### Readiness Improvements for e-Birth Records Standards

# Addendum to the Minnesota e-Birth Records Project: Assessing Readiness for e-Birth Records Standards

Report by Centers for Disease Control and Prevention National Center for Health Statistics



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#### Introduction

This addendum to the Minnesota e-birth Records Project: Assessing Readiness for e-birth Records Standards report to the Centers for Disease Control and Prevention/National Center for Health Statistics (CDC/NCHS) ("Readiness Assessment") provides a progress update on recent activities to improve the readiness of e-Birth records standards. It summarizes initiatives that have had a positive impact on the readiness findings for e-Birth records standards since the publication of this report in April 2014. It also describes recent initiatives that have contributed to progress on recommendations made in the Readiness Report.

#### **Update on Readiness Assessment Findings**

Ongoing activities to support adoption of e-birth records standards continue to increase the readiness to test and implement e-birth records standards. Improvements have been attained in four areas identified in the Readiness Report as key factors contributing to the readiness of e-birth records standards.

## 1. Trial implementation and ongoing improvement of the e-Birth records standards specifications

Continued standards testing has resulted in improvement in the data element mapping for the e-birth records standards. The Integrating the Healthcare Enterprise (IHE) has a change management process that is used to incorporate improvements into a profile specification based on input from commenters and feedback from pilot test implementations. This process was used to clarify and establish mapping specifications for additional data elements during the fall of 2014. Additional trial implementation testing during the 2015 IHE Connectathon confirmed that mapping measures improved to between 79 percent and 94 percent depending on how the data elements are counted. The mappings are utilized to define the data elements that can be pre-populated on a vital records form based on the IHE Birth and Fetal Death Reporting Enhanced (BFDR-E) technical framework supplement.

Significant progress in data element mapping has been achieved. A data element is a defined concept and it includes a set of values which may represent that concept. Data elements can be roughly conceptualized as a question and answer pair. Initial mapping measurement methods in some cases counted components of a data element, thus there were inconsistencies in the denominator when first attempting to measure the proportion of data elements mapped. While efforts as of the 2013 Connectathon reported mapping 51 out of 164 possible data elements (31%), efforts as of the 2015 Connectathon reported mapping 100 out of 126 possible data elements (79%). More recently, the birth data from the Facilities Worksheet for the U.S. Standard Certificate of Live Birth was organized into well-defined data element concepts. Under the new organization of the information, 63 out of 66 of the data element concepts are mapped (95%). As the definition of what constitutes a data element has become clearer, the proportional measure of mapped data elements has become more accurate. Although the measurement of progress over time includes variances, notable progress in data element mapping has been achieved.

Change proposals submitted as of April 2015 recommended additional improvements that would attain mapping specifications for 100 percent of the data elements captured on the Facilities Worksheet for

the U.S. Standard Certificate of Live Birth. More mature mapping methods, now called "derivation rules, have been developed through the continuous improvement efforts on the e-birth standard. Derivation rules define the relationship between incoming data elements available from the Electronic Health Record (EHR) and data elements used on the Facilities Worksheet. They identify the EHR content appropriate for birth and fetal death reporting. The new derivation rules make it possible to express multiple ways to find needed information within EHR summary documents, thus easing the burden on implementers. The flexibility of the new derivation rule syntax makes it possible to create rules that reduce output changes for EHR vendors. Advances in the syntax used to write derivation rules are expected to make data element mapping specifications easier to create, more accurate, and potentially easier to implement.

#### 2. Availability of EHR data to support secondary use

EHR systems collect and organize data in ways that improve workflow for clinicians. As new uses for EHR information become standardized, the value of adding data reuse functionality increases. Systems that support data reuse offer a clear advantage over systems that don't.

The e-birth standards make it easier for EHRs to create re-usable data for vital records (VR) reporting that leverages prenatal, labor and delivery, and newborn data that already resides within the EHR system. Secondary use capabilities can be marketed as a "value add" yielding a competitive advantage for EHRs. When EHRs support data re-use, they save time, reduce processing expense, and reduce human error that may be introduced during duplicate data entry.

