University of Medicine and Dentistry of New Jersey - University of Pennsylvania
New Jersey Comprehensive Immunization Program
(NJ-CIP)

Automated Immunization Evaluation Process

Working Paper

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prepared by

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Introduction

One of the most important features of New Jersey's central immunization Registry is the function that determines whether a given child is up-to-date in his/her immunizations at a given point in time. This "added value" over simple storage of the composite immunization history of the State's children (and potentially adult population as well) will be the core information component that will drive outreach programs State-wide. Level of age-appropriate immunization - at the individual provider level, at a metropolitan, county or regional level, or at the State-level - is also an important measure of the impact of the Registry and its associated programs on the health of the target population. Immunization level is already being incorporated into health care provider "report cards" that will increasingly be used by consumers to judge providers' (particularly managed-care providers) effectiveness.

The individual provider has the responsibility of examining the immunization history of a child and assessing what immunizations are required at a given age. Immunizations are typically delivered as part of a regimen of well-child examinations and, in some cases, special outreach programs in a given locality. In the case of the outbreak of a particular communicable disease (most recently measles), additional immunization programs may be initiated to protect at-risk populations. Providers consult one of at least two normative schedules for immunizations, one prepared and updated by the AAP (American Academy of Pediatrics), and one prepared and updated by the ACIP (Advisory Committee on Immunization Practices). Providers have increasingly been acquiring software capable of assisting with this evaluation.

Since the Registry's immunization record will be more complete than many individual provider records for some patients, and since outreach activities may take place outside of individual provider locations (for public assistance patients especially), it is important that the Registry be able to provide the assessment necessary to accurately judge a child's immunization status.

Two Key Components

There are two key components to creating an automated immunization evaluation process:

- **Uniform Normative Immunization Schedules**: It is essential that there be a single set of immunization schedules that describe the timing of individual vaccine deliveries for children (and adults), recognizing that not all patients will either begin their immunizations nor complete their sequences for individual vaccines at the same time.

- **Immunization Evaluation Algorithm**: Based on the Uniform Normative Immunization Schedules, an algorithm needs to be developed that examines the set of immunizations a patient has received to date and, based on the patient's age, assesses whether the patient is up-to-date or not, what immunizations are still outstanding, and the schedule for their administration.

With these two components developed, a computer system can be created that automates the

assessment as a clinical tool for providers and as the basis for evaluation of target populations.

CDC Vision

The National Immunization Program of the Centers for Disease Control and Prevention has prepared a draft Programmer's Guide to assist in the preparation of an automated immunization evaluation process. The intention of the CDC is to create a definitive guide with two purposes in mind:

- To save the individual states from the effort to develop the algorithms on their own
- To promote as much uniformity as possible to assist in implementing their State Immunization Information System (SIIS) concept.

The CDC vision has each state creating a statewide distributed database for the warehousing of immunization data - a registry of registries. The central state registry contains pointers to the immunization histories located in local systems maintained by individual providers. The central repository only holds actual immunization data for local providers who have no data systems of their own.

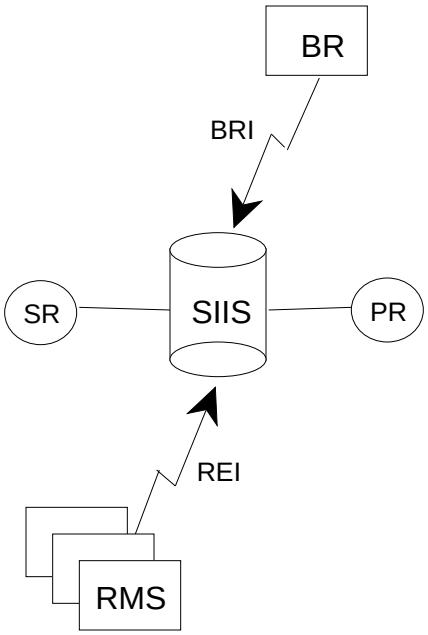

Figure 1 - System Architecture

Figure 1 displays the proposed system architecture. The (SIIS) exchanges information via a Record Exchange Interface (REI) with local Record Management Systems (RMS) located with the providers. The Birth Registry (BR) feeds data into the SIIS via a Birth Registry Interface (BRI). The SIIS has a System Register (SR), a listing of RMS's, as well as a Provider Register

(PR), a listing of immunization providers.

