Enhancing Electronic Health Record Systems to Generate and Exchange Data with Electronic Vital Registration Systems

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Summary

Project purpose

The specific purpose of this project is to develop a roadmap with possible routes for certification of electronic health record systems' (EHR-S) capabilities for generating data for and exchanging data with electronic vital registration systems (EVRS). The more general purpose of this project is to develop a roadmap for enhancing EHR-S to generate and exchange data with EVRS.

What did we do?

To provide context for the project, we reviewed publications, web sites, and unpublished documents related to state and national vital registration systems, electronic health record systems (EHR-S), and certification programs for EHR-S. We also conducted telephone interviews with 42 experts, such as state health department vital records managers and informaticians, health care providers and medical informaticians, certification experts, and EHR-S and EVRS vendors. Interview questions focused on potential barriers, facilitators, and next steps to enhancing EHR-S to generate and exchange data with EVRS.

What were three main things that we learned from our interviews?

1. What's the goal? Respondents typically pointed out that EHR-S/EVRS[1] certification and enhancing EHR-S to generate and exchange data with EVRS should not be regarded as goals in and of themselves. Rather, we were told that the clearly stated goals for proceeding need to be improving the quality[2]—that is, accuracy, completeness, and timeliness—of vital records data, delivered through state and national systems that are economical and efficient.

2. Where's the evidence? Respondents often viewed EHR-S/EVRS certification and EHR-S 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.

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[1] In this 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.)

[2] In this 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.

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3. Where's the market? EHR-S vendors, hospitals, and state health departments (SHDs)[3] usually expressed little interest in EHR-S/EVRS certification and EHR-S enhancements for EVRS.

What else did we learn about barriers and facilitators?

Despite the three main findings from our interviews, our analyses of those interviews also made us realize that the barriers reported by respondents could usually be matched with facilitators reported by themselves or other respondents. The barriers and facilitators mentioned by our 42 respondents relate to planning and stakeholder engagement; national and state policies; data quality; workflows; and health information technology. Frequently mentioned facilitators included providing incentives for developing and implementing EHR-S/EVRS; designing EHR-S/EVRS to minimize unstructured data; configuring EHR-S/EVRS to support quality improvement programs; developing a long-term plan for SHD implementation of HL7 messaging standards; and implementing EHR-S/EVRS pilot projects with planned variation and common metrics.

What are the roadmap and routes to enhancing EHR-S to generate and exchange data with EVRS?

Based on our environmental scan and interviews, we developed a roadmap with six potential routes for enhancing EHR-S to generate and exchange data with EVRS. We adapted the DHHS Enterprise Performance Life Cycle to serve as the framework for the roadmap and its six routes. See the figure 4 below. All routes start with stakeholder engagement and a requirements assessment and then diverge during the design phase of the Life Cycle. The six routes are:

> Route 1: Continue current vital registration (VR) processes
>
> Route 2: Improve workflow for current VR processes
>
> Route 3: Provide direct user access to the EVRS from the EHR-S
>
> Route 4: Collect data for EVRS using third party applications that run within the EHR-S environment
>
> Route 5: Develop EHR-S module to collect and transmit VR data
>
> Route 6: Extract available VR data from EHR-S and complete form manually

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[3] In this report, state health departments (SHDs) refer to the 57 U.S. vital records jurisdictions.

What are the certification and conformity assessment options?

Certification—a specific type of conformity assessment—is one potential tool among others to improve system performance. During our interviews, EHR-S vendors stated that they would only undertake certification of their systems for vital records functionality if such certification were mandated by state or federal government regulations or there were significant incentives provided for certification that made certification cost effective.

Given the current lack of mandates and incentives for certification and assuming that during the requirements analysis there is support for some form of conformity assessment, two possible options should be considered:

1. Including vital registration (a) as a public health registry under Stage 3 of meaningful use, or (b) in future editions of the Office of the National Coordinator for Health Information Technology's (ONC) EHR certification criteria.

2. Demonstrating a marketing advantage for vendors through a declaration of conformity (DOC) for their EHR-S to the vital records requirements of the HL7 Public Health Functional Profile. A DOC would be much less costly and resource intensive than certification and might be easier to justify to EHR-S vendors.

How should specific routes be chosen for enhancing EHR-S to generate and exchange data with EVRS?

Specific routes in the roadmap should be chosen using explicit criteria. These criteria include: whether to choose a route or routes for births, fetal deaths, or deaths, or any combination of these; maximizing quality—accuracy, completeness, and timeliness—and efficiency of vital registration systems; minimizing costs of design, development, testing, implementation, deployment and maintenance; maximizing speed of implementation and deployment; maximizing likelihood of SHD acceptance of a particular route; and maximizing the value proposition for SHDs, data providers, and vendors.

What is an appropriate framework for proceeding with certification or other conformity assessment options?

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.

Figure 4. Routes for Enhancing EHRS to Generate and Exchange Data with EVRS
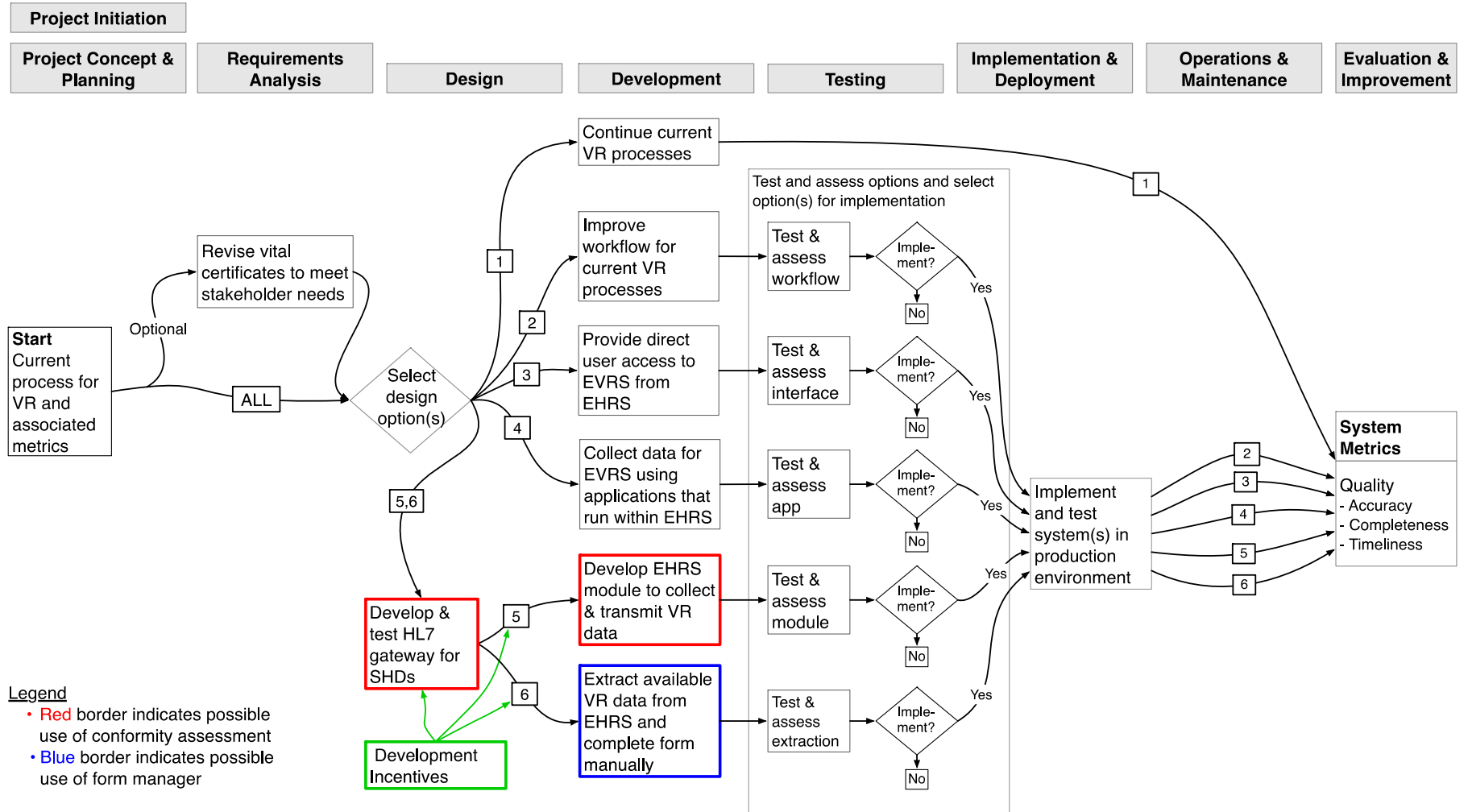
Enhancing Electronic Health Record Systems to Generate and Exchange Data with Electronic Vital Registration Systems

Project purpose

The specific purpose of this project is to develop a roadmap with possible routes for certification of electronic health record systems' (EHR-S) [4] capabilities for generating data for and exchanging data with electronic vital registration systems (EVRS), as specified in the Health Level Seven International (HL7) EHR-System Public Health Functional Profile (PHFP) for birth, death, and fetal death reporting.[5]

The more general purpose of this project is to develop a roadmap for enhancing EHR-S to generate and exchange data with EVRS.

What did we do?

Environmental scans

To provide context for the project, we reviewed publications, web sites, and unpublished documents related to state and national vital registration systems, electronic health record systems (EHR-S), and certification programs for EHR-S. Given the project's focus on paths to certification, we also reviewed examples of "roadmaps" developed by various health organizations.[6]

<u>Vital registration system</u>

The purpose of the U.S. vital registration system is twofold. First, the system legally registers births and deaths, records fetal deaths, and produces permanent legal records for selected life

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[4] In this report, EHR-S refers to hospital in-patient systems for births and fetal deaths, and to hospital in-patient systems, nursing home systems, and ambulatory systems for deaths. Epic, Cerner (including Siemens), and Meditech currently dominate the in-patient EHR-S market.

[5] The HL7 EHR-System Public Health Functional Profile, Release 2 — U.S. Realm (March 2015) "identifies functional requirements and conformance criteria for public health clinical information collection, management and exchanges that include specific public health programs . . . This profile is a U.S. Realm Functional Profile that articulates the functional requirements needed to support data exchange among providers and public health stakeholders including, but not limited to, states, local agencies, and federal agencies." (HL7 2015).

[6] Appendix A lists the materials reviewed for the project, which should be consulted for a more detailed description of these topics.

events, which are used for legal, financial, and other needs. Second, the system produces statistical information about those life events, which are analyzed to provide information about population health. These different purposes impose distinct workflow requirements on vital records data providers and complicate efforts to enhance EHR-S to generate and exchange data with EVRS.

The vital registration system is complex. Vital registration in the United States is a state rather than a federal function, and the vital registration system is composed of 57 separate registration jurisdictions.[7] CDC's National Center for Health Statistics periodically revises the U.S. standard certificates of live births and deaths, as well as accompanying data collection aids such as facility and mother's worksheets.[8] In order to obtain partial federal funding for their vital registration systems through the Vital Statistics Cooperative Program (VSCP), states must transmit birth, fetal death, and death data to NCHS in required data formats and meet data quality standards. Individual states, however, may require vital records data providers—principally hospitals, physicians, medical examiners, and funeral directors—to collect data additional to those on the U.S. standard certificates, and collect the U.S. standard certificate data in data formats that differ from those specified by NCHS. These state variations complicate efforts to enhance EHR-S to generate and exchange data with EVRS.

