-intensive for states to manage. Data transfer, both state-to-state and state-to-federal government is fraught with both technologic and bureaucratic obstacles. It may be the case that policy decisions made in the 1990’s to give states flexibility in implementing IIS are preventing the potential of immunization registries from being realized today.
Theoretical Perspective
*A Path Dependence framework for understanding immunization registry development*

In this study I want to construct a storyline for the development of immunization information systems in the United States after the 1993 Childhood Immunization Initiative provided funding for their implementation. I hope to better understand how historical precedent and the competing agendas of state and federal policymakers contributed to the CDC’s decision to serve as a grant-funding body for the establishment of local- and state-based IIS, rather than as an administrative body overseeing a national immunization registry. I am interested in this question because I believe the lack of communication between state IIS and the lack of oversight at a national level may created fundamental logistic obstacles that stand in the way of our country’s goal of universal childhood immunization.

Analysis of past policy decisions is difficult. As Churchill said, “History is written by the victors” – and in politics, when ultimately one policy is victorious, the pathways that might have led to an alternative policy become obscured. This process is compounded by the passage of time, and because many of the decisions surrounding the development of IIS were put in motion two decades prior to this report, the effect of time is considerable. In this paper I will rely on a *path dependence* framework, in which “prior choices, especially about the appropriate scope of government...inevitably influence national preferences for health policy” (Tolleson-Rinehart, Peterson, 2011.)

In-depth interviews of elite stakeholders are a well-studied way to gather social science data. And to the extent that policymakers themselves can recall in detail the substance of their deliberations, interviews enable one to place policy decisions in context in a way that media reviews or reviews of public record do not. According to Jennifer Hochschild, elite interviews allow us to ascertain, “What do people think happened, and why? How do they see the trajectory of the event?”

Early policy discussions regarding IIS occurred at the local, state, and national level contemporaneously, in different institutions and organizations, for decades. So although my research
findings will necessarily be presented in a certain order, the stakeholders’ views cannot be seen as sequential. Rather it is my assumption that a fluid dialogue was occurring simultaneously between experts at multiple levels in the fields of immunization policy, health policy, and health services delivery. It is the aim of these in-depth interviews to better characterize this dialogue, and hopefully determine which voices and perspectives were ultimately heard loudest.

I selected respondents in an attempt to provide a balance of perspectives from former federal government officials and current and former leaders of the most prominent immunization stakeholder groups. The National Immunization Program (NIP), a branch of the CDC, directs national immunization policy and conducts the annual National Immunization Survey. The Advisory Council on Immunization Practices (ACIP) is a standing task force of pediatricians, scientists, and child health experts who make immunization recommendations. The National Vaccine Program Office is a coordinating office under the U.S. Department of Health and Human Services that, among its many functions, serves a secretarial function to the National Vaccine Advisory Committee (NVAC), a standing immunization policy group established by the Childhood Immunization Initiative. Respondents from each of these groups share a unified vision of universal childhood immunization – and diverse opinions of how best to achieve it.
Methods

This is a qualitative study that triangulates medical and public health literature and elite interviews with policymakers to generate data. In order to better understand the role of immunization registries in the context of other public health strategies, I performed a systematic review of interventions aimed at improving immunization rates in the pediatric population. The search strategy and results are included in Appendix 1.

After receiving approval from the Institutional Review Board at the University of North Carolina at Chapel Hill, I conducted in-depth interviews with policymakers and stakeholders in immunization policy. I recruited interviewees by sending a standard email invitation to those whom I had identified through my review of the literature and the congressional public record as being substantially involved and expert in immunization registry systems. I scheduled 5 telephone interviews and 1 in-person interview with the six respondents who were willing to participate. At the beginning of each interview I read a standardized explanation and agreement document, and asked respondents’ permission to record the interview on a digital voice recorder, and to identify them by name, position, and by direct quotation. Requests for anonymity of any degree were respected.

Interviewees included the former Director of the U.S. Department of Health and Human Services, the current and former directors of the National Immunization Program, the director of the National Vaccine Program Office, consultants to the CII from the UNC Sheps Center, and the director of the North Carolina Immunization Registry, among others. The complete interview protocol and list of respondents is presented in full in Appendix 4.

Interviews were transcribed by the principal investigator and coded by hand based on thematic organization. I used the interviews to supplement my understanding of the existing literature on immunization information systems and my recommendations for their continued improvement.
**Results**

Six respondents, with diverse involvement in immunization policy and immunization information systems, both current and contemporary to the 1993 Childhood Immunization Initiative, completed 20 to 50 minute interviews.