Maximizing the reuse of available EHR data increases the benefit implementers can attain through use of the e-birth standards. As the data specified in the e-birth standards expands to address more of the data elements needed by a birth registry, the incentive for EHR vendors to make birth information available as reusable structured data increases.

Trial use of the e-birth record standards by industry-leading EHR and VR system vendors benefits the industry as a whole. Test implementations developed by vendors with large installed bases, such as Epic with an estimated 67 percent market share, maximize the return on investment in standards creation. This in turn lowers the costs of standards adoption for smaller implementers who benefit as more refined standards become available for their use.

In preparation for the 2015 IHE Connectathon, an increase in participation was noted in technical sessions offered to support vendor adoption. NCHS supported collaboration with EHR and VR System vendors to enhance the e-birth standards. Vendor representatives from Epic, Cerner, Siemens, and Genesis participated to provide feedback on the standards and to learn from experienced e-birth record standards implementers. Efforts to continuously improve the e-birth standards are making it more feasible for EHR and VR system vendors to support data reuse by birth registries.

#### 3. Support for implementation of e-birth records standards through meaningful use incentives

Ongoing collaboration with professional bodies keeps e-birth record standards on the agenda of health information policy discussions. The National Committee on Vital and Health Statistics (NCVHS) (<a href="www.ncvhs.hhs.gov">www.ncvhs.hhs.gov</a>), the statutory public advisory body to the Secretary of Health and Human Services, held a meeting on May 28, 2015 that included an eVital Records project demonstration

presented by representatives from a state VR agency, a provider organization, and EHR and VR system vendors.

Participation in National Association for Public Health Statistics and Information Systems (NAPHSIS) (<a href="www.naphsis.org">www.naphsis.org</a>), a national nonprofit organization representing the state vital records and public health statistics offices in the United States, keeps more than 250 public health professionals in each state, the five territories, New York City, and the District of Columbia, apprised of the advances in e-birth standards.

The methodology used by the Office of the National Coordinator for Health Information Technology (ONC) to advise implementers on the use of interoperability standards is changing. As of 2015, ONC expects to annually update the Interoperability Standards Advisory on an annual basis through a transparent and structured process that includes advice from the Health Information Technology (HIT) Standards Committee (ONC's federal advisory committee) and the public at large. To the extent possible, updates to future advisories will be done in a manner that seeks to minimize the potential for unnecessary sunk costs and to promote the entry of innovative standards. It is expected that stakeholders who administer government programs, procurements, and testing or certification programs with clinical health IT interoperability components would first look to an advisory in order to leverage the standards and implementation specifications listed to achieve their interoperability goals.<sup>1</sup> This change represents new and more frequent opportunities for e-birth standards to be recognized as the "best available" standard for reporting information to birth registries. Language in the proposed rulemaking establishes a new broader requirement for public health reporting that opens the door for other public health reporting standards. NCHS has recommended to ONC the following list of "best available" standards for the purpose of birth and death reporting to Federal and local vital records agencies:

- HL7 Version 2.5.1 Implementation Guide: Birth and Fetal Death Reporting, Release 1.1 (US Realm - Draft Standard for Trial Use)
- HL7 Version 3 CDA R2 Implementation Guide: Birth and Fetal Death Reporting, Release 1 (US Realm - Draft Standard for Trial Use)
- HL7 Version 2.5.1 Implementation Guide: Vital Records Death Reporting, Release 1.1 (US Realm Draft Standard for Trial Use)
- HL7 Version 3 CDA R2 Implementation Guide: Vital Records Death Reporting, Release 1 (US Realm - Draft Standard for Trial Use)
- IHE Birth and Fetal Death Reporting Enhanced (BFDR-E)
- IHE Vital Records Death Reporting (VRDR)
- HL7 EHR-S FM Public Health Functional Profile, Release 2 (includes a Vital Records domain)

#### 4. Collection of self-reported civil information

<sup>&</sup>lt;sup>1</sup> 2015 Interoperability Standards Advisory (Draft), Office of the National Coordinator, http://www.healthit.gov/standards-advisory

