An Exegesis of Investigation into the Utilization of
Immunisation Information Systems in Public Health

An Exegesis Submitted to Charles Sturt University
for the Doctorate of Health Science

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Certificate of Authorship

I hereby declare that this submission is my own work and that, to the best of my knowledge and belief, it contains no material previously published or written by another person nor material which to a substantial extent has been accepted for the award of any other degree or diploma at Charles Sturt University or any other educational institution, except where due acknowledgement is made in the portfolio. Any contribution made to the research by colleagues with whom I have worked at Charles Sturt University or elsewhere during my candidature is fully acknowledged.

I agree that this exegesis be accessible for the purpose of study and research in accordance with the normal conditions established by the Executive Director, Library Services or nominee, for the care, loan, and reproduction of theses.
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Abstract

This exegesis is the culmination of research performed over the last seven years for the Doctorate of Health Science program that was completed while I worked at the Centers for Disease Control and Prevention (CDC). In order to help form the direction of the research for this project, I began with a high-level review of the immunisation information systems in the United Kingdom and Australia. Since I worked as an immunisation information systems consultant at the time, this comparison of the immunisation information systems in Australia and the United Kingdom provided me with a new view of how this type of system could function and helped to determine the approach a study of the systems in the United States. While the UK and Australia were able to gain general acceptance of the idea of the government operating a computer system that contained patient data, the US Congress forbade the CDC from developing a similar system. This resulted in a range of issues that had to be addressed that were very different from the Australian or UK experience.

The US program was directed at developing state level systems that could interact across state boundaries. As a result, the multitude of systems created their own difficulties. These included interstate privacy concerns, problems of funding duplicate systems in multiple states in an era of shrinking federal public health budgets, as well as the fact that the technology involved in managing physician’s offices and patient records were rapidly outpacing the IIS program. After 2001 the focus of the federal government was also shifting and directing funding to technology areas related to terrorism.
The problem that was chosen as the focus for further research was related to the issue of proper support for these systems. The Office of Management and Budget (OMB) defined criteria that required programs to demonstrate a positive impact in order to receive further funding. The IIS program at CDC had never been evaluated for public health impact, nor was there an evaluation plan in place that could provide that information. Following OMB’s requirements, I designed an impact study using childhood vaccination rates as the impact of interest. This part of the doctoral project was designed to evaluate the impact of the federal immunisation information system investment.

The analysis of funding, information system completeness, and immunisation rates found that the measure of full functionality as defined by the National Vaccine Advisory Committee was a significant predictor of whether the change in immunisation levels was above or below the median change, but only for those projects that started with the lowest immunisation levels. The restrictions created by following OMB guidelines meant that the data available was not sufficient to develop a more specific relationship between the variables.

Due to the limitations of the statistical results, the final section of this research project focused on developing a logic model that could be used to develop future evaluations of programmatic impact. This model was proposed as a means of planning both the data collection and impact analysis of discreet aspects of the IIS program in the United States. The immunisation program at CDC is currently working to this idea one step further and will be publishing a logic model for the overall program in the near future.
## Table of Abbreviations

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<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tr>
<td>ACIP</td>
<td>Advisory Committee on Immunization Practices</td>
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<td>ACIR</td>
<td>Australian Childhood Immunisation Register</td>
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<td>AIRA</td>
<td>American Immunization Registry Association</td>
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<td>ALERT</td>
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<td>BMJ</td>
<td>British Medical Journal</td>
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<td>CASE</td>
<td>Computer Assisted Systems Engineering</td>
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<td>CDC</td>
<td>Centers for Disease Control and Prevention</td>
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<td>CHI</td>
<td>Consolidated Health Informatics</td>
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<td>CI</td>
<td>Confidence Interval</td>
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<td>Electronic Health Records</td>
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<td>FERPA</td>
<td>Family Educational Rights and Privacy Act</td>
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<td>GA</td>
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<td>GPRA</td>
<td>Government Performance Results Act</td>
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<td>HHS</td>
<td>Health and Human Services Department</td>
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<td>HIPPA</td>
<td>Health Insurance Portability and Accountability Act</td>
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<td>HIT</td>
<td>Health Information Technology</td>
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<td>HTML</td>
<td>Hypertext Markup Language</td>
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<td>IIS</td>
<td>Immunisation Information System</td>
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<td>IRAR</td>
<td>Immunization Registry Annual Report</td>
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<td>IRSB</td>
<td>Immunization Registry Support Branch</td>
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<td>IT</td>
<td>Information Technology</td>
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<td>NEDSS</td>
<td>National Electronic Disease Surveillance System</td>
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<td>NHIN</td>
<td>National Health Information Network</td>
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<td>Acronym</td>
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<td>NHS</td>
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<td>NSF</td>
<td>National Science Foundation</td>
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<td>NVAC</td>
<td>National Vaccine Advisory Committee</td>
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<td>OMB</td>
<td>Office of Management and Budget</td>
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<td>OR</td>
<td>Odds Ratio</td>
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<td>PA</td>
<td>Pennsylvania</td>
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<td>PHIN</td>
<td>Public Health Information Network</td>
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<td>PISC</td>
<td>Primary Immunisation Series Coverage</td>
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<td>PMA</td>
<td>President's Management Agenda</td>
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<td>ROI</td>
<td>Return On Investment</td>
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<td>RWJF</td>
<td>Robert Wood Johnson Foundation</td>
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<td>SD</td>
<td>Standard Deviation</td>
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<td>UK</td>
<td>United Kingdom</td>
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<td>VFC</td>
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Section 1: Introduction

In a surprisingly short period of 40 years, computer based information systems have grown from very uncertain beginnings. They are now considered to be ubiquitous and indispensable forces in the "third wave" economies, which are marked by a predominance of information-processing activities (Saraswat 2002). The rapid growth in the capabilities of information technology and its widespread deployment in a variety of organizational roles have created two philosophical problems (Saraswat 2002). First, advances are being made with such speed that practitioners have not been able to develop a historical perspective on information technology’s origins or its consequences (Saraswat 2002). Second, this explosive growth has not allowed for the creation of a convincing logical foundation for information technology’s intellectual justification (ibid). Methodologies used for the design, deployment, analysis, and management of computer-based information systems have relied heavily upon the traditional scientific and engineering paradigms of problem solving. Methodological tools (such as Computer Assisted Systems Engineering (CASE)) have remained primarily closed systems (ibid).

Without the philosophical and logical understanding from which to approach the problem, it becomes extremely difficult to understand the complex and uncertain environment in which information systems function (Saraswat 2002). There is now a growing awareness among information technology specialists that fundamental questions about the discipline need to be addressed (Hirscheim, Juhani et al. 1997). In an attempt to illuminate one area of this discipline, this project has explored the implementation of immunisation information systems (IISs) and methods available for use in evaluating their impact. One area about which much has been written concerns the need to advance public health
informatics. Some authors have likened the opportunity created by new technologies to the redefinition of public health (Yasnoff, O'Carroll et al. 2000). There is only limited information however on how to evaluate the success or failure of these types of projects.

**Immunization Information Systems (IIS)**

One example of the advancement of public health informatics has been the ability to consolidate records from multiple physicians' offices, as seen in an immunisation information system (IIS) or registry. IISs have been defined in the United States as confidential, population-based, computerized information systems that collect data on vaccine administration for all or part of a population within a geographic area (Jones, Boyd et al. 2002). The practice of immunisation is recognized as one of the most far reaching public health improvements over the past century (National Immunization Program 1999). It is a method of public health protection that has been recommended across all age groups for a variety of diseases and is therefore considered as a critical clinical preventive service (National Immunization Program 1999). However, the success of this critical service is dependent upon the ability of multiple providers to carefully track the immunisation status for each of their patients and the evaluation of coverage levels for the general population by those entrusted with the responsibility for overall public health (National Vaccine Advisory Committee 1999). Individual records must be kept in order to ensure that the right number and types of vaccines are administered to each person (National Vaccine Advisory Committee 1999). In addition, records for the population are needed to determine overall community (or "herd") immunity and resulting population risk to disease (National Vaccine
Advisory Committee 1999). The volume of record information required creates a tremendous data management, tracking, and retrieval burden (National Vaccine Advisory Committee 1999).

Dr. Solomon proposed in 1991 that registry development efforts should be selected based on their sustainability, use of alternative data sources, and cost effectiveness (Solomon, Henry et al. 1991). This process of project selection has not commonly been used in the public health arena. Political and popular pressures often lead to the implementation of projects that have not been fully evaluated. In addition, policy studies exploring the future of public health often do not fully address the dramatic changes in public health practice that are made possible by new technologies (Guyer, Smith et al. 2000).

The Centers for Disease Control and Prevention (CDC) has worked to develop many health related information systems during its history, and in 1994 began funding immunisation registry systems within state and local health departments (Systems Development Branch 2000). Unfortunately, after ten years of being funded (first by the private sector and then by the federal government), few of these projects were fully operational as defined by the CDC (Boyd and Linkins 2002). In fact, many have experienced complete or near complete failures that have resulted in the project restarting from the beginning in their attempt to develop fully operational systems (Unpublished Immunisation Registry Annual Report data 2002).

These projects have developed (or seek to develop) an extensive variety of systems for achieving the general project aims proposed by the CDC for immunisations. Each project has also used different methods to develop these systems (Boyd and Linkins 2002). These projects therefore provide a ready basis for a case study and statistical analysis of what role federal support played in the
project’s success or failure. This project has been designed to examine the implementation and effectiveness of the IIS program and to explore how to best improve the IIS effort in the United States. The history, impact, and future evaluation needs of the IIS program has been examined, and proposals presented for how to address the many challenges faced by the program both now and in the future.

**International IIS Examples**

In an effort to understand how these systems should operate, this project began by first examining two programs that already exist outside of the United States that seek to implement similar information systems. For this evaluation the immunisation systems developed in both the United Kingdom and Australia were reviewed. A literature review consisting of peer-reviewed articles and published government reports was conducted to provide an overview into the history and operation of the IISs in each of these countries.

**UK and Australian Systems**

Australia and the United Kingdom have both sought to address the large data management requirement of modern health operations by utilizing computerized systems to track immunisation records (Sullivan and Mitchell 1995) (Kable and Harris 1997). Their approaches to this issue have been very different and have had differing impacts on public health in many areas. This literature review explores three distinct areas of public health impact: impact on physicians, on patients, and on public health.
United Kingdom (UK)

This evaluation suggested that the effort in the United Kingdom has focused on an overall electronic patient record (National Health Service 2002). Within this record are included the specific data values and information that comprise an immunisation history (National Health Service 2002). Specific areas of functionality in the computer system are devoted to immunisation record collection and a wide variety of immunisation evaluation utilities (National Health Service 2002). The National Health Service used focused efforts in public health informatics since 1998 directed at creating a unified health information system for electronic medical records as well as the electronic dissemination of general health information (National Health Service 2002). The electronic medical record was envisioned to consist of basic patient information (including vaccination history) which would be shared with appropriate professionals throughout the UK National Health Service (National Health Service 2002). However, evidence suggested that computerized immunisation records were mainly to be found within individual providers’ offices and are electronically shared only on a limited basis (Sullivan and Mitchell 1995). While no evidence could be identified to suggest that records were shared routinely electronically, most studies reviewed explored the use of computerized systems in clinical practice and the impacts on the consultation process, clinician’s performance of task, or patient outcome (Sullivan and Mitchell 1995).

In order to have any impact at all however, immunisation providers must accept the concept and practice of using electronic records (Sullivan and Mitchell 1995). Based on the articles reviewed (including Sullivan's systemic evaluation of
studies published between 1984 and 1994 of describing how systems in general practitioner offices impacted patient care) there appears to have been an acceptance of electronic immunisation records within physician community. Over 90% of UK general practices reported that they were already computerized as early as 1993 (National Health Service 2002). The main area of contention for provider acceptance of computerized records has been the question of record validity (Hassey, Gerrett et al. 2001). Record validity has been repeatedly studied in an attempt to ensure that general practitioner electronic records contain the appropriate data for each patient. The most recent published study of direct importance for this exploration has been Allan Hassey's study published in the British Medical Journal in June 2001. His report stated that 97% if the immunisation records reviewed for the study were accurate based on a comparison of disparate clinical record systems for the medical centre evaluated (Hassey, Gerrett et al. 2001). While patients still use paper immunisation records for their own documentation purposes, electronic patient records are now being considered the standard for medical records (Fleming, Blair et al. 2001). Studies such as this study challenge the basis for concern about electronic medical record validity. However, much work still remains before full acceptance will be possible (Hassey, Gerrett et al. 2001).

The aspect of the electronic medical record system that has had the most direct impact on the consultation process is how it is used in the clinic at the time a patient is being seen (Montgomery, Fahey et al. 2000). Part of the UK effort at computerizing health information has been directed at the development of computerized decision support systems (Montgomery, Fahey et al. 2000). At the most basic level these types of systems would include those that incorporate applications and programs that suggest treatment or diagnosis alternatives for each
patient case (Montgomery, Fahey et al. 2000). More complex versions would model the likelihood of adverse health events and suggest interventions based on patient data and systemic knowledge of general risk factors (Montgomery, Fahey et al. 2000).

For immunisations efforts, expert systems would include those programs that predict immunisations due for a specific patient based on immunisation status, patient age, and additional risk factors or medical contraindications (Delaney, Fitzmaurice et al. 1999). In an evaluation of controlled studies, Dr. Delaney provided the conclusion that "strong evidence exists that some computerized decision support systems can improve physician performance" (Delaney, Fitzmaurice et al. 1999). The studies showed that this improvement was most striking in the areas of reminder and preventative medicine systems (Delaney, Fitzmaurice et al. 1999). Of most import for immunisations were Sullivan and Mitchell’s systemic review of computer use in the primary care setting that identified an increase in immunisation rates by between 8% and 18% (Sullivan and Mitchell 1995). However, these studies did not suggest that this improvement was without any cost.

The main area where studies of the British electronic record system have shown a negative impact is in the area of clinic consultation time (Sullivan and Mitchell 1995). There is strong evidence that these systems have resulted in an increase in the amount of time required for a physician visit (Sullivan and Mitchell 1995). Because of this, the cost and effectiveness of interventions must also be considered in these equations when evaluating decision support efforts (Sullivan and Mitchell 1995). Sullivan and Mitchell’s review of these systems suggested though that the overall consultation time was only increased by 90 seconds on average (Sullivan and Mitchell 1995). While this may not appear to be a
significant increase in consultation time, this represents an average amount. This suggests that some systems did increase the consultation time.

Potentially the most important anticipated benefit for clinical immunisations from electronic record keeping is the issue that full records could be collected from disparate provider sources to create a single and more accurate immunisation record for the patient (Boyd and Linkins 2002). The British system is working towards goals of interoperability with their plans for a national health system, but progress was limited at the time of this review (National Health Service 2002). The current method of operation still relies on the transfer of individual patient records when a patient is seen by another provider (National Health Service 2002).

