

Origin Story:

Creating a Culture of Collaboration

Perhaps the most notable feature of early immunization information system (IIS) development that endures to this day is the strong tradition of sharing and collaboration across the community. This spotlight explores the roots of this hallmark feature—how and why did this collaborative spirit emerge as the first IIS projects took shape, and how was it supported and nurtured over time?

Measles outbreak provides a tragic impetus

In 1990, a Michigan father named Ben Bowman brought two of his daughters into a local immunization clinic. With a wave of measles sweeping the country, Bowman hoped to protect his daughters from infection. The clinic successfully immunized his oldest daughter, Becky, but staff advised Bowman that his younger daughter, Tammy, wouldn't be able to get her shot that day. Records weren't readily available for the children in Tammy's grade, so they asked Bowman to plan on bringing her back later. However, before the clinic would have a chance to track down Tammy's paper records, she would contract the measles that would lead to her death—just one week after her father's unsuccessful attempt to get her immunized.¹

Tammy was one of 89 children who lost their lives to the sudden and devastating measles outbreak that swept the U.S. between 1989 and 1991.² Overall, the outbreak resulted in 27,600 cases, shaking the U.S. out of the complacency it had enjoyed during the dramatic decrease in measles after the vaccine's creation in the 1960s, and the following historic all-time low of measles cases throughout most of the 1980s.³

That measles epidemic served as a catalyst for concerted public and private action around the country, bringing organizations together with a shared purpose and determination. One question emerged: how had these unimmunized children fallen through the cracks, and how could coverage gaps be eliminated in the future? Tammy Bowman's case wasn't widely known, but the resurgence of measles underscored the imperative to track immunizations of infants and toddlers and to look at the coverage levels at the population level.⁴

At this point in the U.S., no consolidated, longitudinal immunization records existed other than what parents might have maintained on paper.⁵ As the need for more consolidated and timely information at the individual and population levels became more apparent, there was growing recognition that *creating a system to track vaccinations was as important as developing the vaccines in the first place.*⁶

But how to develop such tracking systems? Could they be started from birth records and be truly population-based, a new concept for public health? How would the data, stored on paper in many disparate locations, get into the registry? And how would registry information get back to the providers who needed it when computers did not yet exist in clinical areas? Could registries reliably identify pockets of need/under-immunization at a population level? What sort of staff expertise was needed within immunization programs to build these systems and recruit providers? Was a single national registry a possibility, or did they need to be at the community or state level? Could the public sector build a system largely intended for the private sector and have it be accepted and used?⁷

With the benefit of hindsight, it is difficult today to fully appreciate just how large these questions loomed for early planners, and how daunting they were, given the lack of much precedent or experience. Two factors were encouraging for those early planners: immunizations, even before the outbreak, were already an area of shared interest and commitment in both the private and public sectors, and the measles outbreak provided a sense of national urgency across all sectors.⁸



Precursors to IIS

As early as the 1970s, experts in disease prevention recognized the potential of immunization tracking systems as tools to help mitigate the peaks and valleys of disease outbreaks by managing information about children and their immunizations. In fact, during the 1970s, there was an early version of an “IIS” – the “Infant Immunization Surveillance” system, a birth certificate survey designed to follow up with parents. In the 1980s, CDC worked with several health maintenance organizations to evaluate the impact of provider-based registries in their organization.

Seeking answers: All Kids Count is launched

In 1991, still in the midst of the measles outbreak, the Robert Wood Johnson Foundation (RWJF) took action to address these urgent and uncertain questions through funding to support a proof-of-concept initiative.⁹ This initiative would ultimately become a 13-year-long program known as All Kids Count.

The Foundation asked Dr. Bill Foege, previous director of the CDC and then-president of the Task Force for Child Survival (now the Task Force for Global Health),¹⁰ to explore the feasibility and possible approaches of such an initiative. The Foundation then took two crucial steps: it funded creation of a central All Kids Count program office at the Task Force, and it authorized this office to issue one-year planning grants¹¹ to solicit proposed approaches and solutions to the challenging questions being posed nationally.

From the beginning of All Kids Count, Dr. Foege espoused a “let a thousand flowers bloom” approach in recognition that no one had a functioning population-based registry or knew the right way to build one—or even if one would work at all! Developing standards that would succeed for every new system would have been an impossible task in this new, unexplored frontier, so each jurisdiction was left free to innovate on its own. The idea at that time was to develop pilot systems, a proof of concept for immunization registries. Both the 1992 All Kids Count planning grant to 23 projects and the later 1993-1997¹² implementation grants to 24 local, regional or state projects were intended to stimulate innovative work, encourage experimentation and sharing, and serve as model projects for others to replicate and sustain.¹³ The funds were flexible, which was highly valued given the trial-and-error nature of the learning.¹⁴ Most of the grants were at the community or regional level, with only a few state-level grants—in fact, “community-based immunization registries” was the most common term for registries during this time. Not all of these early projects were within the immunization program, and some were even outside of the health department.