The workflows used by hospital data providers for collecting birth certificate and fetal death data typically entail retrieval of data from prenatal care providers, the hospital birth log, medical records, and the mother.[9] See Figure 1.[10] Data from these sources are typically compiled by a birth clerk using facility and mother's worksheets and then entered into an electronic birth registration system (EBRS), which is managed by the state health department (SHD). Different vendors supply EBRS to SHDs in different states, as represented by "Vendor A" and "Vendor B" in Figure 1. Some data for the birth certificate may be available from the

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[7] The 57 registration jurisdictions are the 50 U.S. states, the 5 U.S. territories, New York City and the District of Columbia.

[8] The last major revision occurred in 2003. (NCHS 2003a, b, c) To facilitate the collection of more complete, accurate, and useful data through the certificates, NCHS develops and disseminates specifications for entering and editing data for specific items on the certificates. (NCHS 2012a, b, c) Companies that provide electronic vital registration systems to state health departments incorporate these specifications into their systems, although NCHS does not independently verify the availability of these specifications in EVR systems or the accuracy of data collected by these EVR systems.

[9] See NAPHSIS, *More Better Faster: Strategies for Improving the Timeliness of Vital Statistics.* April, 2013.

[10] Full-page copies of all figures can be found in Appendix H.

hospital's electronic health record system (EHR-S).[11] Multiple vendors supply hospitals and health care providers with EHR-S, as represented by "Vendor 1" and "Vendor 2" in the figure. A major EHR-S vendor often supplies multiple hospitals within a state, and hospitals in multiple states. As a result, EHR-S vendors often have a multi-state and national perspective, rather than a single state perspective. We will discuss other aspects of Figure 1 later in the report.

Figure 1. Current Birth and Fetal Death Registration Process and Possible Routes for Using EHRS to Generate and Exchange Data with EVRS
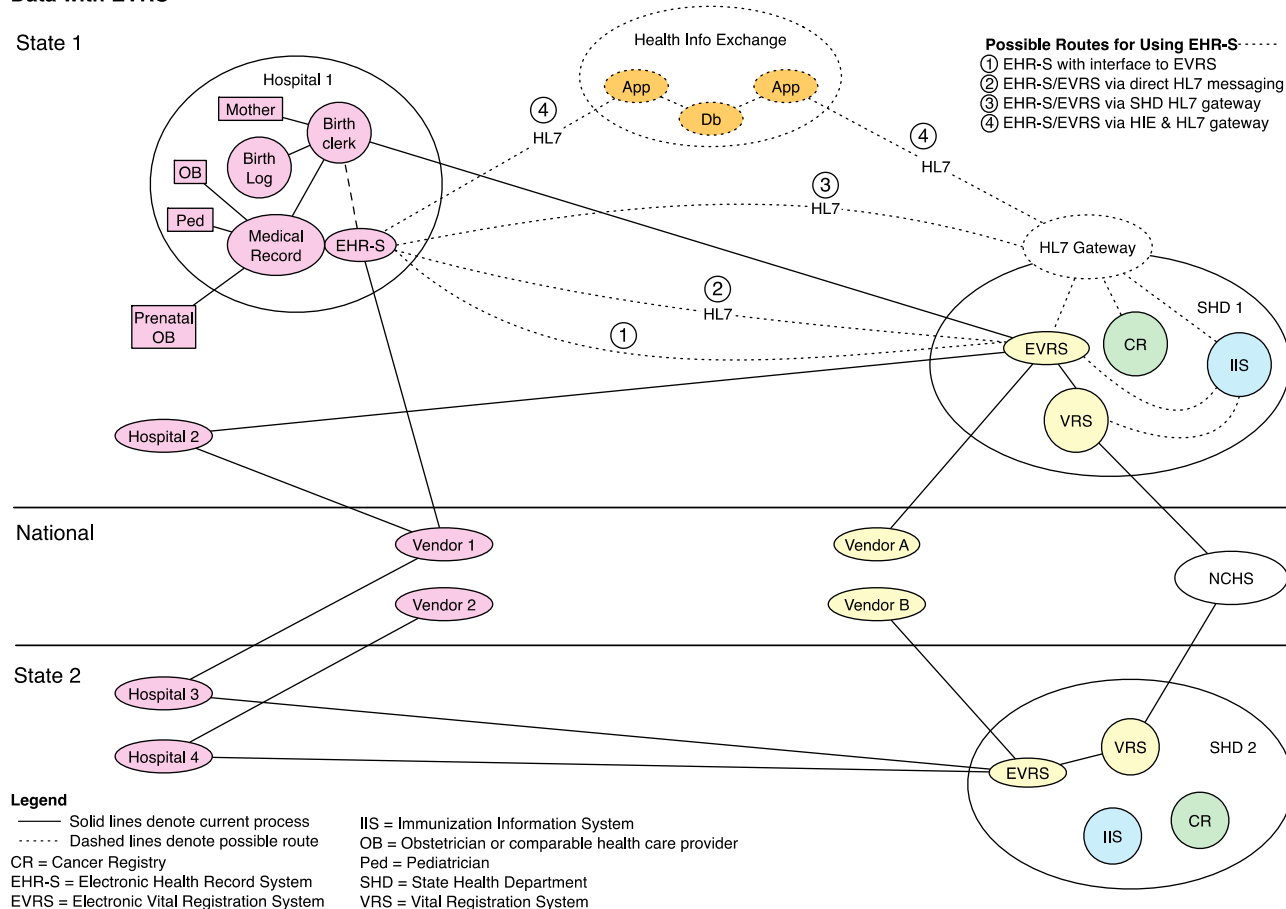
The workflow used by hospital, medical examiners, and funeral directors to retrieve death data requires fewer data sources than for births and fetal deaths: at hospitals, certifying physicians and perhaps clerks retrieve and/or enter the needed data, and funeral directors retrieve needed data from next-of-kin. Forty-four states have electronic death registration

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[11] Some hospitals refer to the EHR-S as an electronic medical record system (EMRS). We will use EHR-S in this report to represent both EHR-S and EMRS.

systems (EDRS), but these states vary in the proportion of deaths registered through their EDRS. For some deaths, no death data are collected through the EDRS, and these deaths are still registered using paper certificates. For some other deaths, only part of the required data is collected through the EDRS. EDRS data are transmitted to the SHD either before or after linkage of the medical data provided by the certifying physician or medical examiner with the demographic and other data provided by the funeral director (see Figure 2). The complexities of these workflows and data retrieval processes, and the relatively greater complexity for births and fetal deaths than for deaths, complicate efforts to enhance EHR-S to generate and exchange data with EVRS.[12]

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[12] In 2012, only 1.4% of U.S. births were out-of-hospital. (MacDorman MF, Mathews TJ, Declercq E. Trends in out-of-hospital births in the United States, 1990–2012. NCHS data brief, no 144. Hyattsville, MD: National Center for Health Statistics. 2014. Available at: http://www.cdc.gov/nchs/data/databriefs/db144.htm.) In contrast, in 2012, 62.0% of U.S. deaths were *not* in a hospital inpatient or outpatient setting (Centers for Disease Control and Prevention, National Center for Health Statistics. Underlying Cause of Death 1999-2013 on CDC WONDER Online Database [Internet]. Available at: http://wonder.cdc.gov/ucd-icd10.html; accessed 23 Jun 2015.)

Figure 2. Current Death Registration Process and Possible Routes for Using EHRS to Generate and Exchange Data with EVRS
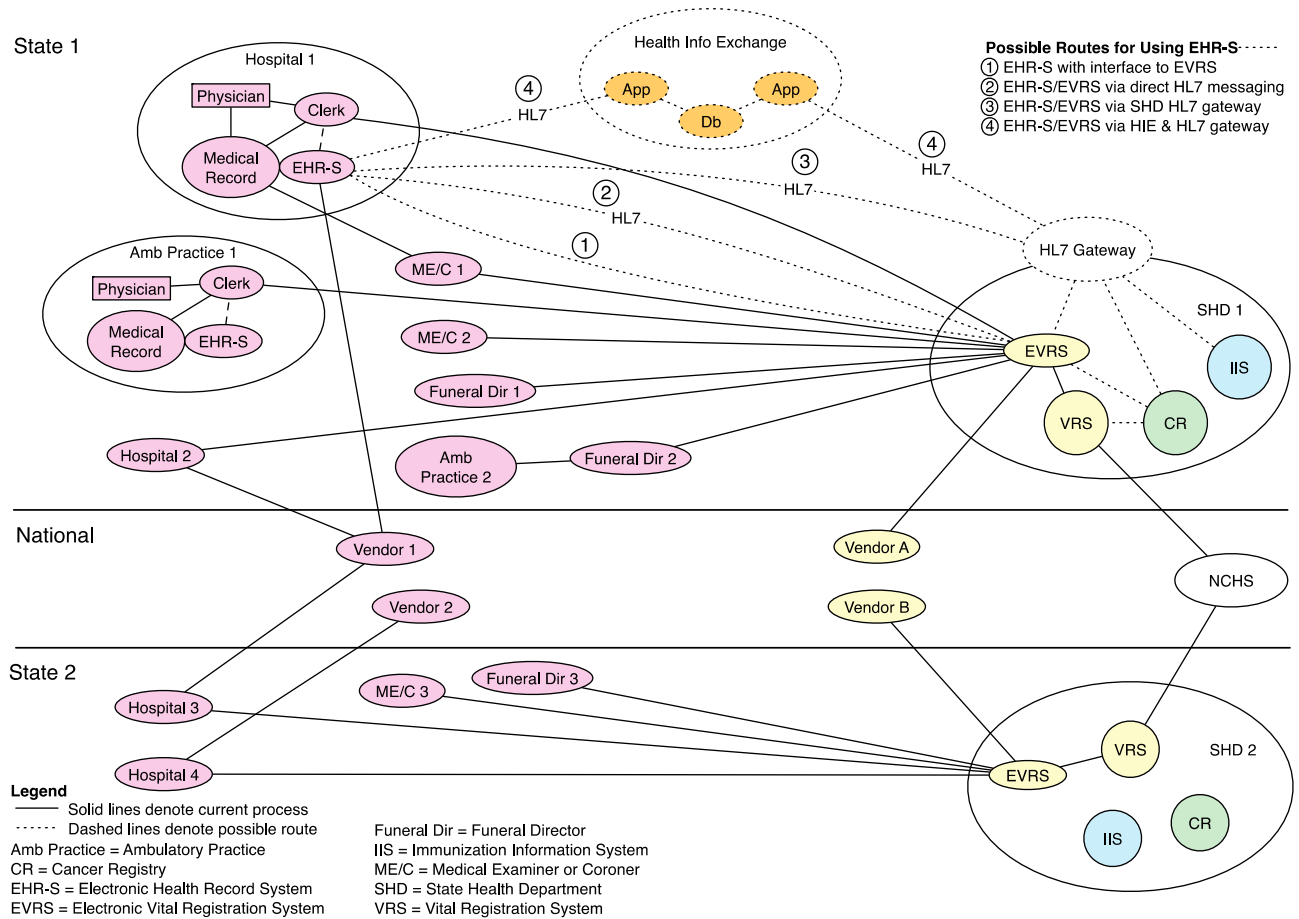
Vital records standards for EHR-S

NCHS works with standards development organizations, such as Health Level Seven (HL7) and Integrating the Healthcare Enterprise (IHE), to incorporate the NCHS certificate data items and specifications into national and international standards. For example, NCHS worked with HL7 to develop the PHFP, which identifies functional requirements for clinical information exchange among providers and public health stakeholders. (HL7 2015). NCHS also developed HL7 V2.5.1 Messaging, and Clinical Document Architecture (CDA) implementation guides (IGs) that have been published as draft standards for trial use (DSTU).[13] IHE has developed and issued technical framework supplements for reporting births, fetal deaths, and deaths.[14] They contain structured profiles based on HL7 standards and NCHS specifications to aid organizations in building systems to "capture and communicate information needed to report births and fetal deaths [and deaths] for vital registration   purposes." (IHE 2014). Nevertheless, the development and publication of standards does not ensure their use.

