



1992 - 2017

**25 YEARS**  
IMMUNIZATION INFORMATION SYSTEMS

Immunization Information Systems:  
The First Twenty-five Years  
A Commemorative History

# Balancing Autonomy and Collaboration: The Evolution of IIS Standards

As IIS grew and evolved in their first 25 years, a balancing act persisted between the desire for local autonomy and the drive for community-wide standards. This spotlight explores how the IIS community grappled with these opposing ideas, and how this distinctive balancing act unfolded over the years.

## A natural tension

The struggle between federal authority and local power has been a defining trait of the United States since its dawn, ever since John Adams and Thomas Jefferson first bitterly argued whether governing powers, from banks to manufacturing regulations, should be centralized.<sup>1</sup> Such tensions are likely unavoidable in any federated system of government.

While the federal level of government can influence policy and performance through funding and other mechanisms (the “what”), the constitutional powers and authorities for public health primarily lie at the state level, and along with it the power to determine the “how” and “how much.” But counter-balancing that constitutional lean toward state powers is the inescapable cost and inefficiency when each jurisdiction must reinvent the wheel for itself—i.e., replicate the same function or solve the same problem that has already been solved more than 50 times before. For IIS, this burden includes the cost of supporting “home-grown systems” or of maintaining commercial systems that are heavily customized jurisdiction by jurisdiction. The IIS community also faces inevitable credibility issues that arise when national efforts to encourage standardized health data exchanges expose the high cost carried by the variable policies and inconsistent standards of locally autonomous IIS.

## In pursuit of consensus: early definitions and performance metrics

In the earliest days of IIS, before this tension had even surfaced, early pioneers relied on individual efforts and experimentation. When IIS first began to emerge in the early 1990s under the All Kids Count grant from the Robert Wood Johnson Foundation, no one knew what community-based immunization registries (as they were known then) should look like—or even if they would work. The motto of this period was “let a thousand flowers bloom,” which was necessitated by the primary goal of this time: to see which largely experimental approaches would work and in what circumstances.<sup>2,3</sup>

While this exploratory approach was necessary in the beginning, many stakeholders viewed this experimentation merely as a temporary stage for early IIS, pointing to the rising need for registries to be in place and serving every community across the country. So, while the pioneers were in the trenches learning what did and didn’t work, CDC, the National Vaccine Advisory Committee (NVAC) and the All Kids Count program staff were collaborating to lay the groundwork for the standards which still exist in updated forms today.

The most obvious standards to establish were the most fundamental: *What is an immunization registry? How will we know one when we see one? What are their primary purposes?*

In 1997, the first formal effort to answer those questions was published as the “12 Attributes of an Immunization Registry,” the forerunner of today’s IIS functional standards.<sup>4</sup> Defining these functions was critical because, by this period, CDC was promoting registries as a key strategy to meet the year 2000 Healthy People immunization objectives and as an allowable activity for federal Section 317 and Immunization Action Plan funding.<sup>5</sup>

These declared attributes set a high bar for IIS programs, many of which were still new and challenged by limited technical expertise and the ongoing need to keep up with rapidly evolving technologies. Early IIS managers were naturally hesitant to let their IIS be measured when the best path to achieving the nascent 12 attributes remained so uncertain.

This hesitancy to be measured became a lightning rod issue in the second round of All Kids Count implementation grants (1998-2000), which aimed to make the most mature IIS programs “fully operational.” But how can an IIS be determined to be fully operational without a definition of what that means, as well as measurable metrics for meeting that goal?<sup>6</sup>

As the 16 All Kids Count grantees came to an agreement on a set of six performance indicators, their discussion highlighted the tension between jurisdictions’ desire for freedom to find the path that would work best for them individually and the need to objectively know if their IIS was successful. These performance indicators can be seen as a precursor of the annual IIS reporting to CDC, today known as the Immunization Information System Annual Report.

Many of today’s functional standards go back to the original key attributes: core data elements, links to birth records, confidentiality and security, and providing data to authorized users. Others reflect newer IIS roles in Vaccines for Children (VFC), such as tracking publicly purchased vaccine, coordinating vaccine recalls and tracking adverse events.<sup>7</sup>

The functional standards took a major leap forward in 2015 with the collaborative development of operational guidance statements (OGS), which provided the operational detail necessary to achieve the functional standards. The OGS were intended to both support IIS program self-assessment and planning toward achieving the standards, as well as inform development of improved metrics. Because CDC’s Immunization Information System Support Branch drew from many standards and best practices in creating these guidelines, the OGS represented a single, consolidated reference containing all the most relevant guidance to achieving the functional standards. This had not arguably been done since the CDC and All Kids Count issued the Community Immunization Registries Manual in 1997 (see below).<sup>8</sup>

As IIS stakeholders developed artifacts like the functional standards and the OGS, they struggled to balance advancing the IIS community by setting high standards for performance with simultaneously acknowledging and addressing the variability in IIS capacity and resources across the community and country.



