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Shoaib Chotoo Patail

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IMPLICATIONS OF A NATIONAL IMMUNIZATION REGISTRY  
AN ALLIANCE TO WIN THE RACE FOR THE FUTURE CARE  
AND ACCURACY OF PEDIATRIC IMMUNIZATION

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A Project  
Presented to the  
Faculty of  
California State University,  
San Bernardino

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In Partial Fulfillment  
of the Requirements for the Degree  
Master of Business Administration

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by  
Shoaib Chotoo Patail, M.B., B.S., M.D., F.A.A.P.

December 2004

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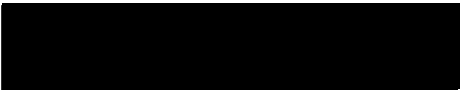
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by


Shoaib Chotoo Patail, M.B., B.S., M.D., F.A.A.P.

December 2004

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## ABSTRACT

Healthcare systems have been challenged to ensure the timely distribution of immunization. Childhood immunizations represent a basic public health strategy for disease prevention, responsibility for which is assumed by child health care professionals and health care organizations in the private sector, which provide the bulk of immunizations, and public providers, the traditional safety net in providing care for many children. Hence, an effective public health program to protect young children from vaccine-preventable diseases must involve public-private sector alliance.

This project examines the role of immunization registries and their effect on a Health Care Delivery System. Based on the findings of the study, the following conclusions can be drawn (1) Recent efforts to attain near-complete coverage of child populations by recommended vaccines have included initiatives by federal and state agencies, as well as private foundations, to develop and implement statewide community-based childhood immunization registries (2) Plans for a single, national registry have been set aside in favor of a national network of local and state registries linked through the use of common definitions and unique child identifiers (3) Both

Operational, technical and financing difficulties have slowed their development (4) The experience in selected areas has provided useful lessons for further development of a registry system and has underscored the potential of such systems to assure the success of childhood immunization initiatives.

The alliance to win the race for the future care and accuracy of pediatric immunization is about being the best total solution for vaccine-preventable diseases in childhood and adult, the latter in future. The recommendation is for the alliance to meet or exceed the latent and manifest needs of the pediatric population and to apply the proposed innovative strategy to win the race for the future immunization registries.

Finally the purpose of this project was the findings of this limited study and to form the basis for conducting a more rigorous examination of the issues and outcomes of registries under the current system and under the new alliance. Such an undertaking would help to determine and improve upon the outcomes achieved in the alliance units.

## ACKNOWLEDGMENTS

This work could not have been possible without the help of many people. First and foremost, I would like to thank the Great Almighty God for giving me health, strength, courage, ability and perseverance to complete this task. I would like to thank my beloved wife and beautiful children (boys) for their understanding and support they have extended for this program. I thank my Chief Edward S. Curry, Doctor of Medicine (M.D.) for providing me flexible work schedule and time off when I needed. I thank Southern California Permanente Medical Group (SCPMG) leader Philip Carney, Jr., M.D., Master in Public Health (MPH), Master of Business Administration (MBA), and Associate Medical Director in Fontana Medical Center. He has provided me the physical and emotional space to pursue one of the biggest endeavors in my carrier. I thank my colleagues Woldermaria Gebreselassie, M.D., MBA, and Director of Dialysis Unit in Fontana and Edward Hess, M.D., MBA, and Chief of Preventive Medicine in Fontana for their encouragement and for their valuable insights.

My two advisors, Sunny Baker, Associate Professor, California State University San Bernardino (CSUSB) and Sue Greenfeld, Professor and Director of MBA (CSUSB) for

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I thank Allan Leibenthal, M.D., Steve Tanenbaum, M.D., Marlene Lugg, Dr. PH, and Diana Wahl, Program Director, Kaiser Immunization Tracking System (KITS) Administrative Team (KAT) who were generous with their time, expertise, and supporting materials to help me do the best job I can do. Dr. Leibenthal has inspired me with his ideas, reference materials and suggestions as well as his expertise whenever I needed him.

I thank members of our Kaiser Permanente-Information Technology (KP-IT) department for providing me the technological information and support. Space limitation restraints me from detailing of everyone listed here and many others not mentioned here.

DEDICATION

To

my beloved wife

Zohra S. Patail

The

most

important

person in my life



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## CHAPTER ONE

### INTRODUCTION

This paper looks at one Information Technology (IT) system utilized in healthcare organizations. The specific IT system focused on is the National, State and Individual Health Organization IT System because it is widely used in Pediatrics and now also in Adult Medicine. Immunization registries are confidential, population-based, computerized information systems that attempt to collect vaccination data about all children within a geographic area. Registries are an important tool to increase and sustain high vaccination coverage by consolidating vaccination records of children from multiple providers, generating reminder and recall vaccination notices for each child, and for providing official vaccination forms and vaccination coverage assessments.

From a strategic standpoint, the National Health objective for 2010 is to increase 95% the proportion of children aged less than 6 years who participate in fully operational population-based immunization registries. According to 2000 data, 24% of United States children are participating in population-based immunization registries [1]. In a population-based immunization registry, children

are entered into the registry at birth through a linkage with birth records. A health care provider also can initiate a registry record at the time of a child's first immunization. If a registry includes all children in a given geographical area and all providers are reporting immunization information, a registry can provide a single data source for all community immunization partners. Such a population-based immunization registry can make it easier to carry out the demonstrably effective immunization strategies (e.g., reminder/recall, Assessment, Feedback, Incentive, and Exchange (AFIX) and Women and Infant Care (WIC) linkages) and thereby decrease the resources needed to achieve and maintain high levels of coverage. Immunization registries also can be used to enhance Adolescent and adult immunization, the latter Flu and Pneumococcal vaccine services and coverage.

The concept of immunization registries is not new. Many individual practices and health plans administer immunizations to their patients. Records of these immunizations often are based on computerized information systems designed for other purposes such as billing. There also is a growing movement toward the development of totally computerized patient medical records called as Automated Medical Record (AMR) also know as Electronic

Medical Record (EMR) at the health plans, local, state and federal level. Although an immunization registry includes all immunizations administered by health care providers participating in the registry, only population-based immunization registries are capable of providing information on all children and all doses of vaccines administered by all providers. The original platform used by organization consists of a loosely coupled various platforms from various companies. To date, more than 250 local public health departments have immunization registries that are in various stages of planning or development. Only a small number of these registries meet the minimum functional criteria of maintaining records on 95% of all eligible 2-year-old children in the target population and providing an electronic immunization record that is accessible to providers [2].

The study of the development of immunization registries across the United States provides an important case study for how public health agencies will use the rapidly developing health information infrastructure to perform health assessment and health assurance activities in a managed care environment.

## CHAPTER TWO

### BACKGROUND

Vaccinations are a critical public health tool: They save lives, reduce health-care costs, and improve the quality of life for persons of all ages. After safe and effective vaccines were introduced, the United States and the majority of other developed countries have experienced greater than 95% reductions in cases of childhood vaccine-preventable diseases, compared with pre-vaccine era levels [3]. Reported cases are at record low levels; however, vaccine-preventable diseases will return if vaccination coverage levels decrease [4]. Lack of a consolidated immunization record may lead to problems with determining individual immunization needs at office visits as well as measuring vaccination coverage levels of a clinician's practice or a community's population.

Scattered immunization records significantly compromise the ability of clinicians to determine the immunization status of their patients who received immunization at other sites of health care. Routinely assessing immunization coverage levels at the practice level, implementing a recall system, and developing

community-wide immunization registries are some strategies to reduce the problem of scattered immunization records.

Routine childhood vaccination is one of the major public health success stories in this century, currently producing the lowest incidence rates of traditional vaccine preventable diseases attributed to the highest vaccination coverage levels for the corresponding diseases. However, the continued success of vaccination is being challenged by an immunization schedule, that is increasing in size, increasing in the number of vaccinations, complexity and by the lack of accessible, unified immunization records. Already, children are recommended to receive a total of 15 to 19 vaccine doses by 18 months of age, compared with only 8 doses by 20 years ago [5]. In addition, new vaccines and new combinations of vaccines will probably become available [6]. New vaccines will continue and perhaps accelerate this trend.

A child usually has two sources of immunization history information, the parent and the health care provider. Because parental records of their child's immunization history have been shown to be unreliable and because health care professionals are required by law to record information about immunization given in their



offices, the health care provider's records are typically viewed as being the most accurate and reliable.

Recent studies have shown that many children are vaccinated away from the primary care office, either at previous provider office or at the health department; most new patients do not bring adequate documentation of their immunization history to the initial visit to a new primary care provider and communication among immunization providers is frequently poor, all of which leads to a lack of unified records at the primary care provider office and an inability to determine vaccination needs accurately.

Lack of a consolidated record is problematic, not only for determining individual immunization needs at office visits, but also for measuring the vaccination coverage levels of a clinician's practice or a community's population. Measuring coverage levels at the practice or community level is an important strategy to improve and sustain high vaccination coverage levels. In theory, the relation between missing vaccinations and misclassification of an up-to-date (UTD) child as not up-to-date (UTD) is exponential, with small amounts of missing information having a very large impact on the accuracy of coverage assessments. Scattered records are a potential source of missing vaccination information at the

provider and community level resulting in over or under vaccination.

### CHAPTER THREE

#### THE IMPACT OF RECORD SCATTERING ON THE MEASUREMENT OF IMMUNIZATION COVERAGE

Stokley et al. [7] have shown that scattered immunization records significantly compromise the ability of clinicians to determine the immunization status of their patients who received immunizations at other sites of health care. Nationally, 22% of children received their early preschool vaccination from more than one health care professional. Among children having more than one immunization provider, these are the some of problems:

1) the records of the child's most recent provider mistakenly indicated that 23% of completely vaccinated children were in fact in need of vaccination, 2) a record from the most recent provider indicating that the child needed additional vaccination up to 18 months series was incorrect 38% of the time for private practitioners and 19% of the time for health department clinics, and 3) the presence of a summary immunization record in the chart was associated with more complete records. Finding from this study provides a national perspective to a problem that has been studied mostly at the local level.

Hamlin et al. [8] showed that records were scattered between two clinics located together in Los Angeles (LA) County. One clinic was a health department clinic and the other was community health center; both were on same floor of the same building. Murphy et al. [9] demonstrated that for children who visited a Dallas county public clinic, incomplete documentation of immunization in both the public clinic and parent's record was associated with a 45% rate of unnecessary immunization. Yawn et al. [10] demonstrated the high degree of record scattering in Olmstead County, Minnesota, and showed that if an immunization registry could combine the records, the ability to correctly classify children's immunization status would increase dramatically. The scattered records is a problem that is national in scope, resulting in misclassification of over 1,500,000 completely vaccinated United States (US) children as being in need of vaccination and that the problem is more serious among private practitioners.