EHR-S/EVRS pilot projects

NCHS funded two pilot projects to explore the use of EHR-S to obtain data for vital records. The Minnesota Department of Health (MDH) worked with a hospital to analyze the workflow for gathering data for completing the birth certificate and whether needed data were available from the EHR-S used by the hospital.[15] The MDH project found that MDH and hospitals support the adoption of e-birth records standards but lack the readiness to fully test and implement them: this important finding will be discussed further below.

NCHS also funded a pilot project in Utah to assess the ability of physicians to provide more timely and higher quality data for death certificates to the Utah Department of Health by entering and submitting data via the hospital EHR. The project showed that using the EHR could increase the number of unique ICD10 codes on death certificates. The greatest challenge

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[13] The messaging IG for vital records death reporting is available for comment until 11 August 2015; the CDA IG for birth and fetal death reporting is available for comment until 13 February 2017 August 2015; and the CDA IG for vital records death report is available for comment until 10 March 2017. All DTSUs are available at: http://www.hl7.org/dstucomments/.

[14] These supplements are the Birth and Fetal Death Reporting-Enhanced (BFDR-E) and the Vital Records Death Reporting (VRDR), which are available at http://www.ihe.net/uploadedFiles/Documents/QRPH/IHE_QRPH_Suppl_BFDR-E.pdf and http://www.ihe.net/uploadedFiles/Documents/QRPH/IHE_QRPH_Suppl_VRDR.pdf, respectively.

[15] The Minnesota project also included participation by MDH staff in the 2013 and 2014 IHE Connectathons to explore methods of extracting, packaging, and transmitting data from an EHR-S to the MCH.

identified in the project was accurately matching and merging data received from hospital physicians via the EHR with data received from funeral directors via the health department's EDRS.[16] Additional findings and recommendations from the Minnesota and Utah pilot projects are included in Appendix B.

Certification

Certification is a specific type of conformity assessment, which is a process to demonstrate that "specified requirements relating to a product, process, system, person or body are fulfilled." (ISO/IEC 2004) The distinguishing feature of certification as a type of conformity assessment is its use of third party, independent testing and verification to ensure that the product, process, or system complies with previously identified criteria or specifications intended to reflect the ability of the process or product to serve its purpose. Certification is one potential tool among others to improve system performance.

With the passage of the Affordable Care Act (ACA) and its requirements for "meaningful use" (MU) and certification of EHR-S, the U.S. Department of Health and Human Services (USDHHS) developed a certification program for MU aspects of EHR-S. Figure 3 depicts the current USDHHS MU certification program, which is managed by the Office of the National Coordinator for Health Information Technology (ONC).[17,18]

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[16] The Utah project also identified the need for better infrastructure for reporting death from physicians to the health department; a significant impact of EHR use on the death certification workflow, especially for funeral directors; and the need for thorough testing of the system before introducing it into daily use.

[17] The first major effort to certify EHR-S in the United States was undertaken by the Certification Commission for Health Information Technology (CCHIT). CCHIT developed a comprehensive, voluntary system for EHR-S certification, which was designed to address both overall EHR-S infrastructure and specific content components and to become more stringent over time through the addition of more specific requirements.

[18] USDHHS released the third stage of MU requirements for public comment in March 2015. These MU requirements include several ways that a health care organization or provider can provide MU of health information, including the submission of data to public health and clinical care registries. (FR 2015)

Figure 3. USDHHS Office of the National Coordinator for Health Information Technology Certification Program for Meaningful Use of Health Information
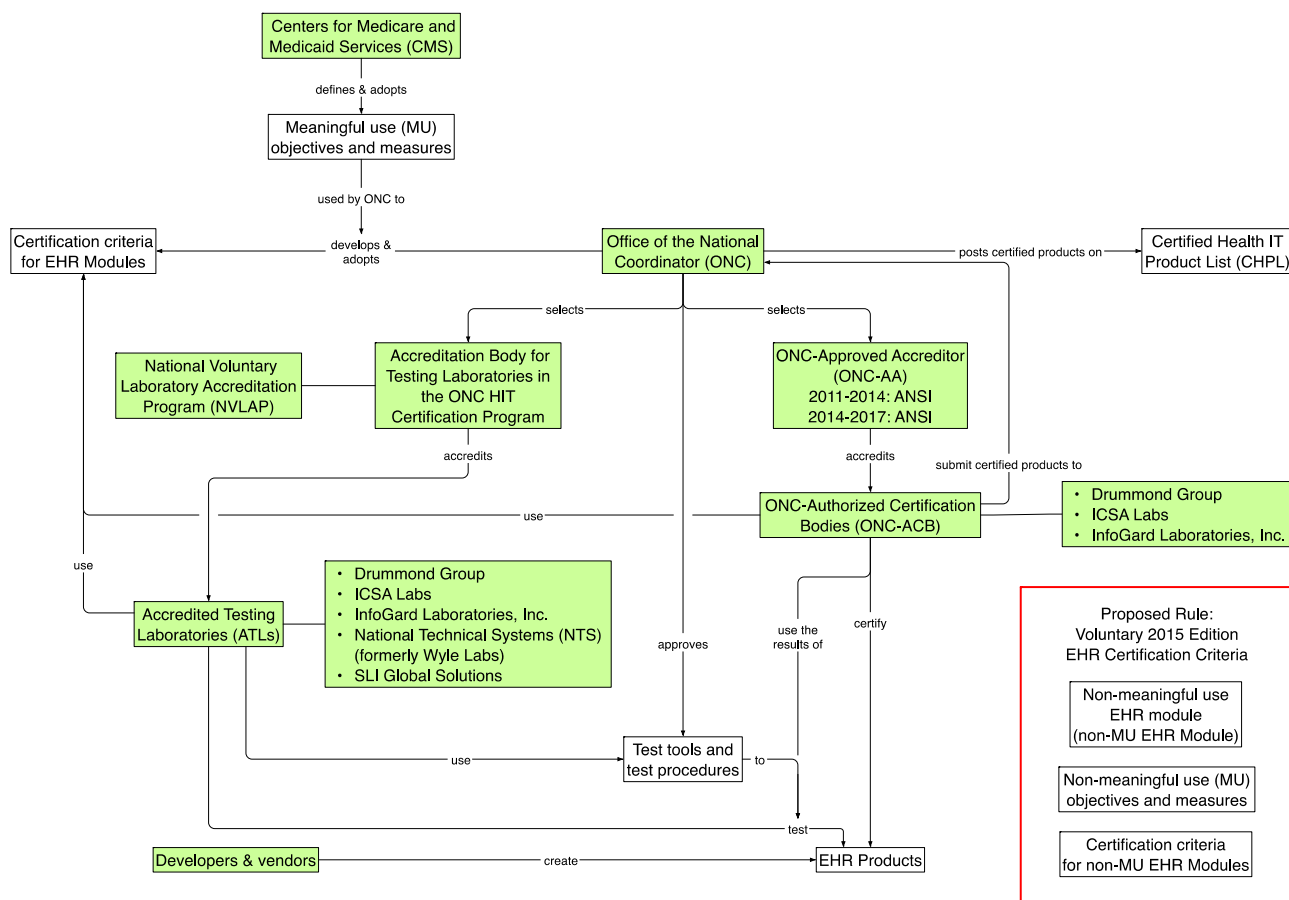
Interviews

Telephone interviews were conducted with 42 experts: 9 state health department (SHD) vital records managers and informaticians, representing 5 separate SHDs; 9 health care providers, 2 health care organization representatives, and 2 medical informaticians; 4 EHR-S and 3 EVRS vendor representatives; 6 certification experts; and 7 additional experts.[19] Interviews were loosely structured, with questions focusing on potential barriers to enhancing EHR-S to generate and exchange data with EVRS, potential facilitators, and next steps. The organizational affiliations of the experts interviewed are listed in Appendix C.

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[19] One consultant took the lead in asking questions for each interview, and the other consultant took the lead in taking notes. The note-taking consultant later summarized the notes, and the other consultant then reviewed and edited the notes.

What were three main things that we learned from our interviews?

What's the goal?

Respondents typically pointed out that certification of EHR-S capacities for generating data for and exchanging data with EVRS specifically, and enhancing EHR-S to generate and exchange data with EVRS more generally, should not be regarded as goals in and of themselves. Rather, we were told the clearly stated goals for proceeding need to be improving the quality[20]—that is, accuracy, completeness, and timeliness—of vital records data, delivered through state and national systems that are economical and efficient.

EHR-S/EVRS certification and EHR-S enhancements for generating and exchanging data with EVRS were typically viewed by respondents as largely untested potential means to achieving the major goals of timely, accurate, and complete vital records data.

Where's the evidence?

State health department respondents, health care providers, and informaticians often expressed skepticism that EHR-S/EVRS certification specifically and EHR-S enhancements for generating and exchanging data with EVRS more generally would either: (a) necessarily improve vital registration workflows within hospitals, between hospitals or medical examiners and funeral directors, and between hospitals and SHDs; or (b) result in improved vital records quality together with improved efficiency and economy.

Respondents often viewed EHR-S/EVRS certification and EHR-S enhancements for generating and exchanging data with EVRS as essentially hypotheses that need to be thoroughly tested, rather than as already proven assumptions. Similarly, respondents often suggested and emphasized the importance of carefully planned and executed pilot projects to empirically test both certification and EHR-S enhancements for EVRS. Finally, respondents also pointed out that evidence relating to EHR-S/EVRS certification and EHR-S enhancements for EVRS needs to be considered separately for births and fetal deaths, on the one hand, and deaths, on the other hand.

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[20] In this 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.

Where's the market?

EHR-S vendors, hospitals, and SHDs usually expressed little interest in EHR-S/EVRS certification and EHR-S enhancements for EVRS. EHR-S vendors pointed to the relatively small market to support development and implementation of EHR-S enhancements for EVRS, the low priority given to vital records by hospitals, and the lack of interest in EHR-S enhancements for EVRS expressed by SHDs. Hospitals point to the low priority of vital records, compared to the much higher hospital priorities of EHR-S enhancements for improving health care quality and patient safety.[21] SHDs point to the substantial investments that have already been made in developing and implementing EVRS for births and for deaths, the costs and uncertainties of implementing another major change in electronic systems, and the lack of federal or state financial support for developing and implementing EHR-S enhancements for EVRS.

What else did we learn about perceived barriers, facilitators, and next steps for EHR-S/EVRS certification and EHR-S enhancements for EVRS?

The three main things that we learned from our interviews may appear to paint a bleak and unpromising picture for the future of EHR-S/EVRS certification and EHR-S enhancements for EVRS. However, when we analyzed our interviews and categorized what our respondents said, we realized that the barriers mentioned by respondents could usually be matched with facilitators mentioned by themselves or other respondents.