The final piece of the SIIS vision will enable states to exchange immunization information as patients move from state to state, or as health care is provided across state lines (very common in metropolitan areas that are adjacent to or straddle state boundaries). A definitive, common automated immunization evaluation process will facilitate inter-state communication and assessment of data.

The CDC Programmer's Guide has three major components:

- A description of the relevant definitions, objectives, features of an automated immunization evaluation process.
- Functional requirements and a general algorithm description
- Detailed methods for implementing and evaluating an automated immunization evaluation process algorithm

The main design features of the CDC approach include:

- Ability to accommodate as many immunization schedules (*i.e.*, rule sets) as required to support different circumstances, including provider preferences, epidemic conditions, or other special circumstances.
- Ability to accommodate any number of vaccine series definitions within a given schedule.
- Recommendation that the algorithm should recommend combination vaccines where appropriate.
- Evaluation function should return to the user either a list of vaccines due on a specified date, the next recommended vaccine, or if up-to-date the next time an immunization is due.

The detailed algorithm describes a logical data model for the parameters necessary for successfully implementing the algorithm, as well as recommendations for the physical data model based on the technologies piloted by the CDC for their test implementation. The algorithm is fairly complicated, as can be seen from this subset of critically important parameters:

- Minimum intervals between doses
- Recommended intervals between doses
- Minimum age for a vaccine

- Maximum age for a vaccine
- Age at which *first* dose in series received
- Age at which *last* does in series received
- Overdue interval (*i.e.*, interval of time past recommended interval during which immunization administration is still considered to be "on time").

NJ-CIP Approach

As the CDC programmer's guide, SIIS model, and required technologies develop, NJ-CIP will evaluate these items and consider incorporating them into the Registry and associated applications and products. Initial emphasis is being placed on the development of the Registry itself, and on the development of a proper set of Uniform Normative Immunization Schedules for the State of New Jersey. The Registry is initially being developed to build the most complete composite immunization record possible, including an automated link to New Jersey's emerging electronic birth record. When completed, the Immunization Evaluation Algorithm will be integrated into the Registry and its products.

Uniform Normative Immunization Schedules

The Program staff have been working closely with representatives of the New Jersey Department of Health, including the State Epidemiologist and the Senior Public Health Advisor, as well as the Chairman of the Infectious Disease Committee of the NJ Chapter of the AAP, and other members of the Department of Pediatrics of the University of Medicine and Dentistry, to develop New Jersey's set of Uniform Normative Immunization Schedules. This work (whose current status is detailed in the **Appendix**) has focused on developing a set of schedules for the key vaccines (Hep B, HIB, DTP, Polio, MMR) based on a variety of starting ages for the initial vaccination. Several schedules were developed for ages starting at birth to several years old. Schedules for different starting ages were considered only when a material impact on the administration of one or more vaccines was detected. The goal was to develop as few schedules as possible while still following the recommended rule sets. The experts are using the AAP and ACIP schedules together as well as their own experience and supplemental CDC directives.

A computer-based simulation, or prototype, was developed to accept an age of initial immunization (in months) and then display the normative immunization schedule for that child. The display is presented in one of three ways:

- By vaccine, displaying the age at which each dose of each vaccine is to be administered.
- By age of administration, displaying the clustering of vaccine doses to show the minimum number of visits to a provider that would be necessary to complete the

entire recommended schedule of all vaccines.

- A cross tabulation, displaying the age of administration of all doses for all vaccines in a single table for a given starting age.

Through an iterative process, the physician team has been discussing and refining its recommendations for the normative schedules. Sensitive to the desire to minimize the number of visits that a child has to make to the doctor for immunizations, the team used the simulation report by age to see where it was possible to adjust the recommendations and minimize lone visits for individual vaccines by combining them with other visits to provide the same level of protection. Additionally, by testing a variety of starting ages, the physician team was able to identify certain anomalies in the proposed schedules and adjust them appropriately.

Additional work was also done to validate the normative schedule algorithms for the case where a child misses a scheduled visit, but eventually receives the vaccine dose (interrupted series). A series of test cases were developed (also found in the **Appendix**) which examine the balance of the child's schedule once the "make up" dose has been administered.

Definition of a "Month"

One very tricky design consideration is the definition of a "month." When moving the algorithm from conceptual discussion to computer code, precise definitions are important. Two definitions are necessary:

- For the purposes of calculating a minimum interval between doses, the medical consultants decided that a month is equal to four weeks, or twenty-eight days.