The rise of IIS: early collaborations and lessons learned

All Kids Count (AKC) took early steps that proved critical to establishing a culture of collaboration from the outset. One was that the program established and supported a community of practice among the grantees to enable sharing of the hard-learned lessons. This included AKC-sponsored regional and national immunization registry conferences from 1994-1999.¹⁵ AKC also worked closely with the CDC’s National Immunization Program as it was developing its own capacity and policies in support of IIS. Other close collaborators included the National Vaccine Advisory Committee, the American Academy of Pediatrics and Every Child By Two. These collaborations nurtured and maintained a broad and shared sense of ownership and commitment to the evolving initiative.¹⁶

Among the challenges being addressed collectively were that:

- The rapid pace at which information technology was evolving made it difficult for public health departments to stay abreast.
- The cost of developing registries was more than anticipated.
- Recruiting doctors in private practice to participate in a registry took longer and was more difficult than anticipated.
- Issues of privacy and confidentiality were complex.¹⁷

What were the major findings from this time? Perhaps chief among them was that developing community- or state-based registries was much more challenging than anticipated, as reported by all of the AKC grantees.¹⁸ Among the many challenges, HumanSoft, a major software vendor, suddenly went bankrupt in 1999, leaving many IIS programs with the source code



“Let a thousand flowers bloom.”

The concept of “let a thousand flowers bloom” was from Mao Tse-tung’s campaign in China during the 1950s. However, Dr. Bill Foege borrowed and used the phrase to capture the innovation and experimentation inherent with the early days of registries. This “parallel research” approach encouraged each grantee to develop a registry based on their unique needs and strengths. As time went on, and promising practices began to emerge, the IIS community moved to more rigorously defined standardized approaches, a move that continues today.

but no support.¹⁹ The internet was unreliable, so floppy disks were often the standard.²⁰ Modems and connection times were slow and computer screens primitive.²¹ Yet, IIS remained ahead of its time, given the technology available in the 1990s.²²

While the technical issues were not trivial, the bigger challenges were operational and policy-related—something which remains true today, even though the technologies have evolved considerably and have made data capture and exchange much more efficient. It's hard to appreciate today how revolutionary it was for public health to develop information systems designed primarily for use in clinical care. Computers were very seldom located in clinical areas until registries were introduced, and new clinical and business workflows had to be developed for each clinic to capture and send the information. The historical relationship of health departments to clinical care had been mostly a regulatory one. With the need to recruit and enroll clinics in the registry, that relationship gave way to one that was more service-oriented. Registry staff spent countless hours traveling from clinic to clinic to individually help clinical staff deal with workflow, technology and privacy issues.²³



The history of immunization records

Prior to the development of immunization registries, immunization relied on unconnected paper records. In this photo from around the 1960s or 1970s, a young boy shows off his “official rubella fighter” immunization card and button after being vaccinated against the disease. Photo credit: the CDC Public Health Image Library.



Lessons learned

The lessons learned from the 13-year All Kids Count program are still relevant today.

- Involve stakeholders from the beginning.
- Recognize the complexity of establishing a population-based information system.
- Develop the policy/business/value case for information systems.
- Define the requirements of the system to support users' needs.
- Develop information systems according to current standards.
- Address common problems collaboratively.
- Plan for change.
- Plan boldly but build incrementally.
- Develop a good communications strategy.
- Use the information (even if not perfect).

Federal policy and funding spurs growth

While the first round of All Kids Count grantees were finding their footing in this new world, CDC and other federal agencies and advisory bodies were tackling registry questions from a broader policy perspective and leading collaborative initiatives to advance IIS development. CDC's National Immunization Program worked closely with All Kids Count grantees and the National Vaccine Advisory Committee (NVAC) to translate lessons learned into guidance manuals and to begin collaborative development of registry standards.²⁴

As important as the All Kids Count funds were for demonstration projects, federal funding made an even bigger impact in supporting state and local immunization program activities, including nascent registry development. Under the George H. Bush administration and on the heels of the measles outbreak, Congress significantly increased immunization funding, which subsequently led to CDC distributing Immunization Action Plan (IAP) funding through the mid-1990s. Immunization programs used these IAP funds for a wide range of coalition-building, education, outreach, mobile vaccine clinics and other interventions, including supporting development and growth of community and statewide registries.