*Immunization Information Systems in Theory and in Practice*

When I asked how policymakers imagined immunization information systems, five of six respondents described state-based systems that would be linked within a larger national registry. While all voiced understanding that there were provisions in the legislation for an integrated national system, interpretations of this national system varied. According to Former Secretary Shalala, policymakers had surveillance in mind from the beginning: “We wanted to make sure, for instance, that when all the kids left New Orleans (after Hurricane Katrina) that a national system would have captured all their vaccine records.” Three respondents suggested that a national immunization registry was considered, but quickly tabled due to concerns about privacy as well as the logistical challenges of maintaining accurate records on such a large number of people. Dr. Victoria Freeman, a consultant to the All Kids Count project at the time, indicated that the integrated system was always intended “to be built from these component pieces, from state registries...that would share information on an as-needed basis. At no point would there be one big registry of data.”

There were obstacles to efficient registry design and operation from the beginning. Several respondents echoed the sentiment of Dr. Lance Rodewald, Director of the National Immunization Program, that it was much more difficult to create registry systems than imagined. Dr. Alan Hinman, who in 1993 was Director of the National Center for Prevention Services, said a national system was quickly tabled because it was considered neither desirable nor essential to have all the information in one place. Hinman spoke to “the oversimplified view of the relative ease with which one could link
information from one place to another...that has proven to be one of our more difficult problems, the sharing of information across jurisdictional lines.”

**Early IIS in the Existing Health IT Infrastructure**

All respondents who were contemporaries of the 1993 Childhood Immunization Initiative emphasized the importance of locating this legislation in the context of existing health information technology in the very early years of the internet. Dr. Hinman described support through federal Section 317 funds for paper-based “immunization follow-up systems” in existence since the 1970’s. “It wasn’t continuous tracking,” Hinman says, “but then we began to get computers. And the ability to handle a lot of information. And so in the late 80’s there was a lot of interest in developing a true follow-up system.”

On the one hand, immunization data was a logical place to field-test electronic health records. According to NVPO Executive Secretary Dr. Bruce Gellin, with immunizations “it was pretty clear what you were supposed to measure, and when you were supposed to measure it, and you could compare what you got to what you should be getting and see how well the IIS were doing.”

Developing IIS “in the infancy of health IT” as one respondent put it, meant it was difficult for policymakers to conceptualize what an ideal registry system would look like. Functional standards for immunization registries were not codified until 1997 (Linkins 2001) and this was cited by a health policy analyst at the NVPO as a possible reason for the differences in state registries, particularly the early ones. The fact that the impetus for registry development occurred before internet use was widespread was also crucial to the conceptual development of IIS. As one respondent put it, “the web was just SO new – but now it seems the logical thing to do, to have a web-based application.”

Three respondents went so far as to say that those states later to establish registries “may be able to avoid making the mistakes the early adopters made” (Hinman interview.) Late-adopter states are more likely to have web-based systems that use the Wisconsin Immunization Registry platform (WIR, 17
of 56 registries) and are thus more amenable to data sharing. As Hinman puts it, many of the “indigenous” registries are now “coming to the end of their useful lives because they were developed using older operating systems.” Overall, respondents pointed to the variety of data elements captured, the lack of a universal identifier (such as social security numbers) and the various platforms used as significant barriers to developing an integrated national system.

**Privacy and Confidentiality of Health Information**

Overall, privacy, confidentiality, and security were mentioned an average of three separate times per respondent. “We were somewhat naïve back then, in terms of what information we thought could be shared,” said Dr. Freeman, and the unique vulnerabilities presented by immunization data became apparent. “One thing that keeps coming up,” said Dr. Hinman, “is suppose you’re an estranged spouse. And you want to be able to demonstrate that your estranged spouse, who has custody of the child, is guilty of neglect by not having the child immunized. It’s pretty obvious there would be problems with a system where parents had open-access.”

Individual states have their own rules about privacy and confidentiality, and according to Dr. Hinman it has taken many years for memoranda of understanding to be forged between states – even adjacent states like Washington and Oregon with similar registry systems and overlapping border communities.

**The States’ Role and Fears of “Big Brother”**

Public health in general and immunization delivery specifically has traditionally been the purview of state health departments, but the 1993 CII, with its expanded VFC funding and emphasis on developing registries, marked an unquestionable sea change in federal involvement. As Dr. Rodewald put it, “the concern as always was with Big Brother, that the federal government would have too much
identifying information.” The strong anti-big-government sentiment was anticipated by CII advocates. According to Secretary Shalala, “the public health community did not want to build a national bureaucracy when we were so desperate for funds.” The perception that a national system would just be “politically...way too hot” (Freeman), combined with the success of small registries such as those funded by the All Kids Count project set the stage for a “local solutions to local problems” approach to registry development, in which the states’ demonstration projects would be grantees of the CII. This system kept both accountability and sensitive personal health information at the local level.