Previous findings report a lack of policies to support using e-birth record standards for collection of civil and medical information. An expanded version of the BFDR Profiles was developed in 2015, called BFDR Enhanced (BFDR-E). The IHE BFDR-E profile does not include all of the civil information for birth registration due to policies requiring that civil information be self-reported by the parent(s) on the birth record. NCHS and other vital records stakeholders agreed to limit the scope of the first iteration of the e-birth record standards to exclude select demographic information and focus on the collection of relevant health data. The eVital Standards Initiative provides support for the development of Vital Records (VR) standards to enable interoperable electronic data exchanges among electronic health record systems, U.S. vital records systems and potentially other public health information systems for birth, death and fetal death events. The initial goal for the initiative will be to monitor and assess the quality of the data that will be exchanged between EHR and VR systems through the implementation of demonstration projects utilizing this initial set of standards.

As techniques to reuse EHR data become more readily available and testing confirms data accuracy and quality, it may become more feasible to consume demographic data from the EHR to populate information required by the Mother's Worksheet. This decision will need to be revisited by VR stakeholders as e-birth record standards implementation progresses nationally.

As EHR data processing capabilities improve and policies evolve, NAPHSIS and state vital records agencies need to remain involved in this emerging area of data exchange. Presently, there are many challenges with including patient-reported information as electronic data. Focus on patient engagement is increasing and new policies and standards are being developed to address how to include patient reported information. The e-birth record standards are well positioned to leverage those advancements. Standards such as Retrieve Form for Data Capture and Structured Data Capture are making it possible to include human involvement in the data collection process. These standards are well suited for including patient and civilian participation. Ongoing participation in efforts where these foundational standards are developed and maintained keeps the developers of e-birth record standards informed of advances that may make reporting of civilian data more feasible to implement.

#### **Action on Readiness Assessment Recommendations**

## 1. Continued expansion and testing of e-birth records standards (Readiness Assessment Recommendation #3)

Continuous improvement efforts with primary implementers has resulted in better and more complete mapping. In the fall of 2014, open working sessions were conducted through NCHS support to enable "observational learning". Vendors who were interested in the BFDR-E profile were invited to join sessions where they watched and listened as implementers prepared for the 2015 Connectathon testing. Several major EHR vendors and new state vital records organizations participated in the learning sessions to support additional testing. Changes being reviewed for implementation in the fall of 2015 are expected to achieve 100 percent data element mapping for demonstration at the 2016 Connectathon. Additional participation in 2016 Connectathon testing is expected as a result.

The number of implementers supporting functionality needed to play a role in the e-birth record standards is increasing. Although uptake for the enhanced HL7 messaging capability was low in 2015,

participation in the base Retrieve Form for Data Capture (RFD) standard remains steady. Introduction of the new Structured Data Capture (SDC) profile led to participation of several new implementers for the Form Manager, Form Filler, and Form Processor roles. These system roles are defined within the RFD profile developed by IHE and are called "profile actors". The SDC profile is based on RFD functionality. It utilizes the same RFD actors and the same RFD retrieve form capability but adds more advanced form definition and form processing capabilities. Profile development for SDC was supported by the ONC and it was created within the larger S&I Framework community. As more implementers of RFD and SDC develop the basic capabilities of the RFD actors, the number of organizations positioned to test BFDR-E grows. NCHS has experienced an increase in inquiries from state vital records agencies and provider organizations about the e-birth record standards, funding resources, existing pilots, and future implementation opportunities.

#### Birth and Fetal Death Profile<sup>2</sup>:

		Form Archiver	Form Filler	Form Manager	Form Processor	Form Receiver
Epic Systems Corporation			*			
Genesis Systems, Inc.				*	*	*
MN Department of Health						*
OZ Systems		*		*		*
Tiani-Spirit Gmbh - Cisco Systems Inc.		*	*	*		*
Utah Department of Health						*

#### Birth and Fetal Death Enhanced Profile<sup>3</sup>:

	Content Consumer	Content Creator	Form Filler	Form Processor	Form Receiver CDA Exporter	Information Recipient (HL7)	Information Source (HL7)
Epic Systems Corporation			*				
GE Healthcare	*						
Genesis Systems, Inc.						*	*
Tiani-Spirit Gmbh	*	*			*		
Utah Department of Health				*			

results.ihe.net/view result.php?rows=company&columns=actor&title=integration profile