## Early IIS standards

The measures for fully operational status in the second round of All Kids Count included the percent of children under age two in the registry, percent with at least one immunization, percent of private providers participating, confidentiality and security, production of recall/reminder notices, and immunization coverage reports.

They struck a balance in part by making the best path forward also the path of least resistance, largely through collaboratively developing best practice guidance for the most crucial IIS functions.

## Blazing the trail: establishing best practices for IIS

If defining the *what* for IIS was hard in the 1990s, defining the *how* was even more challenging, given how uncharted the IIS waters were and how varied All Kids Count and other early projects were. But a combination of CDC and All Kids Count staff, with input from dozens of IIS staff and other experts, undertook a massive project in the late 1990s to develop a series of extensive guidance documents known collectively as the Community Immunization Registries Manual.<sup>9</sup> The manual, first published in draft form in 1996 and in final form in 1998, contained four chapters: Planning, Confidentiality, Technology and Operations (with the Confidentiality chapter being updated in 2000). The manual sought to balance the tension between autonomy and community by providing a clear, concrete and practical roadmap for making progress in each of the four areas. The manual could not yet be said to include “best practices,” but it at least contained “promising practices.”

Considerable progress came about for collaboratively defined best practices in 2005 when CDC and AIRA launched the Modeling Immunization Registry Operations Workgroup (MIROW). The purpose of MIROW was—and continues to be—to collaboratively develop and rigorously document best practices, often for the most challenging operational areas in IIS.<sup>10</sup> MIROW has addressed functional and technical topics such as management of patient active/inactive status, vaccine deduplication, data quality assurance, reminder/recall, IIS-VFC collaboration and inventory management, among others. The detailed guidance reflects the collective experience and wisdom of the MIROW workgroup members, and so has a sense of unity and shared purpose in the move toward greater operational standardization. Initial evidence indicates adoption of the recommendations and satisfaction with the development process.<sup>11</sup>

## The rise of standards adoption

In 1993, CDC began looking for ways to exchange immunization histories in registries with administrative data from practice management systems. Susan Abernathy of CDC was charged with researching what solutions providers were using in the private sector that met minimum criteria—e.g., it would need to allow states and providers to use their own systems, should facilitate exchange data with registries, and could eliminate the need for dual data entry, which hampered provider participation. This research unearthed an intriguing finding: HL7 messaging was emerging, especially in large medical facilities seeking to integrate patient data from across disparate systems (including lab, surgery, in-patient care, etc.) within the facility. More importantly, HL7 was the only health data standard that included immunization transactions. HL7 was increasingly looking like the clear way for healthcare to communicate with IIS, and in 1996, HL7 International added vaccine lot numbers to the standard after some negotiations with CDC.<sup>12</sup> The capability to exchange data using HL7 has been a key attribute and functional standard ever since.

Soon thereafter, in 1997, CDC released the first HL7 implementation guide.<sup>13</sup> But it had one major weakness as a guide to implementing a health data standard: it allowed for too much local variability. To address the lack of specificity, a number of interested and forward-looking IIS staff came together to form the Committee on Immunization Registry Standards and Electronic Transactions (CIRSET).<sup>14</sup>

CIRSET advocated strenuously for HL7 as the standard messaging protocol and took responsibility for maintaining the implementation guide. The HL7 standard provided the needed vocabulary to capture immunization messages, while CIRSET provided the context for the messages and feedback to HL7 International to help refine the emerging standard.<sup>15</sup>



### Standards for IIS support of immunization programs

Not all IIS standards are as well known as HL7 and the functional standards. In 2003, AIRA developed a set of standards that identified concrete ways in which the IIS could support other immunization program functions and priorities. Created by the Programmatic Registry Operations Workgroup, the standards came to be known as the PROW Standards of Excellence (available on the AIRA repository). A unique feature of the PROW standards was that they provided for three levels of attainment (equivalent to bronze, silver and gold) reflecting increasing sophistication in how the program was supported by the IIS.



### Finding consensus

At the recommendation of NVAC, a technical working group that included external registry stakeholders and information technology specialists was formed in 1999.

The purpose of the group was 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.

However, achieving real standardization and interoperability remained elusive due to local interpretations and statutory or other requirements. The push toward greater uniformity in the HL7 standard occurred with some urgency with the arrival in 2009 of the Medicare and Medicaid EHR Incentive Programs, otherwise known up through 2018 as “Meaningful Use.” With this ambitious federal program, major financial and regulatory approaches to standardizing health data capture and exchange took a huge leap forward. In part because the IIS community had been forward-looking years earlier in establishing vocabulary code sets and HL7 exchange standards, provider and hospital reporting to an IIS was included as one of the ways they could earn the incentive payments.

Future chroniclers of IIS history will likely look back on the years 2010-2017 and cite the Meaningful Use program as the major transformative event of that period, largely because it rapidly accelerated the adoption of HL7 immunization messaging, shifted provider interactions with the IIS from people-user interface to machine-to-machine interactions, and increased the number of providers enrolled and volume of immunization data submitted.<sup>16,17</sup>

### The IIS strategic plan promotes standards

In 2012-2013, NCIRD worked with an advisory board to develop an IIS strategic plan describing both current and desired future states for the IIS community. The strategic plan articulated a clear vision for IIS:

*Real time, consolidated immunization data and services for all ages are available for authorized clinical, administrative, and public health users, and consumers, anytime and anywhere.*

The plan also included long-term goals in five areas: nationwide leadership, sustainability, provider services, public health services and interoperable/data management.