According to the interview respondents, after nearly 20 years the states’ reception to the CII has been generally positive. Several stakeholders mentioned state to state variation in registry objectives and standards, but states generally acknowledge that the VFC program is vital and accepting federal 317 funds “carries with it some obligation of meeting federal standards” (Hinman.) Dr. Rodewald noted that states with registries “better integrated into the fabric of primary care” generally have more buy-in from both providers and state policymakers.

*The Measles Outbreak of ’89-91: Dropping the Ball, Throwing the Book*

That the measles outbreak of 1989-1991 exposed important weaknesses in the national immunization strategy was clear from the existing literature. But interestingly, several respondents spoke to the overwhelming galvanizing effect the outbreak had on policymakers to support dramatic changes on a short timetable. “In some ways, the whole vaccine thing was ad hoc. We couldn’t wait for the entire health system to change,” remarked former HHS Secretary Shalala.

As Dr. Rodewald explained:

> What we learned about the epidemiology of measles led to the first Childhood Immunization Initiative (in 1977, which established immunization requirements for school entry) and then there was a period of time when there wasn’t much measles, and the measurement of immunization coverage was stopped. So nobody had any idea what coverage levels were like for small children, and that set the stage...Basically, the measles resurgence was so awful that the book got thrown, thrown at the problem.
Dr. Freeman agreed:

*We had no surveillance at the time – we had an NIS before, but it had been discontinued under Reagan...we had no mechanism to find out if kids were up to date at two, and that’s where you saw so many cases of measles. So it was a case of the ball being dropped, and it wasn’t until something bad happened that it got attention.*

**Quantifying IIS Success**

I asked respondents to what extent they thought registry systems were responsible for the improved rates of pediatric immunization, as compared to other provisions of the Childhood Immunization Initiative. As Dr. Rodewald said:

*One of the problems is to ascribe causality...when the Childhood Immunization Initiative wasn’t set up either as an experiment or a controlled trial or one that was designed to be evaluated such that you could tease out the components of it. But basically the objectives (of increased vaccine coverage) were met in 1997, and the registries weren’t finished by then.*

Secretary Shalala felt registries did deserve substantial credit for “making the decision (to double the budget for vaccines) palatable,” by creating a follow-up and tracking system for immunizations.

Overall registry enrollment in the United States has never reached 95%, and growth of registries has slowed. The CDC reported in 2009 that 77% of children under age 6 participated in an IIS, up only two percent from 2008 (CDC 2010.) According to the 2009 National Immunization Survey, only around 80% of children had completed the recommended seven-vaccine primary series by age 35 months.

Socioeconomic disparities in immunizations still exist, with black and low-income children less likely to receive all recommended vaccines (CDC 2010.) But when asked whether funding should be increased for registry outreach and development, respondents indicated any money might be better spent on improving the interoperability of existing systems. “The more money you have to spend to get tiny little changes, it gets harder politically,” said Dr. Freeman.
Improved rates of immunization combined with the lack of outbreaks over the last 18 years may have generated a sense of complacency around registry uptake and improvement, said respondents. As Dr. Freeman remarked,

*I think just calling attention to something often gets people moving. We often joke...that if your state is ranked 50th, it's probably the best thing that can happen to you, because being 50th gets the attention of legislators. So just with the attention being drawn to immunizations, there was more effort, and we saw improvement in the rates. And I think that took some of the pressure off developing registries...*

Others thought that with registries underway and rates of immunization improving, other aspects of immunization, such as addressing the increasingly complex vaccine schedule, and developing decision tools for clinicians, simply took precedence over time.

*“What gets measured gets done:” Registries and the NIS*

All respondents felt the reinstatement of the National Immunization Survey was crucial to both the political and public health success of the Childhood Immunization Initiative. Having the ability to measure coverage and track the improvements in immunization rates within a year after the legislation passed was vital, as the numbers made it clear that the CII was working.

However, several respondents cited the methods of the NIS as a possible weakness. Data for the National Immunization Survey are collected via random-digit dialing of households, a survey method that until recently was “thought of as the gold standard for these large surveys,” according to a health policy analyst at the National Vaccine Program Office. However, with more and more households giving up land-lines in favor of cell phones, several respondents mentioned the possibility of biased NIS results. And according to Dr. Rodewald, NIS results have tended to overestimate immunization levels when compared with the data from state registries – probably because the NIS is more likely to count invalid doses of vaccine, while registries capture only doses administered in the correct time frame.
Acknowledging that the national data we have are not perfect, three respondents suggested that in the next decade it may be possible to use the existing resources presented by state IIS as “a national starting point” (Rodewald) for the survey. Dr. Hinman conjectured that at some point the NIS might even become unnecessary, when immunization status can be assessed directly by querying registries and EHR systems. Provided privacy and confidentiality concerns can be addressed, respondents were optimistic about the future use of registry data for surveillance and creating policy.