The final area reviewed for this project was the impact of the British electronic medical record system on patients. Sullivan and Mitchell’s work has been used to suggest that the use of these systems have not negatively impacted patient satisfaction (Sullivan and Mitchell 1995) (Note, this issue was selected as the course of study for analysis of the United States IIS program). However, they were unable to come to any conclusions as to how these systems impacted patient outcomes (Sullivan and Mitchell 1995). While the lack of evidence for negative patient impact may seem promising, some physicians have the opposite view. Letters to the British Medical Journal have stressed this opposing view by identifying several areas of contention. One area of contention was the concern about increased patient consultation time. While a slight increase in consultation time may not seem drastic, the increase without measurable improvement in patient satisfaction is cited as a serious drawback (Thornett, Szkandera et al. 2002). These letters also drew attention to issues that many patients have expressed concern over in the United Kingdom, namely the disclosure of medical
information, patient confidentiality, and the potential that these systems could serve as a barrier for the development of an empathic relationship between doctors and patients (Thornett, Szkandera et al. 2002). Unfortunately studies are not available that settle this question and further work is needed to ensure that the doctor-patient encounter and patient satisfaction are not negatively impacted by these systems (Thornett, Szkandera et al. 2002).

**Australia**

While Australian efforts at computerizing medical information has included the development of electronic health records, there has also been an additional concentrated effort to create a data system containing all immunisation records for children under seven years of age. In response to decreased immunisation coverage and increased childhood disease incidence, the Australian government initiated the National Immunization Program in 1995 (Kable and Harris 1997). Under this program, immunisation was recognized as a core preventive activity in general practice. The low immunisation coverage rates, while being a major health concern, were recognized as a health problem that Australian General Practitioners have sufficient opportunities to address (Australian Bureau of Statistics 1994). Research showed that many opportunities for vaccination were being missed, including the average seven times per year that children under 6 visit their general practitioners for intercurrent illnesses (Australian Bureau of Statistics 1994). The National Childhood Immunization Program immediately upon its creation worked to coordinate efforts to improve vaccination coverage rates (Kable and Harris 1997). Some encouraging results were immediately reported. Physicians began increasing the number vaccinations provided during a single visit and lowered the
rate of inappropriately delayed vaccinations due to mild infections (Kable and Harris 1997). Unfortunately, few general practitioners were consistently administering opportunistic immunisations (Kable and Harris 1997). One of the barriers inherent in the present system that was identified by the National Immunization Program was the lack of an adequate record system that could alert physicians of vaccinations due (Kable and Harris 1997). The Australian Childhood Immunisation Register was established in January of 1996 in order to help overcome this barrier (Kable and Harris 1997). This system was designed to not only to collect vaccination status information for individuals, but also to collect information on community vaccination rates and to create reminders for patients and parents of vaccinations due (Kable and Harris 1997).

This more focused approach to electronic immunisation tracking appears to have had a more dramatic impact than the generalized approach taken by the British. The evaluation of the registry for 1999 by Human Capitol Alliance suggested that support from immunisation providers was strong (Health Capital Alliance 2002). The system has allowed general practitioners to better monitor immunisation rates and to initiate additional efforts to raise vaccination levels (Health Capital Alliance 2002). For example, a randomized controlled trial demonstrated that home vaccination for children behind on their immunisations was effective, acceptable, and relatively inexpensive (Bond, Nolan et al. 1998). However, this intervention was only possible because the immunisation register was able to provide identifier information on children who were behind on vaccinations (Bond, Nolan et al. 1998). Unfortunately this study also highlighted one area of concern that has been expressed by General Practitioners, that of data accuracy. In the study by Bond et al, over fifty percent of the children originally identified as behind on immunisations turned out to be up to date based on the
parent’s record (Bond, Nolan et al. 1998). In the Human Capitol Alliance evaluation of the registry for 1999, many practitioners expressed concern for the validity of data within the Australian Immunisation Register. This same evaluation however also found that 75% of the providers in the study thought that the data quality had improved since the system's inception. Nevertheless, many providers still pointed to inconsistencies that caused the system to incorrectly estimate immunisation coverage due to inaccurate patient data (Health Capital Alliance 2002). Kable suggested that the streamlining of the reporting method for general practitioners could overcome some of these problems. He also suggested that the installation in provider’s offices of computers that could automatically report to the Australian Immunisation Register could also improve data quality and reporting compliance (Kable and Harris 1997). This suggested that providers should be educated to ensure that they are aware of the impact and implications of failing to report to the system (Kable and Harris 1997).

In contrast, the data inaccuracy also has had a negative impact on the public’s perception and acceptance of the system for the opposite reason put forth by immunisation providers (over estimation of coverage) (Health Capital Alliance 2002). Underreporting of vaccination events by vaccination providers has resulted in the delivery of inappropriate overdue reminders for patients and wasted follow-up efforts (Health Capital Alliance 2002). Even so, parental acceptance of the registry has been very high, with 98% reporting satisfaction with the system and 38% rating the service as excellent (Health Capital Alliance 2002). The evaluation of the registry for 1999 by Human Capitol Alliance suggested that while some areas for concern remained the overall data quality for the Australia Childhood Immunisation Registry was good (Health Capital Alliance 2002). Major data concerns identified dealt with data timeliness and completeness rather than
accuracy (Health Capital Alliance 2002). Even so, studies by Herceg have indicated vaccination performance by general practitioners can be improved through provider and public education and dissemination of appropriate information (Kable and Harris 1997). The Australian Childhood Immunisation Register can fill some of this need even while there are concerns about data quality (Health Capital Alliance 2002).

Comparison of the UK and Australia Approaches

The studies that were identified relating specifically to the differing areas of system impact suggested that the two systems have had differing impacts in the three areas of consideration: Physicians, Public Health, and Patients. Physicians appear to have been more accepting of the computerized systems in the United Kingdom. Australian general practitioners had more concerns with the validity of register data. However, the Australian system had been better able to provide consolidated records from multiple immunisation providers. The Australian system has also had more of a measured impact on general public health as measured by immunisation coverage rates. It has been used to augment additional new immunisation efforts such as home vaccination and other targeted outreach efforts. Finally, while patients and the general public appear from these studies to be more comfortable with electronic medical systems in the United Kingdom, the overall impact and public attitude has received much more attention in Australia. It appears that the largest factor in the difference between acceptance levels is simply the extent to which these systems pervade the British health system. Electronic records systems in 2002 still appeared to be relatively new to both the
public and practitioners in Australia while they saturated the medical system in the United Kingdom.

The main areas for improvement are also very different between the two systems. In the United Kingdom, the studies reviewed suggested that the main function that could most improve the British system would be increased communications and data sharing abilities. The Australian system on the other hand is much more advanced in the area of data transfer, but most needs to improve the resulting data quality problems created by widespread data sharing and data collection/reporting problems. While each system has room for improvement, they both have had positive impacts on each national immunisation program and can serve as models for other countries who are seeking to improve or create electronic immunisation tracking systems.

Section Updates: Developments since these Systems were Originally Considered

The initial evaluation of the UK and Australian systems took place in 2002. Since then more material has become available for review in the United States and many changes have taken place in these two systems. Recently in Australia, the debate over whether the immunisation register should be expanded has been raised in the Medical Journal of Australia. The argument put forth by Susan Skull and Terence Nolan in 2007 was that since the register only includes funding for the inclusion of vaccinations given to patients up to 7 years of age, and since the number of vaccinations available for patients over 7 years of age has increased, it would make sense to expand the register to include vaccinations given at older ages (Skull and Nolan 2007). In fact, the Australian government had performed a
scoping exercise to explore the need for an immunisation register that covered all vaccinations an individual may receive throughout their life.

In the United Kingdom there has been a continued effort to develop what Sean Brennan described as the largest IT project in world history (Brennan 2005). While there have been the directional changes and cost overruns one might expect for a project of this size, there has been considerable progress made (Brennan 2007). However, the summation of the current state of the project provided by Brennan brings one back to the basic issues involved with all IT projects:

1. The conflict between those who wish to simply deliver a system and those who wish to change the way the recipient of the system does business continues to exist (Brennan 2007).

2. Political leadership is critical to any project of this size (Coiera 2007).

3. Evaluation of the impact of the program is essential to both the post-implementation and formative stages of the project (Coiera 2007).

Use of the immunisation information in the UK has expanded to the point where the program COVER (Cover of Vaccination Evaluated Rapidly) pulls data from the existing system to estimate immunisation coverage levels in England, Scotland, Wales, and Northern Island (HPA COVER Team 2006). At the same time, the National Programme for Information Technology only half way through planned implementation. Interviews conducted by Currie and Guah suggest that the programme is under threat from conflicting requirements in an increasingly complex healthcare environment (Currie and Guah 2007). It is helpful to note however that even though the environment is more complex, the Health Protection Agency, National Public Health Service for Wales, CDSC Northern Ireland, and Health Protection Scotland manage to collate UK immunisation coverage statistics.
from the computerised child health records (Health Protection Agency 2009). Data from the most recent quarter available (January-March 2009) suggest that the surveillance and tracking of immunisation indicators in this manner is having a positive impact on public health (Health Protection Agency 2009). This data may suggest that the UK direction of relying on electronic health records rather than a central immunisation registry may provide similar benefits to an IIS. This question warrants further study in future comparative evaluation of the impact of national efforts to collect vaccination coverage data.
Immunisation registry development in the United States has taken a wide variety of paths. Each state and local/territory grantee has had the ability to design their registry to fit their specific needs in any way they see fit. The CDC has provided recommendations on standards, but until 2004 had not required that these standards be used. One area where there is agreement between projects however is the purpose of immunisation information systems. This is perhaps best delineated by Dr. Sinn when he wrote that “the purpose of an immunisation information system is to increase the efficiency and effectiveness of immunisation related practices” (Sinn, Kronenburg et al. 1997). What functions should be impacted and how these practices were to be made more efficient has been interpreted differently by multiple projects.

These systems have been considered essential tools to increase and sustain high vaccination coverage by consolidating vaccination records for children from multiple providers (National Vaccine Advisory Committee 1999). IISs have been seen as such a promising tool that one of the Healthy People 2010 national objectives is to increase the number of children with records in a fully operational population-based IIS to 62% of the population under 6 years of age (Department of Health and Human Services 2007).

**Initial Efforts**

Immunisation registries had been developed across the United States on a small scale since the 1970’s (Saarlas, Hinman et al. 2004). Local and state level projects
sought to respond to vaccine preventable disease outbreaks by providing a more
detailed view into the vaccination status of the local population (Saarlas, Hinman
et al. 2004). This effort continued, project by project, until 1991 when the Robert
Wood Johnson Foundation (RWJF) developed a grant program to encourage the
development of immunisation monitoring and follow-up systems (Saarlas, Hinman
et al. 2004). This was in response to a surge in measles outbreaks in the 1980’s,
which drew national attention to problems with immunisation coverage (Saarlas,
Hinman et al. 2004). This was intended to be a straightforward project that would
last for only five years (Saarlas, Hinman et al. 2004). The stated goals of the
program in 1991 were to:

1. Produce a documented increase in the rates of immunisations among
   preschool children.
2. Decrease the incidence of vaccine-preventable disease, and
3. Assist grantees with exploring the use of information systems to support
   broader preventive service needs of their population.

(Saarlas, Hinman et al. 2004)

To be considered fully operational, a project had to meet the following
standards:

1. Include 95% of the target population under age 2 years.
2. Ninety five percent (95%) of the children in the system had to have
   at least one immunisation recorded.
3. Ninety percent (90%) of private and public immunisation providers
   submitted data to the IIS.
4. Security and confidentiality policies must be in place to protect
   system data.
5. The system must be able to produce reminder and recall notices for children needing immunisations.

6. The system must be able to produce immunisation coverage reports.

(Robert Wood Johnson Foundation 2007)

By the end of the initial 5 year program, none of the original grant recipients had achieved a “fully operational” IIS (Robert Wood Johnson Foundation 2007). RWJF continued its support of the immunisation information systems and by 2004 had invested 13 years and over $30 million in an effort to promote immunisation information systems (Robert Wood Johnson Foundation 2007). However, increasing immunisation rates and decreasing vaccine preventable disease were no longer focused on as program goals. In part, this was due to the fact that registries had not reached the participation goals as the program had hoped. In 2003, Kristin Saarlas wrote in the Journal of Public Health Management Practice that the percentage of children 24 months of age with up to date immunisations was reported to be below 80% by all but one. At that time, none of the IIS systems had fully populated databases or complete immunisation records for every child (Saarlas, Edwards et al. 2003). One of the most critical lessons learned during the RWJF program was that immunisation information systems were much more complex and difficult to make fully operational than originally thought (Robert Wood Johnson Foundation 2007).

Federal Initiatives

The federal government started supporting immunisation registries with significant funding in 1994, but this support was dramatically increased after 1998
with President Clinton’s Presidential Directive to the Department of Health and Human Services to work with states to create an integrated IIS (National Vaccine Advisory Committee 1999). According to the National Immunization Program’s annual budget process, between 1998 and 2005 the federal government invested over $250 million in immunisation information systems. This investment aimed at creating a network of interoperable state and local IISs rather than a single national system (National Vaccine Advisory Committee 1999). Rather than an evaluation of whether state or national systems might be more useful, this was a directive from the US Congress. While there may have been many pros and cons for choosing a national system versus a state and local based series of projects, this was not a direction that was explored by CDC due to Congressional instruction.

The federal government adopted standards for IIS projects to help determine what was required for a project to be deemed successful. In an effort to harmonize the basic operations of these differing IIS efforts, the National Vaccine Advisory Committee developed 12 functional standards that all IIS programs should follow. These functional standards were:

1. **Electronically store data on all National Vaccine Advisory Committee (NVAC)-approved core data elements**

   **Definition** - The registry’s computer database must contain fields that correspond to all NVAC-approved core data elements. These elements are the following: 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. The core data elements comprise the basic set of data that registries use for exchange with each other. They are designed to
standardize a set of patient demographic and vaccine event elements considered essential to non-duplicative record exchange between registries. The mother's name element refers to current legal mother (who may or may not be the birth mother). A registry receives credit for the inclusion of patient and mother names by collecting at least a surname and one other name element.

2. Establish a registry record within 6 weeks of birth for each newborn child born in the catchment area.

Definition - Identifying information from a population-based data set (e.g., vital statistics) is sent to or retrieved by a registry regularly in a computer file format to generate patient records. This file must require little (if any) manipulation by registry staff for the data to be entered into the immunisation registry. Such information is available in the registry within 6 weeks of birth.

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

Definition - The registry provides a method that allows providers to access and retrieve immunisation records prior to or at the time of a scheduled patient encounter. This standard accommodates registries that do not operate continuously (e.g., closed Sundays and holidays) and those that send and receive non-electronic records in order to allow access to users without electronic capabilities. For example, providers can request and receive the immunisation record(s) needed from the registry prior to the
scheduled encounter. This can include printed patient lists, flags on charts, fax request, or phone requests.

4. **Receive and process immunisation information within 1 month of vaccine administration**

   **Definition** - The registry receives and processes immunisation information within 1 month of vaccine(s) administration. The resulting record must then be available for systematic recall in the patient’s overall immunisation history.

5. **Protect the confidentiality of health care information**

   **Definition** - The registry has implemented written confidentiality policies and procedures, including administrative and technical practices to protect health care information. The policies and procedures must be consistent with applicable state, local, and Federal law (HIPPA or other privacy laws), and with the recommended specifications and guidelines outlined in the updated manuals published by CDC except where they conflict with applicable local legislation.

6. **Ensure security of health care information**

   **Definition** - The registry has implemented written security policies and procedures, including administrative and technical practices and physical safeguards to protect health care information. The policies and procedures are consistent with applicable state, local, and Federal laws. The CDC registry manual served as the recommended specifications and guidelines in
2002 due to delays in implementation of the Health Information Privacy and Protection Act (HIPPA).