<sup>&</sup>lt;sup>2</sup> IHE Connectathon Results Database, Result Matrix for integration\_profile: "Birth and Fetal Death Reporting", June 17, 2015. <a href="http://connectathon-">http://connectathon-</a>

<sup>&</sup>lt;sup>3</sup> IHE Connectathon Results Database, Result Matrix for integration\_profile: "Birth and Fetal Death Reporting-Enhanced", June 17, 2015. <a href="http://connectathon-results.ihe.net/view-result.php?rows=company&columns=actor&title=integration-profile">http://connectathon-results.ihe.net/view-result.php?rows=company&columns=actor&title=integration-profile</a>

#### Structured Data Capture Profile<sup>4</sup>:

	Form Filler	Form Manager	Form Processor	Form Receiver
California Department of Public Health				*
Centers for Disease Control and Prevention				*
CRG Medical, Inc.				*
Data Consulting Group, Inc.		*		
Epic Systems Corporation	*			
Food and Drug Administration				*
JBS International,Inc.		*	*	*
mTuitive, Inc.	*			

In 2015, NCHS issued two Request for Proposals (RFPs) to solicit state agencies interested in pilot testing the e-birth record standards beyond the annual testing offered through the IHE Connectathon. One of the pilots aims to improve the timeliness and quality of mortality records processed through the state's Electronic Death Registration (EDR) system for transmission to the NCHS. Improving the timeliness, quality, and accuracy of EDR data collection will strengthen the National Vital Statistics System (NVSS) as a whole and enhance the Vital Statistics Cooperative Program (VSCP) at all levels.

The second project will evaluate the quality of selected birth data extracted from EHR systems in two diverse VR jurisdictions and compare it to the information reported on birth certificates for selected maternal and child data elements for a retrospective sample of births. Upon successful completion, the selected state health departments will have a methodology and metrics for initial assessment and ongoing quality control of birth certificate information received from EHRs. This project aims to show that as the current manual reporting process is replaced with automated reporting, the quality of data is maintained or improved.

Earlier testing in Minnesota on EHR extracted death registry information showed significant improvements in timeliness and qualitatively better data. Data extracted from the EHR provided significantly more information, making cause of death information more meaningful.<sup>5</sup>

## 2. Provide resources and technical assistance for readiness and implementation (Readiness Assessment Recommendation #4)

The IHE process supports ongoing refinement to the profiles. The profiles provide valuable guidance to implementers. IHE training sessions and workshops are designed to educate and assist vendors with the implementation of standards. Presentations about the e-birth record standards are offered regularly. IHE's library of recorded presentations serves as a resource to help implementers interested in adopting these new standards.

<sup>&</sup>lt;sup>4</sup> IHE Connectathon Results Database, Result Matrix for integration profile: "Structured Data Capture", June 17, 2015. <a href="http://connectathon-">http://connectathon-</a>

results.ihe.net/view result.php?rows=company&columns=actor&title=integration profile

<sup>&</sup>lt;sup>5</sup> Duncan, Jeffrey. Senior Health Informaticist. Utah Department of Health. Interview. May 29, 2015.

A new validation tool for the HL7 V2.5.1 Vital Records Death Reporting message was created by the National Institute of Standards and Technology (NIST). The tool may be utilized by pilot testers and implementers to validate sample messages produced by their systems. It accommodates testing specific jurisdictional requirements that extend beyond the national death reporting requirements. The current NIST tool supports context-free testing with support for context-based testing under developed. Context-free testing confirms the structure and format of the information. Context-based testing validates the accuracy of the content in the represented information for a specific scenario. The tool is available at: <a href="http://hit-testing2.nist.gov:8093/cf-validator/#/home">http://hit-testing2.nist.gov:8093/cf-validator/#/home</a>. NCHS plans to expand the suite of available conformance testing tools to include the HL7 Vital Records Death Reporting CDA, and the HL7 Birth and Fetal Death Reporting V2.5.1 and CDA Implementation Guide.