The Future of Registries

When asked, no respondents thought policymakers should revisit the idea of a national immunization registry in the context of national health reform. All respondents, however, indicated they expected something looking “more like a national system” to develop out of integrated state registries in the next decade. Moving towards a national system, for most respondents, entails developing standards for registry development, and changing systems to accommodate bidirectional data sharing – from EHR’s to registries, and vice versa. All respondents anticipated the provisions within PPACA and the HITECH act to substantially accelerate these changes. In fact, the transmission of immunization information to a registry is one of the selection items that providers can use to attain the meaningful use designation with their EHR, according to Dr. Rodewald.

One respondent wondered what IIS would have looked like if they had developed out of the electronic medical records of today – if, rather than pulling information from paper records into a primitive computer system, gathering immunization data was as simple as querying an EHR for that data and sending it automatically to a central surveillance system. Several respondents said privacy and confidentiality would be even bigger concerns today, but that having separate registries might become less important as more efficient methods of data transmission from existing EHR’s are developed.
Potential integration of registry data with data on other preventive services was cited by several respondents. Said Secretary Shalala, “It’s not just reminding people about vaccines. It’s reminding people to come in for mammograms, for all the prevention stuff. The third phase of the All Kids Count project funds demonstration projects to registries that are integrating with other child health screening programs, such as newborn hearing tests, heel-stick screening, and child lead testing.

But first, as Dr. Freeman put it, “the IT backbone of the U.S. healthcare system has to improve.” Simply collecting registry data will not provide the quality information needed to follow trends in immunization among a highly mobile population. According to Dr. Rodewald, registry utility is in the design, not the quantity of data: “Just having 100 million EHR’s – that means you have 100 million EHR’s. That doesn’t tell you whether 98% of them are immunized.” Most respondents indicated that even though health information technology has changed dramatically since 1993, they feel registries are poised to do more.
Discussion

In the course of these structured interviews with policymakers, I witnessed several themes emerging as explanations for the structure of immunization information systems. Concerns about privacy, confidentiality, and information security were paramount. Stakeholders were resistant to the idea of establishing new federal government programs and felt strongly that the states were best equipped to develop registries that met the needs of their populations. The measles epidemic created a sense of urgency that propelled transformative system change in search of an *ad hoc* solution. And all this occurred just barely in advance of an internet technology explosion that would leave many registries with outdated systems just a few years after they had been created.

In politics, stakeholders (here, states, the federal government, the public health community) battle over control of a set of political outcomes (high levels of immunization) that have benefits (lower burden of infectious disease and higher quality of health care, by traditional metrics.) In the case of developing immunization registries, it made sense to view states as the “experimental democracies” to test the viability of registries as new social programs (Discussion with Dr. Kristin Goss, 4/20/2011.) And because incremental change is almost always more palatable to policymakers than sweeping change, building upon the successes of the All Kids Count program was the most pragmatic political strategy.

By all accounts, immunization information systems have been a success for states, with healthy provider buy-in and high immunization rates as an indirect, if not direct, consequence. But the continued success of IIS depends on their no longer operating independently. Priorities for national immunization policy should include enforcement of functional standards for IIS, diversifying the providers eligible to use IIS, and developing the technology needed to seamlessly integrate IIS data both between states and at a national level.
References


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Johnson, J. (January 2011). *Personal communication*


Tables and Figures

### Recommended Immunization Schedule for Persons Aged 0 Through 6 Years—United States • 2011

For those who fall behind or start late, see the catch-up schedule.

<table>
<thead>
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<th>2 months</th>
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<th>4–6 years</th>
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<td><strong>Measles, Mumps, Rubella</strong></td>
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<td><strong>Hepatitis A</strong> (HepA)</td>
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**Note:** This schedule includes recommendations as of December 21, 2010. Any dose not administered at the recommended age should be administered at a subsequent visit, when indicated and feasible. The use of a combination vaccine generally is preferred over separate injections of its equivalent component vaccines. Considerations should include provider assessment, patient preference, and the potential for adverse events. Providers should consult the relevant Advisory Committee on Immunization Practices statement for detailed recommendations [http://www.cdc.gov/vaccines/pubs/acipacip.html](http://www.cdc.gov/vaccines/pubs/acipacip.html). Clinically significant, rare adverse events that follow immunization should be reported to the Vaccine Adverse Event Reporting System [http://vaers.hhs.gov](http://vaers.hhs.gov) by telephone, 800-822-7967. Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.