7. **Exchange immunisation records using Health Level Seven (HL7) standards**

   **Definition** - The registry has a function, at the central level, that creates, receives, and properly processes the HL7 messages, as specified in NIP's Implementation Guide for Immunisation Data Transactions using Version 2.3.1 of the Health Level Seven (HL7) Standard Protocol, published in June of 1999. While one of the goals of this standard was to enable transfer of records between state registry systems, this issue would have to be negotiated between each state individually. This was in part due to local privacy concerns and differing legislative restrictions on interstate data transfer. Each state choosing to transfer data across state lines is required to negotiate that transfer 1:1 with the receiving state program. No federal legislation currently defines how those agreements should occur.

8. **Automatically determine the routine childhood immunisation(s) needed, in compliance with current Advisory Committee on Immunization Practices (ACIP) recommendations, when an individual visits a physician**

   **Definition** - The registry has an automated function, accessible at the provider level, which determines needed routine childhood immunisations in compliance with current ACIP recommendations using an individual's current immunisation history.
9. **Automatically identify individuals due/late for immunisation(s) to enable the production of reminder/recall notifications**

   **Definition** - The registry has an automated function that can produce a list of individuals who, as of a given date, are due or late for immunisations according to the registry's algorithm described in functional standard 8. The output from this function provides information that allows for the production of reminder or recall notices.

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

    **Definition** - The registry has an automated function to assess immunisation coverage (e.g., % of children "age-appropriately" immunized) as of a given date for an individual provider's practice, for the registry's entire catchment area, and for subgroups within a practice or the catchment area (e.g., children of a certain age).

11. **Produce official immunisation records**

    **Definition** - The registry has a function that allows authorized users to produce a copy of an individual's immunisation history that is accepted as an official immunisation record.

12. **Promote accuracy and completeness of registry data**

    **Definition** - The registry has developed and implemented a data quality protocol that combines all available data relating to a particular individual into a single, accurate immunisation record.

   (Systems Development Branch 2001)
These standards were identified by consensus through a series of surveys and focus group research used to determine what functions were considered vital to registry operations by immunisation program managers and registry developers, users, and other concerned stakeholders (Systems Development Branch 2001).

In an effort to monitor this investment, CDC developed a questionnaire designated as the Immunization Registry Annual Report (IRAR). The IRAR was designed to measure the level of participation in the IISs of immunisation providers and patients and to track the implementation of the 12 functional standards that the government considered essential for IIS operation (Boyd and Linkins 2002). This report was sent to all programs that receive federal immunisation funds each year under Public Health Service Act (Boyd and Linkins 2002).

One of the most critical aspects of the federal initiative towards the development of IISs was this designation of standards to define success. While the federal government did not tell projects how to build their systems, they did describe functionality that was minimally necessary in order for these systems to meet program goals and to perform as an interoperable network of systems (National Immunization Program 2001).

The Impact of Measuring Efforts

Another lesson from the IIS experience that can be applied to the Health Information Technology (HIT) initiative is how the focus of oversight of the program can influence the development of the National Health Information Network (NHIN). The federal government has used to the IRAR to bring attention
to aspects of the program that need improvement. Nineteen ninety-nine was the first year when the IIS projects completed the IRAR. At that time, only 69% of projects reported implementing registries, though funding had been made available for five years (Systems Development Branch 2000). Planning or pilot testing registries were reported by 26%, while three reported no activity on registries at all (Systems Development Branch 2000). Two projects failed to respond to the IRAR entirely (Systems Development Branch 2000). By gathering this information and publishing the results, the Systems Development Branch prompted many projects to focus their efforts on beginning implementation. Few projects wished to be identified as lagging behind the rest of the nation in implementation and quickly moved to meet the requirements for implementation (Linkins 2001).

In 2000 implementation was no longer the biggest issue, but the Systems Development Branch had concerns over whether projects were meeting the functional standard requiring them to have population based systems (Systems Development Branch 2001). In responding to revised IRAR, 32 projects claimed to operate population based registries while 15 were planning to do so (though they may have had systems that did not qualify as population based in place). The remaining four projects reported pilot testing such registries (Systems Development Branch 2001). Once again, by bringing attention to this specific functional standard, the federal government was able to prompt projects to focus on their efforts to meet this standard. The following year again showed a welcome increase in the area stressed in this report.

By 2002, the concern was no longer about whether the IIS included the whole population, but whether they generated the initial IIS records using population based information such as vital statistics records. Only 37 projects could claim to have population based registries under this definition, seven were
pilot testing such registries, and seven had plans to do so (Bartlett 2004). After 2002, most states had adopted this requirements and the federal government stopped reporting which states were operating or planning IISs. The focus instead became levels of participation and interconnectivity with other health management programs (Rasulnia and Kelly 2005).

For the IIS program, each year the annual report was published with an editorial note touting the progress for the year and focusing one or two areas that the government felt deserved special attention. In 1999 the IIS program concerns were for the challenges facing registries, particularly in the area of privacy (Systems Development Branch 2000). The Health Information Portability and Accountability Act (HIPAA) had only recently been put in practice, and security and privacy in registry operations were stressed (Systems Development Branch 2000). The need to ensure provider participation was also stressed. However, the highest priority was placed on discussing the need to fully fund IISs, stressing their potential savings to the program and their use in promoting safe vaccination practices (Systems Development Branch 2000). This served to focus the national debate around IIS funding and prompted IIS projects to focus on meeting the demands of HIPAA (Systems Development Branch 2000).

In 2000, ensuring provider participation was still being stressed as a major problem by the IIS program (Systems Development Branch 2001). The need for complete participation was pointed out using statistics on child mobility and the number of doctors seen by each patient (Systems Development Branch 2001). The IIS program also initiated a discussion about the disparity between public and private immunisation provider participation (Systems Development Branch 2001). It was found that these programs had started well in the public sector but were slow to make the shift into the private physician’s office (Systems Development Branch
2001). By opening this discussion, the IIS program sought to identify over the next year potential means of improving the adoption of IISs by private physicians (Systems Development Branch 2001).

As the IIS program matured, the tone of the editorial reports changed. In 2001 participation levels were still mentioned, but the direction of editorial comments shifted from merely collecting data to encouraging the active use of available data (Boyd and Linkins 2002). This was done by presenting success stories from various grantees, such as San Antonio’s use of registry data programmatic decision support during the introduction of new vaccines (Boyd and Linkins 2002). San Antonio's data demonstrated that there were disparities in how different populations were being provided the new pneumococcal conjugate vaccine (PCV7) (Boyd and Linkins 2002). Providers who did not participate in the Vaccines for Children program began using the vaccine soon after licensure for privately insured patients (Poydence 2001). Due to a delay in the addition of the vaccine to the federal purchase program, there was a slower uptake among VFC-eligible children (Poydence 2001). Additional examples were provided, including the use of registry data to measure the effectiveness of reminder recall systems (Romey 2001), identify the causes of delayed immunisations (Canavan 2001), and to track how quickly and thoroughly changes in the immunisation schedule were implemented (Canavan 2001). This change in reporting had the desired impact of stressing the use of data as seen in the increase in reports and publications about the effectiveness and use of registries in the following years.

In 2002, the IIS program focused on data quality and potential measures of registry data completeness. Comparisons of IIS data to the national survey of immunisation rates as well as chart audits were considered (Barker 2003; Khare, Piccinino et al. 2003). This evaluation was completed because the IIS program had
come under fire regarding the quality of data contained in the registries and whether that data could really be used for programmatic decision-making. National Immunization Survey (NIS) data in 2002 suggested that 44% of children between the ages of 19 and 35 months participated in immunisation registries (Barker 2003). This was similar to the results reported in the Immunization Registry Annual Report for 2002 (43%). However, when it came to assessing the completeness of registry data the results were not quite so compatible. A comparison of immunisation records in four registries (three states and one city system) and the NIS results found that in each case the NIS coverage estimates were higher than those supported by IIS records, and that approximately 40% of the records for individuals in IISs were incomplete (Barker 2003; Khare, Piccinino et al. 2003).

In 2003, the federal health IT focus was on data standards and interoperability. The Consolidated Health Informatics (CHI) program had developed messaging standards for immunisation information, and this was seen as a first step in truly moving towards the goal of interoperability between projects (Rasulnia and Kelly 2005). In 2003 36% of respondents reported using the Health Level 7 standards for communication that were being adopted by CHI but which had been promoted by CDC for use in immunisation information systems for several years (Rasulnia and Kelly 2005). By 2004, the IIS program needed to respond to the creation of the President’s Management Agenda for evaluating federal programs. This required another change in the focus of the annual editorial message. The IIS report began to stress the criticality of project plans, milestones, and documented improvement due to the program (Urquhart, Kelly et al. 2005). IISs were informed that in coming years their programs would be reviewed more closely by the federal government, and that the limited resources of technical
assistance and programmatic evaluation would be directed at the areas of the
program needing the most improvement (Urquhart, Kelly et al. 2005).

Comparison to UK and Australian Efforts

In comparison to the United Kingdom and Australian efforts, the United
States has taken a path much closer to that of the UK. While the focus on state IIS
projects is similar to the Australian model, the development of a program to
develop an NHIN is in some ways similar to the UK model. However, while the
UK has been aiming to implement a central system, the United States has
continued to focus on a more federated model. However, the use of the data from
the immunisation register is more advanced both with the immunisation registry in
Australia and with the use of electronic medical record data in the United
Kingdom. The United States stands to learn much from a continued examination
of how both immunisation registries and electronic medical records systems are
implemented in other countries.
Section 3: Current IIS Challenges

Immunisation registries in the United States were first funded at the national level in 1994 (National Vaccine Advisory Committee 1999). Since then there have been some true success stories including the state immunisation registry in Oregon. This system has been used to limit the impact of vaccine shortages, study the impact of the removal of thiomersal as a vaccine preservative, as well as to handle routine immunisation program activities (Canavan and Crawford 2002). Unfortunately there have also been projects that have not performed up to expectations and that continue to struggle (Jones, Boyd et al. 2002). The national project has reached a point in its lifecycle where the program faces multiple challenges and opportunities. These challenges include changes in privacy concerns, reductions in funding levels, the continuing development of new electronic medical record systems, the changing views on the importance of immunisation registries due to the new focus on terrorism in the United States, and questions about the overall need of these systems. Each of these challenge areas are discussed in more detail below. However, one can readily see that what is at stake when the registry project addresses these issues is not just the direction of the program, but also the existence of the program.

Challenge Area 1: Privacy Concerns Related to Information Technology

At the time of the original review, immunisation registries stood to both potentially benefit as well as be threatened by changes in privacy concerns that have occurred between 2001 and 2004. Since the attack on the World Trade Center in 2001, a drastic change has occurred in the attitude of many U.S. citizens
towards government collection of information. The terrorism threat (or perceived increase in threat) has made the general public much less concerned about the use of massive government databases. However, there is also concern that the extensive (and potentially draconian) use of such systems may result in a backlash against such systems, whether they are related to counter-terrorism or public health (Electronic Privacy Information Center 2003).

One of the most publicized efforts at creating a national database of personally identifiable information came with the Department of Homeland Security and their development of a system for tracking all air travellers. The system was scheduled to go into effect in 2003, but due to extreme backlash related to privacy concerns the project was cancelled. However, the Department of Homeland Security has been able to move forward with a database of travellers who are not United States Citizens. While there has been international denouncement of this and other security measures, the United States has currently withstood international pressure while bowing to internal pressure (Seifert 2004).

As with the example above, the immunisation registry effort has faced attacks based on privacy concerns even though the intent of the various immunisation registry projects is strictly for the public good. The goal of eliminating unnecessary injections for children and the potential for improved immunisation levels in the United States are worthy goals (Jones, Boyd et al. 2002). However, these and other goals for the development of a national network of immunisation registries have failed so far in outweighing the public’s concerns for privacy. Immunisation registries are commonly restricted in what information they can collect, who that information can be shared with, and how the information can be used. Some states have even enacted laws forbidding their state registry from sending information across state lines (Horlick 2003).
The CDC rarely intrudes in state affairs. In fact, when a disease outbreak occurs in a state, the impacted state must request assistance from the CDC before this federal agency can take any action. In this climate, it is virtually impossible for the immunisation registry development project to be able to require from the federal level that states transmit data among the states or between the states and the federal government. Such a mandate would have to come from Congress, and the privacy lobby so far has prevented this from happening. In light of the prominence of computer systems related to the new Department of Homeland Security, one can easily see why immunisation registries have not been brought to the forefront of the fight between privacy concerns and the public good. It is impossible to guess which direction the final choice will go between privacy and public interest. At the time this section was written, the Presidential elections in November 2004 were expected to have a large impact on whether this type of system moved forward. In the United States, the Republican Party traditionally has been more in favour of supporting individual privacy while the Democratic Party has often sided with the “public good”. At that time the next election would not only determine which party would be involved in these decisions, it was also to likely determine the outcome of court battles brought by privacy advocates against national data collection efforts. One consideration at that time was that the Supreme Court of the United States was currently balanced between conservative and liberal forces. It was anticipated that if the Republicans won the election it would have given a conservative president the opportunity to change the balance on the Supreme Court by appointing two new conservative justices. This would give the conservatives a strong majority on the court, allowing for the reversal of past rulings that supported national data collection for public health. The end result could be the elimination
of not only the immunisation registry program but also many other public health data efforts (Cornell University 2003).

Like many social dichotomies (such as conservative or liberal, freedom or security), the current battle between privacy and public health tends to follow a pendulum swing pattern over time. Currently it appears that we are in a time in history where the events of the past two years will either boost the pendulum of public opinion further into the privacy arena, or it will signal the reversal of the public opinion in favour of public health. It is too early to know at this point, but the elections in November 2004 provided a strong indication of what the future holds for public health data systems. If the nation continues to value privacy over public health, we will likely witness the collapse of the immunisation registry efforts in the United States. If public opinion changes in favour of national data collection, immunisation registries will still face the problems discussed in the following sections (Wellman 2000).

Challenge Area 1 Update: Time has shown that while there were reasons for these concerns, they have yet to manifest. While the Republicans won the election in 2004, there has been little action regarding expanded regulation of immunisation information systems at the federal level. This debate has largely been left to the states to determine, and the elections in 2004 turned out to have had much less impact in this particular area than anticipated.

Challenge Area 2: Decreased Funding

Another problem that immunisation registry projects must face is a decline in project funding. Funding for immunisation registry projects is in serious
jeopardy of being decreased or eliminated in favour of investment into other activities. One federal example brings this issue into sharp focus. Since 2001, IT development efforts at the CDC in the United States has become less focused on promoting immunisation registries and more focused on national monitoring systems for disease and symptom surveillance. This is largely due to the increased concern with terrorism and biological attacks (Hensley 2003). With limited funding available, resources for these new projects often come at the expense of existing projects such as immunisation registries. As a case in point, one can look at the Immunization Registry Support Branch (IRSB) at the National Immunization Program (NIP) in CDC. This branch in 2001 had a cadre of 16 full time staff and fellows working to promote registry development and to standardize registry communication. In January of 2003, that branch has been reduced to six full time staff. The remaining staff members have been pulled away into smallpox, bio-surveillance, and bioterrorism related system integration activities. This trend does not appear to be reversing, but rather may result in the dissolution of the team tasked with promoting immunisation registry development. This would eliminate the group tasked with ensuring that a national system of state immunisation registries develops and prospers in the United States (Boyd 2003).