The barriers, facilitators, and next steps mentioned by respondents are catalogued in Appendix D (barriers) and Appendix E (facilitators and next steps). These tables are organized by type of barrier, facilitator, or next step: general; planning and stakeholder engagement, including business case and marketing; national and state policies, including mandates and incentives, and state variability; data quality; workflows; health information technology, including EHR-S/EVRS design, EHR-S/EVRS implementation, and certification. In addition, Appendices D and E also indicate whether each barrier or facilitator affects data providers (hospitals or physicians), vendors (EHR-S or EVRS), and state health departments. The impacts of each barrier or facilitator are also described.

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[21] One hospital-based health care provider emphasized the importance of high quality birth data to health care providers, patients, hospitals, Centers for Medicare and Medicaid Services, and health departments, among others, for improving maternal and child health.

In the following Table 1, we abstracted the most important reported barriers from Appendix D and their matching reported facilitators from Appendix E. In the following Table 2, we summarized the most important reported barriers and reported facilitators separately for data providers, vendors, and SHDs.

Table 1. Summary of major reported barriers and facilitators for improving the ability of EHR-S to generate and exchange data with EVRS[22]

Type	Barrier	Facilitator
Planning and stakeholder engagement		
Planning	-Systematic testing, development, and implementation of EHR-S/EVRS[23] requires long-term strategic planning and phased implementation over 10-15 years	-Developing realistic long-term strategic plan, with intermediate steps, for EHR-S/EVRS development and implementation
Stakeholder engagement	-No customer interest in EHR-S/EVRS	-Engaging EHR-S/EVRS stakeholders through advisory committee
Business case and marketing	-No empirical value case for EHR-S/EVRS, hence no financial return for investing in development	-Developing viable business case for data providers, vendors, and SHDs to design, develop, and implement EHR-S/EVRS, including value of data that would be available for various uses
National and state policies		
Mandates and incentives	-Lack of financial incentives for developing and adopting EHR-S/EVRS	-Providing incentives for EHR-S/EVRS development and implementation
State variability	-State variability in vital records data items, and variability in required data items among different programs and in different states	-Surveying and then minimizing jurisdictional variation in birth, death, and fetal death requirements
Data quality	-Lack of evidence of vital records data quality and relevance to clinical practice	-Configuring EHR-S/EVRS to support quality improvement programs
Workflows	-Complicated workflows for vital registration	-Surveying data provider workflows to identify current inefficiencies and potential improvements feasible with and without EHR-S/EVRS
Health information technology		
EHR-S/EVRS design	-State variability in vital records data items, and variability in required data items among different programs and different states	-Conceptualizing EHR-S/EVRS solutions not requiring separate configurations for all EHR-S and EVRS now operating in all vital records jurisdictions
	-No empirical business case for EHR-S/EVRS	-Implementing EHR-S/EVRS pilot projects for births, deaths, and fetal deaths with planned implementation variation and common metrics
EHR-S/EVRS implementation		-Learning from mistakes of EHR-S implementation
Vital records data exchange	-Lack of SHD readiness for receiving HL7 messages	-Developing realistic long-term plan (10-15 years) for SHD implementation of HL7 -Developing single national approach for SHD cross-program approach to HL7 implementation
Certification	-Certification problematic: costly; diverts resources from important EHR-S development priorities; requires ongoing resources; data lacking about whether certification improves data quality	-Exploring other conformity assessment options as alternatives to certification -Developing certification and/or other conformity assessment tiers

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[22] Based upon interviews with 42 experts. See Appendix C for a list of the experts' organizational affiliations.
[23] In the table, "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, fetal deaths, and deaths, i.e., the EHR-S and EVRS exhibit interoperability. (HIMSS. Definition of interoperability [Internet], 2013. Available at: http://www.himss.org/library/interoperability-standards/what-is-interoperability.

Table 2. Summary of major reported barriers and facilitators for improving the ability of EHR-S to generate and exchange data with EVRS, organized by data providers, vendors, and state health departments[24]

	Type	Barrier	Facilitator
Data providers			
Hospitals	Policies: mandates and incentives	-Lack of financial incentives for implementing EHR-S/EVRS[25]	-Providing incentives for implementing EHR-S/EVRS
	Market for EHR-S/EVRS	-EHR-S/EVRS low priority for development compared to other EHR-S components	-Providing incentives to EHR-S and EVRS vendors to develop and implement EHR-S/EVRS
	HIT: EHR-S/EVRS design	-EHR-S cannot populate all EVRS data items	-Designing EHR-S/EVRS to minimize unstructured data
	HIT: certification	-Certification does not address complex workflow problems	-Surveying and analyzing data provider workflows to identify current inefficiencies and potential improvements feasible with and without EHR-S/EVRS
Physicians	Workflow	-Different data needed for clinical practice, patient safety, quality improvement, and vital records	-Configuring EHR-S/EVRS to support quality improvement programs
	HIT: certification	-Certification does not address complex workflow problems	-Surveying data provider workflows to identify current inefficiencies and potential improvements feasible with and without EHR-S/EVRS
Vendors			
EHR-S	Policies: mandates and incentives	-Lack of financial incentives for developing and implementing EHR-S/EVRS	-Providing incentives to EHR-S and EVRS vendors to develop and implement EHR-S/EVRS
	Policies: state variability	-State variability in vital records data items	-Surveying and then minimizing jurisdictional variation in birth, death, and fetal death data items
	Market for EHR-S/EVRS	EHR-S/EVRS low priority for development compared to other EHR-S components	-Providing incentives for developing and implementing EHR-S/EVRS
	Market for EHR-S/EVRS	-No customer interest in EHR-S/EVRS	-Providing incentives for developing and implementing EHR-S/EVRS
	HIT: EHR-S/EVRS design	-Absence of structured data for some vital records data items	-Designing EHR-S/EVRS to minimize unstructured data
	HIT: EHR-S/EVRS design	-EHR-S cannot populate all EVRS data items	
	HIT: vital records data exchange	-Lack of readiness for receiving HL7 messages	-Developing long-term plan for SHD implementation of HL7
	HIT: certification	-Certification problematic	-Exploring other conformity assessment options as alternatives to certification -Developing certification and/or other

[24] Based upon interviews with 42 experts. See Appendix C for a list of the experts' organizational affiliations.
[25] In the table, "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, fetal deaths, and deaths, i.e., the EHR-S and EVRS exhibit interoperability. (HIMSS. Definition of interoperability [Internet], 2013. Available at: http://www.himss.org/library/interoperability-standards/what-is-interoperability.

Type		Barrier	Facilitator
		conformity assessment tiers	
EVRS	Policies: mandates and incentives	-Lack of financial incentives for developing and implementing EHR-S/EVRS	-Providing incentives for developing and implementing EHR-S/EVRS
State health departments			
	Policies: mandates and incentives	-Lack of financial incentives for developing and implementing EHR-S/EVRS	-Providing incentives for developing and implementing EHR-S/EVRS
	Data quality	-Lack of evidence of EHR-S data quality and that EHR-S/EVRS will improve data quality	-Implementing EHR-S/EVRS pilot projects with planned implementation variation and common metrics
	HIT: EHR-S/EVRS design	-EHR-S cannot populate all EVRS data items	
	HIT: vital records data exchange	-Lack of readiness for receiving HL7 messages	-Developing long-term plan for SHD implementation of HL7

Abbreviations HIT: Health information technology; Policies: National and state policies

What are the roadmap and routes to enhancing EHR-S to generate and exchange data with EVRS?

Project development life cycle framework

The DHHS Enterprise Performance Life Cycle (EPLC) is adapted here as the framework to describe the roadmap and routes for enhancing EHR-S to generate and exchange data with EVRS. The EPLC is intended by DHHS as a "solid [information technology (IT)] project management methodology that incorporates best government and commercial practices through a consistent and repeatable process, and provides a standard structure for planning, managing and overseeing IT projects over their entire life cycle."[26] The DHHS EPLC has been adapted and extensively used by CDC and NIH.[27,28] Although the EPLC as designed by DHHS includes ten life cycle phases, the project development life cycle (PDLC) used as the framework here includes nine phases. These phases and their key components are described in Table 3.

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[26] U.S. Department of Health and Human Services. Enterprise Performance Life Cycle: Overview Document. Washington, D.C: 2012 Jul 18. Available at: http://www.hhs.gov/ocio/eplc-lifecycle-framework.pdf. Accessed 2015 Apr 17, p. 3.

[27] Centers for Disease Control and Prevention. Welcome to the CDC uniform process [Internet]. Available at: http://www2.cdc.gov/cdcup/#.VTGXja1Vikq. Accessed 2015 Apr 17.

[28] National Institutes of Health. Enterprise Performance Life Cycle (EPLC) and the NIH Enterprise Architecture [Internet]. Last updated: 2013 Mar 1. Available at: https://enterprisearchitecture.nih.gov/pages/EPLCandEA.aspx. Accessed 2015 Apr 17.

Table 3. Project Development Life Cycle

1. Project Initiation
   - Need for and goals of project
   - Leadership
   - Governance
   - Stakeholders
2. Project Concept & Planning
   - High level requirements
   - Project charter
   - Project management plan
3. Requirements Analysis
   - Engage stakeholders
   - Determine stakeholder data needs
   - Describe current VR process (data, workflow, infrastructure)
   - Assess performance of current system
   - Develop requirements for improved VR system
4. Design
   - Identify and review design options
   - Select option(s) for development
5. Development
   - Develop VR process option(s) (policy, data, & workflow changes; apps; IT infrastructure)
6. Testing
   - Develop plan for testing VR option(s)
   - Identify suitable settings for testing option(s)
   - Test and assess option(s)
   - Select option(s) for implementation
7. Implementation & Deployment
   - Develop plan for implementing VR option
   - Select sites for implementation
   - Train staff and provide support for implementation
   - Implement and test system(s) in production environment
   - Identify and address implementation issues
8. Operations & Maintenance
   - Support ongoing VR systems operations
   - Monitor performance of VR system
9. Evaluation & Improvement
   - Periodically evaluate and modify VR system to ensure optimal performance

Sources: USDHHS 2012, PHII 2013

Relationship of project development life cycle framework to facilitators

Selected facilitators described by our respondents for improving the ability of EHR-S to generate and exchange data with EVRS are arrayed in the project development life cycle framework in Table 4.[29] The facilitators included in Table 4 pertain only to the initial six phases of the PDLC framework, due to what was and was not mentioned by respondents. The

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[29] The facilitators included in Table 4 constitute a subset of those in Tables 1 and 2 and in Appendix E.

facilitators in Table 4 also do not describe all actions needed within the PDLC for conducting a project for improving the ability of EHR-S to generate and exchange data with EVRS.