Watson et al. [11] showed one source for scattered records - only 22% of parents brought their immunization records to an initial visit to a new primary care clinician. This happened despite parents who were reminded to bring their child's immunization record at the time of

making an appointment. While parents are waiting for the appointment center's receptionist, they are reminded by the continuous recording playing during waiting. Many studies have shown that parents do not know the immunization status of their children. In general, parents believe that their children are fully vaccinated when, in fact, they may not be up-to-date. Thus parents cannot be relied on to know the vaccination needs of their children. One can raise questions like: 1) what are the causes of scattered records? 2) What are consequences of scattered records? and 3) What can we do to reduce their impact? First, causation might best be answered by looking at the relation between mobility, changing providers, and insurance related referrals to health departments. Second, consequences might include both under vaccination and over vaccination. For instance, a reluctance to vaccinate by a provider or by the parents when there is uncertainty about the completeness of vaccination records might lead to miss opportunities to vaccinate. Conversely, vaccinating children with incomplete records may lead to over vaccination. Just as under vaccination exposes children to unnecessary risk of vaccine-preventable disease, over vaccination exposes children to unnecessary risk of adverse events from vaccines. Third, support and guide the

development of immunization registries that will eventually help clinicians keep track of the immunization status and needs of their patients.

There are several reasons for needing complete immunization records at the offices of immunization providers. As a result of the studies that demonstrated the potential to improve immunization coverage by reducing missed-opportunities, providers are strongly encouraged to vaccinate at every opportunity. Even if it is over immunization for individual children, the records are essential to determine their need for vaccination at the time of the office visit. Failure to assess accurately implies failure to make a correct clinical decision whether to vaccinate and with what vaccines.

For health care providers, complete records are needed to assess accurately the immunization coverage of their patients - something that all providers, public and private, are being asked to do. Without complete records, the assessment shows substantially lower coverage than may actually be the case and information that would help clinicians improve their immunization practices might be rendered inaccurate. A benefit of these assessments is to quantify the degree of missing records for clinicians, which in turn, should lead to more complete records.

The data support the development of community immunization registries that communicate with registries of other communities. Once a system of registries is in place, the problem of scattered immunization records could be greatly reduced in magnitude.

## CHAPTER FOUR

### IMMUNIZATION REGISTRY-BASED RECALL SYSTEM

All immunization providers should operate a recall system to bring children in need of vaccination back to the office for vaccination and other clinical preventive services. Recall system list patients belonging to a practice that cannot be documented to be up-to-date on immunizations. All immunization providers should operate also on a Current- and Past-due system to give vaccination to children in need of vaccination. Immunization recall for specific vaccines may be necessary to "catch up" children with newly available vaccines, recall children after vaccine shortages and revaccination for a non-immunogenic (one that did not confer immunity) vaccine given previously. A recent meta-analysis concluded that patient reminder/recall typically boosts immunization rates by 5 to 20 percent point [12]. Although many pediatric reminder/recall studies have contacted under immunized families by mail and/or telephone, several studies have included case management or home visitation [13, 14, 15]. Most reminder/recall interventions have directed at routine childhood immunizations, but several studies have focused recall efforts on annual influenza



immunization of children with asthma [16, 17]. Recall interventions for specific vaccines have not been well studied in children (until recently when Hepatitis A vaccine has been recalled by the pharmaceutical company) but may be highly relevant in the setting of intermittent vaccine shortages. Nationwide vaccine shortages have recently occurred for Varicella (chicken pox) vaccine; the Diphtheria, Tetanus toxoids, and acellular Pertussis (DTaP) vaccine; the Measles, Mumps, and Rubella (MMR) vaccine; and the pneumococcal conjugate vaccine (PCV7), and provider are encouraged to track and recall children who miss doses because of shortages [18, 19, 20].

Reminder/recall and immunization registries may augment the uptake of new vaccines such as PCV7 and Hepatitis A. Soon after the February 2000 licensure of PCV7, the Advisory Committee on Immunization Practices (ACIP) [21] and the American Academy of Pediatrics (AAP) [22] recommended universal PCV7 immunization of children aged 23 months and younger, with a schedule of "catch-up" doses for children 7-23 months of age who were not immunized as infants.

The socioeconomic circumstances of a population may present a barrier to successful recall. Research has shown that poverty and minority race or ethnicity predict

underimmunization and these characteristics were prevalent in several studies [23, 24, 25].

In several published studies in which immunization recall was effective in disadvantaged populations, letter and/or telephone recall was combined with outreach and case management. In a recall intervention with "impoverished and middle-class children" in Upstate New York, letter and telephone recalls were supplemented by outreach that included home visitation [26].

To avoid recalling fully vaccinated children whose medical records are showing missing vaccinations that were actually administered, the office staff needs to make a judgment about the completeness of the record. The same procedure should be adopted for a Current- and Past-due system. If the staff determines that the record may be incomplete, an attempt to determine the true immunization history could precede the recall patient.

Because of frequent relocations of jobs and places, regional registries will be helpful with recall efforts only if information regarding accurate telephone numbers and addresses are frequently updated at multiple points of care. The use of emergency contact information within registries may help but will require effort and resources to incorporate. Immunization interventions such as

reminder/recall, when used in disadvantaged population, may require a stepped approach, including adjunctive case management and home visitation for difficult-to-reach families. Regional registries that aggregate immunization data from all providers in an area can improve tracking and delivery of immunization in more transient populations. Only with a better understanding of the match between the type of intervention and the targeted population will we be able to best direct resources toward improving immunization rates.

## CHAPTER FIVE

### VACCINE ADVERSE EVENT REPORTING SYSTEM (VAERS)

The signs and symptoms of terrible and horrifying diseases such as gasping for breath and desperate hacking of whooping cough (Pertussis), the iron lungs and braces of polio, and the birth defects from rubella, for many people today, those are the stuff of history books, as a result of and thanks to vaccines. But the rare case of vaccine-associated paralytic polio (VAPP) or the death of an infant soon after receiving a dose of pertussis vaccine may make people wonder: are vaccines safe enough, or could they be safer?

Vaccines are one of the most cost-effective measures in the public health [27]. Nevertheless each vaccination involves benefits and risks. While the benefits far outweigh the risks and costs, no vaccine is perfectly safe. The safety of vaccine is usually evaluated and assessed in initial pre-licensure (preliminary) clinical trials. Such trials usually have sample sizes as required by The Center for Disease Control and Prevention (CDC) and the Food Drug Administration (FDA) are insufficient in numbers to detect rare adverse events. In addition, vaccine trials are usually held in well-defined,

well-controlled, and homogenous populations with relatively short follow-up periods that may limit their full assessment. Post-licensure drug evaluations have relied on passive surveillance system to monitor adverse events. Such systems are more practical and less expensive than controlled trials; however, their data are usually inadequate and inconclusive to determine causality [28].

The Center for Disease Control and Prevention (CDC) and the Food Drug Administration (FDA) within the Department of Health and Human Services oversee different aspects of immunization activities in the United States. To ensure public confidence and the safety of vaccines, the CDC and FDA together are responsible for monitoring the safety of all vaccines licensed for use in US.

The FDA and the CDC developed, The Vaccine Adverse Event Reporting System (VAERS), a system in response to the National Childhood Vaccine Injury Act of 1986. The VAERS is one cornerstone in vaccine safety monitoring. It provides a central registry where providers, vaccine manufacturers, patients, or the parents of the patient can report to the CDC and FDA about adverse events that individuals may experience following vaccine administration.

CDC and FDA conduct analyses of VAERS data to identify potential new vaccine safety concerns. The findings of analyses may contribute in turn to improving knowledge of immunization benefits and risks, identifying windows of opportunities to revise precautions and contraindications, and the development of ever-safer vaccines. Besides identifying previously unknown adverse events, VAERS is an important tool for monitoring individual lots of vaccines. If there really is a problem with a lot, the CDC and FDA move very rapidly to get rid of that lot off the market. The finding of problem in one lot allows evaluating the "sister" lots as well to determine the problem in the bulk of lot or just a mere chance variation. Another key factor to assess the significance of the number of the adverse events is the size of the lot. A lot with hundreds of thousands of doses is found to be associated with more events than a lot with tens of thousands of doses.

The report of an adverse event to VAERS should not be documentation that a vaccine caused the event; the providers should not make that judgment. Reporting same unusual events and occurrences in clusters from different providers provide CDC and FDA to revisit the safety of the new vaccines. VAERS is designed to detect signals or

warnings that there might be a problem rather than to answer questions about what caused the adverse event. These signals can lead to hypotheses about causality, which can then be tested by other methods, such as epidemiological or laboratory studies. Increase in events of intussusceptions (invagination of distal part of intestine into proximal segment - telescoping effect) reported to VAERS resulted in recall and withdrawal of Rotavirus vaccine (Rota-shield®) from the market after.

The utility of passive surveillance has several potential limitations. Many events that might be associated with vaccines go unreported. Underreporting is often a major problem, limiting the system's ability to detect new or rare events. Despite underreporting, the reporting sensitivities of the reporting and monitoring systems for certain serious events appear to be higher than those of other passive surveillance systems that monitor adverse drug reactions. Such systems in Britain, for example, receive reports on from only 1% to 10% of events estimated to have occurred [29].

Clinical information obtained on report forms is often inadequate for assessment, and reports may be biased to prevailing concepts of adverse events and changing publicity [30]. An increase in reported events may be

owing to an increase in the number of doses of vaccine administered, information that may not be readily available.

Reporting of adverse events appears to depend on a host of factors, such as clinical seriousness, temporal proximity to vaccination, and health care workers' awareness of and obligation to report particular adverse event [31].

Despite of all the existing flaws, if reporting is reasonably consistent, it may be possible to detect changes in trends of known common adverse events. In addition, passive surveillance remains a potentially cost effective way to monitor rare adverse events that cannot be detected in relatively small and short pre-licensure clinical trials. Case reports received by the VAERS can be used to generate hypothesis that can be evaluated in controlled studies, such as large-linked databases in which exposure and outcome variables are computerized [32].

#### National Vaccine Injury Compensation Program (NVICP)

Significant adverse events to vaccination are unlikely but do occur. In 1986, Congress enacted the National Childhood Vaccine Injury Act, establishing the



NCICP, managed by the Human Resources and Services Administration (HRSA). The idea was to facilitate compensation for vaccine-injured children, avoiding the delays and uncertainties of the tort system, and to protect the vaccine supply in a climate where manufacturers were concerned about the rising and unpredictable cost of litigation [33]. For known adverse reactions, plaintiffs have no need to prove the causation, whereas not related adverse reactions; the vaccination must be shown responsible for the adverse event. The plaintiffs have the right not to accept the decisions from the compensation program and can file a civil suit. As of September 2001, about 1,600 claims have been compensated and more than \$1 billion awarded to petitioners and their attorneys. A trust fund, from which awards are paid, is funded by an excise tax of \$0.75 per vaccine antigen purchased [34].