Shifting priorities are not the only kind of problems creating a funding shortage for immunisation registries. Overall support for information technology investment is also at risk. In fiscal year 2004 the CDC expected to receive a $34.5 million reduction in funding related to information technology. The share for the NIP is expected to be $3.4 million in 2004. While federal funding for immunisation registries is not the sole source of funding for these projects, $3.4 million dollars translates into a fifteen percent reduction in the funds available for immunisation registries. Some states would easily be able to cover the cost of fully
funding their immunisation registry efforts since they already fund over 85% of their project from internal state funds. However, other states rely on federal funding for over 80% of their registry budget (Fontanesi, McKenna et al. 1999). Any reduction in the level of federal funding in these states could easily result in the cancellation of their immunisation registry activities. This would seriously jeopardize national efforts to make immunisation information available nationwide to any provider who has a legitimate need for the patient data.

Even states that do not rely on federal funding for the operation of their registries are not immune to funding problems. The poor performance of the economy in the last 10 years has left many states with serious budget deficits. While there are many options for cutting funding that do not include cuts in public health, many of these states also tend to be the ones that do not have fully functional registries. It is much easier to cut a project that has yet to demonstrate that it is beneficial than it is to cut a project that is fully operational and has shown tangible results. This could easily result in a situation where there is no base level of functionality available between different states. If even one state failed to push forward with funding for their immunisation registry the federal goal of an interconnected system of registries across the United States would be a failure. For this reason, the federal government has begun studying the viability of regional systems that support states that have functional systems or are continuing development (Canavan 2003).

Funding has not always been a problem for immunisation registries. In the late 1990’s immunisation registries benefited from a dramatic increase in funding and fiscal support from both the federal government and state governments. Some states also sought alternative funding sources. One such attempt involved charging the medical insurance establishment a fee based on the percent of the population
the company covered in a specific state. Operating costs could then be split among the various insurance companies (Brand 2003). Unfortunately, exploration of alternative funding took place in only a few states. Most continued to rely either entirely on federal funding or on a combination of federal and state funding. These states are now the ones most at risk as state and federal spending for immunisation registries dries up. In times of fiscal problems, public health data collection can become seen as a luxury by politicians and budget analysts. Immunisation registry projects have not yet provided definitive proof that such data collection improves public health in a quantifiable manner. While many studies have been conducted to show the benefits of various state and local projects, these studies have quickly become outdated in the face of rapid technological development. This leads one to the next risk faced by immunisation registries in the United States.

Challenge Area 3: The Pace of Development in other Electronic Medical Record Fields

By far the largest challenge facing immunisation registries in the United States today is the development of technology alternatives that have reduced the perceived value of immunisation registries. When immunisation registries were first funded by the federal government in the early 1990’s, most physicians still did not use computers in their offices. Today computers are not only increasingly commonplace in physician offices but many doctors are increasingly reliant on electronic medical records. There are over 400 companies in the United States that offer clinical practices some means of capturing administrative and medical data on their patients through a variety of software and hardware solutions. Software has been developed for every standard office computer and operating system that
will allow a physician to track patient visits, verify insurance, schedule
appointments, and track all medical procedures performed for billing purposes.
These systems have become so prevalent that the United States Congress chose to
create the Health Information Privacy and Portability Act to institute some level of
control over how information was collected and how it was shared. There are still
occasional physicians who rely on paper patient records rather than computerized
data in their practices, but they are becoming harder and harder to find (Centers for
Disease Control and Prevention 2001). Given this increase in electronic data
storage, immunisation registries must demonstrate that they continue to be useful
tools.

Immunisation registries currently do only one thing that has not been
implemented in other medical record systems. Vaccination records from multiple
doctors are collected in an immunisation registry, where office medical record
software tends to be limited to information from a particular doctor. These
systems have not been developed into data repositories that can be queried for
patient information provided by multiple physicians in disparate locations to
retrieve a complete medical history. Some companies are starting to build into
their systems the capability to communicate between offices that use a single type
or brand of software. However, in most cases adding information from another
doctor can only be accomplished through basic import and export utilities built into
the software that require the physical copying of data carried from another
physician’s office. These utilities are not beneficial when information is needed at
the time or point of service (Boyd 2003). Immunisation registries have yet to be
surpassed in their ability to provide up to date information on a child’s
immunisation history collected from multiple sources. While this ability is still
fragmented, many states have at least managed to include the majority of
physicians from their specific state. Interstate transport of information to date remains virtually nonexistent (Jones, Boyd et al. 2002).

Immunisation registry projects currently have two directions in which they may readily develop. The first option is to continue to provide physicians with a separate source of data that is not available in their own medical software. Most often access to this information is through a defined piece of software designed specifically for the collection and retrieval of immunisation records. This however is a temporary solution because such systems would eventually be made redundant by increasing advancement in the portability of electronic health information between physicians’ offices or clinical practice data systems. A second option would be to focus on information interchange between public health registries and private electronic medical record systems. This would provide a source of medical information not readily available today while eliminating one of the biggest challenges that immunisation registries face. Over the past 10 years registries projects have found that immunisation providers will not participate in data collection if the registry requires them to enter data that they have already entered in another location or another application. Registries therefore may focus on linking to medical record systems and providing a secure source of data for exchange between multiple systems. Again, efforts in this direction could potentially be overshadowed by continuing advances in the field of medical information portability, but it offers the opportunity for registries to have a longer useful lifecycle as a repository for immunisation information. A third option is to reduce investment in immunisation registries and to focus on new and emerging technologies. The main drawback with this option is that the federal and state governments have most often been several years behind the private sector when it comes to adopting new technology. It has been stated that the national effort to
develop immunisation registries can be likened to attempting to solve the problems of 1980 with technology from 1990 in the year 2000. In order to be effective under this option the national immunisation effort would have to reverse a history of lagging behind the private sector in technology application (Holbrook, Keshavjee et al. 2003). While this could be done, it would require a major shift in how government interacts with private companies. It would also require a willingness to abandon an effort in which it has heavily invested over the past 10 years. As with most government bodies, the federal government of the United States is not known for its willingness to change strategic direction after a project has been created and heavily funded.

Challenge Area 4: Perceived Importance Due to New Terrorism Focus

Though there are many indications that immunisation registries are threatened in the United States as mentioned above, there is one area that holds promise for the advancement of the national immunisation registry project. This advancement may be in modified form, but the systems may still progress. The new focus on bioterrorism in America has forced a re-evaluation of the public health information technology infrastructure. In the early 1990’s there was virtually no public health infrastructure for information technology. A large amount of the investment in immunisation registries in the 1990’s went to developing an infrastructure upon which immunisation registries could be built. Regardless of the final outcome of immunisation registry efforts in the United States this investment in the technology infrastructure of the national public health system has had lasting benefits that can be used to advance additional information technology projects (Jones, Boyd et al. 2002; Holbrook, Keshavjee et al. 2003).
One example of a project that has used the infrastructure built to support immunisation registries is the national vaccine safety network. Prior to immunisation infrastructure investments vaccine safety data was collected through the mail or fax on paper forms. As immunisation clinics had computers installed to support their participation in the immunisation registry effort, they also gained access to electronic data collection tools for vaccine safety reporting. Materials that previously had to be ordered and printed at a large expense to the federal government could now be reached by the clinic on the internet, thus saving the cost of shipping and printing hard copies of the information. This was just one of many immediate benefits to clinicians from the addition of computers to their work environment. The CDC have also used this infrastructure investment for use in protecting the public health (Larson 2003).

One example of the projects that have benefited from the massive investment in immunisation registries by the United States is the Health Alert Network. The Health Alert Network is a system of email, fax, web, and automated phone messages to warn physicians or any unexpected events that would impact their ability to administer vaccines. Since September 2001 this network has taken on a more terrorism related focus, but it is still used for general disease outbreak notification and other public health messages (Larson 2003). This notification system would not be able to reach as many people as quickly as it does without the prior investment in public health infrastructure by immunisation registry projects.

National Disease Surveillance has also built upon the foundation provided by immunisation registry investment. The National Electronic Disease Surveillance System (NEDSS) is a combined project that seeks to incorporate all reportable disease surveillance efforts into one system. The resulting software communicates through the Internet and provides rapid dissemination of pertinent
information and collection of such information at the CDC. Without the investment in immunisation registries by federal and state government agencies most public health clinics would still not be connected to the Internet. Disease reporting in this manner is easier and quicker than prior paper reporting methods, and it allows scientist to review disease trends as they evolve rather than waiting several weeks to see what today’s disease pattern has been. While investment in this system has been extensive over the past three years, the NEDSS concept would not be possible without the improvements in the public health information technology infrastructure provided by prior immunisation registry development (Andrus 2003).

What is the existing need for immunisation registries?

The final threat to the development of immunisation registries in the United States is the concern about whether or not these systems are still needed. An argument can be made for either eliminating or evolving the immunisation registry effort into other projects. In this scenario, immunisation registries would change to encompass other public health data needs and would merge with existing public health databases. Lead surveillance, the Cancer Registry, and Environmental Health database all are examples of systems that have been connected in some way to immunisation registries. By strengthening this link and merging system projects, the CDC could effectively streamline their efforts in information technology development while at the same time advancing the goals of each separate project.

It is helpful to review the purpose originally put forth for immunisation registry development in the United States when one considers whether these
systems are still needed. First, immunisation registries were created in an effort to improve physician recordkeeping. Registries were supposed to consolidate chart information so that physicians could review a patient’s immunisation history quickly and easily. Clinic software today however does an admirable job of this and in some cases can perform this task more readily than an immunisation registry. Immunisation registries therefore no longer fill a void in data collection at the provider level since other systems are available for the same function.

Secondly, immunisation registries were designed to improve the portability of vaccination information between one physician’s office and another. This has been accomplished on the local and state level, but the United States has yet to reach the goal of information portability between states. For this task there is not currently an alternative system that could be used to serve the same function. Clinical software manufacturers are working towards this goal, but the function is not yet widely available in the private sector. One could say then that registries are still needed to serve this function until alternatives have evolved. Another goal of immunisation registries was to develop systems that would be able to automate many of the routine functions performed in immunisations such as reminder notices, schedule calculation, and coverage level assessment. Once again, immunisation registries have been left behind by private sector developments. Clinical practice software often includes the ability to calculate schedules and clinic coverage levels, while also providing patient reminder notices. Registries serve a very useful function by automating these activities, but now there are many versions of clinic software that can perform the job as well or better than the traditional immunisation registry.

As noted, the main feature that immunisation registries can provide for physicians that is not currently available elsewhere is a location to find information
from multiple clinics on a specific patient. There are larger public health benefits of immunisation registries. One benefit to a national system of immunisation registries would be the ability of use the databases to determine vaccination coverage for different communities. The CDC currently spends over $1.5 million per year to conduct the National Immunization Survey. This survey is telephone based and relies on parental recall of immunisation status with verification by the patient’s physician. If there were a national network of immunisation registries, this survey would be unnecessary. The calculation of immunisation rates could be completed by sampling the data within a registry. This not only would cost just a fraction of the National Immunization Survey cost, but it also has been suggested that such an evaluation would be more accurate than the current survey.

Having immunisation data available at the state or national level also would allow for the evaluation of immunisation trends. Registries have already been used to study the uptake of new vaccines and the impact of vaccine shortages on immunisation rates. If this data was available across the United States, the CDC would be able to distribute vaccine more equitably and funding based on population and public need. Where this information is unavailable, funding decisions must be made based on self-reported estimates of vaccination activity. These estimates have commonly been poorly done, with the result that some states end up with more vaccine than needed while others run out of vaccine at the end of the year. States that use immunisation registry data to verify their vaccine needs have been much more accurate in their funding and vaccine request than states without registry data (Jones, Boyd et al. 2002; Centers for Disease Control and Prevention 2003).

The public health need for this information is readily accepted in the United States, but the method for collecting the data is a point of contention. The
alternative to immunisation registries would be for physicians to submit the data from their existing clinical operations software. This would eliminate the need to sustain two similar data entry requirements while potentially providing the public health community with the information required to manage vaccine efforts. However, unless the data was stored in a central database that could be queried by the clinician’s office software this data set would still not be able to replace the immunisation registry. Communications between systems has become the latest focal point of the immunisation information technology effort, and it will likely continue to be a factor no matter whether immunisation registries continue to be developed or if they are incorporated into other information technology efforts.

Conclusion

Of the issues identified in this review, the advancement of alternative technologies and the question of need for the system are the most critical factors considered. These two issues will determine what form the collection of immunisation data finally takes in the United States and how useful the information is to public health. The investment in the information technology infrastructure of the public health system for immunisation registries has provided collateral benefits for newer projects. These projects include disease surveillance and health alert notification. The turmoil currently being experienced by the immunisation registry project is likely to continue for the next year through the Presidential election, but a determination of the future direction of the project must be agreed upon in the near future. Otherwise, the immunisation registry project will continue to absorb resources needed elsewhere while potentially not supporting the overall strategic goals of the CDC for information technology in the
United States. Management of the NIP is currently pressing for such a review to take place in fiscal year 2004.

Section Updates

Though this section was written in 2003, the basic challenges facing immunisation information systems in the United States have changed little in the intervening five years. Political and privacy challenges remain in place, and funding remains a major concern for these systems. I believe that the increased ties that have developed between IIS leadership and the Office of the National Coordinator for Health Information Technology have improved, but not settled the issue of how IIS programs will operate in a new technology framework. These issues remain to be addressed.
Section 4: The Need for Evaluation

“Government likes to begin things—to declare grand new programs and causes and national objectives. But good beginnings are not the measure of success. What matters in the end is completion. Performance. Results. Not just making promises, but making good on promises. In my Administration, that will be the standard from the farthest regional office of government to the highest office of the land.”

Governor George W. Bush (Office of Management and Budget 2002)

When George W. Bush took office in 2000, one of the many administrative areas where he sought to make major changes was in how we looked at government operations. In his President’s Management Agenda, he stated that:

“New programs are frequently created with little review or assessment of the already-existing programs to address the same perceived problem. Over time, numerous programs with overlapping missions and competing agendas grow up alongside one another—wasting money and baffling citizens.”

(Office of Management and Budget 2002)

Through the President’s Management Agenda (PMA) initiative he sought to force government agencies to ask some basic questions for existing government programs. First, is the program needed? Second, is it a wise use of the organization’s finite resources? Finally, could those resources be used better elsewhere? By asking these questions, the goal was to create the following operational changes:

Shift the burden of proof. In today’s bureaucratic culture the people who propose changes in existing programs must demonstrate that the change is needed. Under the new management agenda, program proponents bear the burden of proof to demonstrate that existing programs actually
accomplish their goals, and can do so more efficiently than alternative methods or programs.

*Focus on the “base” not the “increment.”* Debates on policy and budget most often focus on the incremental increase (or decrease) in program funding and operations. These debates fail to take into consideration whether the program as a whole (the base) is achieving its goals. The management agenda seeks to reverse this presumption so that the current year’s funding level is the starting point for considering future funding.

*Focus on results.* The desire to address a problem cannot be the sole justification for spending of public money. Performance-based budgeting seeks to ensure that money is allocated both on the basis of perceived need and by what a program is actually accomplishing.

*Impose consequences.* Under the current system there are rarely consequences attached to poor program performance, though there are some incentives to improve. This approach rarely elicits improvement from underperforming agencies. Agencies need to instead identify mismanaged, wasteful, or duplicative programs with a focus on redesigning them, cutting their funding, or eliminating them.

*Demand evidence.* A wide variety of agencies and programs do not have rigorous evaluations to demonstrate that they are effective. This evidence is
considered a prerequisite for continued funding under the President’s Management Agenda.