1. **Hepatitis B vaccine (HepB),** (Minimum age: birth)
   - Administer monovalent HepB to all newborns before hospital discharge.
   - If mother is hepatitis B surface antigen (HBsAg)-positive, administer HepB and 0.5 mL of hepatitis B immune globulin (HBIG) within 12 hours of birth.
   - If mother’s HBsAg status is unknown, administer HepB within 12 hours of birth. Determine mother’s HBsAg status as soon as possible and, if HBsAg-positive, administer HBIG (no later than age 1 week).
   - **Doses following the birth dose:**
     - The second dose should be administered at age 1 or 2 months. Monovalent HepB should be used for doses administered before age 6 weeks.
     - Infants born to HBsAg-positive mothers should be tested for HBsAg and antibody to HBsAg at 1 to 2 months after completion of at least 3 doses of the HepB series, at age 9 through 18 months (generally at the next well-child visit).
     - Administration of 4 doses of HepB to infants is permissible when a combination vaccine containing HepB is administered after the birth dose.
     - Infants who did not receive a birth dose should receive 3 doses of HepB on a schedule of 0, 1, and 6 months.
     - The final (3rd or 1st) dose in the HepB series should be administered no earlier than age 24 weeks.
2. **Rotavirus vaccine (RV),** (Minimum age: 6 weeks)
   - Administer the first dose at age 6 through 14 weeks (maximum: 14 weeks 8 days). Vaccination should not be initiated for infants aged 15 weeks 0 days or older.
   - The maximum age for the final dose in the series is 8 months 0 days.
   - If Rotarix is administered at ages 2 and 4 months, a dose at 6 months is not indicated.
3. **Diphtheria and tetanus toxoid and acellular pertussis vaccine (DTaP),** (Minimum age: 6 weeks)
   - The fourth dose may be administered as early as age 12 months, provided at least 6 months have elapsed since the third dose.
4. **Haemophilus influenzae type b conjugate vaccine (Hib),** (Minimum age: 6 weeks)
   - If PRP-OMP (PedvaxHib or Comvax [Hib-PRP]) is administered at ages 2 and 4 months, a dose at age 6 months is not indicated.
   - Hibrix should not be used for doses at ages 2, 4, or 6 months for the primary series but can be used as the final dose in children aged 12 months through 4 years.
5. **Pneumococcal vaccine,** (Minimum age: 6 weeks for pneumococcal conjugate vaccine (PCV7); 2 years for pneumococcal polysaccharide vaccine (PPV23))
   - PCV is recommended for all children aged younger than 5 years. Administration of 1 dose of PCV to all healthy children aged 24 through 59 months who are not completely vaccinated for their age.
   - A PCV series begins with 7-valent PCV (PCV7) should be completed with 13-valent PCV (PCV13).
   - A single supplemental dose of PCV13 is recommended for children aged 14 through 59 months who have received an age-appropriate series of PCV7.
   - A single supplemental dose of PCV13 is recommended for all children aged 60 through 71 months with underlying medical conditions who have received an age-appropriate series of PCV7.

- **The supplemental dose of PCV13 should be administered at least 8 weeks after the previous dose of PCV7.** See MMWR 2010;59/No. RR-11.
- **Administer PPSV at least 8 weeks after last dose of PCV to children aged 2 years or older with certain underlying medical conditions, including a cochlear implant.**
- **Influenza vaccine (seasonal),** (Minimum age: 6 months for trivalent inactivated influenza vaccine (TIV); 5 years for live, attenuated influenza vaccine (LAIV))
   - For healthy children aged 2 years and older (i.e., those who do not have underlying medical conditions that predispose them to influenza complications), either LAIV or TIV may be used except LAIV should not be given to children aged 2 through 4 years who have had whooping cough in the past 12 months.
   - Administer 2 doses (separated by at least 4 weeks) to children aged 6 months through 8 years who are receiving seasonal influenza vaccine for the first time or who were vaccinated for the first time during the previous influenza season but only received 1 dose.
   - Children aged 6 months through 8 years who received no doses of monovalent 2009 H1N1 vaccine should receive 2 doses of 2010–2011 seasonal influenza vaccine. See MMWR 2010;59/(No. RR-8):23–25.
- **Measles, mumps, and rubella vaccine (MMR),** (Minimum age: 12 months)
   - The second dose may be administered before age 4 years, provided at least 4 weeks have elapsed since the first dose.
- **Varicella vaccine,** (Minimum age: 12 months)
   - The second dose may be administered before age 4 years, provided at least 3 months have elapsed since the first dose.
- **For children aged 12 months through 12 years the recommended minimum interval between doses is 3 months.** However, if the second dose was administered at least 4 weeks after the first dose, it can be accepted as valid.
- **Hepatitis A vaccine (HepA),** (Minimum age: 12 months)
   - Administer 2 doses at least 6 months apart.
   - HepA is recommended for children aged older than 23 months who live in areas where vaccination programs target older children, who are at increased risk for infection, or for whom immunity against hepatitis A is desired.
- **Meningococcal conjugate vaccine, quadrivalent (MCV4),** (Minimum age: 2 years)
   - **Administer 2 doses of MCV4 at least 8 weeks apart to children aged through 10 years with persistent complement component deficiency and anatomic or functional asplenia, and 1 dose every 5 years thereafter.
   - Persons with human immunodeficiency virus (HIV) infection who are vaccinated with MCV4 should receive 2 doses at least 1 week apart.
   - Administer 1 dose of MCV4 to children aged 2 through 10 years who travel to countries with highly endemic or epidemic diseases and during outbreaks caused by a vaccine serogroup.
   - Administer MCV4 to children at continued risk for meningococcal disease who were previously vaccinated with MCV4 or meningococcal polysaccharide vaccine after 3 years if the first dose was administered at age 2 through 6 years.
Figure 3. List of Functional Standards for Immunization Registries. Reproduced from Freeman VA, DeFriese GH. The Challenge and Potential of Childhood Immunization Registries