CHAPTER SIX  
PROGRESS IN THE DEVELOPMENT OF IMMUNIZATION  
REGISTRIES IN THE UNITED STATES

Immunization registries are confidential, population-based computerized systems that collect vaccination data about all children within a geographic area. By providing complete and accurate information on which to base vaccination decisions, registries are key tools to increase and sustain high vaccination coverage. Registries consolidate vaccination records of children from multiple health-care providers, identify children who are due or late for vaccination, generate reminder and recall notices to ensure that children were vaccinated appropriately, and identify provider sites and geographical areas with low vaccination coverage. One of the national health objectives for 2010 is to increase to 95% the proportion of children aged less than six years who participate in fully operational, population-based immunization registries [35].

To assess the status of immunization registry development, Center for Disease Control (CDC) analyzed data from 1) 1999 Immunization Registry Annual Report (CY 1999 IRAR) of 64 Jurisdictions (grantees) that receive

federal immunization funds under section 317d of the Public Health Service Act. Finding from this analysis showed that substantial progress has been achieved in the United States in developing and implementing community-based and state-based immunization registries [36]; 2) 2000 Immunization Registry Annual Report (CY 2000 IRAR) of sixty-two (62) jurisdictions (guarantees) indicated that approximately half of the guarantees are operating population-based immunization registries that target their entire catchments areas; however, approximately seventy-five percent (75%) of children aged less than six years still need to be included in an immunized registry to reach the national health objective [37]; 3) CDC analyzed data from fifty (50) states and the District of Columbia (DC) from the calendar year 2000 Immunization Registry Annual Report (CY 2000 IRAR) to assess current registry activity. This analysis indicated that thirty-two (32) of fifty-one (51) guarantees (sixty-seven percent-67%) are operating population-based immunization registries. These 32 projects represent forty-nine percent (49%) of the US population aged less than six years [38]; and 4) Report from the calendar year 2001 (CY 2001 IRAR), summarized data indicate that approximately half of the United States children aged less

than 6 years are participating in a registry, achieving the national health objective will require increased immunization provider participation [39].

Immunization Registries are in the Senate limelight. On June 26, 2003 the United States Senate Appropriations Committee took up the bill that funds all the federal programs under the Department of Labor, Health and Human Services (HHS) and Education, and related agencies for fiscal year 2004. This is the bill that each year funds the National Immunization Program under Center for Disease Control (CDC) - the source of the grants ("317") to states, some cities and territories for their immunization programs. The majority of federal dollars for registries comes from this source.

After a committee drafts its bill and approves it, the bill is reported with a committee report. Every Child By Two (ECBT) in its discussions with the Senate Appropriations Committee staff contributed its ideas for the report, Senate Rpt. 108-081. The following committee report language encourages registry development nationwide.

"The Committee recognizes that immunization registries, like all database systems, continue to require funding. The committee's goal is to

have registries up and running in all states. CDC must remain vigilant in offering the best technical assistance to States. Immunization providers lose interest if they have learned a new system that fails and registries are only as good as the numbers of accurate records they hold. The Committee understands that immunization registries are able to perform many of the functions required of State immunization programs, including immunization surveillance, vaccine inventory, vaccine For Children (VFC) compliance, school surveys for compliance with immunization requirements, reminder notices to patients, immunization records for parents, etc."

Both the House and Senate Appropriations Committees approved their "labor/HHS/Education" bills on June 26, 2003. The next step is for each chamber to take its bill to the floor, amend, and pass it. Then the two versions will go to a conference committee made up of appropriators of each chamber chosen by the leadership to conference this particular bill. The conferees come to a compromise version of the bill, which is voted upon in each chamber, and sent to the President for his signature [40].

Considering that this is the largest of the 13 appropriations bills and covers a huge number of programs, ECBT is very pleased to see the recognition afforded immunization registries.

## CHAPTER SEVEN

### COST OF IMMUNIZATION REGISTRIES

Success in immunizing the pediatric population has progressed to the point that disease burden is essentially zero for many of the childhood vaccine preventable diseases; however, reaching this level has required substantial resources in the form of time, personnel, and financing, raising concern about our ability to maintain this degree of disease protection. These concerns have been voiced by the National Vaccine Advisory Committee (NVAC), Institute of Medicine (IOM), and the CDC.

The belief is that registries should be able to generate an individual's unified immunization record from multiple providers, identify when a child is eligible for immunization and when they may be post-due, create population level coverage rates, as well as provide reports to individual providers about their clientele's coverage rates in a far less costly and more timely manner than any present system. While some of these factors have been looked at, it is unclear what the cost of meeting these goals will be, who incurs the costs and who may benefit.

The importance of understanding the capitalization requirements was clearly stated by NVAC: "The barriers to creating a national system of state-based registries are mainly political and financial rather than technical." The National Vaccine Advisory Committee further stated that the "Centers for Disease Control and Prevention should pursue immediately further study to completely characterize start-up and maintenance costs of registries and compare these to costs of alternative systems" [41].

Maintaining quality while controlling costs became a dominant challenge in the 1980's as employers reeled from multiple years of double-digit inflation of healthcare costs. Successfully competing in a global economy was contingent on meeting this challenge. This employer mandate for change in the name of cost control gave birth to Managed Care. Managed Care is defined as "Any system of delivering health services in which care is delivered by a specified network of doctors and hospitals who agree to comply with the care approaches established by a care-management process. Providers may receive a capitated payment for providing all medically necessary care to enrollees or may be paid on a fee-for-service basis. Managed care often involves a defined delivery system of



providers with some form of contractual arrangement with a health plan."

Capitation is a closed economic system. It links the delivery and financing of healthcare. Capitation is essentially shifting the insurance responsibility and risk from health plans to medical groups and hospitals. Regulation and ethics constrain pure market place activity. The further away from the bedside, the more visible the unbridled marketplace. The pharmaceutical and in particular new vaccinations and medical device (i.e., the number of syringes) and the resources needed to implement the registry usually exhibit the most prominent behavior in healthcare.

Quality, service and cost all have agency metrics. The presence of quality, service and cost metrics on the same Balanced Scorecard operationalized this concept. Healthcare resources are finite, like other parts of our economy. Cost controls and differential resource allocations are inevitable. Appropriate allocation of finite resources to promote the most good for the most people is an essential part of good stewardship.

Current financial instability may reflect an under-funding of the healthcare system. The Balanced Budget Act 2002 [42], mandates reduction in Medicare

reimbursement at a time when an increasingly younger population in need of beneficial medical advances (i.e., new and more sophisticated and refined vaccines) increases cost structure to provide state-of-the-art care. A softening economy will eventually create a more flexible pool and may make employers more reluctant to accept ongoing premium increase.

In California, premium-charged that is to employers is thirty percent (30%) less than the Midwest and fifty percent (50%) less than the East Coast. A California Medical Association analysis of medical loss ratio (defined as the amount of premium dollar spent on health care vs. administrative, profit and other expenses) shows for for-profit Health Maintenance Organizations (HMOs) in the range of 80-85% while non-profit HMOs such as Kaiser and like is usually listed around 95%. Wall Street engenders financial discipline for operations but also demands quarterly earnings. The number of employers providing healthcare in California is 48%. Nationally it is 61%. The number of uninsured in U.S. is 43.6 million (15.2%). This increased by 2.4 million in 2002. The fastest rising group of uninsured people in the U.S. is the middle class. Some predict public outcry when ranks of the uninsured increase from 43 million to 65 million in

the near future. Medicare will be broke by the year 2019 [43]. The U.S. must find a way to provide health care coverage to all Americans by the year 2010 to mitigate the pain and suffering caused by the uninsured in America [44].

The medical informatics is not the first industry to be confronted with the need to anticipate the cost of development and deployment of an application. Such diverse industries as banking, manufacturing, shipping and retailing have been confronted with the need to predict costs, anticipate benefits, and develop a realistic capitalization plan for large distributed computer applications (Cost Estimating Group 1999; International Society of Parametric Analysts 1998) [45].

Developing a means of supporting registries over the long term requires information on costs to operate registries. Based on one study, maintaining a nationwide network of registries for children aged 0 to 5 will require an estimated \$78.2 million. This amount incurred on maintaining a nationwide network of registries would be offsets by not having manually retrieve: a) records for school entry; b) from child care/day care; c) change in provider; d) Health Plan Employer Data Information Set (HEDIS) reports; e) not having to carry out the National

Immunization Survey; and f) prevention of over immunization that was estimated at \$113.8 million annually [46].

The real costs and the real opportunity to convert an electronic database into a functional registry that aligns with policy objectives are dependent upon the adequate allocation of resources to administrative efforts. If a registry is administratively viewed solely as an alternative to the paper chart and business processes are not reengineered, then, overall costs may be quite low. However, if the registry is to serve its intended purpose of improving immunization coverage rates, then adequate administrative time and money must be allocated to reexamine and redesign organizational practices. This is simply the cost of doing business.

CHAPTER EIGHT  
PERCEPTIONS AND EXPERIENCES OF CLINIC STAFFS  
USING AN IMMUNIZATION SYSTEM

Despite the proliferation of immunization registries, little work has been done to evaluate qualitatively the perceptions and experience of using an immunization registry by clinic and office staff. The challenges identified to registry implementation in private practice through focus groups with pediatricians, family medicine physicians, and office managers include concerns regarding double entry of data, slowing of patient flow, staff time consumed for data entry, disproportionately high costs for small practice groups with limited staffs, and high staffs' attrition rate [47].

In one survey [48], sixty percent (60%) of pediatricians, forty-seven percent (47%) of family medicine physicians, and seven hundred and seventy five (775) of registered nurses (RN) and nurse practitioners (NP) stated that immunization registries represented the "best chance to resolve the documentation problem." However, respondents who were familiar with their local registry were less likely to believe that registries would

solve documentation problems. They were more likely to believe that registries were not yet of practical value.

The perceptions of provider site personnel who interact with a registry are important because the successful registry (immunization and demographic records) requires both accurate and timely entering of the records. This information is also important for health care providers who currently participate in a registry or whose participation is under consideration.

Differences were observed in subjects' perceptions of an immunization registry across provider sites. Although most subjects had positive attitudes toward the registry, they did not necessarily believe that the registry decreased their workload. The latter indicated that, as a result of having the registry, they provided more immunizations, printed more immunization records, and entered more data than they did before the registry was implemented. The ability to access immunization registry data and actual use of the registry seem to be related to training of clinical personnel, location of the registry terminal, user friendly system in place, and helpfulness and availability of registry staff. This concludes that obtaining the opinions of immunization registry users is

an important strategy to evaluate the usefulness of  
registry and address possible areas of improvement [49].