(Office of Management and Budget 2002)

Political leaders and the public agree that scarce federal resources should be allocated to programs and managers that deliver results (Office of Management and Budget 2002). However, in practice this is seldom done simply because the evidence of those results is not properly collected and presented (Office of Management and Budget 2002). In an effort to redress this inefficiency, the President’s Management Agenda sought to require agencies to begin collecting such information to be used in making future funding decisions.

One project that this requirement applies to is the immunisation registry effort funded by the CDC and the NIP. Over the past decade, the United States government has invested over $225,000,000 on the public health information technology infrastructure in the form of funding for immunisation registries. However, by 2004 the efforts to evaluate the impact of this investment on the national immunisation program have been limited to individual projects or locations and not to the overall investment. In order to continue the investment, a review of the effectiveness of the program was required by the President’s Management Agenda guidelines and Congressional budget language. This study was in many respects an effort to meet those requirements under the restrictions provided by the Office of Management and Budget.
Section 5: Evaluation

Study Purpose

As with many other government programs it is essential to be able to identify a measurable impact on the intended target for any information technology investment. Since taking the oath of office, President Bush has advanced a philosophy of performance management (Office of Management and Budget 2002). A critical piece of information needed to implement performance management is accurate and timely information on the impact of a program. While this appears straightforward on the surface, collecting such information can be a long and arduous task, complicated by federal regulation, lack of appropriate data, and the lack of scientific methodologies that have been demonstrated and evaluated for use in reviewing large program initiatives. This part of the doctoral project was designed to evaluate the impact of the federal immunisation information system investment. Given an increasingly tight federal budget and the expanding range of information technology investments by the federal government, it is necessary to ensure that each investment project has a measurable impact on public health.

One of the most contentious issues in the evaluation of large projects is the selection of criteria by which to measure success. Information technology investments are most often measured by the level of operability achieved by the software and hardware used for the project (Boyd and Linkins 2002). This study seeks to take the evaluation of success to a more fundamental level: Did the project produce the impact on the program objective that was intended? By evaluating information technology investments at this level, one can discern whether the overall project is producing the results needed by the supported
program. This is critical in information technology, because the best system in the world (as deemed by operability) is still a poor investment if it does not achieve the objectives for which it was intended. Similarly, a system that is not fully successful in terms of the technical details of the project may still be a wise investment if it achieves the desired results.

Study Overview

The United States (US) Government has been investing federal funding and providing technical support in 64 state, local, and territorial immunisation projects which implement the routine immunisation activities nationwide since 1994 (Zimmerman, Mieczkowski et al. 2001). As a part of this effort, the immunisation projects across the country are required to develop a computerized system that can track immunisation histories for the population within their jurisdiction (Linkins 2001). These systems should be instrumental in achieving and sustaining a high immunisation coverage both with the primary vaccination series\(^1\) as well as with the subsequent immunisations (Wooten, Darling et al. 2007). In the future, these disparate systems are expected to integrate across the nation to provide a seamless network for information exchange as people move from one physician or location to another (Wooten, Darling et al. 2007)

Immunisation information system development in the United States has taken a wide variety of paths. The CDC has provided recommendations on standards, but until 2004 had not required that these standards be used. Each state and local/territory recipient of federal funding has had the ability to design their

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\(^1\) The primary series is defined as \(\geq 4\) doses of diphtheria, tetanus toxoid, and acellular pertussis vaccine; \(\geq 3\) doses of polio virus vaccine; \(\geq 1\) dose of measles, mumps, and rubella vaccine; \(\geq 3\) doses of *Haemophilus influenzae* type b vaccine; \(\geq 3\) doses of hepatitis B vaccine; and \(\geq 1\) dose of Varicella vaccine [4]
system to fit their specific needs. The IIS in the states also differ with regard to the target age group. While in some states IIS include a wider age range of population, children under 6 years of age were identified by CDC as the main focus for federal efforts at creating IIS programs, and one of the Healthy People 2010 objectives is to increase the number of children under 6 years of age participating in an IIS to 62% (Department of Health and Human Services 2007). In identifying this goal, the term “participating” was defined as any child of the appropriate age who had two or more immunisations included in the IIS (Department of Health and Human Services 2007).

One area where there is agreement between immunisation projects, however, is that the overall purpose of IIS is to improve the effectiveness and efficiency of immunisation practices (Sinn, Kronenburg et al. 1997). However, these are process goals, while the evaluation of IIS programs should ultimately focus on the desired outcomes: increased immunisation levels and reduced vaccine-preventable disease burden.

As IIS become increasingly integrated and intertwined with the immunisation program in the United States, there is a need to evaluate the impact of the national investment in IIS both to justify previous and future investments, and to better understand the role that IIS had played in supporting the national immunisation goals. To our knowledge, there has been no scientific analysis to date of the impact of the overall program investment for the national effort to develop IIS projects. On an individual project basis, there are examples that could be used to justify arguments for and against further information system investment. For example, the state of Wisconsin has created a system that is now being used by several other states (Bartlett 2004). In contrast, by 2002 there were still seven states that reported no current IIS activity (Bartlett 2004). This study was
designed to evaluate the overall investment of the United States federal government in IIS technology within the 50 states and the District of Columbia and to provide a reliable measure of investment impact for use in informing the debate regarding future funding for the program using the following available data: Immunisation rates and change over time as measured by the National Immunization Survey (NIS), IIS progress as measured by the Immunization Registry Annual Report (IRAR), and federal financial investment in the projects as measured by budgetary amounts allocated to the support of project IIS efforts.

Methods

Information technology investments are most often measured by the level of operability achieved by the software and hardware used for the project (Thomas and Jugdev 2002). However, the critical question is whether an IT investment produced the impact on the program objective that was intended, because the best system in the world as deemed by operability is still a poor investment if it does not achieve the objectives for which it was intended. Conversely, a system that is not fully successful in terms of the technical details of the project may still be a wise investment if it proves to be more useful in achieving the desired public health results. In case of federal investment in IIS programs, two key questions to be answered by an evaluation are (1) if the federal support resulted in the desired level of IIS operability, and (2) if the IIS helped achieve and sustain high immunisation coverage and thereby reduce the risk and/or burden of vaccine-preventable disease.

Two hypotheses were examined in this study. First, we hypothesized that the level of investment in IISs would have a positive impact on the level of
operability of the IIS as measured by the IRAR. Second, it was hypothesized that the level of operability of the IIS would have a positive impact on immunisation coverage. These measures were selected based on expert consultation with the Centers for Disease Control and Prevention. The sources for these measures were required to come from existing data sources by OMB mandate.

To test these hypotheses, we considered the IISs implemented in immunisation projects serving the population of the 50 states and the District of Columbia, hereafter referred to as “projects”. The study period included was from 1999 to 2005. These dates were selected because they were the only times for which the necessary data was available. For each of the projects, three parameters of interest were considered: (1) the change in immunisation coverage level for each project during the study period between 1999 and 2005, (2) the level of federal financial investment in the IIS projects, and (3) the level of success of each project IIS. According to a recommended approach to evaluating federally funded programs, each of these parameters was determined using the available and/or routinely collected data and reports (Office of Management and Budget 2002). Consultation with experts as CDC suggested that these were the most useful measures and data sources given the restrictions imposed by OMB to use existing data.

The project-specific immunisation rates for 1999 and 2005 as determined by the National Immunization Survey were abstracted from the published data (Centers for Disease Control and Prevention 2007). These years were selected because 1999 was the year immediately prior to when IIS progress reports were initially generated, and the rates measured in 2005 were collected two years after the final published IIS progress report available at the time the study was conducted. Two years (2004 and 2005) of immunisation rates post available IIS
data for this study were included to provide time for delayed impact of the system on immunisation rates. The percentage point change in immunisation coverage from 1999 to 2005 was then calculated for each of 51 projects.

Data on the federal financial investment in IIS projects were abstracted from the annual cooperative agreement request from each state (unpublished data). These requests detail proposed spending by each project for a variety of immunisation activities, including IIS development and support. The abstracted financial data for each year (1999-2003) were added together by project and included in the study dataset. For each of the projects, the level of IIS success was determined by considering three dimensions: (1) the IIS functionality, (2) the degree to which the health care providers actually use the IIS for planning and implementing immunisation activities, and (3) the proportion of children aged <6 years participating in IIS.

The IIS functionality was determined from the Immunization Registry Annual Reports (IRAR) provided by each of the projects and compiled by CDC. The IRAR is an annual self-reported survey of project activity. CDC uses the IRAR to measure a projects level of functionality, how many providers participate in the system, and how many children are included in the system (Linkins 2001). The measure of IIS functionality was determined by assessing whether the projects had met each of 12 functional standards for Immunisation Information System operations (Systems Development Branch 2001). To be considered fully functional, an IIS must be able to perform each of these functions which have been detailed in prior publications (Systems Development Branch 2001). We used the IRAR to determine the degree to which the project had succeeded in meeting these functional standards by calculating the percentage of affirmative answers on the IRAR for each question addressing the twelve functional standards. These
measures were the only sources of functional performance data available due to the restraints placed on research by OMB.

The second measure considered in evaluating the IIS success was the extent to which immunisation providers actually used the IIS to record immunisation data. These data are collected in the IRAR in two categories: public immunisation providers and private immunisation providers, which are measured separately due to the many inherent differences in the level of participation of public and private providers (Linkins 2001). One of the most striking differences between these categories of immunisation providers is the percentage of the population served, which varies greatly by state (LeBaron, Lyons et al. 2002). Since the creation of the Vaccines for Children program, public and private providers have been considered as two distinct groups with specific needs (Santoli, Rodewald et al. 1999; Zimmerman, Mieczkowski et al. 2001; Groom, Kolasa et al. 2007). Immunisation information systems have also required different approaches to gaining participation by providers in each category (Kairys, Gubernick et al. 2006). For these reasons, the population of immunisation providers in these two groups could not be simply added together. However, because each group served different amounts of the population, a weighting methodology had to be developed. For example, if an IIS program had 100% of the public providers in their area included participating in the IIS but the public sector only served 10% of the childhood population in that state, having 100% participation of this group would have much less impact on the effectiveness of the immunisation program than if the public sector instead served 90% of the population (Linkins 2001). For the purpose of this study, these two measures of immunisation provider participation were combined and weighted using the percentage of immunisations administered in the public or private sector for each state. The weights were based on the previously
published study of immunisation administration distribution by public and private sectors (LeBaron, Lyons et al. 2002).

The weighted provider participation scores were derived from the following equation:

\[ \text{Weighted provider participation score} = (A \cdot \frac{C}{E}) + (B \cdot \frac{D}{F}) \]

Where

- \( A \) = The percent of immunisations administered in the private sector;
- \( B \) = The percent of immunisation administered in the public sector;
- \( C \) = Private providers participating in the immunisation information system;
- \( D \) = Public providers participating in the immunisation information system;
- \( E \) = Total number of private providers in the immunisation information system area;
- \( F \) = Total number of public providers in the immunisation information system area.

The third measure of immunisation information system success was the proportion of children aged <6 years participating in the IIS. This parameter was calculated for each project from the reported percentage of children under 6 years of age who had two or more immunisations recorded in IIS as reported in IRAR, and the corresponding 2000 U.S. census estimates of the total population of children aged <6 years. Census estimates were used as the baseline population data because these estimates have been tested and validated over many decades. This source provides the best data available regarding population age breakdowns.
and numbers. Alternative sources for population estimates were not available that would have matched the extensive testing of the Census population estimates.

Finally, we combined the three measures of IIS success (the IIS functionality, the degree to which the health care providers actually use the IIS to record immunisations, and the proportion of children aged <6 years participating in IIS), into a single value for “total IIS success” using the following formula:

$$((\text{Functional Standards}) + (\text{Weighted Provider Participation}) + (\text{Child Participation Functional Standards})) / 3 = (\text{Total IIS Success})$$

The validity of this measure was considered in terms of content, face, criterion, and construct validity. For content validity, this measure was based on a survey designed to measure compliance with functional standards, and identifies child and provider participation levels. These measures were based on the requirements defined by the NVAC as previously described. This covers the principles of content validity described by Mildred Patterson in the book Understanding Research Methods because it has content covering 100% of the criteria defined by the NVAC report on IISs. The questions were also reviewed for common understanding through in person reviews of the survey responses with the respondent each year. Face validity was addressed by the review and commentary provided by respondents during these reviews. Respondents were asked to tell CDC whether they felt the questions addressed the functional standards and participation rates appropriately, and any question that did not pass this review were modified or removed from the questionnaire.

Criterion validity (both concurrent and predictive validity) was a more difficult issue. Because this type of analysis had not been previously performed,
there was no “gold standard” that could be used as a reference measure. While this measure was created in consultation with experts at CDC, there was no other measure available to use to evaluate the validity coefficient of this outcome measure. Finally, as a unique evaluation tool there is no measure of construct validity available. This form of validity will only be available once further evaluations of the IIS program are conducted. This measure was therefore considered to have both content and face validity, but no available comparison measures for use in determining criterion or construct validity. As such, it remains the best measure currently available for defining IIS success.

The data were compiled and analysed using a SAS JMP software, Version 7 of the JMP system for Windows, Copyright © 2007 (SAS Institute Incorporated 2007). The association between the factors of IIS success, the federal investment for IIS, and the change in immunisation coverage was evaluated both by bi-variate analyses and in multivariate models using unconditional logistic regression.

To test the hypotheses that federal investment for IIS and IIS success had an impact on immunisation coverage levels, the change in immunisation rate was first converted to a dichotomized variable with a value of either above or at and below the median change value of 6.8 percentage points. This was done because of the limits of the National Immunization Survey. These limits restricted meant that the numeric value of the change was not statistically significant in many states. However, in consultation with the experts in NIS methodology during this study it was proposed that a dichotomized variable would be more reliable based on sampling methodology. It was the opinion of the experts at the National Immunization Program that this was the only method of using the data likely to provide reliable results. Logistic regression was then used to determine if the study variables were associated with which group the projects were in based on
this measure. Because a higher rate of change may be easier to achieve in areas with initially lower coverage than in those with higher coverage, in the second analysis the projects were split into two groups: those with 1999 coverage at or below the median level for all projects (≤74.9%) and those that were above the median rate.

Finally, the association between the federal investment for IIS and IIS success levels between 2000 and 2003 was examined through a bi-variate analysis. Projects were categorized into two groups as either being at or below the median IIS change in success score (≤.1177) or above the median change score from IRAR responses.

Results

Total federal investment from 2000 through 2003 in state IISs ranged from $1.16 to $63.23 per child based on the 2003 census figures averaging $12.92 (SD $15.23, median $8.56). Between 1999 and 2003, annual federal investment in IISs as measured in terms of dollars per child in the federally targeted age groups varied widely. In 2000, project budgets for immunisation information systems identified planned spending of between $0.07 and $4.37 per child for use on IIS activities, averaging $0.88 (standard deviation (SD) $0.90, median $0.55). By 2003, this had increased to between $0.19 and $16.03 per child per year, averaging $2.86 (SD of $2.97, median $1.93) (Figure 1).
Figure 1. Federal Government Investment for Immunisation Information System (IIS) Development per Child Under 6 Years of Age by Immunisation Project*, United States of America, 2000-2003 (N=51).