Table 4. Facilitators of routes for enhancing EHR-S to generate and exchange data with EVRS

Type of facilitator	Project initiation	Project concepts and planning	Requirements analysis	Design	Development	Testing
Plan and stakeholder engagement						
Stakeholder engagement	-Convene and engage stakeholders[30] -Appoint steering committee	-Convene and engage stakeholders -Steering committee review master plan	-Steering committee revise master plan	Steering committee revises master plan		
Plan	Plan as systems problem with multiple layers	Develop short-, mid-, and long-term master plan for EHR-S/EVRS, with communications plan[31]	-Conduct and analyze surveys[1]	-Plan jurisdictional pilots with planned variation and common metrics		
Business case and marketing		Plan surveys	Conduct surveys	Design business case components		
Key decisions	Choose steering committee members	Develop master plan	-Revise master plan -Plan jurisdictional pilots	-Choose design alternatives -Plan pilots -Choose mandates and incentives -Plan changes to data provider workflows		
National and state policies						
Mandates and incentives		Assess feasibility of mandates and incentives: (1) financial incentives; (2) VSCP mandate; (3) Meaningful Use mandate; (4) PHAB standards	Evaluate options for mandates and incentives	Choose mandates and incentives		
State variability		Plan surveys	-Conduct surveys -Evaluate state variability and options for minimizing variability			

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[30] Stakeholders include SDH registrars and informaticians, EHR-S and EVRS vendors, clinicians, data providers, professional associations.
[31] Short-term plan includes surveys of (1) jurisdictional and data provider workflows for births, fetal deaths, and deaths; (2) jurisdictional HL7 readiness; (3) jurisdictional specific data items for births, fetal deaths, and deaths.

Type of facilitator	Project initiation	Project concepts and planning	Requirements analysis	Design	Development	Testing
Data quality			-Identify birth, fetal death, and death data items most likely to have conflicting EHR-S data	Configure pilots to support quality improvement programs		
Workflows		Plan surveys	-Conduct surveys -Identify workflow inefficiencies	Evaluate and choose options for re-engineering provider workflows		
Health information technology						
EHR-S/EVRS design		Conceptualize solutions (1) not requiring separate configurations for each jurisdiction, (2) supporting physician and hospital quality improvement programs	Develop requirements for bi-directional EHR-S/EVRS meeting clinical needs	-Evaluate major design alternatives: (1) single national platform; (2) separate products for top ten EHR-S vendors; (3) separate platforms for each jurisdiction -Design to minimize double entry of data and unstructured data		
EHR-S/EVRS implementation				Learn from mistakes of EHR-S implementation	-Draft implementation guides -Leverage other CDC tools to facilitate implementation	-Implement EHR-S/EVRS[32] pilots with planned implementation variation and common metrics
Vital records data exchange		Develop 5-10 year plan for jurisdictional HL7 implementation	Conduct surveys	Develop national approach to cross-programmatic implementation of HL7	Provide CDC support for SHD adoption of HL7	Provide CDC support for SHD implementation of HL7
Certification		Learn from Meaningful Use certification	Explore conformity assessment option alternatives to certification	Develop certification and/or other conformity assessment tiers		

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[32] In the table, "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, fetal deaths, and deaths, i.e., the EHR-S and EVRS exhibit interoperability. (HIMSS. Definition of interoperability [Internet], 2013. Available at: http://www.himss.org/library/interoperability-standards/what-is-interoperability.

Roadmap and routes

Based on the findings of our interviews, we developed a roadmap with examples of potential routes for enhancing EHR-S to generate and exchange data with EVRS (Figure 4). Other potential routes exist, and actual routes would be developed through completion of the requirements analysis and other phases of the PDLC.

Figure 4. Routes for Enhancing EHRS to Generate and Exchange Data with EVRS
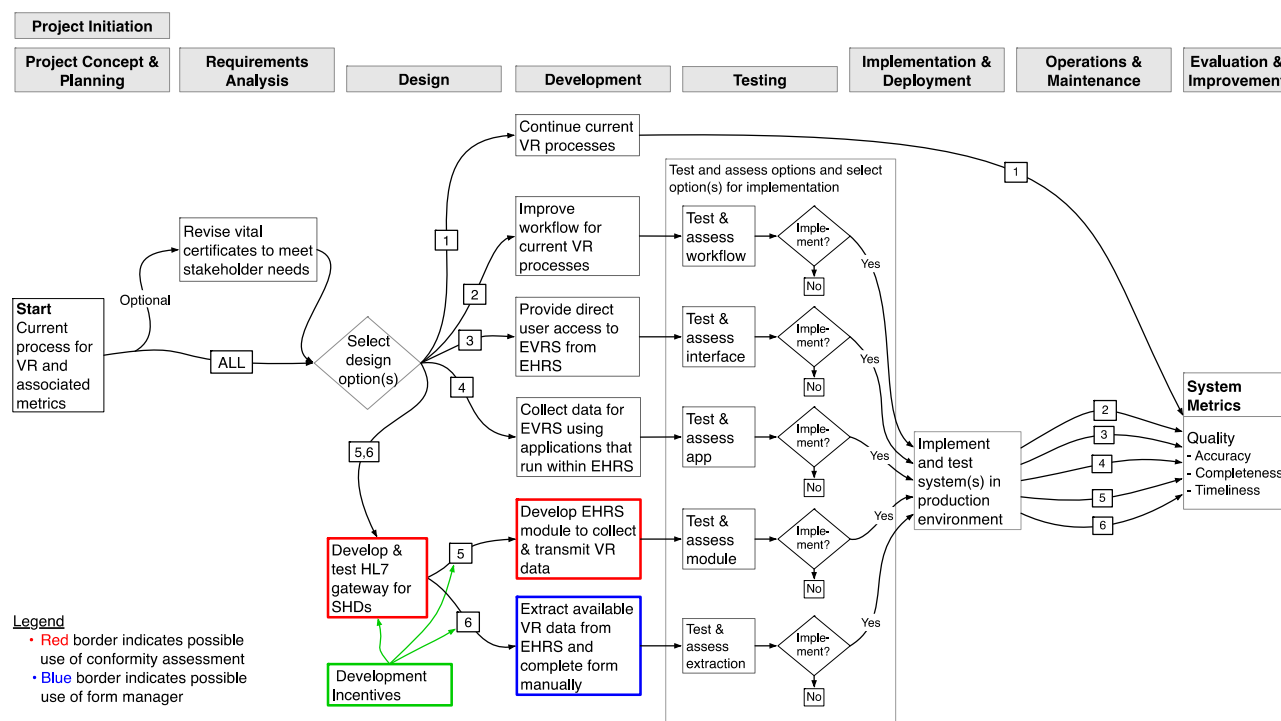
Roadmap overview

The phases of the PDLC, which provide the overall structure for the roadmap, are listed at the top of the roadmap. Starting from the left with the current VR process, six routes proceed to the right, which represent different approaches to enhancing EHR-S to generate and exchange data with EVRS. All routes share the same road for the initial four phases of the PDLC with an optional side-trip to revise current vital certificates to better meet stakeholder needs. This initial shared route includes engaging stakeholders and determining their information needs; describing the current VR process (data, workflow, infrastructure); assessing the performance of the current VR system; and developing requirements for improving the VR system.

At the design phase, the six routes diverge for the development and testing phases. The final step of the testing phase is the selection of one or more routes for reaching the final destination of improved VR system metrics.

All routes include project initiation, development of the project concept and plan, requirements analysis, and the review and selection of EHR-S/EVRS design options for development. These four phases lay the foundation for the remainder of the trip and the decision of which route or routes should be pursued.

Route 1: Continue current VR processes for data collection and transmission

Route 1 represents a decision at the end of the design phase to continue the current process for VR, including existing policies, procedures, and workflows. This decision would be based on completion of a requirements analysis, including discussions with stakeholders, identification of the requirements for VR data collection and transmission, and an analysis of the current VR process and its performance. Such a decision would acknowledge that the existing VR system is doing a satisfactory job of meeting stakeholder needs, that the existing system should continue in place while other routes are explored, or that there are insufficient resources or political will to modify the existing system.

Route 2: Improve workflow for current VR processes for data collection and transmission

Route 2 is a variation of Route 1 with added workflow improvements. It recognizes the fundamental soundness of, or need to continue, existing VR processes for data collection and transmission, while acknowledging that specific changes to the VR system's workflow identified during the requirements analysis could improve the system's performance. Such changes might occur at the provider, state, or national level, depending on the findings of the requirements analysis.

Route 3: Provide direct user access to the EVRS from the EHR-S

Route 3 responds to suggestions made during our interviews that a straightforward approach to addressing the "integration" of EHR-S and EVRS would be to provide direct access to the EVRS through the EHR-S and its user interface. This route might be implemented through an

EHR-S menu choice for completing a birth or death certificate, which would launch the EVRS and potentially login the user based on EHR-S login credentials. The user would enter all required data directly through the EVRS user interface: no data for the EVRS would be derived from the EHR-S. Thus, some birth or death certificate-related data might be entered twice and be present in both the EHR-S and EVRS, but this route would ensure that all VR data would be collected using all of the NCHS edit specifications incorporated into each state's EVRS. This route would not require EHR-S vendors to develop VR modules or applications for their systems, but would require building the functionality to launch an external application.[33] Route 3 would also obviate the need for state health department capability to receive and parse VR-related HL7 messages.

Route 4: Collect data for EVRS using third party application (app) that runs "within" EHR-S environment

Route 4 also responds to suggestions made during the interviews. This route would involve development of one or more third party "apps" for each of the major EHR-S that would interface directly with state or local EVRS to provide needed data.[34] For those EHR-S that adopt the Fast Healthcare Interoperability Resources (FHIR) version of HL7, this route could take advantage of the SMART platform—and associated profiles and apps—currently under development and testing for the FHIR version of HL7.[35] These apps could include the NCHS edit specifications for vital certificates and would allow providers to enter data for vital certificates through their EHR-S in a structured environment. Like Route 3, Route 4 would not require EHR-S vendors to develop VR modules or applications for their systems and would also obviate the need for state health department capability to receive and parse VR-related HL7 messages.

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[33] Healthcare organizations may prohibit the use of external applications not under their control, including web browsers, for security reasons.

[34] The security of third-party applications would be a major concern for healthcare organizations before authorizing their use.

[35] HL7. FHIR: Welcome to FHIR [Internet]. Available at: http://www.hl7.org/FHIR/. Accessed: 2015 May 3.

Route 5: Develop EHR-S module to collect and transmit VR data

Route 5 requires each EHR-S vendor to develop one or more modules or other EHR-S-based means for collecting and transmitting data for vital records and state health departments to develop or otherwise have available gateways for receiving and parsing HL7 messages. Several HL7 standards and profiles and IHE technical framework supplements have been developed to facilitate the development of standards-based VR functionality within EHR-S.[36] Although this route does not require manual data entry into the EVRS or a third-party application, as do Routes 1-4, manual entry might still be needed for those data items not collected through delivery of care and recorded in the EHR-S. An additional challenge for this route and Route 6 below are the differing vital certificate data requirements for the states and the potential need for EHR-S vendors to interface their systems with multiple EVRS. Adopting Route 5 would be facilitated if SHDs harmonized their requirements toward a nationwide standard, as SHD immunization and cancer registries have done in recent years.

Route 6: Extract available VR data from EHR-S and complete form manually

Route 6 uses data available in EHR-S to partially complete vital certificates and then relies on a person—for example, a birth clerk—to complete data items that cannot be completed with available EHR-S data. This route includes "retrieve form for data capture" (RFD)[37] and associated form managers (Figure 5).[38] Once data needed for a certificate are complete, the final step in RFD uses a form receiver to transform data into an HL7 message or CDA document that is transmitted to the state health department. Alternatively, the completed form can be "consumed directly" by the SHD's EVRS, assuming that the EVRS is able to handle the form. Other vehicles that don't rely on RFD might also be available for navigating Route 6.

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[36] These profiles, standards, and technical frameworks address the collection of data for vital records through an EHR-S and the message content and structure for transmitting VR-related data.