CHAPTER NINE

PRIVACY RIGHTS, HEALTH INSURANCE PORTABILITY AND  
ACCOUNTABILITY ACT (HIPPA), AND THE  
IMMUNIZATION REGISTRY

Protecting privacy, security and maintaining confidentiality are essential to developing immunization registries. Moreover, registry developers must consider privacy, security and confidentiality concerns in light of their communities' values and special needs. The privacy, security and confidentiality concerns of immigrant communities must also be considered. Federal government should work with key stakeholders, including Center for Disease Control and the National Committee on Vital and Health Statistics, to develop and disseminate model policies and legislation for registries that enable exchanging information while protecting privacy, security and confidentiality. At a minimum, the health plans should

- Ensure that patients and parents are notified of the existence of the registry and of the information contained in the registry;
- Inform patients and parents the purpose of the registry and its potential uses:



- Permit patients and parents to review and amend registry information
- Accept responsibility for registry information protection and reliability;
- Give the option to the parents to decide whether their children will participate in a registry
- Should limit access to registry information and maintain audit trail to monitor records access. Each person should have access to his or her own records and to audit trails.
- Impose strong penalties for the unauthorized use of registry data and enforce consistently.
- Avoid using registry data in a punitive fashion against parents and patients (e.g., denial of health insurance coverage; US Department of Justice (DOJ), Immigration and Naturalization Service (INS) tracking of immigrants; or other law enforcement purposes) and must be prohibited.
- Ensure to protect the privacy, security and confidentiality if registries are to be integrated with more substantial health information systems.

HIPAA is the acronym for the Health Insurance Portability and Accountability Act that was signed into law on August 21, 1996, Public Law 104-191. This law impacts all areas of the health care industry and was designed to provide insurance portability, to improve the efficiency of health care by standardizing the exchange of administrative and financial data, and to protect the privacy, confidentiality and security of health care information.

On April 1, 1997, the Departments of Labor, Health and Human Services and the Treasury issued interim regulations that interprets many of the provisions of the new laws. The Department of Labor's regulations interprets amendments made to the Employee Retirement Income Security Act (ERISA) and potential problems and unwarranted intrusions into health care of the Final Privacy Rule of HIPPA of 1996.

In response to HIPPA, a CDC-led Privacy and Confidentiality Implementation Team with representatives from the National Vaccine Program Office (NVPO), state health departments, and the All Kids Count (AKC) program, developed specifications for protecting the privacy of registry participants and the confidentiality of registry data. Their report was reviewed by privacy consultants and

other stakeholders and approved by National Vaccine Advisory Committee (NVAC) in February 2000 [50].

These specifications are based on the following principles:

- An immunization registry is a tool for monitoring and improving population-based health and personal health. The information contained in the registry provides vaccination decision support. Registries do not replace parental or provider responsibility.
- Protecting privacy and maintaining confidentiality are essential to successfully developing immunization registries.
- Confidential policies are designed to balance clinical and public health information needs with personal privacy rights.
- Confidentiality policies are based on fair information practice, including each person's right to know what information regarding him or her is in the record and how it might be used and to request amendments or corrections to that record.

- Deciding whether to participate in a registry and deciding whether to vaccinate are separate decisions.
- All immunization registries, including registries that are part of integrated information systems, must ensure privacy protection.

Minimum specifications include but are not limited to, the following:

- (1) Confidentiality policies: All immunization registries must have a written confidentiality policy that is consistent with applicable laws and applies to everyone who has registry access.
- (2) Agreement to protect confidentiality: All authorized registry users must sign an agreement indicating that they understand the terms of the confidentiality policy, including the penalties for violations, and that they agree to comply with that policy. An employer can sign the agreement on his or her employee's behalf.
- (3) Notification/Disclosure: Patients or parents or legal guardians must be notified of the registry's existence, what information will be contained in it, how the information will be

used, with whom the information will be shared, the procedures for review and correction of information, and how to exercise choice regarding participation.

- (4) Choice: Parents must be able to choose whether to participate in the registry and to change their decision at any time if they opt in or out of registry. Parents and patients must not be penalized for non-participation. Personally identifiable information of those who have chosen not to participate must be protected.
- (5) Use of immunization registry information: Each Registry must identify and define the purposes of which it collects immunization information and inform all authorized users and parents or guardians. Information in the registry must only be used for the purposes for which it was collected. If information needs to be used for other than the said purposes, then parents and patient need to be informed and require consent from the parents and patients.
- (6) Access to and disclosure of immunization registry Information: Policies must define who will have access to registry information and

specify to which information to those persons will have access. Policies must ensure that only authorized users can provide information to or receive information from registry and that procedures are in place for handling requests from persons and organizations that are not authorized users. Due to these various new and emerging technologies, particularly in the area of access control, the Internet and remote access security are in the process of been implemented.

- (7) Penalties for unauthorized disclosures: Policies must define what constitutes a breach of confidentiality and delineate the legal and administrative policies for the inappropriate use or disclosure of information. Penalties must also need to be enforced.
- (8) Data retention and disposal: Policies must address the amount of time the information will be held in the registry and whether it will be deleted or archived at the end of that period. Registries must have written policy that provides for the storage and disposal of all forms of confidential records.

Reports from states indicate that confidentiality policies are being developed or modified to be consistent with these specifications. CDC continues to provide technical assistance to states regarding these specifications. Additionally, CDC is assessing how well the minimum specifications apply to more substantial, integrated information systems and to data sharing between managed care organizations like HMOs and registries. CDC and its partners are also exploring other privacy concerns, including whether persons attaining age 18 years should be notified that they are in registry or that their information is being archived.

As registries mature, interstate exchange of immunization information will become more important and critical. Presently, inconsistent state and organizational laws control information sharing. States with stringent legal protections might not allow disclosure to states with less protective laws. Therefore, CDC is facilitating guideline development for the interstate exchange of information.

Parents are educated of the registry, its purposes, goals and potential uses during routine educational sessions offered at the birth hospital. During such education sessions, or at any later date, parents are

allowed to opt out of a registry. In communities where explicit consent is preferred, the opting in or informed consent is offered. Parents have never been penalized for not participating in a registry. It is strictly voluntary.

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## CHAPTER TEN

### STATE IMMUNIZATION REGISTRY LEGISLATION

A concerted effort to develop immunization registries in state and local communities has been under-way since 1993. Although immunization registries are currently operating or planned in every state, few contain complete immunization histories on all children for the targeted population or have the active participation of all providers [51, 52, 53].

As of June 2003, 22 of 51 states (43%) have laws and 3 of 51 states have rules (6%) that specifically authorize the establishment of an immunization registry (authorizing law) and ten states (20%) have laws that address the sharing of immunization information (immunization information-sharing laws), but do not specifically authorize the establishment of an immunization registry. Two states (4%) have laws that allow the sharing of health care information without consent between providers involved in a patient's care (i.e., health care information-sharing laws; these laws do not refer to immunization information explicitly. The remaining 14 states (27%) currently do not have authorizing laws or rules, immunization information-sharing laws, or health

care information-sharing laws. The immunization registry-related legislation is distinct from state laws governing the confidentiality of medical records.

#### Mandated Reporting and Penalties for Failure to Report

Thirteen (52%) of the 25 state authorizing laws or rules also mandate provider reporting to the registry. Providers are required by law to report immunizations to the registry in Arizona, Arkansas, Connecticut, Georgia, Maine, Maryland, Michigan, Mississippi, Tennessee, Texas, Vermont, and by rule in Delaware and West Virginia. In Maryland and Tennessee, reporting is mandatory only for public providers, and in Vermont, providers are required to report to the Department of Health. In seven of the 13 states with mandatory provider reporting (54%), parents or guardians may opt out of the registry or limit access to the information contained in the registry.

Reports indicate that even in states with mandatory reporting, not all providers are reporting to the registry. Only four of the 13 states (31%) with laws or rules that mandate reporting (i.e., Arizona, Arkansas, Michigan, and West Virginia [rule]) have laws or rules that contain penalties for failure to report to the

immunization registry. There were no reports of sanctions being utilized.

#### Immunity Provisions

Eleven of the 25 states (44%) with authorizing laws or rules provide some type of immunity from civil/or criminal liability for providers and other health care professionals who report information to (and in some cases, obtain information from) the registry in good faith. Some of these laws also provide immunity from liability for authorized persons in schools, childcare facilities and other entities.

#### Penalties for the Improper Disclosure of Information

Eight of the 25 states authorizing laws or rules (32%) contain penalties for the improper disclosure of information (i.e., Arizona, Delaware [rule], Idaho, Indiana, Michigan, Texas, Utah [rule], and West Virginia [rule]). Two of the ten state immunization information-sharing laws (20%) contain penalties for the improper disclosure of information (i.e., Nebraska and South Dakota). The improper disclosure of immunization registry information is frequently a misdemeanor; there may be civil and professional sanctions as well. Other

state laws also contain penalties for the improper disclosure of confidential medical information (e.g., Rhode Island), and in states such as Georgia, computer fraud laws contain penalties for the improper use and disclosure of confidential information.

### Consent

Parental or guardian consents for a child to be in an immunization registry or for their immunization information to be shared can be required by law or immunization registry policy. The type of consent required varies. Of the 51 states surveyed, 12 states (23%) require explicit consent (verbal, written or both), and 37 states (73%) have implied consent to share information with registries. Two states (4%) are in such an early stage of development that they (Alaska and Wyoming) have not addressed and decided whether to use explicit or implied consent [54].

### Required Written or Verbal (Explicit) Consent

Twelve (23%) of the 51 states have laws or state health department policies that require children's parents or guardians to give explicit consent to participate in the registry. In some states, consent to share immunization information may include sharing with the

department of health, schools, and daycare providers, in addition to the health care providers. In four of 12 states that require explicit consent (33%) (i.e., California, Idaho, North Dakota, and Texas), consent is required by law, and in the remaining eight states (67%) the state health department policy requires consent (i.e., Hawaii, Illinois, Kansas, Massachusetts, New Jersey, New Mexico, New York, and Virginia). In all but two of the 12 states that require consent, written consent must be obtained. North Dakota requires either verbal or written consent to share information. California law requires verbal consent, and that the health care provider must first disclose to the parent or guardian certain information including what information would be shared, with whom and under what circumstances, and should the parent or guardian give consent for this information to be shared with the registry? In many states, even when consent is obtained, access to demographic data is controlled, and only immunization data are released.

#### Implied Consent

In 37 (73%) of the 51 states, consent to be in the registry or to share immunization information is implied, i.e., a child's immunization is included in the registry

and/or shared without explicit authorization by the parent or guardian. In 25 of these 37 states (68%), there are provisions that allow parents either to opt out of the registry or to limit access to the information contained in the registry. In 12 of these 37 states (32%), there are currently no provisions to opt out or to limit access to the information contained in the registry; thus participation is mandatory. However at least three of these 12 states are considering implementing an opt-out mechanism.

The means of opting out varies; the process may entail a verbal request, a telephone call, or a signature on a vaccine administration form. In some states, if a parent chooses to opt out of the immunization registry, the information stays in the provider's office, and no immunization information is shared with the department of health, or any community, regional, or state-wide database. In other states, if a parent chooses to opt out of the registry, the immunization data remain in the centralized registry, but access to the information is limited or not allowed [55].