- For the purposes of allowing a provider to determine when a subsequent visit should be scheduled for a child, a month is equal to a calendar month. For example, if today is January 17 and another vaccination is due in one month, the appointment target date is February 17, adjusted *forward* to account for days when the provider site is not open. For a hypothetical visit that needs to take place one month after the current visit, the rules for shortened months are as follows:

		Next Visit Date
Today's Date	**January 29**	March 1
	January 30	March 2
	January 31	March 3
	March 31	May 1

Immunization Evaluation Algorithm

The Program has developed a preliminary database design to accommodate both the normative immunization schedule, and the actual immunization transactions themselves. The normative immunization schedule is found in a series of tables displayed in Figure 2.

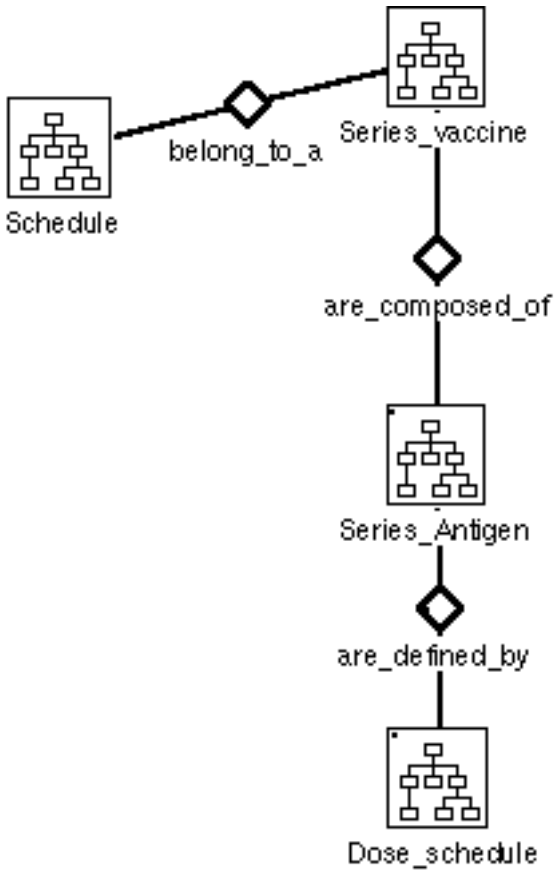

Figure 2 - Database Design for Normative Schedule

Each Vaccine is tracked in a Series_vaccine which contains such data as the age of the first dose, the total number of doses in the series, the minimum and maximum age for this vaccine (in months) if applicable, and a flag indicating this vaccine can be taken all of one's life. A Schedule (or Normative Schedule) is defined to identify a set of Series_vaccines grouped together for the purpose of evaluation as a set. Each Series_vaccine is composed of Series_antigens which identify the individual Antigens that make up the vaccine (see discussion of antigens later). Dose_schedules contains the normative information for each antigen in the vaccine, with one row/record for each dose of each antigen of the vaccine. Other information includes the minimum, recommended and maximum (overdue or "grace period") intervals from the dose to the *previous* dose in the series, the minimum age for the dose, and the age at which the next dose may be skipped (if applicable). A sample Dose_schedule is displayed in Figure 3. This sample is shown by vaccine; the actual programming will store this information by antigen.

	vaccine_ID	dose_#	intervals			minimum age	maximum age	comment
			minimum	recomm.	maximum			
1	DTP	1	1	0	1	1	83	
2	DTP	2	1	2	1	2	83	
3	DTP	3	1	2	1	3	83	
4	DTP	4	6	6	1	4	83	
5	DTP	5	1	10	1	48	55	
6	HIB	1	1	0	1	1	60	
7	HIB	2	1	2	1	2	16	min booster interval 2 months
8	HIB	3	1	2	1	3	15	min booster interval 2 months
9	HIB	4	2	6	1	4	15	

Figure 3 - Sample of Dose_schedule Table (Normative Matrix)

Immunization transactions are stored for each patient in a series of tables displayed in Figure 4 (only tables relevant to the present discussion are displayed). Doses captures the immunizations themselves, including the vaccine, lot number (optionally), date of service, provider code, injection site or method, dose number if the dose was valid based on the normative schedule, and adverse reaction information. A relationship is made to a look-up table of Vaccines which themselves are related to the appropriate Antigens.