Among other rich detail, the plan acknowledged the ongoing challenge to balance autonomy and community, and an urge to accept some jurisdictional variability as necessary and inevitable even as the community strove for ever-increasing harmonization and standardization.

The key challenges identified in the plan were:

- Standards were not coordinated nationwide across all immunization stakeholders.
- Different jurisdictions applied some IIS interoperability standards inconsistently.
- No nationwide policy for interstate data exchange existed
- Neither VFC nor Section 317 funding programs contained an IIS line item.
- Challenges remained to ensure immunization data in IIS were complete, accurate and acquired in a timely manner.<sup>18</sup>

The IIS strategic plan was updated in 2017 to provide a renewed focus on making progress in the key areas of:

- Enhancing IIS performance
- Promoting adherence to IIS standards
- Sustaining the IIS community
- Influencing and monitoring the health IT environment

The section in the plan on increased adherence to standards reflects the increasing emphasis on community standards over jurisdictional autonomy: “The ability of IIS to demonstrate adherence to national standards increases the credibility and value of IIS, contributes to improved program sustainability, and advances performance. It is important for CDC and the IIS community to promote standardization, develop new IIS standards and best practices for high-priority needs, and reduce implementation variability across the community to ensure IIS remain relevant in an evolving health IT ecosystem.”

The most visible manifestation of the move toward standardization at the end of the first 25 years is AIRA’s Measurement and Improvement Initiative, established to incrementally assess IIS programs on key areas of functionality, all with an eye toward ensuring uniform adoption of the community’s standards.<sup>19</sup> This initiative, among many others, highlights how standards have gone from being the heroic efforts of a few to an integral part of how the IIS community operates today.<sup>20</sup>

The history of tension between local autonomy and nationwide standardization is not unique to IIS; in fact, it’s deeply embedded in public health, as it plays an increasingly integral role in a digital health information ecosystem. But the IIS community was an early adopter of standards—functional, vocabulary and exchange—which has helped the community adapt to and thrive in this new era. The IIS community’s long journey to developing and agreeing upon shared standards blazed a trail that other public health programs—many just now grappling with the same balancing act—can perhaps follow.

## Citations and notes

1. John Ferling (2004). *Adams vs. Jefferson: The Tumultuous Election of 1800*. New York: Oxford University Press.
2. Kristin Saarlans et al., “All Kids Count 1991-2004: Developing Information Systems to Improve Child Health and the Delivery of Immunizations and Preventive Services,” *Journal of Public Health Management & Practice* 10 (November 2004): S3–15.
3. This story is chronicled in more depth in a different spotlight in this series, *Origin Story: Creating a Culture of Collaboration*.
4. See *Origin Story: Creating a Culture of Collaboration* for the full text of these 12 attributes.
5. Robert W Linkins and Suzanne M Feikema, “Immunization Registries: The Cornerstone of Childhood Immunization in the 21st Century,” *Pediatric Annals* 27, no. 6 (June 1, 1998): 349–54; NVAC 6/12/1999, <https://archive.hhs.gov/nvpo/report071100.pdf>
6. All Kids Count: a national Program. [https://www.rwjf.org/content/dam/farm/reports/program\\_results\\_reports/2007/rwjf69200](https://www.rwjf.org/content/dam/farm/reports/program_results_reports/2007/rwjf69200)
7. CDC Programmatic Goals and IIS Functional Standards 2013-2017
8. Bill Brand, written comments 6/20/2017
9. See *Community Immunization Registry Manual*, 1997 in the AIRA repository.
10. <http://www.immregistries.org/mirow>
11. Warren Williams et al., “Development and Utilization of Best Practice Operational Guidelines for Immunization Information Systems,” *Journal of Public Health Management and Practice* 17, no. 5 (2011): 449–56.
12. Susan Abernathy, interview 6/5/2017
13. See *Immunization Data Transactions Using the HL7 (Ver. 2.3) Standard Protocol*, 1997 in the AIRA repository.
14. Mike Flynn, interview 4/18/17
15. CIRSET eventually merged with AIRA by 2005, forming the basis of AIRA’s Standards and Interoperability Steering Committee.
16. Noam Arzt, interview 4/21/2017; Bill Brand interview 04/25/2017; Therese Hoyle, interview 04/21/2017; Sue Salkowitz, interview 4/7/17
17. For more information, see *IIS Technology Over Time: Impact and Changing Roles*, another IIS history spotlight in this series, available in the AIRA Repository.
18. <https://www.cdc.gov/vaccines/programs/iis/strategic-plan/iis-2018-2020.html>
19. <http://www.immregistries.org/measurement-improvement>
20. Mary Beth Kurilo, interview 4/27/2017

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