## Notification

States that inform parents that their child's immunization information will be in the registry, or that it will be shared, or both, are said to provide notification. As of June 23, 2003, 36 of 51 states (71%) provide notification to the parents or guardians. Twelve of the 51 states surveyed (24%) do not currently provide notification, and the remaining three (5%) have not yet addressed the issue of notification [56].

Law or policy may require notification about the registry. The form and type of notification differ by state. In 12 of the 36 states (33%) that provide notification, required written or verbal (explicit) consent serves as notification. In the remaining 24 states (67%) that provide notification, consent is implied and the form of notification varies. Only five of the 36 states (14%) explicitly require notification by law (i.e., California, Idaho, Tennessee, Texas) and Rule [Utah]. In all of these except Utah, consent serves as notification. Other types of notification include verbal notice by a health care provider, a sign posted in the provider's office, a statement on the vaccine administration form, or a letter or brochure provided to the parents.

## CHAPTER ELEVEN

### IMMUNIZATION TRACKING SYSTEM (ITS)

This paper examines at one Information Technology system utilized in Health Care Organizations. The specific IT system focused on is the National, State and Individual Health Organization IT System because of its widely used in the Pediatrics and now also in Adult Medicine. The following criteria will be focused on:

1. Strategic Impact
2. Changing Technology Platform
3. Assimilation of Emerging Technologies
4. Sourcing Policies
5. Application Development Process
6. Partnership of the Three Constituencies

#### Strategic Impact

From a strategic standpoint, the National Health objective for 2010 is to increase to 95% the proportion of children aged less than 6 years who participate in fully operational population-based immunization registries. According to 2000 data, 24% of United States children are participating in population-based immunization registries [57]. In a population-based immunization registry, children are entered into the registry at birth through a



linkage with birth records. A health care provider also can initiate a registry record at the time of a child's first immunization. If a registry includes all children in a given geographical area and all providers are reporting immunization information, a registry can provide a single data source for all community immunization partners. Such a population-based immunization registry can make it easier to carry out the demonstrably effective immunization strategies (e.g., reminder/recall, Assessment, Feedback, Incentive, and Exchange (AFIX) and Women and Infant Care (WIC) linkages) and thereby decrease the resources needed to achieve and maintain high levels of coverage. Immunization registries also can be used to enhance Adolescent and adult immunization, the latter Flu and Pneumococcal vaccine services and coverage.

#### Changing Technology Platform

The concept of immunization registries is not new. Many individual practices and health plans administer immunizations to their patients. Records of these immunizations often are based on computerized information systems designed for other purposes such as billing. There also is a growing movement toward the development of totally computerized patient medical records. Although an

immunization registry includes all immunizations administered by health care providers participating in the registry, only population-based immunization registries are capable of providing information on all children and all doses of vaccines administered by all providers. The original platform used by organization consists of a loosely coupled various platforms from various companies. At present every health plan has its own software or has vendors who helped in maintaining this software.

The constant reviewing of the process is an integral part of the program, looking for ways to improve the immunization as well as registry rate. To implement the system, each health plan has a supreme body/committee to look after implementing, maintaining, securing and sharing the data. The committee is comprised of physicians, nurses, ITS from each medical center, and the IT specialists from the main regional office. The team recommends the value-added program to ITS. A feature, such as, "current-and past-due" system in the program, is added where physicians and the nurses identify the members who are behind their immunization. When the member check-ins at the front desk, the computer generates Computer Processing Record (CPR) that "flags" on the right side of invoice indicating that patient is delinquent in his/her

immunization. This process has shortened the turn around time for the providers to look into patient's shot record. It has also increased immunization rate at the national level. We can immunize patients without patients and parents having immunization record with them or patient medical record and have minimized the missed opportunities considerably.

Employees receive training by the IT department and after undergoing successful training assign the password to the employees. All passwords are confidential. Passwords, whether Generic or Personal are distributed after the user exhibits competency in using ITS. Each person completes formal training and demonstrates competency in using his/her assigned password before being allowed to use ITS. After the ITS' training process, the user is only allowed to browse data and manipulation of the system is not allowed.

#### Assimilation of Emerging Technologies

Health industry recently is forced by federal HIPPA act to enforce privacy and security of patient data. As a result, various new and emerging technologies, particularly in the area of access control and Internet and remote access, are in the process of being

implemented. The immunization tracking system (ITS) has implemented strict security levels. The following describes the system that has been implemented at Kaiser Permanente Health Organization.

1. The employee completes a "System Access Request" form. The form is signed by the Department Administrator and submitted to the Regional Security Administration or the ITS/Immunization Coordinator, per each Medical Center or Medical Office Building (MOB) procedure.
2. The Department Administrator and/or ITS/Immunization Coordinator determine security levels.
  - a. Display (inquiry) only: allows review of data via Generic Identification (GID) and password. Each user who needs a personal password must complete a "System Access Request" form. The ITS Coordinator, or the Computer Training and Support Department distribute passwords, after the ITS training process. The user is only allowed to browse the data and manipulation of the system. All passwords are confidential.

- b. Data Entry: allows review (display) and entry/alteration of data via a personal/private user ID and password.
  - c. Default Table Maintenance: allows review and maintenance of manufacturer names and lot numbers.
- 3. Each terminal is labeled with its own, specific GID. This GID is readily available to all staff accessing the terminal/Personal Computer (PC) for the purpose of ITS review and/or data entry.
  - 4. Passwords, whether Generic or Personal, are distributed after the user exhibits competency in using ITS. Each person completes formal training and demonstrated competency in using his/her assigned password before being allowed to use ITS [58].

### Sourcing Policies

The IT department determines the value of a combination of outsource and in-house technology, outsourcing or in-housed technology. Besides, the information or processes contained within this program and database are considered to be highly confidential and that is the important aspect to bear in mind when contracting

outsourcing. Sourcing is a buzzword now. However, everybody remembers the mistakes, bad goods, late deliveries, wrong labels/wash and unreliable communication but not the successes. There are three keys for success, Price, Quality and on time delivery.

The advantages of outsourcing are cost, quality and lagging IT performance at home, supplier pressure, access to special technical and application skills, and other financial factors. The disadvantages are lack of real time update information, gap in management, methodologies, right equipment, transport protocol and clear channel capability are among the problems. Another problem often stemmed from using middlemen or broker for certifying off shore site. Their role is to provide overseas management and offshore performance evaluation to guide companies to the best contact center outsourcing. Some companies build their own centers offshore from ground up, thereby, keeping strategic assets at home. They called this as "Global Reach Gateway" - all technology including traditional mainframes, Automatic Call Distribution (ACD) and client systems reside at home. The countries mostly for outsourcing are Ireland, India, Philippines, and China [59].

## Application Development Process

The process of developing a new application starts from the internal user base that is outside of the technical IT group. These groups start by defining their needs as the end users of the product. Needs review panel, which includes both the end users and IT technical staff, is created to review the needs and evaluate those needs that are consistent with company objectives. Only after the resultant document is approved, is actual development started with in-process review and testing by both the users and IT implemented as part of progress review. The ITS Administrative Committee monitors and implements application development process.

## Partnership of the Three Constituencies

The constituencies include IT management, user management, and general management. The key to the partnership is effective communications amongst all parties in order to secure their participation and ultimate accomplishment of the organization's goals and objectives. The key to the success is an outstanding relationship and understanding among all three constituencies. Any new technology before being implemented goes through extensive involvement and

participation of all three constituencies. By ensuring the participation of all parties, resultant work appeals to all the constituencies because they feel a part of the process and achieved the corporate goal.

The other side of the coin is that keeping all the constituencies together requires major efforts in communications and people skills. The politics of who really should be in control is always an issue. Is it the technical IT people, the user base, or the general management? Such situations usually resolve after facilitative and effective communication among the three groups.



CHAPTER TWELVE  
INITIATIVE ON IMMUNIZATION REGISTRIES  
CREATION AND FRAMEWORK

This initiative on immunization registries creation and framework started on July 23, 1997 when President Clinton celebrated the successful attainment of the 1996 Immunization goals established by the national Childhood Immunization Initiative (CII). An important additional goal was to build a sustainable system to maintain high immunization coverage in young children.

The following is the excerpted from Mr. President's speech.

"Almost a million children under the age of two are still missing one or more of their recommended shots. We have to make sure that every child now is safe from every vaccine preventable disease. As parents move from place to place, they often leave their children's immunization records behind. Their new doctors often cannot get access to these records. So I'm directing Secretary Shalala to start working with the states on an integrated immunization registry system. It may have something to do with whether their children live or die. And we have to do it and do it right" [60].

Soon after the celebration, CDC began discussing and looking for the response to the President's directive. National Immunization Program (NIP) of CDC assembled a planning task force of staff from CDC, AKC, and the National Vaccine Program Office (NVPO) to review ongoing immunization registry development efforts and to consider various alternatives to address the President's challenge.

The result of these efforts and deliberations was the formation of a new entity - the Initiative on Immunization Registries, led by National Vaccine Advisory Committee (NVAC) with support from NIP and NVPO. Four NVAC members formed a workgroup on Immunization Registries to guide the Initiative. Representatives from stakeholders (e.g., provider organizations, managed care plans, local and state health departments, parents and consumer groups, and the health information system community) were joined to participate as consultant members. The Workgroup launched the Initiative at a meeting on March 13, 1998, in Houston, Texas. As an expansion of that initial meeting, the Workgroup began a collaborative project to develop a plan to facilitate and coordinate a nationwide network of community- and state-based immunization registries. The Workgroup identified four main issues that would provide the conceptual framework for the Initiative:

1. Protecting the privacy of individuals and the confidentiality of information.
2. Ensuring provider participation.
3. Overcoming technical and operational challenges.
4. Determining resources needed to develop and maintain immunization registries [61].

### Workgroup Activities

The Workgroup conducted four public meetings between May-July, 1998. The meetings were convened to identify challenges and solutions related to each of these issues and to ensure input from stakeholder groups and the general public. The meetings provided a forum for expert testimony and a discussion among all walks of life that would be affected directly or indirectly. Each meeting also provided opportunities for public comments and questions. To ensure input from cross-section of parents, the Workgroup asked NIP to sponsor a series of parent focus groups. Approximately 20 focus groups were conducted between September-October, 1998. The focus groups were comprised of racial-makeup, socioeconomic, and urban/rural characteristics of the communities [62].