1. Electronically store data on all NVAC-approved core data elements. (patient name (first, middle, and last); patient birth date; patient sex; patient birth state/country; mother’s name (first, middle, last, and maiden); vaccine type; vaccine manufacturer; vaccination date; and vaccine lot number)

2. Establish a registry record within six weeks of birth for each newborn child born in the catchment area.

3. Enable access to and retrieval of immunization information in the registry at the time of encounter.

4. Retrieve and process immunization information within 1 month of vaccine administration.

5. Protect the confidentiality of health care information.

6. Ensure the security of health care information.

7. Exchange immunization records using Health Level Seven (HL-7) standards.

8. Automatically determine the routine childhood immunization(s) needed, in compliance with current ACIP recommendations, when an individual presents for a scheduled immunization.

9. Automatically identify individuals due/late for immunization(s) to enable the production of reminder/recall notifications.

10. Automatically produce immunization coverage reports by providers, age groups, and geographic areas.

11. Produce official immunization records.

12. Promote accuracy and completeness of registry data.
Appendix 1: Interview Template and Fact Sheet

Hi ______________, thank you so much for talking with me today.

Before we begin, I need to give you some introductory information about my project. I am an MD/MPH candidate at The University of North Carolina at Chapel Hill. I am conducting research as part of my Master's Paper.

As you know, I asked to interview you because of your knowledge of immunization policy and immunization information systems. I am interested in your views about early immunization registry policy and the development of state and local-based immunization information systems.

My faculty adviser is Dr. Sue Tolleson-Rinehart, who is a faculty member of the UNC Schools of Public Health and Medicine. We hope this analysis will help policymakers understand how current immunization information systems came into being and implications for the future interoperability of immunization information systems in particular and electronic health records in general. My advisor and I do hope that the results of this study will be published in a scholarly journal.

The interview has several questions, all in open-ended format. The interview should last anywhere from 20 minutes to one hour, depending on the availability of your time and what you want to tell me. I would like to record this interview on a digital voice recorder, but I will not record this interview without your permission. If you do grant permission for this conversation to be recorded, you have the right to revoke recording permission and/or end the interview at any time. I will transcribe the interview, and I will give you a copy of the transcript.

If you have any questions about the research now, please feel free to ask. If you have questions later about the research, you may contact me by phone at (919) 357 1156 or by e-mail at megan_jordan@med.unc.edu. Dr. Tolleson-Rinehart and I hope to publish the results of this project, and will be glad to make the findings available to you.

Risks and Benefits: I know of no risk to you from completing this survey. While you may not benefit personally from completing this survey, I believe that you will be helping the larger health care community by enabling us to understand the importance of immunization policy for maintaining high levels of pediatric immunization.

Before we continue, would you please agree to any or all of the statements I’m about to read?

☐ I AGREE to having this interview tape recorded with a digital voice recorder.
☐ I GIVE PERMISSION for the following information to be included in publications resulting from this study:
  ☐ my name  ☐ my title  ☐ direct quotes from this interview

_________________________________________  ___________________________
Participant name                                    Date
Thank you for your help with my project! Let’s get started.

Can you describe your position for me, and to what extent you are involved with immunization policy currently?

Can you describe your involvement with immunization policy in 1993, when the Clinton Administration launched the Childhood Immunization Initiative?

As I understand them, the main components of the Childhood Immunization Initiative were to provide funding for universal vaccination of U.S. children, to make provisions for expanded outreach programs, and to develop an integrated immunization tracking system. I’m most interested in getting your views about this last provision to develop the integrated tracking system.

From your expert standpoint, and from your observations, what do you think policymakers and advocacy groups thought such a tracking system would look like?

In your opinion, how does the current structure of immunization information systems compare to what the National Vaccine Advisory Committee envisioned?

Would the data captured by a national registry be different from state registry data?

Considering the limits of internet technology at the time, how did you envision the “integrated immunization tracking system” conceived by the Clinton Administration?

Was the development of a single national immunization registry ever considered?

    Why or why not?

To what extent do you think concerns about privacy of health information impeded the development of an integrated national registry system?

    What about resistance to new federal government programs?

    What about the lack of a universal identifier?