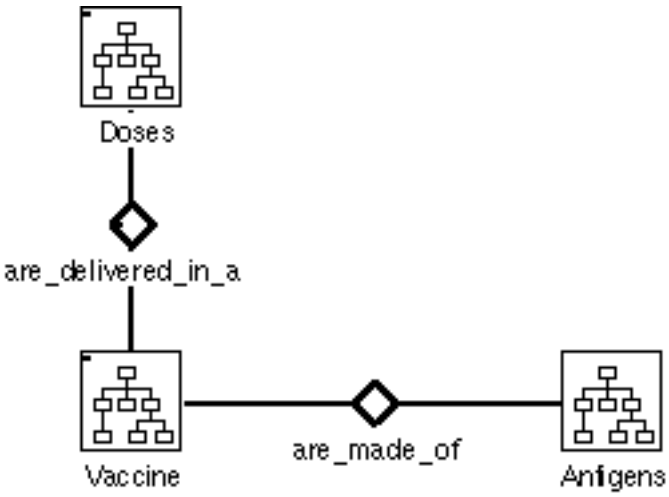

Figure 4 - Database Design for Immunization Transactions

A sample of part of the Doses table for an individual child is displayed in Figure 5.

	person_ID	vaccine_ID	date	dose_#
1	10001	DTP	4/15/1994	1
2	10001	DTP	6/25/1994	2
3	10001	POL	4/15/1994	1
4	10004	POL	4/30/1994	0
5	10004	MMR	5/31/1994	1
6	10005	DTP	8/31/1994	3

Figure 5 - Sample of Dose Table (Actual Matrix)

Evaluation consists of assessing the actual immunizations delivered as they are stored in the Doses table (Figure 5) with a normative schedule as represented in the Dose_schedule table (Figure 3). This evaluation is done for three purposes:

- To assess whether the actual immunization doses received should be counted as "valid" for the purpose of determining whether a child is at an age-appropriate level of immunization.

- To predict either the next visit due for immunizations, or an entire series of visits, for a particular child to advise the child or parent on when to return to the provider.

- To serve as the basis for developing summary statistics for a particular practice or population when assessing age-appropriate levels of immunization.

To conduct the evaluation, the system will calculate the age of the patient and the interval between the dose being administered and any previous valid dose to determine whether the dose being administered is valid according to the normative schedule. If so, the next incremental dose number is stored along with the transaction; if not a dose number of zero is stored along with the transaction. Rather than drop an invalid dose, the information is stored for further study.

The final step of the assessment is the calculation of the future doses of all vaccines. These are the doses yet to be delivered to the child based on the Dose_schedule table. They are calculated based on the recommended intervals by projecting from the last valid dose administered for each vaccine. It is expected that an end-user software product implementing this design would display vaccines, the valid doses already delivered by date, and the future doses that should be delivered. Doses of vaccines that could be administered immediately (which of course changes daily) would display as being due "today" rather than past due.

Open Design Issues

A number of issues have been uncovered in the team's review of CDC documents and in the work done with physicians on the Uniform Normative Immunization Schedules:

Antigens versus Vaccines

Preliminary NJ-CIP Registry design focus groups have determined that it would be better to maintain normative schedules, and test those schedules, for individual antigens of combined vaccines (e.g. for Measles, Mumps and Rubella separately instead of MMR as one unit) even if at present the schedules would be identical. There is a concern that emerging tetramune vaccines introduced in the middle of a child's series might require antigen-by-antigen review to determine the immunization status. Additionally, the team recognizes the potential that the recommended schedules for a particular antigen in a combination vaccine may change at some point in the future prompting a change in the vaccine that may be difficult to evaluate in the middle of a patient's series or across patients consistently.

The CDC Programmer's Guide contains a brief discussion of this issue, but then does not address it either in its data model or algorithm.

Vaccine Manufacturer Anomalies

In at least one case (Merck HIB) a particular vendor requires a different schedule than all other vendors for its version of the same vaccine. Does this suggest that schedules will need to be vendor-specific, and that the Registry will be required to have vendor (and/or lot number) information in order to appropriately evaluate a patient?

Software performance tradeoffs

As described above, there are several steps necessary in assessing whether children are up-to-date in their vaccinations: determining whether doses already administered are valid based on a normative schedule; and calculating future doses to indicate when a child needs to return to his or her provider again. These calculations may be compute-intensive, network-intensive, or both, and tradeoffs will be necessary in developing a given software application. The primary tradeoff is between performance of the application and timeliness of the update to the database. The challenges of providing real-time access to multiple users at multiple sites only makes this problem more acute.

Next Steps

NJ-CIP will continue to work on these open areas, especially once the repository design itself is completed and an initial database implemented. The Project will continue to dialogue with the CDC and monitor developments in its documents.