## Workgroup Findings

The establishment of immunization registries is a complex and convoluted endeavor that has been most successful at the local and state levels. Much of the current variation in registry is a by-product of varying state laws. The public meetings recommended that registries must be tailored to the local need as envisaged in state laws and as a result a (a single national immunization registry" is not the answer. Rather, the most feasible approach to universal coverage of U.S. children by immunization registries (as envisioned by President Clinton) is to establish a nationwide network of community/local/state population-based registries that are capable of sharing information in cost effective manner while maintaining privacy and confidentiality. The main challenge to this recommendation is to maintain appropriate coordination with these activities while working to resolve registry-specific issues and continuing to move forward expeditiously [63]. Progress has also been made in enabling registries to exchange data by using standard coding and transmission rules defined by the Health Level Seven (HL7) standard [64]. In 1995, CDC began developing the standard HL7 immunization messages and an implementation guide for immunization record transactions.

These messages became a part of the final, balloted HL7 standard in 1977. In 2002, CDC received funding from NPVO to develop a computer application that performs HL7 message functions [65]. Plans include placing this application in the public domain so that each registry developer does not have to develop an application independently. The technical focus of CDC's registry activities is related to identifying methods to ensure reaching the 2010 health objective.

## CHAPTER THIRTEEN

### KAISER IMMUNIZATION TRACKING SYSTEM (KITS)

#### Mission Statement

- To assure the timely and accurate entry of immunization data in KITS
- To develop and apply quality control measures to monitor the accuracy of KITS data
- To assist in achieving our Organization's strategic goals on immunization rates
- To participate in immunization registry at local, state and federal level

#### Goal

Kaiser Permanente Health Organization goal is to research, design, oversee the development of a computerized Southern California Kaiser Immunization Tracking System (KITS), which is accessible at all points of care in the region. The system must improve service, increase member and provider participation and satisfaction, and satisfy legal reporting requirements, while being cost-effective and contributing to the community at large.

## Introduction

The Southern California Kaiser Permanente Medical Care (SCKP) Program includes eleven medical centers and over fifty clinics where more than two million members receive inpatient, outpatient, and emergency care. A centralized mainframe computer system supports over 30,000 terminals in these locations with regional information systems.

Prior to the implementation of KITS, the recording and tracking of immunizations were dependent upon manual notations in patient charts. All reports were either handwritten or typed. Statistical data collection had to be performed manually.

Many of the patients/members do not always visit the same facility for medical care. Often, they will go to clinics near their workplace or along their commuting route to work. If an inoculation or skin test were administered at such a clinic, the chart at the patient's primary care facility would not always be updated. In addition, the updating of a patient's chart at his/her regular clinic could be delayed if the chart was not available during visit.

Contacting patients during vaccine recall was a time consuming, arduous process as the charts had to be

reviewed manually to determine whether a particular vaccine (identified by Manufacturer and Lot Number) had been administered. Only then could each identified patient be contacted.

Maintaining adequate, up-to-date immunizations was left up to the primary health care provider. The mere size of membership in a large HMO makes the task of assuring that a member has the proper inoculation at the specified time a difficult one at best. In order to assure that a patient was adequately immunized if information in the record was doubtful, providers would administer inoculations "just to be safe." This practice led to many instances of "over immunization."

With the need for all health care organizations to reduce costs and comply with the National Childhood Injury Act, mechanisms had to be developed and in place to prevent both "over" and "under" immunization conditions.

The Northern California Kaiser Permanente Region had previously developed an immunization tracking system that was chosen as a baseline for the Southern California version. It was modified from its original form to operate within Southern California Kaiser Permanente (SCKP) technical environment and additional functionality was added to meet client/user requirements.



KITS was piloted in April 1994 at Kaiser-Panorama City, followed by implementation with rapid rollout to all areas of the Southern California Region with the exception of Orange County. The rapid rollout was made possible by the using the "Train the Trainer" method.

Vaccines are grouped by the traditional "family" groupings. For example, PDRIX includes the diphtheria, tetanus, acellular pertussis, Hepatitis B and Inactivated Polio Vaccine. Vaccines are coded in the Inoculation Agent tables and are associated to "family" and to antigen (disease). Functions within the system support the display of a patient's complete history of inoculations and display of all skin tests. A user may navigate between these inquiries directly and select individual records for detail viewing.

Entry functions include multiple entries of inoculations for a given patient plus one skin test for that patient, entry of a given inoculation (e.g. Influenza vaccine) for multiple patients (such as at a flu clinic), updating skin test information with the results, and detailed entry of given inoculation for a given patient with the ability to record medical commentary for that particular administration.

Reporting functions address charting, patient request, and state required information. Chart summaries are produced daily whenever an immunization is administered or skin test is reviewed within that day. Patients may request and receive a printed listing of all inoculations during their visit without delay. In addition, a cooperative effort between SKCP and the Immunization Branch of the California Department of Health Services has resulted in redesigning the California Immunization Record to print directly on laser printers during the patient's visit.

Currently KITS has more than five millions inoculations, and more than one million skin tests. Some data are historical, extracted from our medical records, End-User Tracking System (EUTS), non-Kaiser provider sources, etc., but the majority consists of information entered at the time of service at our facilities.

#### Unique Features

- The sign-on procedure for KITS requires an ID (Gxxxxxx) and a password which link the computer terminal to a specific module and a refrigerator where vaccines are stored. In order to enter or modify data in KITS, a second level of security

sign-on consisting of a User ID (Kxxxxxx) = employee number) and a personal password is required. The user has three attempts to key in the correct ID and password combination. If unsuccessful after the three tries, the password will be revoked.

- To facilitate data entry and minimize error, default tables are set up. The default table lists all the vaccines in use for the module: a code name, manufacture, and a lot number identify each vaccine. When a vaccine is no longer stocked in the refrigerator, it should be removed from the default table. When a new lot is opened, the lot number should be immediately updated in the default table.

Because immunization is the cornerstone of preventive care, it is important that KITS is used to registers each patient's immunization history. KITS can serve organization well only if the data are accurate. Our goal is to monitor, improve and maintain the accuracy of KITS data.

## Organization

### KITS Administrative Team (KAT)

#### Functions:

- Acts as KITS Data-owner
- Identifies and targets specific projects for quality improvement
- Develops methods (procedures) for auditing and/or quality improvement
- Continually improves KITS functionality, making it more user-friendly and less error prone
- Coordinates efforts in improving immunization rates
- Exchange Data with other systems
- Plans and participates in projects that will enhance the public awareness of the importance and functionality of KITS

#### Composition:

- Data-owner/chairperson
- Physicians
- Immunization Tracking Service Department (ITSD) -Point of Care Systems and Client Services
- Department Administrator
- Users (Nursing staff)

- Research and Development (R&D)
- Clinical Services
- Clinical Systems Development

Ad-Hoc

- Pharmacy
- Medical Records

#### Local KITS Team

Functions:

- Responsible for the training and retraining of KITS users
- Offers KITS users good and prompt support
- Conducts KITS quality improvement measures
- Design and assists in project to increase immunization rates

Composition:

- A designated persons from Area Administration
- Area Quality Management Office
- Area KITS Physician Liaison
- Area KITS Coordinator [66]

Prior to implementing KITS, it was not possible to ascertain errors and/or omissions in administration of recording of immunizations. The use of KITS automated tool

has brought many of these problems to the surface, giving us the opportunity to improve procedures and practices in order to offer the best quality of care and service to our members. Acceptance to KITS in the Southern California Kaiser Permanente Region has been outstanding, due to the ease of use and region-wide access to the data in all clinical settings. The members of the Kaiser Immunization Tracking System Administrative Team are supporting the registry funding bill, Senate Bill (SB) 1764 (Speier) for the State of California.

## CHAPTER FOURTEEN

### VAXTRACKING SYSTEM

VaxTrack, formerly known as Inland Empire Immunization Tracking System (IETS), the San Bernardino and Riverside Counties pediatric immunization registry, and an offshoot of a system initially designed to serve public health and private provider clients in San Bernardino County. In 1992, The Robert Wood Johnson Foundation, a private foundation awarded funds to the Department of Public Health to plan and develop a San Bernardino County automated computerized immunization information system. The Department was one of 12 grant recipients nationwide. The California Department of Health Services (DHS) began providing support in 1997 to facilitate use of the system by local private and public health care immunization providers.

In 1993, a public health Information technology staff designed the software, Immunization Tracking System (ITS) and was implemented in public health immunization clinics in 1994. Initially it was limited to the data on all public health clients born in 1988 or later and were entered into the ITS. Later all children born in or to the residents of San Bernardino County were also added to the

registry. By the end of 1994, all public health clinics were enrolled and participated and date was entered in the registry. By that time, the registry became the default system for immunization records for children under the age of six in the Department. Since then, the program underwent many testing and suggestions on system changes and development. From this point, the registry was enrolled with children after birth through an interface with the Vital Statistics section of the Department of Public Health. The registry also mails postcards to children under the age of three in the county when they are due for immunizations. If the child's record shows immunization, reminders follow the Advisory Committee on Immunization Practices (ACIP) schedule. If the child has no immunization, generic reminders at two, four, six and twelve month of age are generated reminding that immunization are due and offering a referral phone number for physician referral services [67].

In 1995-96 California passed legislation that allowed counties to run registries to share data with other providers of immunizations with disclosure to parents prior to sharing. The specifications of data that could be shared and with whom were set in the California statute. Once the legislation went into effect, San Bernardino



County began campaigning to recruit private medical providers to join the registry. As a result, in 1996-97 about a hundred private offices, both large and small, were recruited. The first provider was a community coalition that offered immunizations in the desert and had recurrent immunization clinic within a group of communities. The first providers also worked on the system and offered suggestions for design and implementation. Providers were linked to the system through dial up to a toll free number and entry through a modem pool to the database. Real-time access was available twenty four-seven (24/7) through this system. The software to run the system resided on the computer in the provider office and technical staff from the Department of Public Health had to install the software.

The number of private providers increased gradually over the next three years. Provider ranges from solo practice to a large five office pediatric practice with almost hundred physicians. Special free clinics through schools, hospitals and other agencies are also enrolled in the program. The bulk of providers were recruited through immunization assessments in the private sector. Providers with deficiencies in record keeping or reminder/recall were urged to use the registry to overcome these barriers.

Providers without computers or limited staff tended to be the least likely to use the system. In this period, the funding from the Robert Wood Johnson Foundation was running out, but the State of California began supporting county registries through Federal dollars derived from savings provided through the Vaccine For Children (VFC) program. In 1998, San Bernardino County started negotiating with Riverside County that had an initial registry within the Department of Public Health, using commercial software. This software had limited registry functions (primitive) and was not supported or improved over the course of time. The Riverside County expressed an interest in joining hands with the San Bernardino system and using the latter registry.

A new method of access in 1998 came about exploring options of access through the worldwide web. Using the Citrix software, the ITS could be accessed through placement of an active X control on the provider machine. The active X control is the only element on the provider machine. The actual registry software is accessed through the control and resides on a server in the San Bernardino County secure facility. A provider with a computer and access to the web could interface with the registry. This development simplified the installation process so that

non-technical staff could do the provider office visits with a few exceptions. More providers joined the registry once this option was available.