*Fifty-one immunization projects presented here include those implemented in each of the 50 States and the District of Columbia.
IIS scores similarly varied by project, but overall scores increased over the four years of this study. The average IIS success score increased from 0.41 in 2000 to 0.59 in 2003. More impressive than the average score, however, was the decrease in the number of projects that scored lowest for IIS success (scoring 0-0.25), from eleven in 2000 to two in 2003 (Figure 2). Correspondingly, the number projects with the highest success scores (scoring 0.751 to 1.0) increased from six in 2000 to 11 in 2003. Yet, in each year, a number of projects either reported no data or not enough data to calculate a total IIS success score in certain years: Four projects did not return enough data in 2000 and 2001, five in 2003, and seven in 2004.

Figure 2. Immunisation Projects* by the Total Immunisation Information System Score and by Year of Report, United States of America, 2000-2003 (N=51).
*Fifty-one immunisation projects presented here include those implemented in each of the 50 States and the District of Columbia.

Figure 2a. Immunisation Projects* by the Total Immunisation Information System Score and by Year of Report, United States of America, 2000-2003 (N=51)**.

*Fifty-one immunisation projects presented here include those implemented in each of the 50 States and the District of Columbia.

**N shown in the chart includes states with a zero value (reported no activity). States not reporting were excluded.

Immunisation coverage levels have been at record highs in the U.S. for many years (Darling 2006). Overall, in 1999, 73.2% of U.S. children aged 19 and 35 months had received the full 4:3:1:3:3 series (National Center for Health Statistics and National Immunization Program 2000). By 2005, primary series vaccination coverage rose to 80.8% (Darling 2006). During 1999-2005, in 51 immunisation projects under evaluation the primary vaccination series coverage among children aged <6 years varied between -4.7 and 15.2 percentage points (Figure 3) (Centers for Disease Control and Prevention 2007).
Figure 3. Primary Immunisation Series\(^2\) Coverage of Children Aged 19-35 Months in 1999, and the Percentage Point Change in Primary Immunisation Coverage between 1999 and 2005, by Immunisation Project*, United States of America (N=51).

\(^*\)Fifty-one immunisation projects presented here include those implemented in each of the 50 States and the District of Columbia.

\(^2\) Primary immunization series is defined as ≥4 doses of diphtheria, tetanus toxoid, and acellular pertussis vaccine; ≥3 doses of polio virus vaccine; ≥1 dose of measles, mumps, and rubella vaccine; ≥3 doses of *Haemophilus influenzae* type b vaccine; ≥3 doses of hepatitis B vaccine; and ≥1 dose of Varicella vaccine
The relationship between federal investment, IIS scores, and the percentage point change in immunisation coverage levels between 1999 and 2005 was evaluated using logistic regression models. When all 51 projects were considered, the federal investment in IIS projects was a significant predictor of for the level of increase in vaccine coverage between 1999 and 2005 both in bi-variate analysis and while controlling for the IIS score (Table 1). No association was observed between IIS score and the level of vaccine coverage change (Table 1).
Table 1. Association Between the 1999-2005 Federal Government Investment in Immunisation Information System (IIS) Development and the 1999-2005 IIS Scores with the Increase of the Primary Immunisation Series\(^{[3]}\) Coverage among Children Aged 19-35 months at or above the Median Coverage Increase* Observed between 1999 and 2005 for All 51 Immunisation Projects**, United States (N=51).

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**Median primary immunisation coverage increase from 1999 to 2005 for all 51 projects was 6.8 percentage points.

**Fifty-one immunisation projects considered in this analysis include those implemented in each of the 50 States and in the District of Columbia.

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\(^{[3]}\) This series is defined as \(\geq 4\) doses of diphtheria, tetanus toxoid, and acellular pertussis vaccine; \(\geq 3\) doses of polio virus vaccine; \(\geq 1\) dose of measles, mumps, and rubella vaccine; \(\geq 3\) doses of *Haemophilus influenzae* type b vaccine; \(\geq 3\) doses of hepatitis B vaccine; and \(\geq 1\) dose of Varicella vaccine \(^{[4]}\)
In contrast, when the 26 projects with coverage scores at or below the median were separately analysed, IIS score was a significant predictor of the level of change in coverage both in bi-variate and univariate analysis (Table 2).


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*Median primary immunisation coverage increase from 1999 to 2005 for all 51 projects was 6.8 percentage points.

**26 immunisation projects considered in this analysis include those implemented in the following states: Alabama, Alaska, Arizona, Arkansas, California, Colorado, Delaware, District of Columbia, Idaho, Illinois, Indiana, Kansas, Louisiana, Maryland, Michigan, Missouri, Nevada, New Mexico, Ohio, Oklahoma, Oregon, Tennessee, Texas, Utah, Virginia, Washington.
Analysis of the remaining 25 projects with 1999 immunisation coverage above the median value did not indicate that the level of change in immunisation coverage was related to either IIS score or federal investment (Table 3).


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*Median primary immunisation coverage increase from 1999 to 2005 for all 51 projects was 6.8 percentage points.

**25 immunisation projects considered in this analysis include those implemented in the following states: Connecticut, Florida, Georgia, Hawaii, Iowa, Kentucky, Maine, Massachusetts, Minnesota, Mississippi, Montana, Nebraska, New Hampshire, New Jersey, New York State, North Carolina, North Dakota, Pennsylvania, Rhode Island, South Carolina, South Dakota, Vermont, West Virginia, Wisconsin, Wyoming.

In a separate analysis, the evaluation of the relationship between federal investment in IIS projects and the level of success as measured by IIS score failed to indicate any statistically significant association between the level IIS achievement and the level of federal investment (data not shown). As an additional test, responses to individual questions from the 2003 IRAR were compared to the change in immunisation coverage over the period of the study. In this evaluation there were several questions that were identified that had a
correlation with other measures in the study. These questions covered the following areas:

1. An IIS’s ability to process immunisations within a month from when the vaccinations were provided was correlated with the level of change in vaccination coverage over the time period of this study (Pearson 0.0339, RSquare 0.103). These values indicated a limited impact, but the correlation was evident whether the change in vaccination was used as a dichotomized or continuous variable (prob > [t] 0.0173, prob > t 0.0086). While there is correlation, this relationship could be explained through factors that were not included in this study. For example, programs with more overall funding may have both improved coverage and the ability to ensure that records are processed within one month.

2. An IIS’s security policy matching CDC recommendations was also correlated with the level of change in vaccination coverage. Those projects with this match were more likely to be in the group with higher positive change in coverage (Pearson 0.609, RSquare 0.0811). While this also was true when evaluated against change in vaccination coverage as a continuous variable (prob >[t] 0.0402, prob > t 0.0201), the most likely explanation is that this variable is collinear with another more critical variable not included in the study.

3. IIS’s which had data quality protection measures in place that met the functional standard requirements also were correlated with the change in vaccination coverage, with those projects having measures in place more likely to be also be in the group with higher coverage (Pearson 0.339, RSquare 0.1031). Again, was also partly found when using a continuous variable for change in coverage (prob > [t] 0.0531, prob > t 0.0265). The question remains as to whether this correlation is due to another variable that was not included or it there was some relationship between these variables.
4. Federal investment into IISs was found to be correlated with multiple questions on the IRAR. Those programs with more funding per child were found to be more likely to have a security policy matching CDC guidelines (prob > chisq 0.0500, RSquare 0.2348), have a confidentiality policy (prob > chisq 0.0407, RSquare 0.1551), and be able to produce an official immunisation record from their systems (prob > chisq 0.0401, RSquare 0.2574). More interestingly, these projects were also more likely to be able to provide coverage reports by age (prob > chisq 0.0457, RSquare 0.0816), provider site (prob > chisq 0.0083, RSquare 0.1971), and by geographical unit (prob > chisq 0.0030, RSquare 0.1962). None of these correlations are particularly strong, but they may indicate that higher investment may be one of the factors needed to achieve these areas of functionality. This would need to be studies in more detail that is possible with this research project in order to determine causality.

As with any research, the analysis in this section were reviewed to ensure that potential data issues did not confound the results. As a final review, each of the results in this section was subjected to further analysis in an effort to identify any issues related to nonlinearity. However, no issues were identified.

Discussion

These results indicates that the federal investment in IIS projects has achieved to some degree the original goal, which was to improve immunisation coverage thereby reducing the risk and/or the burden of vaccine-preventable disease in the population, and that the states with initially lower coverage appear to have benefited from IIS implementation. However, the results have multiple limitations that limit the recommendations that can be drawn from these statistics.
This study has five specific limitations that should be considered while interpreting the results. First, the federal investment data used in IIS projects are budgeted investments, not actual dollars spent. While it can be assumed that actual spending was close to what was budgeted, there is no data available to evaluate how accurately the budgeted amounts reflect the actual expenditures. Second, the data on any additional investments in the state IIS projects, i.e. above and beyond of the federal investment, was not available. This introduces the possibility that the overall investment in the IIS in some states may have been actually underestimated. Subsequently, it may be plausible that the overall IIS investment could be more directly related to IIS success, which was not evident from our study.

Third, the study results indicate that there was an association between a greater investment in the IIS project and subsequent improved in immunisation coverage. The data was insufficient, however, to further evaluate whether this was because of direct investment in the IIS or if this was an indication of greater investment in the immunisation program overall. Since the model, which included all 51 projects, did not indicate an association between IIS success and subsequent change in immunisation coverage, this question should be evaluated through further study.

Fourth, the national immunisation survey over the time period considered in this study documented a statistically significant change in immunisation rate estimates in only 14 states (Centers for Disease Control and Prevention 2007). The survey did not have a level statistical power sufficient to detect a statistically significant change in immunisation rates in 37 states and the District of Columbia. While it would be possible to expand the NIS to improve the sensitivity of the
survey, this would required an unrealistic additional expenditure (estimated at $10 million).

Finally, the IIS success score calculated for this study assumed that all items in the survey were equally important since no variance in importance was suggested by the original NVAC report (National Vaccine Advisory Committee 1999). However, many items were answered in the same way by all respondents. For example, all registries said that they collected many of the basic identifying data recommended in the NVAC report. These similar responses could have impacted the model’s ability to provide a score by which to measure the differences in IIS progress.

This study has succeeded in using the available and/or previously collected data and reports for the purpose of evaluation of a federally funded project. However, several areas of the IIS project that deserve further study beyond of what the available data could support.

For example, the data at hand would not allow an evaluation of the potential IIS impact on segments of the population smaller than the state level, such as traditionally underserved inner city areas or other hard-to-reach sub-populations. While the NIS does not provide data at such a level, many projects have provided evidence of a positive IIS impact on immunisation coverage in previously under-immunized population groups. For example, Oregon has used their IIS to identify factors that contribute to lower immunisation rates, thereby improving their ability to properly target their intervention efforts (Canavan and Crawford 2002). Minnesota has used their IIS to improve immunisation rates among low-income and rural children (Hellerstedt, Olson et al. 1999). The New Jersey project used the IIS to help improve immunisation practices within specific doctor’s offices (Kairys, Gubernick et al. 2006). Targeted research into these areas
would provide a more definitive answer as to what impact the investment in IIS projects have had in various population subsets.

In addition to an analysis of the population subsets, an evaluation of the overall IIS investment including federal, state, local, and private investment in these systems would be needed in order to provide a definitive answer to the question of whether the level of investment is directly related to the success of the project. However, it should also be noted that there are multiple other factors that go into IT project success aside from the level of investment. Some of these factors include project management, executive support, and change management (Nah, Lau et al. 2001). A case study evaluation taking these variables into account could provide a more definitive answer as to what impact the fiscal investment had on the IIS project.

Further, the individual factors of IIS success may also merit additional study. A study designed to evaluate the NVAC functional standards could provide the information needed to direct state projects to target those functions with the greatest impact on immunisation coverage. Providing this targeted direction would allow projects with less functionality or funding to be able to focus on the most important functions, thereby improving their ability to provide the greatest impact with the least investment possible.

Finally, while this study has provided evidence that the investment in IIS projects is associated with improvements in immunisation coverage rates by using the available data and reports, one must ask whether in the end these are the only factors that should be considered in an IIS evaluation. To fully appreciate the role that IIS may play in not only achieving, but also sustaining high immunisation coverage, a strategic review of the approach to evaluating the outcomes of the
federal government investment in IIS implementation may be necessary to identify additional factors for measurement.

The results of the study suggest that, overall, federal IIS investment was associated with an overall positive impact on primary series vaccination coverage among children aged <6 years in 51 immunisation projects during 1999-2005. This result may reflect, at least in part, the positive effect of the federal funding support on the components of the state immunisation systems other than IIS. In contrast, the IIS success was associated with an increased level of percentage point change in coverage rates only for the group of immunisation projects that started out with IIS implementation in 1999 with lower immunisation coverage rates (<75%), but not for the entire group of 51 projects considered in this analysis.
Section 6: Future Evaluation Framework

The investment in IISs in the United States has one overriding goal: To decrease incidence of vaccine preventable diseases by helping to improve timeliness of immunisation according to the routine schedule and, ultimately, achieve and sustain high routine immunisation coverage (Linkins 2001). For the federal government, investment in IISs has focused on children ages 0-6, i.e. the target group for the vaccines recommended by the routine childhood immunisation schedule in the United States even though in most states IISs focus on a wider range of ages (Figure 4) (unpublished data from the 2006 IRAR). The difference in target age groups serves as just one example of how state IIS projects have followed different implementation paths. This creates a situation where it is difficult to conduct a comprehensive program evaluation or impact assessment from the national perspective. It is therefore essential to determine the most appropriate means for program evaluation.
Logic models provide a systematic visual method of presenting the different components of a project and how they interact to produce a particular outcome (McLaughlin and Jordan 1999). IISs have been envisioned to operate in many different forms and fashions, but those funded by the United States Government participate in the federal immunisation program which has as the primary objective to improve immunisation coverage among children aged 0-6 years, and they each include the same or similar basic elements (National Vaccine Advisory Committee 1999). In order to create a starting point for further discussion it is essential to describe the theoretical basis from which the logic model was drawn. Theories related to behavioural change including planned behaviour, information processing, message design, and social cognitive theory played an important role in the development of the IIS logic model.
The theory of planned behaviour suggest that the intention to perform a
behaviour can be predicted by the attitudes a group holds regarding that
behaviour, their subjective norms, and the ability they have to perform a given
behaviour (Ajzen 1991). In this theory it is suggested that intention correlates
with actions (Doll and Ajzen 1992). While there are many factors impacting uptake
of electronic systems in the health field, the user having a proper attitude towards
the system is critical (Sullivan and Mitchell 1995). This theory translates to the IIS
program because behavioural change and proper attitudes are essential to
increasing intention to participate as well as actual participation in the program.

Another applicable theory to the effort to create an IIS logic model is that
of information processing. McGuire’s hierarchical steps of information processing
can help strategists manage expectations regarding the size of behavioural impacts
of a program (McGuire 1972). This model suggest that there are several broad
stages of messaging processing that mediate the impact of communication. These
are attention, comprehension, and acceptance. Each of these stages relies on
specific aspects that can be measured and used in program evaluation. Attention
requires exposure, overcoming distractions, and awareness. These aspects can be
measured by overall incidences of being in the presence of a message and
awareness of that message. Comprehension requires understanding of the message
provided, and acceptance of the message leads to action and finally to behavioural
change. Because of the variability in how individuals receive and process
messages, part of the audience is lost at each stage. This theory therefore suggests
that high levels of exposure are required in order to create an impact on the
behaviour of a population (McGuire 1972). This theory suggests that the IIS
projects must use multiple means and messages to influence behaviour and
increase participation in the program.
In IIS projects as in other public programs, message design is critical to any communication or educational effort. Theories of message design can be used to direct educational campaigns in the IIS community. These theories seek to explain how to build awareness of a project. One example would be the effort to use a brand to evoke interest and identification with the message (Louis, Sutton et al. 1991). While there is no national “branding” for IISs, there are many individual projects that have used one form of branding or another. One example would be the Oregon IIS called “ALERT”. Oregon has designed messages around the ALERT brand that stress the benefits to parents and the safeguards for privacy and confidentiality (Canavan and Crawford 2002). This also serves as a very positive message. Monahan suggest that positive messages are more likely to be remembered, change attitudes, and promote compliance with a desired behaviour (Monahan 1995).