[37] For more information about RFD, see IHE. Retrieve Form for Data Capture [Internet]. Available at:
 http://wiki.ihe.net/index.php?title=Retrieve_Form_for_Data_Capture. Last updated: 2013 Nov 12. Accessed: 2015 May 1.

[38] An example of an RFD for collecting birth certificate data is Epic's Stork Obstetrics/L&D Information System. See Epic. Specialties: Deeper Functionality: Specialty Add-ons [Internet]. Available at: http://www.epic.com/software-specialties.php. Accessed: 2015 May 1. (Personal communication, Michelle Williamson, NCHS, June 2015)

Figure 5. Use of Retrieve Form for Data Capture (RFD) to Facilitate Birth Registration
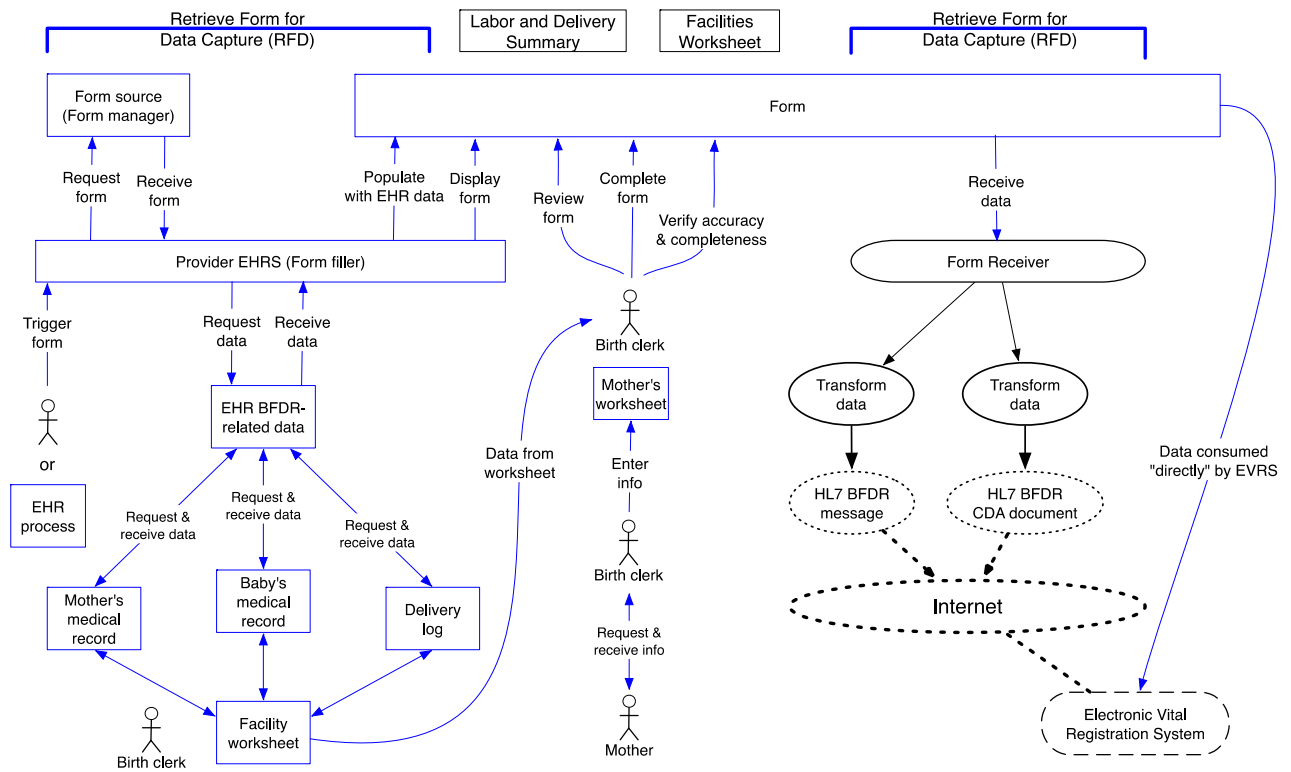
These routes differ in important ways that affect data collection, data management, data storage, and data transmission. Table 5 describes some differences among the routes, and Appendix F provides examples of activities required to complete the different routes.

Table 5. Conditions for Six Possible Routes for Enhancing EHR-S to Generate and Exchange Data with EVRS

	Route[39]					
	1	2	3	4	5	6
Condition						
Place of data entry	EVRS	EVRS	EVRS	App[40]	EHR-S	EHR-S[41]
Manual data entry	Yes	Yes	Yes	Yes	Maybe	Maybe
Double data entry	Yes	Yes	Yes	Maybe	No	No
Place of data storage	EVRS	EVRS	EVRS	EVRS	EHR-S	EHR-S

<u>Other considerations</u>

During the design phase for the routes described above, consideration should be given to these suggestions made during the interviews:

1. Use of a single nationwide platform for "interfacing" EHR-S vital records data with state EVRS. Such a single platform—akin to a nationwide health information exchange— might be able to address the variation among EHR systems, EVR systems, and individual state vital records data requirements. The Public Health Community Platform (PHCP)[42] may be a nascent example of such a platform.

2. Development of separate interfaces for each of the EHR systems with the largest market shares. These interfaces would present a common interface to EVR systems and facilitate EVR systems' access to "standardized" EHR-S data, thereby reducing the need for SHDs to work with multiple EHR-S.

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[39] Routes:
    1 = Continue current VR processes
    2 = Improve workflow for current VR processes
    3 = Provide direct user access to EVRS from EHR-S
    4 = Collect data for EVRS using applications that run within EHR-S
    5 = Develop EHR-S module to collect and transmit VR data
    6 = Extract available VR data from EHR-S and complete form manually
[40] Third-party EVR application (i.e., "App") accessed through EHR-S.
[41] Some data items are entered into and then extracted from EHR-S, and others are entered manually into a form using *request for data capture.* (See Figure 5 and the detailed description of Route 5 within the text.)
[42] Association of State and Territorial Health Officials. The Public Health Community Platform [Internet]. Available at: http://www.thephcp.org/. Accessed: 2015 May 3.

3. Other innovative approaches to reducing the variation of EHR system interfaces for EVR systems, and reducing the variation of EVR system interfaces for EHR systems. The goal would be to simplify the data exchange between EHR-S and EVRS and substantially reduce system development and maintenance costs for EHR-S and EVRS.

Certification and conformity assessment options

Conformity assessment is a process to demonstrate that "specified requirements relating to a product, process, system, person or body are fulfilled." (ISO/IEC 17000) It is intended to ensure buyers, sellers, consumers, and regulators that a product or system meets specific requirements intended to reflect its ability to serve its purpose. The activities that comprise conformity assessment can "include (1) a supplier's declaration of conformity, (2) sampling and testing, (3) inspection, (4) certification, (5) management system assessment and registration, (6) the accreditation of the competence of those activities, and (7) recognition of an accreditation program's capability." (NIST 2012)[43]

Conformity assessment can be "conducted by (1) a *first party*, which is generally the supplier or manufacturer [of the product or system]; (2) a *second party*, which is generally the purchaser or user of the product; (3) a *third party*, which is an independent entity that is generally distinct from the first or second party and has no interest in transactions between the two parties; and (4) the government, which has a unique role in conformity assessment activities related to regulatory requirements." (NIST 2012) Thus, the *independence* and the *level of rigor* of the assessment can vary according to the confidence in the product or service that is needed.[44] (See Figure 6.)

Standards are an integral part of conformity assessment activities and can have a significant effect on a conformity assessment program. Conformity assessment "form[s] a vital

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[43] See also American National Standards Institute. National conformity assessment principles for the United States, 2nd edition. Washington, DC: ANSI; 2007. Available at: http://publicaa.ansi.org/sites/apdl/Documents/News%20and%20Publications/Brochures/USCAP%202011.pdf.
[44] The required level of confidence is influenced by the level of risk that users are willing to accept for a non-compliant product or system, i.e, a product or system more likely to fail or not serve its purpose. Thus, a supplier's declaration of conformity (1st party) is generally used "when the risk associated with noncompliance is low; there are adequate penalties for placing noncompliant products on the market; and there are adequate mechanisms to remove noncompliant products from the market." In contrast, certification often focus on "product characteristics related to health, safety and protection of the environment," where risk associated with noncompliance is high. (NIST 2012)

link between standards (which define necessary characteristics or requirements) and the products [and systems] themselves." (NIST 2012)

Certification is a specific type of conformity assessment, which is distinguished by its use of third party, independent testing and verification to ensure that the product, process, or system complies with previously identified criteria or specifications intended to reflect the process's or product's ability to serve its purpose.

Figure 6. Risk and Conformity Assessment: How Much Confidence is Needed?
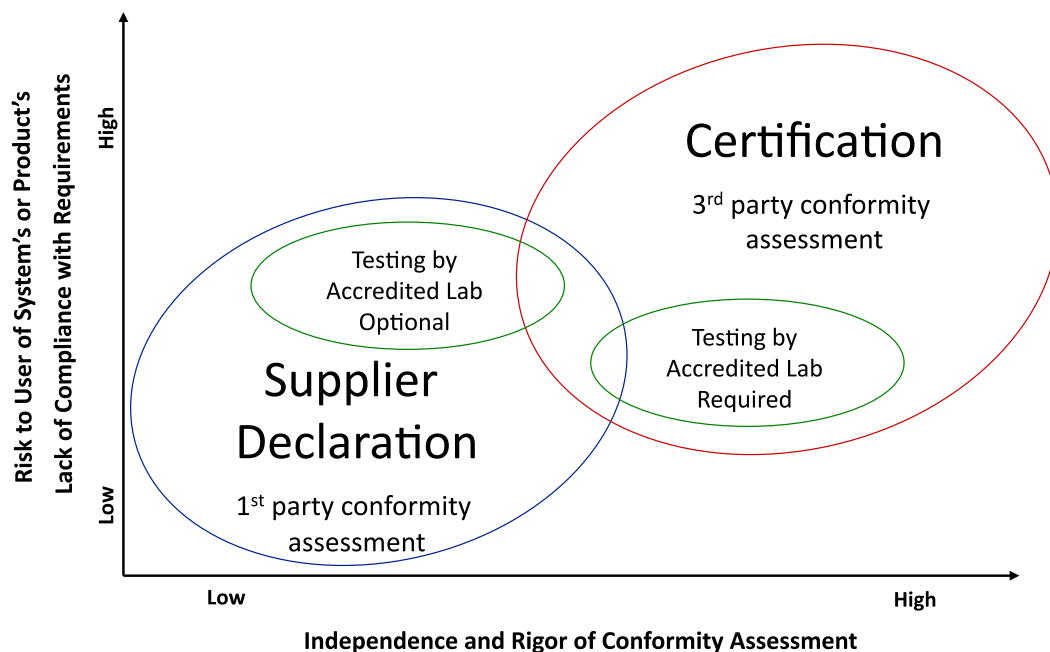
Adapted from Carnahan L. National Institute of Standards and Technology, 2015

Figure 7 presents a flow chart of the possible routes for conformity assessment of EHR-S to generate and exchange data with EVRS. The chart reflects repeated statements by those we interviewed that EHR-S vendors would only undertake certification of their systems for vital registration functionality if certification were mandated by state or federal government regulations or there were significant incentives provided for certification that made certification cost effective for vendors. Most vendors and most health care providers did not think that certification would provide a market advantage for a particular EHR-S, given the low priority of vital registration functions compared to EHR-S functions related to patient safety, quality improvement, meaningful use requirements, and patient management.