In 1999, Inland Empire Health Plan (IEHP), the public version of Medi-Cal Managed Care for San Bernardino and Riverside County, agreed to submit data to the registry for their members. IEHP collects immunizations encounter data from the PM-160 submitted by providers. In order to report to the registry in a timely and complete manner, the data is collected to pay the providers a premium per immunization, an incentive and enticement for the providers. In tandem with the year 2000 computer issues, staffs imported data from IEHP and entered negotiations with Molina, the private Medi-Cal Managed Care, to do the same. Since the end of 1999, data from at least one health plan has been submitted weekly to the registry.

In 1999 and early 2000, Riverside County joined the registry to form the Inland Empire Immunization Tracking System (IEITS). Riverside received funding from the State for the merger. Riverside also received First Five Funding (FFF) to support private provider recruitment only in that County. However, the funding did not cover the San Bernardino technical staff on behalf of Riverside,

limiting the expansion. Consequently, Riverside interfaces with the registry purely through Internet connections.

Since 2000 the registry has continued to grow in the private sector in both counties. Provider participation in VaxTrack registry is growing. There are currently 133 organizations on the registry with others in the enrollment process. Two Health Plans regularly submit data to the registry.

Joint Advisory Coalition Members are:

- San Bernardino County Department of Public Health
- Riverside County Department of Public Health
- Riverside Regional Medical Center
- Women's and Children's Health
- Kaiser Permanente Fontana Medical Center
- LaSalle Medical Associates
- Loma Linda University Medical Center
- Moreno Valley Clinica Familiar
- Redlands Community Hospital

The registry is now designated as the official record for all children of all ages in both county public health clinics. The statute was also modified to allow agencies such schools, child care, WIC, and Department of Public

and Social Services (DPSS) offices who do not give shots but need to assess immunization status to access the immunization section from the registry.

VaxTrack has only two full-time staff in San Bernardino County: a programmer and help desk clerk. The registry has chosen to apply resources to keep technology and hardware up to date in order to expand as data and enrollments grow. This limits expansion and introduces uncertainty into the effort. The national standard of Health Level Seven (HL7) for data exchange will have to be addressed next fiscal year that will take resources from the programmer to implement these efforts. Also large provider groups wish to design batch loads from their computer systems, billing or appointment based, directly to the registry. These efforts take significant time from the programmer. Other issues include reluctance by some providers to utilize electronic records, misunderstanding of both California law and HIPAA's impact on registry operation and providers inability to devote staff to data entry in the registry given the difficult economic climate for private medical providers in California. VaxTrack has avoided inter-jurisdictional disputes between the entities in the registry by not addressing these issues at this juncture.

VaxTrack has brought data to immunization efforts in San Bernardino and now Riverside Counties. Health plans that serve clients in either or both counties use registry data in their Health Plan Employer Data and Information Set (HEDIS) efforts. Both Medi-Cal managed care plans use the registry data as their first cast at HEDIS immunization data. They supplement the registry with provider review, but the registry enabled them to spend less time determining their HEDIS rates. San Bernardino County staff review over 100 private provider offices each year for up to date status of 24-month-old children and immunization practices. The registry is often the origin of data for these reviews, which saves time in the provider offices.

In 1999-2000 registry data was used to answer a number of questions about immunizations in San Bernardino County. As of March 15, 2004 there are 774,298 children in the VaxTrack System with 56.0% of those children having immunization in their records. Records average 9.7 vaccines per child with more than 4.2 million vaccines in the registry [68].

At present VaxTrack has grown significantly without Significant problems. The ongoing issues for the registry is financial support sufficient to cover the expenses of

technical and support staff to keep the registry operating.

In 2002, IEITS was re-named VaxTrack, a more useful name with opportunities for design and modification. This resulted in purchasing the websites VaxTrack.org, VaxTrack.com to allow providers to remember and access comfortably.

Acceptance to VaxTrack among private and public health providers in San Bernardino and Riverside counties has been excellent, due to the support system provided by VaxTrack team in both counties and the ease of use and county-wide access to the data in most of the clinical settings.

## CHAPTER FIFTEEN

### CONCLUDING REMARKS: GETTING AHEAD OF THE CHANGE

#### CURVE - A WORK IN PROGRESS

Since Immunization Tracking System is considered the legal clinical chart and documentation for immunizations, accuracy, security and privacy of the data is the most important aspect of the system. By following its stringent and strict rules and regulations, policies and procedures (P&P) and instructions, a high level of data accuracy can be achieved. Without immunization, the communicable diseases are fatal. Currently in California, approximately 25% of our two-year-old children are not fully immunized against preventable and deadly diseases [69]. This gap in immunization coverage puts not only children but also everyone at risk of disease outbreaks. Nearly 10% of these children reach school age and school registration without being fully immunized and must be "caught up" in order to enroll in school, a time-consuming and expensive burden on school districts. Funding for California's immunization registry system would provide a vital public health tool that is essential to securing the health of our children by attaining the statewide goal of having 90% of our children fully immunized at the appropriate ages.



The majority of health professionals in states agree that there are two issues that must be addressed to achieve the goal of 95% immunization level. The first one is the need for a comprehensive system to help parents, providers, and health systems efficiently and accurately track a child's immunization history, children must have twenty (20) plus vaccines before they reach school age; hence the necessity of full funding for states immunization registry system. The second issue is a serious gap or disparity between health access and the outreach needed for many children who live in low-income families. This issue cannot be fully addressed until the immunization registry system is fully funded and fully functioning to provide the data needed to develop targeted outreach and educational campaigns. The registry system can also help track adult vaccines, such as for influenza and pneumococcal vaccines.

As the states struggle to secure a balance budget, they must look at areas that are cost efficient. The state immunization registry system is one way a state can realize substantial savings. Lacking a fully functioning immunized registry system costs the Californian's health care system \$32 million in unnecessary duplicated vaccines, lost staff time manually tracking children's

immunization records and in unnecessary outbreaks of preventable diseases [70]. Immunizations are the single most cost effective health intervention. The immunization registry will help reduce the health care costs.

Immunization registries are essential management tools for making sure every child gets immunized on time. The federal government's *Healthy People 2010* objectives assert that 95% of children under age six should have records in an immunization registry by 2010. Nationally, all fifty states are developing registries, and over thirteen states have fully functioning, fully populated systems. California's Statewide Immunization Information System (SIIS), a system of nine regional immunization registries (Los Angeles, Orange County, VaxTrack [formerly known as Inland Empire Immunization Tracking System], San Diego-Imperial, San Joaquin County) coordinated by the California Department of Health Services, Immunization Branch, has only 20% of children's records in the regional registries, reflecting inadequate funding of the system.

With more than 500,000 babies born in California each year, and many families moving in and out of the state, and in and out of the various counties in the state, the immunization registry system is critical to keeping every

child safe and health. The State of California needs a fully funded immunization registry system to achieve important public health goal. Senate Bill (SB) 1764 (Speier) [71], the registry funding bill, is an important first step toward accomplishing that goal. While it may not accomplish registry funding in the coming fiscal year, it is an opportunity to educate policy makers and legislatures about the registry; what it can do and why it is worth spending limited tax dollars to build and the support system. This bill is supposed to be presented and will be heard in the Senate Health and Human Services Committee on April 2004. Members of this committee were apprised that this bill is important to a broad base of their constituency.

Emboldened by its superior outcomes in immunization registry, the state searched for opportunities to leverage its intellectual capital. To market its superior outcomes of immunization registry - improved quality of life, employability, and survival-and lower global cost of care, the state has taken several positive actions.

For the past twenty-five years, Medicare has borne over 75 percent of the cost of health care including immunization. However, Medicare is slowly shifting the cost of care to Employer Group Health Plans (EGHPs) and

other private insurers. Many health organizations including private medical providers are facing rising immunization registry cost for four reasons: (1) the increasing number of immunizations, (2) cost-shifting by Medicare, (3) poor health outcomes under the current fee-for-service (FFS) system, and (4) advances in high-tech quality medical care [72]. Another challenge is that whether we can afford to continue to develop and support registries, and if so, who will pay for them. In a slowing and weak economy with increased demands on public health dollars, more funds than are currently available must be committed to allow the continued operation of those registries that are functioning at a fully operational status and complete the implementation of those still in process. The CDC has committed a portion of Section 317 funds [73] to the process and other federal dollars have been identified and offered. More money, from diverse sources, both public and private, will be necessary if these goals are to be accomplished. It is high time for a new national coalition and alliance of public and private sector organizations with a commitment to national immunization goals (public health, private health care providers and health plans, and pharmaceutical companies) to address these issues, and identify ways in

which a mixture of public and private support can assure the availability of these vital health information systems in every American community.

According to Hamel and Prahalad [74], Return on investment (ROI) or Return on Assets (ROA) or Return on Capital (ROC) employed has two components: a numerator-net income-and a denominator-investment, or net assets, or capital employed. (In service industry, a more appropriate denominator may be head count). Managers know that raising net income is likely to be harder than cutting assets or head counts. To increase the numerator, top management must have a sense of where new opportunities lie, must be able to anticipate changing customer needs, and must have invested in building new competencies, and so on. So under intense pressure for a quick ROI improvement, executives reach for the lever that will bring the fastest, surest result: the denominator.

The United States (US) and Britain have produced an entire generation of managers obsessed with denominators. They can downsize, de-clutter, de-layer and divest better than any other managers. Even before the current wave of downsizing, U.S. and Britain companies had, on average, the highest asset productivity ratios of any companies in

the world [75]. Denominator management is an accountant's shortcut to asset productivity.

Do not misunderstand. A company must get to the future, not only first, but also for less. But there is more than one route to productivity improvement. Just as any company that cuts the denominator and maintains revenues will reap productivity gains, so too will any company that succeeds in increasing revenue stream atop slower-growing or constant capital or employment base. Although the first approach may be necessary, we believe the second is usually more desirable.

In a world in which competitors are capable of achieving 5%, 10%, or 15% real growth in revenues, aggressive denominator reduction under flat revenue stream is simply a way to sell market share and the future of the company.

It is refreshing to see SCPMG - a mature health organization-wisely move away from simple denominator management (head count reduction) to innovative strategies that enable the organization to compete in future. Using terms borrowed from Hamel and Prahalad, not only is SCPMG avoiding the "social costs of such denominator-driven job losses," but it is getting out in front and remaking the rules of the profession for a better tomorrow for all

stakeholders. This practicum is about the alliance between SCPMG and State and National Registry to run the state of the art immunization registry at the State and National level. It is also about SCPMG shedding the "great company disease" (phrase from Hamel and Prahalad) and using health care discontinuities to change the shape of the industry and devoting its resources to build competencies and opportunities for its future. To achieve this innovative mission in immunization registry, SCPMG needs

- (1) Resilience to withstand resistance, surprises, missed deadlines, and hostile responses from the environment
- (2) Commitment to superior care at a lower global cost
- (3) Compete for the future of immunization registry despite formidable roadblocks.