    Was there a lack of resources at a federal level?

In the same way that complacency about measles led policymakers to discontinue the National Immunization Survey in the mid 1980’s in the face of budget cuts – do you think high levels of immunity and relatively few outbreaks have weakened the drive to continually refine immunization tracking systems?

Are you aware of any stakeholders who were involved in this legislation who would have liked to structure the immunization tracking system differently?

    [If so,] Do you know what they hoped to see it become?
How much credit do you think immunization information systems *themselves* – as opposed to other developments – deserve for the improvement in rates of children receiving the primary series of immunizations by age 2?

How do you think existing immunization information systems could be improved?

Do you think the current administration should increase funding to immunization information systems, or would funding be better spent expanding patients’ and providers’ access to immunizations?

Do you think the idea of an integrated national tracking system should be revisited?

To your understanding, how is registry data used at the national level?

What improvements (if any) in immunization information systems do you see as coming out of the “meaningful use” EHR provisions of the Patient Protection and Affordable Care Act?

Do you have a vision for what the ideal IIS would look like?

Can you think of any other obstacles existing registries face to realizing that vision?

Is there anything else you think I should have asked about?

Thank you very much for your time.
Appendix 2: List of Interview Respondents and Positions

Donna Shalala, PhD
President of the University of Miami
Coral Gables, FL

Alan Hinman, MD, MPH
Fmr. Director of the National Center for Prevention Services
Fmr. Director, CDC Immunization Division
Fmr. Assistant Surgeon General, U.S. Public Health Service
Senior Public Health Scientist, Task Force for Global Health
Decatur, GA

Lauren Wu, MHS
Policy Analyst Fellow, National Vaccine Program Office
U.S. Department of Health and Human Services
Washington, DC

Lance Rodewald, MD
Director, Immunization Division
Centers for Disease Control and Prevention
Atlanta, GA

Bruce Gellin, MD, MPH
Director, National Vaccine Program Office
U.S. Department of Health and Human Services
Washington, DC

Victoria Freeman, DrPH, RN
Former Consultant to the All Kids Count Program
Cecil G. Sheps Center for Health Services Research
University of North Carolina at Chapel Hill
Chapel Hill, NC

All interviews were conducted in May 2011.
Appendix 3: A Review of Strategies to Increase Immunization Rates

Introduction

With the exception of being born in a hospital, immunizations are often an infant’s first contact with the health care system. In the United States, a newborn receives the first dose in the Hepatitis B immunization series within a few hours of birth. That first dose may be the simplest and most sure. In the subsequent twelve months, (s)he will receive 18 more doses of vaccine to protect her from rotavirus, diphtheria, tetanus, pertussis, polio, pneumococcal pneumonia, *haemophilus influenzae*, and influenza virus (CDC 2011).

Completing the recommended primary series of immunizations is fraught with difficulty for many parents and pediatricians, largely due to the increasing complexity of the immunization schedule, demands on primary care providers, and the fragmentary nature of the U.S. immunization delivery system (Szilagyi, Vann, Bordley *et al* 2005). In 2009, only 80% of preschool-age children had completed the primary series of immunizations as recommended by the American Academy of Pediatrics, with pockets of substantial under-immunization remaining in urban underserved areas (CDC 2010).

Because immunization status is often used by governmental agencies, insurers, and healthcare delivery organizations as a measure of the timeliness and comprehensiveness of children’s health care, diverse interventions have been tried to improve immunization rates. Most are practice-level interventions that can be tailored to the chief impediments to immunization in a particular community or practice. The objectives of this paper are to review the literature assessing the effectiveness of three of the most prominent and promising strategies to increase immunization among pre-school-age children: reminder systems, which work at the level of the patient, chart audits and AFIx, which work at the provider level, and immunization registry use, which works at the level of the practice or community (Hambidge, Davidson, Phibbs, *et al*, 2004).
Search Strategy and Selection Criteria

Google Scholar and PubMed were used to search for English-language articles published from the year 2000 onward that tested strategies or interventions for improving immunization rates. Studies published before the year 1999 were not included, because the immunization delivery system in the United States has changed substantially since the expansion of the Vaccines For Children program in the early 1990’s. Additional abstracts were hand-searched from the citations of other sources. Returned abstracts were filtered to exclude studies that did not test interventions on pre-school-age children. Studies that included pre-school-age children along with older children and adults were not excluded. Types of studies included randomized controlled trials, interrupted time series, controlled before-and-after studies, a 2000 meta-analysis, and a 2002 Cochrane review.