Given the current lack of mandates and incentives for certification and assuming that during the requirements analysis there is support for some form of conformity assessment, two possible options should be considered:

1. Including vital registration as (a) a public health registry under Stage 3 of meaningful use, or (b) in future editions of the ONC's EHR certification criteria.[45]

2. Demonstrating a marketing advantage for vendors through a declaration of conformity (DOC) for their EHR-S to the vital records requirements of the HL7 Public Health Functional Profile. A DOC would be much less costly and resource intensive than certification and might be easier to justify to EHR-S vendors.

Depending upon which of the six routes is chosen as detailed in Figure 4, certification or another type of conformity assessment for the EVRS should also be considered.

Figure 7. Routes for Conformity Assessment of EHRS to Generate And Exchange Data With EVRS

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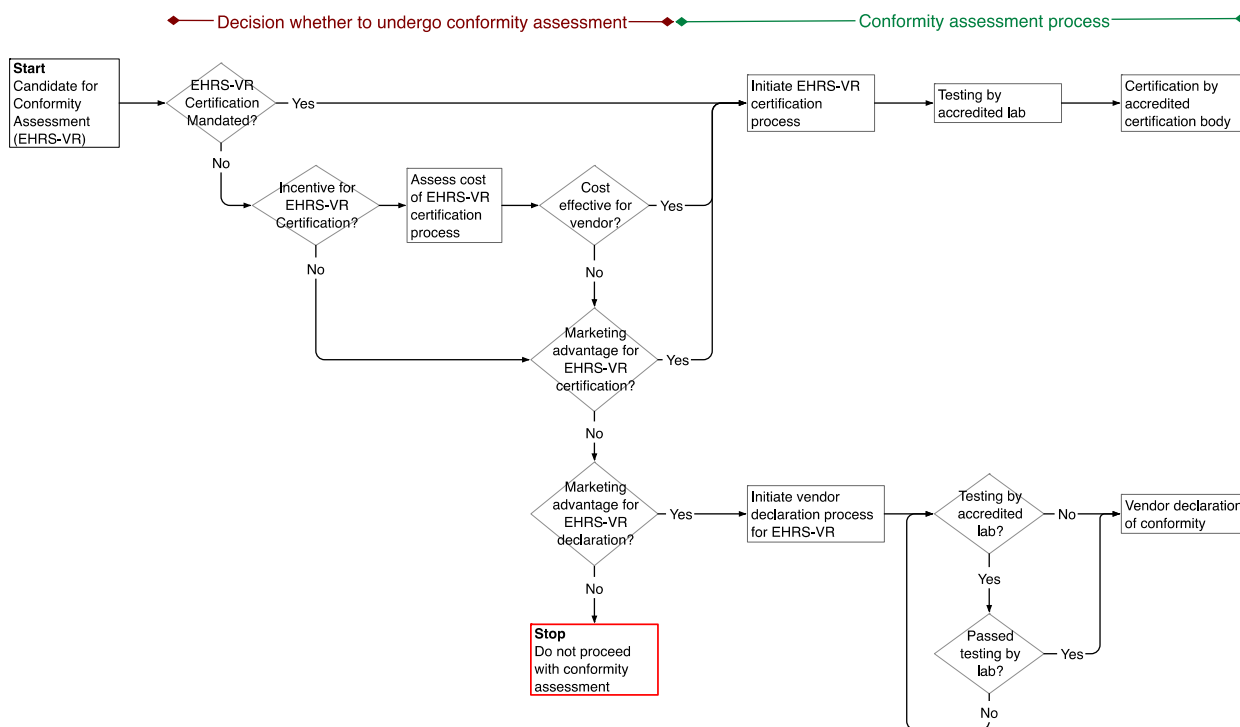
[45] HIMSS recently introduced "ConCert," a comprehensive interoperability testing and certification program for EHR and HIE systems. IT system certified by ConCert should be capable of exchanging health information securely and reliably with other certified systems. See HIMSS Innovation Center: Con/Cert [Internet]. Available at: http://www.himssinnovationcenter.org/concert. Accessed: 2015 May 1.

How should specific routes be chosen for enhancing EHR-S to generate and exchange data with EVRS?

The roadmap for improving the ability of EHR-S to generate and exchange data with EVRS includes 6 different routes. As indicated above, these routes are examples, and a PDLC process with ongoing stakeholder engagement may modify the routes described in Figure 4, delete some of those routes, or add new routes. Choices will need to be made among which routes to design, develop, test, implement, and deploy. Choosing among the routes will need to be mediated by the three sets of decisions, which are summarized below.

Births, fetal deaths, deaths

The example routes presented in Figure 4 could apply to births, fetal deaths, and deaths. However, NCHS, SHDs, and vendors will need to establish priorities about whether to pursue a particular route or routes for births or fetal deaths or deaths, or some combination. On the one hand, death certificates require far fewer medical data items and fewer in-hospital data sources than birth certificates, and the medical data for deaths can often be completed by the certifying physician and perhaps a nurse or clerk. As the Utah pilot project suggests, medical data about deaths lend themselves to inclusion as an EVRS interface accessed from the EHR-S (Route 3 or 4) or as an EHR-S module (Route 5). On the other hand, deaths data require linkage with demographic data collected by the funeral director, and in about 20% of deaths a medical examiner or coroner is responsible for medical data entered, introducing workflow complications for data transmittal to SHDs, which are absent from births.

Criteria for choosing among routes

Explicit criteria will need to be used to choose specific routes for design, development, testing, implementation, and deployment. Some criteria lend themselves to quantitative analyses, while others will rely largely upon prior experience. Using the criteria for choosing routes will not necessarily yield clear or definitive choices, and the criteria will need to be individually valued and balanced. Criteria that could be used to choose specific routes include:

- Maximizing quality—accuracy, completeness, and timeliness— and efficiency of vital registration systems;
- Minimizing costs of design, development, testing, implementation, and deployment;

- Maximizing speed of design, development, testing, implementation, deployment and maintenance;

- Maximizing likelihood of adoption by SHDs; and

- Maximizing the value proposition for SHDs, data providers, and vendors, including any secondary benefits for a particular route such as yielding data useful for hospital quality improvement activities.

What is an appropriate framework for proceeding with certification or other conformity assessment options?

Establishing and implementing certification or other types of conformity assessment as tools for improving the ability of EHR-S to generate and exchange data with EVRS are not one-time, one-off, one-and-done decisions and activities. As our respondents made clear to us, certification and other types of conformity assessment need to be recognized and planned for as ongoing activities requiring ongoing attention and ongoing commitment of resources. In conducting certification or other types of conformity assessment, the following issues will need to be considered:

- Governance: Will the certification or other type of conformity assessment process be governed by a federal agency such as NCHS, by a private organization such as CCHIT, by a stakeholder group such as NAPHSIS, or by some combination of government agencies and stakeholder groups?

- Financing: Who will pay to establish and maintain the governance structure and the actual costs of certification and conformity assessment? Will these costs be assumed by NCHS, assumed by vendors seeking certification and conformity assessment for their products, or some combination of government agencies and vendors?

- Laws, regulations, policies: Will certification and conformity assessment require federal or state changes to laws, regulations, or policies, as might be the case if certification or conformity assessment were mandated.

- Implementation: Who will monitor the actual implementation of certification and conformity assessment, and how will monitoring occur?

- Compliance: Once a product has been certified or received another form of conformity assessment, who will follow-up to assure that the product continues to comply despite any seemingly minor tweaks and modifications?

- Enforcement: If a certified product fails to comply following its implementation, who will be responsible for enforcing remedial actions?

- Review and feedback: Finally, who and how will the certification or conformity assessment be reviewed and evaluated over-time, and how will feedback occur to the governing body?

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NCHS 2003b. National Center for Health Statistics. U.S. standard report of fetal death. Revised: November 2003.

NCHS 2003c. National Center for Health Statistics. U.S. standard certificate of death. Revised: November 2003.

NCHS 2012a. National Center for Health Statistics. Birth Edit Specifications for the 2003 Proposed Revision of the U.S. Standard Certificate of Birth. Dated: July 2004; March 2005; Updated: July 2012.

NCHS 2012b. National Center for Health Statistics. Fetal Death Edit Specifications for the 2003 Revision of the U.S. Standard Certificate of Birth. Dated: May 2004; February 2005; Updated: 11 July 2012.

NCHS 2012c. National Center for Health Statistics. Death Edit Specifications for the 2003 Revision of the U.S. Standard Certificate of Death. Dated: May 2004; Updated: 18 February 2005.

NIST 2012. National Institute of Standards and Technology, U.S. Department of Commerce. Global Standards Information: Conformity Assessment [Internet]. Date created: September 03, 2009. Last updated: April 05, 2012. Available at: http://gsi.nist.gov/global/index.cfm/L1-5/L2-45. Accessed 22 April 2015.

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USDHHS 2012. U.S. Department of Health and Human Services. Enterprise Performance Life Cycle: Overview Document. Washington, D.C: USDHHS, 2012 July 18. Available at: http://www.hhs.gov/ocio/eplc-lifecycle-framework.pdf. Accessed 2015 Apr 17.

Appendix A. Materials reviewed for the project.

Vital Registration

General
National Association for Public Health Statistics and Information Systems. *More Better Faster: Strategies for Improving the Timeliness of Vital Statistics.* Dated: April 2013.

National Center for Health Statistics. Specifications for collecting and editing the United States standard certificates of birth and death -- 2003 revision. Dated: 11 October 2001.

Birth & Fetal Death
National Center for Health Statistics. U.S. standard certificate of live birth. Revised: November 2003.

National Center for Health Statistics. U.S. standard report of fetal death. Revised: November 2003.

National Center for Health Statistics. Birth Edit Specifications for the 2003 Proposed Revision of the U.S. Standard Certificate of Birth. Dated: July 2004; March 2005; Updated: July 2012.

National Center for Health Statistics. Fetal Death Edit Specifications for the 2003 Revision of the U.S. Standard Certificate of Birth. Dated: May 2004; February 2005; Updated: 11 July 2012.

National Center for Health Statistics. Mother's worksheet for child's birth certificate. Dated: Final 28 January 2004.

National Center for Health Statistics. Facility worksheet for the live birth certificate. Dated: Final 5 February 2004.

Death
National Center for Health Statistics. U.S. standard certificate of death. Revised: November 2003.

National Center for Health Statistics. Death Edit Specifications for the 2003 Revision of the U.S. Standard Certificate of Death. Dated: May 2004; Updated: 18 February 2005.

National Association of Public Health Statistics and Information Systems. Electronic death registration standards and guidelines, version 2.0. Dated: 2004.

Steering Committee to Reengineer the Death Registration Process, Division of Vital Statistics, National Center for Health Statistics, Centers for Disease Control and Prevention. Toward an Electronic Death Registration System in the United States: Report of the Steering Committee to Reengineer the Death Registration Process. American Journal of Forensic Medicine and Pathology. 1998(Sep);19(3):234-241.

EHR standards related to vital registration

HL7 – Clinical Document Architecture (CDA)

HL7 Public Health and Emergency Response Work Group. Implementation Guide for CDA Release 2: Birth and Fetal Death Report, Release 1: HL7 Draft Standard for Trial Use - U.S. Realm, January 2014.

HL7 Public Health and Emergency Response Work Group. HL7 Implementation Guide for CDA Release 2: Birth and Fetal Death Report, Release 1 - US Realm, Draft Standard for Trial Use, February, 2015.