The main cause of a patient's death with communicable diseases is non-immunization. Lifestyle choices and media mudslinging have profound impact on the ability to escape or be a victim of communicable diseases. Whereas people in the Third World are suffering from poverty, famines, draught, floods, hurricanes, pestilence, and calamities, the developed nation are from self-inflicting injuries. Whereas the developed nations look abhorrently down upon

the collective suicide committed by the people in the Third World through genocide and civil wars, they fail to see their favorite game - Russian roulette with resisting immunizing and criticizing the registry.

Drucker believes the developed nations are committing collective suicide through today's low birth rates. He says this by looking at the future through the prism of today - the "events that have already happened, irrevocably, and that will have predictable effects in the next decade or two... the future that has already happened [76]." Looking from the viewpoint of medical professional, the author believes the developed nations are committing collective suicide by playing Russian roulette with lifestyle choices. The people of Third World can escape civil wars and dodge the bullets from AK-47/Klashnikovs and bazookas, but here people cannot escape the claw of the "good," "easy," and "fast" life. To drastically change the quality of life and survival of patients with communicable and fatal diseases, developed nations must change the root causes of the diseases. They have to prevent the disease by design, induce remission or retard its progression as soon as they discover it, and in advance cases, have potent tools at their disposal to effectively alleviate its consequences. That is what SCPMG



is trying to do. The point is: there is unlimited room for innovation and for "creating new market space," the term from Kim and Mauborgne [77] in health care and thus, a boundless capacity to achieve superior outcomes in immunization care. What we need is the commitment to the vision of a better future for all patients and to compete for it. SCPMG is taking the first step in making this untapped innovative strategy in immunization registry a reality.

Perfection is the enemy of achievement. Seeking perfection in the process of performing a task may be a subscription for failure. Accomplishing a task, however imperfectly, is better than a perfect job half-done. This was an important lesson for researcher amidst the joy and drudgery of completing this Practicum. It is also a lesson for the budding alliance that is setting out to start the innovative venture described herein. The strategy of continuous quality improvement advocates, "doing the right thing right the first time," but we must hasten to add, "If you know it, can do it or can acquire it." Alliances and the races to win the future are undertakings that cannot be designed or done perfectly.

Debra J. Lipson [78] compares partnership with marriages and says, "Some are based on necessity, some on

convenience, some on synergy, and others on arrangements by third parties." She quotes Harvard Professor Rosabeth Moss Kanter's five stages in the development of organizational alliances: Engagement, selection or courtship, setting the housekeeping, learning to collaborate, and changing within." She notes, "The endurance of organizational partnership, just as some would say of marriage, depends on continued mutual benefit of the alliance to each of the participants." Thus, the stability of the alliance between immunization registries will depend on its ability to deliver value to its customers and confer mutual benefit to each partner. According to Doz and Hamel, the alliance advantage is in the art of creating value through partnering. Strategic partnerships have become central to competitive success in the fast-changing global markets. They say,

In this new world of networks, coalitions, and alliances, strategic partnerships are not an option but a necessity - be it Toyota's network of suppliers, Microsoft's extended family of independent software developers, the member airlines in the Star Alliance, or the disparate group of companies cooperating with Motorola in launching dozens of communication satellites. To

fully exploit the opportunities open to it, a company today must have an ability to conceive, shape, and sustain a wide variety of strategic partnerships [79].

Frequently the skills and resources essential to a firm's future prosperity lie outside its boundaries. The race for the world and the race for the future will be won only through an alliance advantage. Factors that ensure the success of joint ventures include growth potential, strategic complementation of partners, careful deliberations that promote trust and understanding, and the development of appropriate corporate culture [80]. Many factors are accelerating alliance formation: globalization, rapid technological advances in information, communication, travel, and high-speed changes in all sectors of the economy. In today's networked world, no company can go it alone.

Doz and Hamel cite three features of the race for the future that will make alliance essential: (1) Today's great opportunities require the melding of skill and resources that few possess entirely, (2) The digital revolution is being built not on vertically integrated "industrial" firms, but on "seamless" networks that must be standardized across vast expanses and complimentary

applications, and (3) The uncertainty inherent in the information economy calls for joining complimentary skills and insights to reduce uncertainties and to accelerate learning.

Furthermore, although value creation through an alliance may take a long time, the primary purposes of an alliance are three (Doz and Hamel)

1. Co-option: Co-option turns potential competitors into allies and providers of complementary goods and services that allow new business to develop.
2. Co-specialization: Co-specialization is the synergistic value creation that results from combining the previously separate partners' resources, positions, skills, brands, relationships, and knowledge resources. Since today's opportunities are system and solutions rather than discrete products, co-specialization is essential in refocusing the narrow range of core skills and competencies that today's firms' posses.
3. Learning and internalization: An alliance is way for learning and internalization of new skills, especially those that are tacit, collective, and embedded (hard to acquire).

The alliance between immunization registries covers all three primary purposes of an alliance.

An alliance has many disadvantages as well. It is an evolving process (rather than a static structure) that requires complex strategic assessment as opposed to simple cost-benefit analysis. People have to manage moving targets instead of a set of objectives, strike multiple bargains instead of implementing a single bargain, create and maintain options instead of making commitments, and contribute to competitiveness of the partners instead of achieving longevity. Conflicts are omnipresent because unlike old partnerships that depend on collaboration and competition, risk of unbalanced dependence, and an enlightened mutual interest instead of trust. Furthermore, instead of being monogamous relationships, today's alliance partners have many other partners. Similar to the U.S., British and Soviet alliance of World War II, each partner may be managing a web of alliances that may not be compatible with other partners. As such, trust diminishes, and only enlightened self-interest rules these relationships.

The alliance to win the race for the future care and accuracy of Pediatric immunization and its registry, the alliance partners have to improvise as they travel along

the path that leads to their vision. Completing the task and milestones along the way, however, imperfectly, is more critical than having a perfect start or perfect "incomplete tasks."

The National Immunization Registry is in offing. Several attempts have been made to bring major players to participate in National and State Registries. Participation in immunization registries will continue to increase. The development of childhood immunization registries has widespread support among parents and providers and the required technology is becoming relatively less expensive and simpler. Immunization registries are part of the current trend to computerize medical data in the United States. To be successful, registries must be seamlessly integrated into the current provider environment and create no additional burdens.

Progress over the past ten years has been remarkable, demonstrating the effectiveness and utility of childhood immunization registries and developing the technical know-how to make these systems work efficiently in community- and state-level immunization endeavors. It is now high time to finish the job. National programs of this magnitude cannot be assumed to be the sole responsibility of under-funded public health agencies alone. This is an

area crying out for public-private sector alliance and collaboration. "You only think you're short of resources until you come up with a creative solution" [81]. "Never doubt that a small group of the thoughtful committed citizens can change the world. Indeed, it is the only thing that ever has" [82]. "We must become the change we want to see" [83]. The fact that the focal intervention is now fully demonstrated and technically feasible makes the task that much easier.

To sum up the potential benefits of Immunization registries, the benefits are as:

Parents benefit because registries can

- Consolidate into one database all vaccinations a child has received.
- Help ensure vaccinations are current with recommended schedules.
- Provide reminders when a vaccination has been missed or ineffective vaccines were given.
- Help ensure timely vaccinations for children whose families move or switch health-care providers.
- Prevent unnecessary (duplicative) vaccinations.

- Immediate and automated printing of the California Immunization Record (yellow card) at patient's or school request [84].

Communities benefit because registries can

- Help control vaccine-preventable disease.
- Identify high-risk and under-vaccinated populations.
- Help prevent disease outbreaks.
- Link with other health database and other state registries.
- Provide statistics of community and state vaccination rates.
- Streamline vaccination program management.

Public health officials benefit because registries can

- Target intervention and evaluating programs.
- Ensure that providers follow the most current recommendation for vaccination practice.
- Promote reminder and recall of children who need vaccinations.
- Facilitate introduction of new vaccinations or change in the vaccination schedule.
- Help monitor adverse events.



- Data fields to allow the reason for non-immunization (patient/parent refusal, presence of disease, medical contraindication including adverse reaction) [85].

Health care providers and health plans, and health-care purchasers benefit because registries can

- Consolidate vaccinations from all providers into one record.
- Provide an accurate immunization history for any child, whether a new or continuing patient.
- Provide data regarding vaccinations due or overdue.
- Provide current vaccine recommendations.
- Produce reminders and recalls for vaccination due or overdue.
- Complete required school, camp, and day care immunization records.
- Reduce physician's paperwork.
- Facilitate introduction of new vaccinations or change in the vaccination schedule.
- Help manage inventories.
- Reinforce the concept of the medical home (i.e., a primary care practice in which the patient has

a relationship with one provider who is familiar with all aspects of that patient's medical care and accountable for coordinated, comprehensive care).

- Generate vaccination rate for regulatory bodies and for employer's groups.
- On-line, real time, local, state and nation wide availability of immunization data (24/7) [86].

In conclusion, this project analyzes the various issues of "Implications of a national immunization registry: An Alliance to Win the Race for the Future Care and Accuracy of Pediatric Immunization," such as the challenges, potentials and the progresses of childhood immunization registries. It also covered the various problems associated with its implication as well as its overall productivity and cost effectiveness.

Several recommendations were provided for dealing with issues to be concerned about "Implication of a National Immunization Registry: An Alliance to Win the Race for the Future Care and Accuracy of Pediatric Immunization," in order to derive maximum value from the use of the immunization registries in a health care delivery system.

Being a member of Kaiser Immunization Tracking System Administrative team, my role along with the rest of the members is to

- Act as KITS Data-owner.
- Identify and targeting specific projects for quality improvement.
- Develops methods (procedures) for auditing and/or quality improvement.
- Continually improve KITS functionality, making it more user-friendly and less error prone.
- Training and retaining of KITS users.
- Offer KITS users good and prompt support.
- Coordinate efforts in improving immunization rates.
- Exchange Data with other systems (registries when fully developed).
- Plan and participate in projects that will enhance the public awareness of the importance and functionality of KITS as well local, state and national registry.

My role was initially confined to our vertically Integrated Health Care Delivery System (Kaiser Permanente). In 2003, I had joined San Bernardino and

Riverside counties Immunization Registry Program (VaxTrack). Currently, I am a member of Joint Advisory Coalition Committee of bi-county Immunization Registry.

Finally, on a personal note, medical school had taught me the art of pattern recognition to deal with a vast array of medical conditions and the associated "pull-down menus" of the treatment options. On the other hand, my education in Master of Business Administration (MBA) taught me the art of thinking through relationships over time (planning, designing, organizing, directing, implementing and controlling). More importantly, I discovered that both help me to weigh and consider the consequences of my actions. Ultimately, it is my actions that determine the outcomes of the application of principles of medicine and business administration. However, independent of the principles of medicine or business, I found both to be complementary in making me a whole person.

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