After only 24 days in office, President Bill Clinton announced a comprehensive childhood immunization initiative designed to assure that all children in the United States received immunizations against vaccine-preventable diseases.²⁵ President Clinton stressed that entering infant birth and immunization data into registries would help track children who needed vaccination by notifying parents and providers that their children were due for shots.²⁶ In late 1997, President Clinton issued a presidential directive to Secretary of Health and Human Services Donna Shalala “to start working with states on an integrated



Immunization history

Children in 1940s New York hold their immunization cards as they wait to receive their vaccinations. At this time, each child's card would serve as the only record of the immunization. Photo credit: Library of Congress

immunization registry system...we have to do it and do it right."²⁷ By 1998, the National Immunization Program advocated state- and community-based immunization registries as a key strategy to meet the year 2000 Healthy People immunization goal and sustain it into the 21st century.²⁸

Among the federally funded programs enacted under President Clinton was the Vaccines for Children (VFC) program, which enabled a massive shift from vaccines being delivered equally in the public and private sector in 1992, to over 70% delivered in the private sector by 1997.²⁹ This shift increased the pressure to recruit private providers to the registry, which in turn required greater understanding of clinical workflows, billing systems, vocabulary codes and evolving technologies.

Other federal initiatives supporting registries came from NVAC, which was very active in developing policy and collaboratively helping to guide CDC activities through the 1990s. NVAC launched its Initiative on Immunization Registries in 1997, which included public hearings and parent focus groups. In 1999, the committee issued its report, *The Development of Community- and State-based Immunization Registries*.³⁰ That report

highlighted four challenges that are just as present today as in 1999:

- Protecting each person's privacy and the confidentiality of registry information.
- Ensuring participation of vaccination providers and recipients.
- Overcoming technical and operational challenges.
- Determining resources needed to develop and maintain immunization registries.

The IIS community also benefited from the support of many nonprofit and professional associations, who worked with federal and state programs developing policies, interventions and funding mechanisms to improve immunization delivery and to support registry growth. These organizations included the American Academy of Pediatrics, as well as Every Child By Two, which was a key advocate for registries.^{31,32} Such local and national advocacy helped to coordinate powerful registry endorsements from pediatric, family practice and school nurse national associations, and also explored how to resolve legal and policy issues involving registries. The active and willing

engagement of so many organizations was vital to early IIS, helping to sustain the culture of collaboration and information sharing, and focusing on a clear and shared goal of improved immunization delivery and coverage.

Despite the range of challenges facing early IIS, by 2000, the Institute of Medicine could write that "...immunization registries offer one of the most useful instruments for assessing the population-specific effectiveness of health and medical care programs."³³

The drive toward collaboratively-developed standards

During the second half of the 1990s, defining and moving toward more standardized IIS operations became the clear path forward for benefiting the community. While the "let a thousand flowers bloom" stage was a necessary first step to forge into unknown territory, once the early explorers made their discoveries and determined what did and did not work, the need emerged to bridge these disparate systems and develop a standardized approach.

In 1995, a CDC-AKC collaborative defined nine core data elements that each registry should store.³⁴ That same year, CDC published the first HL7 implementation guide, aimed at helping registry developers and managers become familiar with electronic message standards for health systems.³⁵

As knowledge and best practices grew along with the number of registry projects across the country, CDC, AKC and several immunization program managers defined in 1997 the "Twelve Key Attributes of an Immunization Registry" (see inset box), the first comprehensive IIS functional standards.

The 1999 NVAC report cited above also led to the establishment of the Technical Working Group, composed of external registry stakeholders and information technology specialists, to:

- Reach agreement on standard vocabularies and protocols for data transfer.
- Serve as consultants to CDC and recommend registry functional standards.
- Assist in determining a registry accreditation or certification method and provide ongoing quality assurance monitoring.
- Indicate ways to facilitate the integration of registry functions into existing information systems.

Among the achievements of the Technical Working Group was to develop a proposed registry certification program in 2001, calling for the creation of a National Immunization Registry Certification Commission. The certification process was to be a voluntary one based on a self-assessment to determine how well the registry could meet functional standards. The working group was careful to differentiate certification from evaluation, noting that "certification assesses attainment, while evaluation measured



What's in a name: from "registry" to "IIS"

"Immunization information system" was not the first term used to denote a vaccine tracking system. The earliest terms, used in the 1990s almost exclusively, were "immunization registries" or "community immunization registries," reflecting the city, county or regional geographic focus of most early programs. Even as the term "registries" was the most common vernacular, the term "statewide immunization information system" or SIIS began to appear, reflecting the movement away from local to statewide systems.[†] Eventually, "statewide" was dropped in favor of using "immunization information system" (IIS) as a universally applicable term, in large part to convey the sense of highly functional, sophisticated information management tools rather than a one-way "data morgue," which was often associated with the registry label. By its 2003 Progress Report, CDC formally defined IIS as an immunization registry with added capabilities, such as vaccine management, adverse event reporting, lifespan vaccination histories, and interoperability with electronic medical records.[‡] The branding preference for registries to communicate their broader value soon became "immunization information system," "IIS" or "integrated information system," for those that captured other child health information such as lead or BMI.