Patient Reminder and Recall Systems

Direct reminders to the patient’s parent or guardian are some of the most frequently used approaches to improving childhood immunization rates. Reminders may include phone calls, letters, or postcards. Phone calls or messages may be delivered by any member of the health care team or by robotic dialing. Such communications may include information about the patient’s next appointment as well as a message that the patient is due or past due for an immunization dose. An excellent meta-analysis of reminder and recall systems by Szilagyi, Bordley, Vann, et al showed that overall, interventions in pediatric settings increased immunization rates by about 25% and were more effective than any intervention in the setting of adult immunization. Reminder/recall interventions were most effective in pediatric practices that were in academic or private practice settings. Live-caller telephone reminders were more than twice as effective as robotic call reminders, postcards, or letters at increasing immunization rates in children, but were also the most costly (Szilagyi, Vann, Bordley et al, 2000).
Several studies included in the meta-analysis incorporated cost-effectiveness data, with the cost of additional interventions ranging from around $10 per year per additional appropriately immunized child to $63 dollars per year. However, the authors noted that it is difficult to estimate the gains and savings incurred from the receipt of appropriate preventive services in a completely-immunized child (Szilagyi, Vann, Bordley et al, 2000.)

A 2004 cluster randomized controlled trial tested several interventions designed to improve receipt of well-child services in a disadvantaged population of over 2500 infants at Denver Health Systems in Colorado. These interventions included telephone and mail reminders as well as clinic-based strategies modeled after the AFIX system, discussed below. The two intervention arms of the study showed a 5-6 % increase in immunizations delivered to young children, but the difference, while clinically important, was not statistically significant. The authors posit that while such interventions may work well in more affluent, academic, or private settings, patient-based interventions are not as effective in pockets of urban, low-income, disadvantaged patients. The clinic-based interventions, while useful to improve care coordination, may not be sufficient or time- or cost-effective (Hambidge, Davidson, Philbbs, et al 2004).

**Provider Chart Audits, Immunization Information Systems, and AFIX**

Taking full advantage of existing immunization registries (commonly termed Immunization Information Systems, or IIS) would allow providers and health care organizations to attack the problem of under-immunization from a different angle. IIS as they were initially envisioned would generate reports to providers about their provision of immunization services, and would have the ability to generate reminder and recall notices to parents without the action of the provider (Freeman, DeFriese, 2003). But several studies have documented that the same issues of complexity and time pressures that
plague immunization delivery also make providers less likely to use IIS tracking systems (Dombkowski, Leung, Clark, 2007 and Kolasa, Lutz, Cofsky, Jones 2009).

A study published in 2009 tested the effectiveness of provider chart audits in improving both the completeness of the IIS and rates of immunization coverage in Philadelphia. Philadelphia has its own IIS, and providers who receive vaccine under the federal Vaccines for Children Program are mandated to participate in the IIS. The study authors used IIS data to identify over 7000 children who were not-up-to-date for immunizations at 10 months of age. Study researchers then conducted a chart audit at the patient’s last care provider; if immunizations were indeed not-up-to-date, outreach interventions at the patient level were conducted at 13 and 19 months. These interventions successfully brought half of the previously not-up-to-date children up-to-date on their immunizations. More interestingly, 64% of children who were missing doses of vaccine according to the IIS were found to be up-to-date after the chart audit. The study authors concluded IIS completeness and provider participation remains an issue that must be solved before IIS data can be viewed as an accurate measure of immunization rates (Kolasa, Lutz, Cofsky, Jones 2009).

The Assessment, Feedback, Incentives, and Exchange system (AFIX) was conceived by the Centers for Disease Control as a quality-improvement strategy that capitalizes on IIS information to increase immunization rates. Operating at the provider level, AFIX uses IIS data to provide “report cards” to providers on their immunization services and incentives to reward high-level performance or improvement (CDC, 2011). Several early studies demonstrated the effectiveness of AFIX in the mid-1990’s, and the program now exists in all 50 states. A 1999 retrospective study examined immunization coverage of children 19-35 months in four states and two cities, before and after the implementation of AFIX. Overall, the states/cities studied (Missouri, Colorado, Louisiana, Iowa, Boston, and Houston had an average immunization coverage rise of 5 percentage points per year (LeBaron, Mercer, Massoudi, et al, 1999).
Conclusion: A Multi-level Immunization Strategy

In improving immunization rates for pre-school-age children, providers and practices face unique challenges which depend upon the demographics of their patient population and the resources of their practice and community. A one-size-fits-all solution to low levels of immunization will likely not be effective. If we are to reach the goal set by Healthy People 2010 that 90% of children be appropriately immunized by age 2 (CDC 2010), a combination of patient-based reminder systems, practice-based incentives and assessments, and systems-level utilization of the information provided by IIS will be necessary.

More research is needed to determine whether we should place more emphasis on immunization outreach, tracking, and parental education or whether taxpayer dollars are better spent on provider assessment, feedback, and incentive programs. And further studies must evaluate not only on strategies proven to increase immunization in high-resource areas, but on what works in disadvantaged populations where pockets of substantial under-immunization persist.
References