The final theory considered in the development of this logic model is social cognitive theory. This theory relates to the interplay of environment, behaviour, and intrapersonal factors (Bandura 1986; Baranowski, Perry et al. 1997). Environmental factors in an IIS project would include a physician’s peers, patient’s parents, other authority figures, and government medical recommendations. The interplay between the various segments of the population helps to reinforce participatory behaviour as more people become convinced of the benefits of the program. Providers become instrumental in convincing their patients to participate. As patients transfer to other non-participating providers they serve to reinforce the need to participate by requesting that the new provider access their records through the IIS rather than bringing a paper copy to the new office as in years past (Dietsch, Rodriguez et al. 2002). Social cognitive theory details the interaction of perception both in terms of the expected outcome of the behaviour
Proposed Model

The elements considered for the proposed logic model for IIS projects included a specific inputs, activities, short term and mid-term outcomes, and two long-term outcomes. Inputs are those resources required to support the program. Activities are defined as actions that are required to achieve the desired outcomes. Outcomes are the results expected from the actions at different points in time (McLaughlin and Jordan 1999). IIS projects seek to support overall efforts to reduce vaccine-preventable disease incidence in at least three ways: (1) through improved immunisation practices (e.g. timely administration of age-appropriate immunisations according to the routine childhood immunisation schedule); (2) by providing complete immunisation histories to identify incompletely immunized children; and (3) by facilitating immunisation program planning activities (Sinn, Kronenburg et al. 1997). A detailed description each of the sections of the logic model provides framework for future discussion on how the logic model can be used to evaluation.
Figure 5. Proposed Logic Model for Immunisation IIS projects

**Inputs**

There are seven inputs included in this model that impact the ability of IIS projects to achieve the previously stated outcomes. The first three are resources that directly impact the activities described in the model. First are the IIS professionals. This group includes people devoted to the development, implementation, and utilization of IISs. These individuals represent the federal government as well as state and local IIS project personnel. The second input is the medical community. Included in this group are providers of immunisations, vaccine manufacturers and distributors, insurance companies, and any medical professionals that have either a direct or an indirect impact on the use of IISs. This
group serves as both one of the most important user groups for IISs, but it also serves as an input due to their influence on how these projects are structured. The third group includes IT professionals, referring to those individuals working to develop both IISs and other means of capturing electronic medical data. This group is a critical input because the usability and interoperability of these systems serve as critical variables influencing to provider and patient acceptance of IISs (Kairys, Gubernick et al. 2006).

There are also four inputs that create the environment in which these resources operate. The initial environmental input is Federal, state, and local legislation or rules. Legislation and rules can server to define who will be included in an IIS and how that IIS must interact with both providers and patients. These laws also often address issues of privacy and confidentiality that impact how an IIS must be operated (National Vaccine Advisory Committee 1999). The second environmental inputs are the current professional medical and clinical guidelines regarding immunisation practices. These guidelines provide a framework which serves as the basis for patient care and influences how immunisation providers perform clinical work (National Immunization Program 2001). The third environmental input is the Health Information Technology initiative. This initiative serves as a guide providing input into the model regarding how medical electronic information systems should work together (Department of Health and Human Services 2007). Finally, existing electronic sources of immunisation history data also play a major role in determining how and if providers and patients will use an IIS and how those interactions will take place. The criticality of this input is evident in the issue of double data entry that plagued the early attempts at IIS projects (Linkins 2001).
Activities

Seven potential activities aimed at increasing participation in IISs are included in this logic model. These IIS activities are those actions that the previous input resources can take to influence participation. The first two actions incorporate educational campaigns both for providers and for patients. These campaigns could include a variety of media programs and educational efforts encouraging participation and providing information about the projects (Dietsch, Rodriguez et al. 2002). The third activity is closely related to these campaigns and uses internet websites such as the American Immunization Registry Association (AIRA) website to disseminate information about IIS projects. These sites provide information and educational material designed to both promote IIS projects and to share knowledge about how to make them more effective (Dietsch, Rodriguez et al. 2002).

A fourth activity, which also addresses educational efforts, concerns improving community relations. Community relations in this model are considered to be those activities that serve to help develop a feeling of trust in the community towards the utilization of the IIS. Security and confidentiality are major concerns when a patient or provider chooses whether to participate in an IIS, and the community relations activities serve to address those concerns (Canavan and Crawford 2002).

The fifth activity in this model is most closely related to the IT professionals resource. The technology to create and operate an IIS has existed for many decades. However, much work remains to improving the interoperability and usability of the systems. This includes work towards connecting with external systems to avoid multiple data entry, providing decision support tools for the
provider to create additional benefits of using the system in a physician’s office, and connecting to systems already existing in the provider’s office to avoid duplication of effort (National Vaccine Advisory Committee 1999).

The final two activities are related to a targeted research strategy developed jointly between the federal government and immunisation grantees. Two strategies, one focused on project level research and another at federal cross project level research would be designed to help identify best practices and to provide a framework from which to develop specific project operational goals and objectives. Research at the national and local level is needed to provide the evidence that can be used in the educational efforts as well as demonstrating how the patient, provider, and immunisation program can all use the IIS program to improve immunisation rates and decrease incidences of vaccine preventable diseases.

**Short-term outcomes**

The most immediate and shortest-term objective is that of awareness of the IIS for both the patient and provider. Theories of behavioural change dictate this as the initial outcome, because without awareness there is no directed change in behaviour (Monahan 1995). For the provider this would be awareness of the IIS and its application in routine clinical work. Awareness of the IIS program begins with knowledge of the potential benefits to themselves and their patients through use of the IIS. This heightens interest in further understanding of how the IIS could be utilized and what impact it might have on the operation of their practice. This awareness and interest can be generated by appealing to immunisation providers goals. The IIS program is addressing at least three goals of providers:
(1) To provide better care for their patients, (2) to provide efficient and effective service, and (3) to do so in a manner that produce desired health and business outcomes. It aims to change providers’ attitudes regarding a) beliefs regarding the usefulness of IIS projects, b) behavioural norms, in terms of how their current standards of practice could be improved, and c) perceived control, or how strong is their belief that participation in the IIS will be beneficial both to them and their patients (Dietsch, Rodriguez et al. 2002).

For patients, the outcomes described also begin with awareness of the IIS. IIS program communications with patients is designed to work differently than with providers however. Benefits for physician practices are deemphasized, while issues of direct impact to patients are more directly addressed. These include the safety of the information in the IIS, the benefits of having a single record of vaccine administration that can be used at any doctor’s office, and the benefits to the patient/child of avoiding unnecessary immunisations, which can be caused by fragmentation of a patient’s immunisation history without participation in the IIS. These messages are aimed to change behaviours in terms of comfort with the concept of a medical database, beliefs that their records are safe and will be used to their (or their child’s) benefit, and that it will make their life easier by providing a single source of information regarding their immunisation history.

An important assumption between short and mid-range outcomes is the development of the system into a fully functional IIS as defined by the 12 functional standards proposed by NVAC and recommended by CDC. These functional standards describe how a IIS should operate, data quality standards, and interoperability (Systems Development Branch 2001). This model assumes that the IIS is fully operational based on these functional standards. Unless these standards are met, the short-term goals of provider and patient knowledge of the
benefits of IIS participation could be blocked by the system’s inability to deliver the promised benefits. It is important to keep this in mind while exploring the medium range outcomes in this model.

**Mid-Range Outcomes**

Medium range outcomes for providers, IIS planners believe that as the benefits of IIS participation are internalized those beliefs will lead to specific actions:

1) Creating a positive attitude about IIS participation
2) Actively encouraging patients to participate in the IIS
3) Changing business practices to include active IIS participation
4) Implementing additional improvements in their practice based on the information provided by the IIS.

**Long Term Outcomes**

IIS program planners view the interaction between patients and providers as critical to ensuring the success of IIS activities. Without the belief of both parties that the IIS is a beneficial tool, there is little likelihood that complete records will be available regarding a patient’s immunisation history or that those histories will be used to improve immunisation coverage. The IIS projects seek to motivate patients and providers to actively participate in the IIS, and by so doing improve both the patient’s health and the provider’s practice. As depicted in the model, provider participation may precede patient participation and the reverse
may also be true, but without the help of both parties, the long-term outcomes cannot be achieved.

These outcomes include an increase in the number of patients who are properly immunized, and the final outcome of decreasing rates of vaccine preventable diseases in the population. Provider and patient participation in IISs are seen as necessary but not sufficient to reach the final outcome sought, hence the double-lined box leading to the endpoint of the program. Planners of the IIS program believe that for immunisation rates to be impacted by the use of IISs, the data must not only be included and available to patients and providers when needed, but that the data must also be used to modify immunisation practices. One recent example was the use of IIS data in Oregon to assess the impact of changes to the vaccination schedule. IIS information was used to determine whether physicians were following the new recommendations, if there were other unintended impacts of the rest of the schedule, and where educational efforts might be most beneficial (Canavan 2001).

Use of the Logic Model for IIS Evaluation

The logic model is an important tool in directing the program evaluation process both in terms of process and outcome measures. Through the identification of a model that can be accepted by both the federal and local IIS constituents it is possible to create a clearer vision and purpose for the program. This would also make the development of measurable objectives beyond the 2010 goal of 62% participation easier and facilitate IIS evaluation (Department of Health and Human Services 2007). Though the Immunization Registry Annual Report provides data about IIS progress, it does not provide answers to some of the most
pressing questions about IIS projects regarding how effective the information collected is for programmatic activities.

Each box in the logic model outside of the inputs section can be evaluated either for process or for outcome. For example, communication efforts aimed at increasing provider participation can be measured to see whether they have a discernable impact on provider attitudes, and whether those attitudes are turned into behaviours. Evaluation tools could be designed to measure outcomes of the communication efforts both to providers and to patients. Measuring parental support for the IIS project as well as provider support could allow one to evaluate and target specific communication strategies. A continuous feedback loop between IIS planners and the public is critical to ensuring that the right messages are being used in the right way and having the desired impact.

Discussion

The IIS program is in need of a widely accepted common logic model to that can be used as a program planning, evaluation, and management tool. A mutually acceptable model would be an effective tool for guiding processes and sharing knowledge between all parties involved in the program. Without a widely accepted and agreed upon conceptual structure, it is difficult to provide practical direction to a program that is as decentralized as the IIS project.

The logic model proposed herein represents one potential way to envision the impact and operation of the IIS program. It covers both the program’s activities and underlying assumptions to provide a theoretical framework for the program’s interventions (W. K. Kellogg Foundation (U.S.) 2001). The proposed
logic model could be universally used in developing and providing for the systematic evaluation of IISs in the United States.

There are several strengths of the proposed model. This model was designed to encompass the critical aspects of IIS operations as published in the literature. It also describes the progression towards acceptance and use of the systems by providers and patients while at the same time identifying areas in the process that can be used to improve program evaluation. The weaknesses of the proposed model include the fact that IISs on their own are not sufficient though they are arguably necessary to further reduce the incidence of vaccine preventable disease in the United States. To better understand complex interactions between all of the elements in the program, a much broader logic model would be required that includes all activities that are involved in that long-range outcome. However, given the complexity of the immunisation program, each activity in that broader model would require the development of a sub-model similar to the IIS model presented here.

The development of a logic model that can be shared and used as a common tool and a starting point for IIS evaluation makes it easier to develop the kind of evaluation points necessary to encourage evaluation research that can produce more generalise-able results and stimulate the further support of the program. Just focusing on some of the areas for evaluation depicted in this model would be a good start, but the active participation of the entire IIS community in defining and fine-tuning the proposed model will be critical to create a widely accepted model needed for this program. The model presented here in only intended as a starting point to initiate and facilitate this dialogue. It is hoped that a cohesive model that incorporates the needs of all areas of the IIS program can be completed. This would provide a model that would be easily understood by
potential stakeholders who are currently outside the program, and would provide a basis for evaluation of current activities to probe how the program could be improved.

First, however there must be participation by all stakeholders in the immunisation program. The most critical stakeholder group would be the IIS professionals. Without their participation, it would be impossible to further refine this model enough to make it truly useful for program evaluation. However, it is also critical that other non-IIS stakeholders become involved once this project has begun. The outside view from providers, patients, parent groups, and others involved in the immunisation effort must be included so that the model can be tied back to the overall goal of reducing vaccine preventable diseases.

Immunisation programs in the United States are a dynamic public health effort, and the IISs must be flexible and adaptable to accommodate future changes. The end goal of the effort to define a logic model for IISs is to create a tool that can be used for a continuous and recurrent evaluation and revision process. The authors therefore respectfully submit this initial model in the hopes that it can serve to prompt the adoption of a process by which both the model and the IIS program can continually improve in the rapidly evolving world of health care information technology and its applications to achieve immunisation program objectives.
Section 7: Conclusions and Future Exploration

In 2003, I proposed several policy changes to the leadership at the NIP based on the preliminary evaluation of data collected and an evaluation of the political climate of health information technology development in the United States. This included a view of what the current state of the program was, what external factors were involved, and recommendations on how to adapt to the expected future changes. Included below is a summary of the two policy papers written and presented in 2005.

Policy Recommendations

Where are we today?

Immunisation registries have made dramatic progress in some states, while failing in others. Overall, the mean functional standard score for immunisation registries has increased from 0.684 in 2000 to 0.841 in 2003. Similar increases have been seen in private provider participation (13% to 37%), public provider participation (46% to 75%), and child participation (32% to 49%) in immunisation registries between 1999 and 2003.

While the overall changes in participation levels were positive, not all registries have had positive changes. Childhood participation dropped over the same period in six states, while provider participation dropped in another seven states (two of which were among those with lower childhood participation rates). Six states showed reduced private provider
participation rates in 2003 as opposed to their level reported in 2000, while five states showed a reduction in public provider participation rates. However, the remaining states in these categories all showed at least some level of improvement over the four-year period.

The measure of total registry success (combined value of provider participation, child participation, and functionality) suggested similar improvements between 2000 and 2003, increasing from an average of 0.39 to an average of 0.59. For this measure, there was again a group of five states that had decreasing scores between 2000 and 2003. While more states had individual values that decreased, only five decreased overall by this measure. When using a provider participation score weighted for the percentage of immunisations provided by the private and public sector only four states had a reduction in total registry score. The overall status of immunisation registries continues to improve, but much remains to be done to reach the Healthy People 2010 goals.

In all, there was significant progress in the development of immunisation registries among NIP grantees between 2000 and 2003. However, the current rate of progress does not suggest that the 2010 registry goal of 95% participation will be achieved. If the current rate of increase over these four years continues, one could expect that by the beginning of 2010 there would be fewer than 75% of children participating in immunisation registries. This assumes of course that there are no changes in technology, business practices, or funding that accelerate or slow down further progress.
Changes in the Field of Health Information technology

There are a group of public health informatics initiatives (across federal government) that are going to directly impact immunisation registries in the near future. These include the Public Health Information Network and Consolidated Health Informatics. A more long-term project that will have an even more dramatic impact on immunisation registries is the presidential project that aims to create a national electronic health record. Each project will interact with registries in different ways.