† Examples of early use of "SIIS" include: 1994 CDC Guidelines for Statewide Immunization Information System Version 2.5; 1994 CDC Preliminary Technical Plan for Statewide Immunization Information Systems; 1995 CDC Guidelines for Statewide Immunization Information System Version 2.6; 1996 CDC Guidelines for Statewide Immunization Information System Version 2.8.3.

‡ CDC, "Immunization Information System Progress --- United States, 2003," MMWR 54, no. 29 (July 29, 2005): 722–24.

progress over time." While such a commission and program did not ultimately get launched, the idea of reporting and verifying performance has continued in various forms since.

As registries matured, the trend toward increased rigor and standardization took a huge step forward in 2005 with the establishment of the Modeling of Immunization Registry Operations Work Group (MIROW). This collaboration between CDC and the American Immunization Registry Association (AIRA; more on the origins of AIRA below) embarked on creating a detailed guidebook comprising a growing number of chapters on specific topics, the first being how to manage patients who need to be designated as "moved or gone elsewhere" within the registry. Since its inception, MIROW has followed a rigorous and facilitated approach to business modelling that yields technology-independent, consensus-based guidance.³⁶

Regardless of the standards and technologies being developed and used, there was clear and widespread acknowledgement that registries would require a great deal of collaboration among health departments, private providers, local and professional organizations, and many others.³⁷ (For more on the drive toward standards, see *Balancing Autonomy and Community: The Evolution of IIS Standards*, another spotlight in this series.)

All Kids Count passes the mantle to the American Immunization Registry Association

Through the 1990s and into the new millennium, registry programs continued to grow in the CDC-funded immunization programs. By 1999, only three CDC awardees reported no registry activity.³⁸ As the numbers grew, and the private sector continued its interest in registry development, the All Kids Count conference attracted a growing number and variety of public and private stakeholders, making it no longer an event only for the program's grantees, and now beyond the capacity of AKC to support. At this point, the program's central office saw the need for someone else to take over the registry conference and to continue to engage the private sector.³⁹ CDC's own capacity to support registry activity had grown and become more formalized, allowing CDC to sponsor national immunization registry conferences from 2000-2005 after the All Kids Count funding ended.

Even with these bridge efforts from CDC, the registry community needed a new vehicle to enable and support its collaboration as it moved toward greater adoption of best practices and standards. A working group of state, city and managed care immunization registry managers had proposed formation of an "association of immunization registries" to ensure continued communication and collaboration among immunization registry projects and sustainability of a strong network of registries. In 1999, RWJF awarded funding to All Kids Count's central program office to conduct a feasibility study for such a membership association, including to determine an effective membership structure, identify potential funding sources to sustain the organization, and develop a strategic plan. The results of this effort were promising enough that the CDC entered into a cooperative agreement with the newly formed American Immunization Registry Association (AIRA) in 1999, support of which has continued ever since.⁴⁰

AIRA soon became an effective advocate and support for immunization registry development, continuing the kind of collaborative and supportive environment that AKC and CDC had fostered from the beginning. With members representing nearly all states and many local and territorial jurisdictions, AIRA's work encompasses policy, technical and educational aspects of the IIS community, working together to promote standards, develop and share best practices, and share collective knowledge and successes.⁴¹ Since 2013, AIRA has hosted its own annual national registry conferences.



Twelve attributes of an immunization registry

1. Consolidate all immunization records from multiple providers, using deduplication and edit checking procedures to optimize accuracy.
2. Electronically store all core data elements approved by NVAC.
3. Link electronically with birth certificate data to automatically populate the registry in a timely fashion.
4. Permit providers to electronically retrieve information on all immunization records at the time of encounter.
5. Permit providers to electronically submit information on all immunization encounters on the same day as vaccine administration.
6. Protect confidentiality and security of the registry's medical information.
7. Recover lost data.
8. Exchange immunization records using HL7 standards.
9. Automatically determine the immunizations needed when an individual presents for a vaccination, based on ACIP recommendations.
10. Identify individuals in need of and late for immunizations, and produce reminder and recall notifications.
11. Automatically produce immunization coverage reports by provider and population.
12. Produce authorized immunization records.

All Kids Count, Phase I: Developing Immunization Registries, 1992-1997 (available in the AIRA Repository)

Conclusion

Born out of a national crisis, the IIS community chose the path of collaboration and sharing over the path of competition, which was just as likely given the various organizations involved at the outset. Then, as now, social capital and leadership at all levels of government and across all sectors were essential to IIS development.⁴² The lessons learned across this quarter century have much to teach about the value of working together.⁴³ As the African proverb teaches: *If you want to travel fast, go alone. If you want to travel far, travel together.*



Snapshots

Among the traditions AIRA inherited from All Kids Count was the Snapshots newsletter, which has now been published continuously for over 20 years.

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