## 3. Demonstrate value of and build stakeholder support for e-birth record standards (Readiness Assessment Recommendation #5)

NCHS is developing a long-term plan to convene and engage stakeholders to determine their information needs and to promote the value of e-birth record standards. This will include discussions with stakeholders through advisory committees and on-going outreach utilizing various communication channels such as distribution of written materials and providing e-birth records standards information on the NCHS website. Stakeholders include state vital records agencies, EHR and VR system vendors, clinicians, data providers and professional associations.

NCHS is working on ways to address additional state-level requirements within the e-birth record standards. Mechanisms developed to constrain universal specification designs for U.S. requirements can be applied to further support states and jurisdictionally defined requirements. This will necessitate expansion of the underlying vocabulary to support additional requirements.

#### 4. Implement opportunities for improvement (Readiness Assessment Recommendation #7)

In June of 2015, the Public Health Informatics Institute (PHII) issued a report titled, "Enhancing Electronic Health Record Systems to Generate and Exchange Data with Electronic Vital Registration Systems". It describes a roadmap to enhance EHRs to generate and exchange data with VR systems. The study reviewed publications, web sites, and unpublished documents related to state and national VR systems, EHR systems, and certification programs for EHRs. Telephone interviews were conducted with 42 experts, such as vital records managers and informaticians from state health departments, health care providers, medical informaticians, certification experts, and EHR and electronic Vital Record system (EVRS) vendors. Interview questions focused on potential barriers, facilitators, and next steps for enhancing EHRs to generate and exchange data with EVRSs.

The PHII report explains that EHR/EVRS<sup>6</sup> certification and enhancing EHRs to generate and exchange data with EVRS should not be regarded as goals in and of themselves. According to the PHII report, the

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<sup>&</sup>lt;sup>6</sup> In the report "EHR-S/EVRS" refers to the ability of EHR and EVR systems to "communicate, exchange data, and use the information that has been exchanged" in order to complete registration of births and deaths, and reporting of fetal deaths. In other words, EHR-S and EVRS exhibit interoperability. (HIMSS. Definition of interoperability [Internet], 2013. Available at: http://www.himss.org/library/interoperability-standards/what-is-interoperability.)

clearly stated goal for proceeding needs to be improving data quality and data delivery<sup>7</sup>—that means increasing the accuracy, completeness, and timeliness of vital records data, delivered through state and national systems that are more economical and efficient. Respondents often viewed EHR/EVRS certification, and EHR enhancements for generating and exchanging data with EVRS, as hypotheses that need to be thoroughly tested through carefully planned and conducted pilot projects, rather than as already proven assumptions.

The report concludes that future improvements need to focus on the efficiency of data exchange with VR systems; minimizing costs of design, development, testing, implementation, deployment and maintenance; maximizing speed of implementation and deployment; maximizing likelihood of state health departments (SHD) acceptance of a particular route of adoption (such as births, fetal deaths, or deaths, or any combination of these); and maximizing the value proposition for SHDs, data providers, and vendors.

## 5. Build Offices of Vital Records' e-birth records capacity (Readiness Assessment Recommendation #6)

Funding from NCHS supported pilot activities with departments of health in Utah and Minnesota to help build states' vital records reporting capacity. The activities in Minnesota included an evaluation of the readiness of the Minnesota Department of Health (MDH) and Minnesota birth hospitals for secure standards-based exchange of birth records information using the Integrating the Healthcare Enterprise (IHE) Birth and Fetal Death Reporting (BFDR) Profile and Health Level Seven International (HL7) standard message and document specifications (e-birth records standard). As a result of that project, the Assessing Readiness for e-birth Records Standards report was issued in 2014 to document the readiness for adoption and use of e-birth record standards at that time. This addendum directly addresses the recommendations and next steps identified in that earlier report.