The Public Health Information Network is the next stage of public health surveillance data collection in the United States. This network aims to generate fully interoperable information systems across public health organizations. According to the National Center for Public Health Informatics, “PHIN is a national initiative to implement a multi-organizational business and technical architecture for public health information systems. With the acceptance of information technology as a core element of public health, public health professionals are actively seeking essential tools capable of addressing and meeting the needs of the community” (United States Department of Health and Human Services, CDC PHIN website). This interoperability is to be achieved through a system of standard PHIN functions and specifications, “Preparedness Functional Requirements”, and data exchange and messaging specifications.

Immunisation registries have made great strides in developing HL7 messaging standards for immunisation records, but those efforts will now
have to be incorporated into the overall PHIN structure. Immunisation registries will also be required to meet the standards and specifications set not as part of an immunisation registry effort, but as part of a larger national public health standards effort. As such, Immunisation Registries will change from being the lead determining factor in standards setting to being one of many factors that must be considered.

The Consolidated Health Informatics (CHI) project is a presidential initiative that seeks to adopt a wide portfolio of existing health information standards. The goal is to enable all agencies to communicate health information under the same enterprise business and information technology architectures. Just as Immunisation Registries must follow PHIN guidelines, PHIN efforts serve as a portion of the CHI effort and must comply with the enterprise level goals of CHI. Immunisation registries in the future will address their needs in regards to the enterprise level goals to through the PHIN framework of discussion (Centers for Disease Control and Prevention 2005).

In the long term, the Electronic Health Records initiative will change how registries operate and how clinicians use information. The Health Information Technology Leadership Panel recently made several recommendations regarding how government should speed the adoption of electronic health records. Among their chief recommendations was that “federal purchasing power should be used to accelerate the adoption of health information technology among health care providers” (The Lewin Group Inc 2005). Using the government’s broad market leverage as both a provider and purchaser was seen as key to engaging the private sector and
ensuring that they follow suit. These efforts will have a dramatic impact on how immunisation registries operate in the future.

How must Immunisation Registries Change?

Immunisation Registries must evolve quickly in order to survive the coming changes regarding health information technology. With the determination to use government purchasing power as part of the driving force behind the adoption of electronic health records, those information technology investments that are related to health records but not aimed specifically at this effort will face increasing budget pressure and reductions. While registries addressed the correct problem at the time, there are several major areas of change that will be required for registries to maintain their public health function.

1) Immunisation registries will not be the clinician support tool of the future. The decision support role in the provider’s office is already being usurped by the existing electronic medical record systems. NIP efforts should instead be focused on ensuring that the projects promoting private sector certification of health information technology products incorporate sufficient detail to satisfy the needs of provider clinical decision support and immunisation programs in the clinic setting.

2) Immunisation registries will serve as a source of missing information and a repository for use by public health officials in managing their immunisation program. As such, they will need
to use programmatic, PHIN, and CHI standards to dramatically improve:

a) **Data quality**: The current level of duplication, missing fields, and erroneous data will not be workable in the future. While these areas are improving, much work needs to be done before they can be considered a national standard for immunisation information.

b) **Communication**: While advances have been made in the past ten years to improve communication between systems, a truly national network of public health registries will have to be developed in order to have these systems serve as an authoritative information source for immunisation data.

c) **Messaging**: New messages will have to be developed in order to ensure that immunisation records can be collected from the final electronic health record standard. In the next age of immunisation information, these messages will have to be “multiple use” to ensure that information is collected from a single source as close to the time of administration as possible. Sending the primary information to multiple sources will be more readily accepted than sending duplicate information from secondary or tertiary systems. This will also improve the quality of the data collected by limiting the sources of error in each record.

3) **Funding for immunisation registries will begin to decrease as more focus is put on focusing the government’s purchase power on electronic health records.** The registry program will not be
able to sustain the current level of investment, nor should it once electronic health records begin to be implemented. Only the funding needed to implement an immunisation “registry” for use in the public sector will likely be supported.

What must be done initially to ensure that Immunisation Registries are incorporated into the future of Health Information Technology?

Careful consideration must be given to how the immunisation registry project moves forward over the next several years. While the implementation of electronic health records will not happen overnight, the pressure on funding will be much more rapid. The progress of the registry project to date must be carefully evaluated, and estimates for future development progress must be developed. Currently, our existing direction for immunisation registries is appropriate because it will be several years before electronic medical records and clinical information systems are widely used in the United States. However, there will come a point in the future when it no longer makes sense to maintain an effort to improve the clinical aspect of immunisation registries. While that time is not today, it is this author's opinion that that time is fast approaching. We will have to weigh the expected level of success against the expected implementation of electronic health records. CDC cannot afford to continue investing money in the project if it appears that the project will be obsolete in its current form before completion.
The focus of immunisation registries will need to be redirected toward the goal of interoperability within NHIN and work with CHI. The is a fundamental paradigm shift for immunisation registries moving from the forefront in clinical settings to a support rule in favour of the Health Information Technology concept.

It is therefore recommended that the following steps be taken:

1. **Hold a frank discussion about the future of immunisation registries.** The aim of this discussion would be to reach a consensus regarding the role of immunisation registries after the advent of electronic health records and their supporting systems. This discussion should include key internal and external stakeholders once internal NIP discussions have taken place.

2. **Evaluate the progress of immunisation registries to date and develop expected timelines of improvement based on various scenarios of support and policy change.** This should be done both on the national level as well as at the individual projects. (The return on investment (ROI) may be significantly different between developed and “developing” registries to warrant a staggered implementation of the next step.)

3. **Determine at what point efforts should be scaled back, and at what rate.** This assumes that registries will not be fully functional before electronic health records and/or are being
impacted by funding policy changes to the extent that funding for registries begins to shrink.

4. Track the milestones for registry development (both national and by project) and electronic health record implementation in order to adjust projected timelines accordingly. Timeframes when registry activities should be scaled back or refocused will need to be varied based on changes to the projected timelines.

5. Ensure that the clinical functions of the registry are incorporated into the new private sector certification process for health information systems.

6. Improve the communications standards and interoperability through messaging for immunisation registries.

7. Ensure that the funds spent on immunisation registries are aimed either directly at supporting the future state, or being used to improve the function of the immunisation program during the transition.

In order to ensure that the clinical functions of the registry are incorporated into the new private sector certification process for health information systems, the Immunization Registry Support Branch will need to have resources available to devote to coordination between registries and the new standards setting structure that is being put in place. It is important that IRSB insert themselves into these discussions early so as to be properly connected once the new process gets off the ground. IRSB’s efforts towards the protection of privacy and confidentiality would fit in
this area as well, ensuring that the standards developed for registries are incorporated into the new HIT standards.

Improving communications will require everything from issue one, but will also necessitate additional review of the immunisation registries and the funding that is going towards their performance. Specific requirements and milestones for communicating through the current standards (HL7) (1) need to be in place and projects will need to be held accountable for reaching those milestones. Funding for communications protocols that do not meet or are not aimed at meeting the defined standards and standards proposed by HHS for Health Information Technology (HIT) should be eliminated.

In addition to the directed funding for communications, the IRSB needs to also be able to hold grantees accountable for funding provided for other registry activities. A management plan covering the next three years should be developed for each project. These plans will need to include detailed milestones and goals for the project and incorporate standard earned value management practices so that progress can be readily tracked. Two categories of milestones would be acceptable; those pertaining to meeting existing programmatic needs, and those directed at implementing standards set by HHS for HIT. OMB is requiring that we report on all IT investments, and provide detailed information regarding any cost or schedule variance exceeding 10%. I would propose that we hold the grantees to the same standards, with IRSB working closely with projects that exceed these limits. IRSB will need the resources to monitor and provide technical assistance to projects that are not performing.
There are also several areas where I believe that NIP needs to change direction during the next three years to ensure that we are supporting registries in a way that is compliant with HHS requirements. First is the focus on direct private provider participation. Once clinical HIT systems are in place, this will be a non-issue. We need to make sure that any effort put into this area will provide us with a decent return on our efforts in the short term. Second, we need to redirect registry functionality to the programmatic side rather than the clinical setting. NIP should ensure that registry management plans focus on making the data a useful part of the immunisation program rather than simply a repository of data. Third, our certification efforts should be linked to the HHS effort to promote private sector certification of HIT. Funding for a separate certification process is likely to be extremely difficult to find, so for evaluation purposes NIP should focus on short term alternative strategies until the new processes are in place.

In all, aside from positioning NIP to participate in the national discussion on HIT, the most critical area of focus I believe will be accountability. As funding is redirected to HIT projects, it will be essential to be able to justify the money being spent on immunisation information systems. To do that, we will need to be able to provide OMB level accountability information for each project. This means a drastic change in how we oversee the grantee registry investment and how we award funds. Without this level of accountability, it will be very difficult to get continued or additional funding to ensure that registries are prepared to merge with the national HIT effort for electronic medical records.
Since these recommendations were made, much has changed at the CDC. A major reorganization eliminated the NIP and replaced it with the National Center for Immunizations and Respiratory Diseases. At the same time, the efforts of CDC under the Public Health Information network have become secondary to the national effort to develop a National Health Information Network. However, many of the recommendations made in 2004 were initiated. To describe what has changed in this time I will revisit each recommendation and describe the activities related to those recommendations that occurred between the time 2004 and 2008.

Registry Changes:

1. **Immunisation registries will not be the clinician support tool of the future.**

   This prediction has yet to come to pass, but it is still in this author's opinion a valid assumption. The Office of the National Coordinator for Health Information Technology has worked with the IIS team at CDC to include immunisation functionality and decision support in electronic medical record standards (Office of the National Coordinator for Health Information Technology 2007). At the same time, other decisions support and reporting capabilities that were previously part of IIS efforts are being included in other electronic medical record systems. One of many examples is the effort by Hinrichsen et al published in late 2007 which included vaccine adverse events reporting in an ambulatory electronic medical record rather than in a strict immunisation information system (Hinrichsen, Kruskal et al. 2007). No evidence that this trend will be reversed had been found during this review, and based on the author's participation in the
American Health Information Committee and other national health technology groups the author continues to see this as a forward trend.

2. *Immunisation registries will serve as a source of missing information and a repository for use by public health officials in managing their immunisation program.*

   This activity has already taken place in many areas and is considered by the author to be a continuing trend.

3. *Funding for immunisation registries will begin to decrease as more focus is put on focusing the government’s purchase power on electronic health records.*

   Funding for immunisation information systems has not decreased at the rate initially anticipated. The focus on using the federal investment in health information technology to drive the National Health Information Network development has yet to occur, as standards and functionality for the network are still being discussed. However, this issue still has the potential to complicate future IIS efforts depending on how the next administration chooses to view health information technology and what path they choose to take for implementation.

**Recommended steps:**

1. *Hold a frank discussion about the future of immunisation registries.*

   This has been an ongoing process over the past three years, with multiple meetings and reviews taking place. Most of the focus has actually been
on how to get IIS efforts to work with the NHIN goal, but much less discussion has
taken place regarding the longer-term outlook for IISs.

2. Evaluate the progress of immunisation registries to date and develop
expected timelines of improvement based on various scenarios of support and
policy change.

While the level of evaluation proposed has not taken place, the
Immunization Services Division (ISD) has undertaken an effort to develop a logic
model. This effort began after the logic model in this study was shared with ISD.
This ISD model was focused on improving immunisation levels rather than more
tightly focused on IISs as proposed here, but it did include immunisation registries.
This model is under review and may be used to develop improved evaluation
methods in the future.

3. Determine at what point efforts should be scaled back, and at what
rate.

The movement towards electronic medical records has not been as
rapid as originally anticipated, so this question remains to be answered.

4. Track the milestones for registry development (both national and by
project) and electronic health record implementation in order to adjust projected
timelines accordingly.

A tight timeline and system of milestones for development have yet
to be developed, though the effort is ongoing for some projects below the national
level.
5. Ensure that the clinical functions of the registry are incorporated into
the new private sector certification process for health information systems.

This recommendation has been put into practice, and the IIS community is now working directly with the HIT standards and certification bodies to ensure that IIS functionality is included.

6. Improve the communications standards and interoperability through messaging for immunisation registries.

Messaging standards are now being negotiated on a wider scale to cover not only IIS needs but also the needs of the wider NHIN effort.

7. Ensure that the funds spent on immunisation registries are either aimed directly at supporting the future state, or being used to improve the function of the immunisation program during the transition.

Funds spent on IIS efforts are focused mostly on improving functionality during the period before Electronic Medical Records are in place, but it is the author's opinion that more remains to be done in this area to better utilize and focus the available funds into future directed activities.

Looking towards the future

While today the focus of the federal government is shifting to the development of the National Health Information Network (NHIN), the history of IIS development in the United States can provide key lessons for what issues and pitfalls the NHIN effort may come across. In conclusion for this project, I would
like to highlight some of the IIS development efforts and how they may or may not parallel the development of larger patient health information systems in the NHIN.

The effort of the US IIS program to defining the functional standards for registries is very similar to how the HIT initiative is using use cases to describe what functionality NHIN projects should adopt. Based on the IIS experience, one critical lesson learned that could be brought forward into the HIT effort is that one must ensure that all stakeholders have a say in what standards are being set. This includes not only the opportunity to provide input into the discussion, but also clarity in how the decisions are made and what standards of functionality are being adopted. Without this openness, it can be very difficult to get such a diverse group of stakeholders to agree to the direction being set for the initiative. The IIS program was successful in gaining acceptance of their functional standards because partners were fully aware of how standards were being set. They were able to bring their concerns to the appropriate people, and had a forum for further discussion to raise issues that were not foreseen before the initiative was underway (American Immunization Registry Association 2002).

Data collection is also another area where the HIT initiative could learn from the US IIS effort. The examples in section two of the exegesis regarding data collection using the IRAR show how simply collecting data and reporting on a specific focus point of the program can lead to increased focus on that aspect of the program. The resulting improvement in adoption of the standard that served as that focus indicates that the HIT initiative may be able to apply the same methods to improve adoption of standards that are seen as critical to the NHIN but which may not be currently as prevalent as desired. Another facet of reporting that HIT may consider adopting is the use of an editorial segment of the published report. The HIT initiative could use the same methods to bring attention to new legislation
that impacts the implementation of segments of the National Health Information Network. As the development of the NHIN continues, changing administrations may also create situations where development activities must change to meet new requirements of oversight. By sharing this information in an annual report, the HIT initiative would be able to ensure that the information reached not only the programmatic staff involved directly in operations, but also the general public and politicians impacted by each project so that they understand why some operations may be changed.

Summary of IIS lessons and implications

This project started in 2001 has explored the rich history of IIS development in the United States, evaluated the impact of federal investment in the systems using methods and restrictions from the Office of Management and Budget, and has proposed new direction for the program, new methods for evaluation, and a new focus for the program. The focus now however should turn to the Health Information Technology initiative. The HIT initiative can learn many valuable lessons from the experience of the IIS program. These lessons include how one can underestimate the complexity of this type of program, the criticality of including all stakeholders in an open and clear discussion of the needs and functionality of a health information system, and the importance of focusing evaluation and reporting on the most critical aspects of the program at any given time. By exploring the history of the IIS program and other national and international health information system programs, the HIT initiative can take the best of what worked in each program to improve the chances for a successful implementation of a fully functional NHIN. The IIS program is only one of many
potential examples, but the history, progress, evaluation, and challenges faced by this program can serve as examples of how to make the HIT initiative a success.
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