The 2015 report developed by PHII offers new guidance on potential routes for enhancing digital communication between EHR-s and electronic vital records systems (EVRS). Criteria for finding the optimal route may differ by agencies. Criteria that can be used to choose specific routes include:

- Data quality—accuracy, completeness, and timeliness
- Data exchange efficiency for population of vital registration systems;
- Cost of design, development, testing, implementation, and deployment;
- Speed of design, development, testing, implementation, deployment and maintenance;
- Adoption by SHDs; and
- Value of benefit to be gained for SHDs, data providers, and vendors, including any secondary benefits for a particular route such as yielding data useful for hospital quality improvement activities.

The report describes current barriers and facilitators of electronic information exchange. The framework can be used to guide adoption and inform certification activities and other conformity assessments. It points out a key consideration. As vital records agencies seek to build capacity for working with e-birth

<sup>&</sup>lt;sup>7</sup> In the report, we use *quality* as it applies to vital records to mean that those records and their data are accurate and complete and that the records are completed, processed, transmitted, and made available in a timely fashion.

record standards, certification and other types of conformity assessments need to be recognized and planned for as ongoing activities that will require attention and a commitment of resources.

NCHS is updating available resources to help vital records agencies build capacity for working with ebirth record standards. The NCHS website will include reports, presentations, links and pointers to available e-birth record standards, and information about pilot implementation activities (http://www.cdc.gov/nchs/nvss/about\_nvss.htm#evital\_update\_).

## 6. Align policies to support using e-birth records standards (Readiness Assessment Recommendation #1)

In proceeding with certification or other conformity assessment options, the following considerations will need to be addressed: governance of certification or other conformity assessment, including establishment of criteria and measures; financing; laws, regulations, and policies; implementation; and compliance. The PHII report increases awareness of the broader topics affecting electronic information exchange of vital records, however more needs to be done to achieve progress in these areas. Recent input to national rule-making activities has provided guidance to advance the use of e-birth record standards, but involvement from stakeholders at all levels is needed to address the larger issues of policy and governance, financing, and regulation.

## 7. Leverage activities of the Office of the National Coordinator (ONC) and other Federal Agencies (Readiness Assessment Recommendation #2)

Public comments on proposed rulemaking and MU incentive programs have been submitted to the ONC by representatives from the CDC/NCHS and state vital records agencies. They encouraged a proactive approach to clinical HIT development that analyzes and supports the needs of both clinical care and population health. Recommendations stressed consideration of e-birth standards for population health data that are driven by clinical health. Birth and death reporting data to Federal, state and local agencies were described as essential for key national health and healthcare-related policy decisions; influencing programmatic and policy decisions for state agencies and identifying emerging health trends; measuring progress toward national and state health objectives such as Healthy People 2020 goals.

In response to the insight gained from the industry, the National Proposed Rule Making (NPRM) for Meaningful Use Stage 3 includes support for the use of new innovations and it adds flexibility in the options used to meet objectives for Public Health and Clinical Data Registry reporting. The rule proposes to measure Public Health Registry reporting separately from Clinical Data Registry and Immunization Registry reporting. It defines a "public health registry" as a registry administered by, or on behalf of, a local, state, territorial, or national Public Health Agency (PHA) and which collects data for public health purposes. Any Eligible Providers (EP), eligible hospital (EH), or Critical Access Hospital (CAH) may report to more than one public health registry to meet the total number of required measures for the objective. This change creates opportunities for the use of additional Public Health reporting mechanisms such as those using e-birth record standards to support Meaningful Use Stage 3 objectives.

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<sup>&</sup>lt;sup>8</sup> Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 3, Federal Register. March 30, 2015. http://tinyurl.com/q468940

#### Conclusion

Increasingly, stakeholders are recognizing and acknowledging that e-Birth record standards will strengthen vital records systems to document and improve the health of all people. Progress in the development and use of these standards is an iterative process requiring sustained focus and continuous improvement. The roadmap for success depends on dedication to the ongoing evolution of the e-birth record standards that make data exchange more efficient and more effective. Interest in leveraging data collected in EHR systems is growing, and implementer capacity is expanding. The task of standards development is complex and arduous and the lifecycle for standards adoption is long. However, continuous improvement activities, such as those described in this addendum, accelerate implementation readiness for e-Birth record standards and sustain progress toward more efficient and effective information collection for vital records.