HL7 Public Health and Emergency Response Work Group. Implementation Guide for CDA Release 2: Vital Records Death Report, Release 1: HL7 Draft Standard for Trial Use - U.S. Realm. 2013.

HL7 Public Health and Emergency Response Work Group. HL7 Implementation Guide for CDA Release 2: Vital Records Death Report, Release 1 (U.S. Realm) – March 10, 2015.

HL7 – Transmission of Health Information

[OBJ]

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Appendix B. Major findings and recommendations from the Minnesota and Utah pilot projects on the use of EHR-S to obtain data for vital records

NCHS has funded two pilot projects to explore the use of EHR-S to obtain data for vital records. The first project funded the Minnesota Department of Health (MDH) to work with a hospital to analyze the workflow for gathering data for completing the birth certificate and whether needed data were available from the EHR-S used by the hospital. The project also included participation by MDH staff in the 2013 and 2014 IHE Connectathons to explore methods of extracting, packaging, and transmitting data from an EHR-S to the MDH. Findings and recommendations from the project included the following:

Key Findings
MDH and hospitals support the adoption of e-birth records standards but lack the readiness to fully test and implement them. Stakeholders identified four key contributing factors to the lack of readiness:
1. Current policies do not support using e-birth records standards for collection of civil and medical information.
2. Current meaningful use and health reform incentives do not directly support implementation of e-birth records standards.
3. The IHE BFDR Profile was tested with only one EHR.
4. All birth records data are not available as structured data in the EHR.

The project identified numerous areas that were out of scope for the project but should be considered in future e-birth records standards work.
1. ... Additional research should occur to understand the relationship between e-birth records standards and the present quality of the data.
2. There is a need for standardization and general requirements for jurisdictions' EBRS. ... This is also a possible opportunity to leverage ONC certification of EBRS vendors and products.
3. This project focused on ... parts of interoperability ... but more work is needed to fully realize the need and benefits of interoperability for the birth registration process including the prenatal care providers and NCHS.

Recommendations
1. Align policies to support e-birth records standards.
2. Leverage activities of the Office of National Coordinator (ONC) and other federal agencies.
3. Continue expansion and testing of e-birth records standards.
4. Provide resources and technical assistance for readiness and implementation.
5. Demonstrate the value of and build stakeholder support for e-birth records standards.
6. Build Offices of Vital Records' e-birth records capacity.
7. Implement opportunities for improvement.

NCHS funded a second pilot project in Utah to assess the ability of physicians to provide more timely and higher quality data for death certificates to the Utah Department of Health by entering and submitting data via the EHR. These physicians worked for the largest supplier of health care within Utah, and the project showed that using the EHR could increase the number of unique ICD10 codes on death certificates. The greatest challenge identified in the project was accurately matching and merging data received from physicians via the EHR with data received from funeral directors via the Electronic Death Entry Network (EDEN), the health department's EDRS. The project also identified the need for better infrastructure for death reporting from physicians to the health department; a significant impact of EHR use on the death certification workflow, especially for funeral directors; and the need for thorough testing of the system before introducing it into daily use.

Appendix C. Organizational affiliations of experts interviewed for the project

Organization	Type of Expert
Albert Einstein College of Medicine	HCP
Association of State and Territorial Health Officials	Other
California Pacific Medical Center; California Maternal Quality Care Collaborative	HCP
CentriHealth; HL7 EHR WG	S&C
Cerner Corporation; Cerner Medical Informatics Institute	EHR-S Vendor
Certification Commission for Healthcare Information Technology	S&C
Chickasaw Nation Industries (Consultant)	Other
Cooper University Health Care	HCP
Epic Systems Corporation	EHR-S Vendor
Essentia Health	HCO
Fulton County, Georgia	HCP
Genesis Systems	EVRS Vendor
HL7 EHR WG	S&C
Kaiser Permanente	HCP
Louisiana State Health Department	HD
ManTech	EVRS Vendor
Minnesota Department of Health	HD
National Association for Public Health Statistics and Information Systems	Other
National Institute of Standards and Technology	S&C
Northwestern University Feinberg School of Medicine	MI
NYC Department of Health and Mental Hygiene	HD
Office of the National Coordinator or Health Information Technology	S&C
Public Health Informatics Institute	Other
Regenstrief Institute	MI
Society for Maternal–Fetal Medicine	HCP
University of Colorado School of Medicine; NCVHS (former member)	HCP
University of Pittsburg School of Medicine	HCP
Utah Department of Health	HD
Vanderbilt University School of Nursing	HCP
Vermont Department of Health	HD
VitalChek	EVRS Vendor

Abbreviations: HD: State or local health department staff; HCP: Health care provider; MI: Medical informatician; HCO: Health care organization staff; S&C: Standards and certification expert; EHR-S: Electronic health record system; EVRS: Electronic vital registration system

Appendix D. Reported barriers to enhancing EHR-S to generate and exchange data with EVRS[46]

Type of barrier	Data providers	Vendors	SHDs	Impacts
	47	48	49	
General				
-EHR-S/EVRS as systems problem with multiple layers, such as technical, implementation, and policy and political	X	X	X	EHR-S/EVRS cited as multi-faceted design, development, and implementation requiring broad-based thinking and collaboration
-Systematic testing, development, and implementation of EHR-S/EVRS requires long-term strategic planning and phased implementation over 10-15 years	X	X	X	EHR-S/EVRS cited as major systems change for data providers (hospitals) and SHDs, requiring national collaboration and long-term planning
Planning and stakeholder engagement				
-Minimal empirical value case for EHR-S/EVRS, hence no financial return for investing in development	X (hospitals)	X (EHR-S, EVRS)	X	Data providers (hospitals), vendors (EHR-S), and state health departments (SHDs) all cite lack of evidence-based case for development and implementation of EHR-S/EVRS
-EHR-S/EVRS low priority for development compared to other EHR-S components	X (hospitals)	X (EHR-S)		Vendors hesitant to invest in EHR-S/EVRS because of other, higher priority and more remunerative priorities for EHR-S functions. Data providers (hospitals) most interested in either mandated EHR-S components and/or EHR-S components with demonstrated link to patient safety.
-Minimal customer interest in EHR-S/EVRS		X (EHR-S, EVRS)		Vendors cite lack of SHD, hospital, and clinical interest in purchasing EHR-S/EVRS as major disincentive to its development.
-Minimal consultation on necessary conditions for EHR-S/EVRS success		X (EHR-S)	X	Vendors (EHR-S) and SHDs cite lack of sustained national consultation on conditions that might make EHR-S/EVRS successful
National and state policies				
Mandates and incentives				

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[46] Based on interviews with 42 experts.

[47] Data providers include prenatal care providers, physicians, medical examiners, hospitals, and funeral homes. Where appropriate, the specific type of provider is specified in individual cells.

[48] Vendors include EVRS vendors, EHR-S vendors, EVRS/EHR-S vendors, and forms managers. Where appropriate, the specific type of vendor is specified in individual cells.

[49] SHD: State health departments

Type of barrier	Data providers	Vendors	SHDs	Impacts
-Lack of financial incentives for developing EHR-S/EVRS		X (EHR-S, EVRS)	X	Vendors cite lack of funding for EHR-S/EVRS as major barrier to development. SHDs cite lack of funding for planning EHR-S/EVRS as major barrier
-Lack of financial incentives for adopting EHR-S/EVRS	X (hospitals)	X (EHR-S, EVRS)	X	Data providers (hospitals), vendors, SHDs cite lack of funding for adoption of EHR-S/EVRS as major barrier.
-Lack of financial disincentives for not adopting EHR-S/EVRS	X (hospitals)	X (EHR-S, EVRS)	X	Data providers (hospitals) and SHDs cite lack of financial disincentives and lack of legal mandate for failure to adopt EHR-S/EVRS as major barrier. Vendors cite lack of "regulatory drivers" and adoption mandates for EHR-S/EVRS as major barrier to development and adoption.
State variability				
-Periodic changes in U.S. standard certificates	X	X (EHR-S, EVRS)	X	Data providers (hospitals), vendors (EHR-S), SHDs reluctant to invest in EHR-S/EVRS development and implementation, knowing that U.S. standard certificates periodically change
-State variability in vital records data items, and variability in required data items among different programs and in different states		X		Vendors (EHR-S) cite state variability in vital records data items as major disincentive for developing EHR-S/EVRS
-Multiple patient identification methods for public health programs	X (hospitals)	X (EHR-S)		Data providers (hospitals) cite SHD use of different client identification methods for different programs as disincentive for adoption of any non-mandated EHR-S component, such as EHR-S/EVRS.
-Lack of consistent national approach		X (EVRS, EHR-S)		Vendors cite lack of consistent national approach to EHR-S/EVRS as major disincentive to investing in development.
Data quality				
-Lack of evidence of EHR-S data quality and that EHR-S/EVRS will improve data quality			X	SHDs cite concern that vital records data derived from EHR-S would not equal current vital records data quality
-Lack of evidence of vital records data quality and relevance to clinical practice	X (physicians)			Physicians express concern about quality of vital records data and regard vital records contents as largely irrelevant to their clinical and quality improvement needs
-Need to develop rules about how to reconcile conflicting EHR-S entries when transferring data to EVRS	X (physicians)	X (EHR-S)		Physicians express concern about how conflicting EHR-S entries would be reconciled in EHR-S/EVRS and express need for clear and consistent rules for reconciling conflicting entries
Workflows				
-Different data needed for clinical practice, patient safety, quality improvement, and vital records	X (hospitals, physicians)	X (EHR-S)		Data providers (hospitals, physicians) maintain that vital records data do not meet needs for clinical practice, patient safety, and quality improvement, and hence no interest in developing or implementing EHR-S/EVRS

Type of barrier	Data providers	Vendors	SHDs	Impacts
-Complicated workflows for vital records	X (hospitals)	X (EHR-S)		Data providers (hospitals) and vendors cite complicated hospital workflows and multiple data sources for completing vital records and express skepticism that EHR-S/EVRS could improve workflows
-Role of clerks in data completion	X (hospitals)			Data providers (hospitals) cite role of clerks in completing vital records, and express skepticism that EHR-S/EVRS could reduce role of clerks

Health information technology

Staff

Type of barrier	Data providers	Vendors	SHDs	Impacts
-Lack of staff support for developing EHR-S/EVRS			X	SHD HIT and vital records staff lack time, capacity, and expertise to develop EHR-S interface or gateway
-Staff and vendor turnover	X (hospitals, physicians)	X (EVRS)	X	Vendors (EVRS) and SHDs cite SHD HIT staff turnover as barrier to EHR-S/EVRS development. Data providers (hospitals, physicians) cite changes in EHR-S vendors as barrier to development of EHR-S/EVRS.

EHR-S/EVRS design

Type of barrier	Data providers	Vendors	SHDs	Impacts
-Multiple SHD program interfaces		X (EHR-S)		Vendors cite multiple public health program interfaces and program applications as barrier to development of EHR-S/EVRS
-Absence of structured data for some vital records data items		X (EHR-S)	X	Vendors and SHDs cite lack of completely structured data as barrier to EHR-S/EVRS
-EHR-S cannot populate all EVRS data items	X (hospitals)	X (EHR-S)	X	Data providers, vendors, SHDs question utility of EHR-S/EVRS if it cannot populate all vital records data items
-EHR-S multiple vendors with multiple interfaces		X (EVRS)	X	Multiple EHR-S within a single state could require SHDs to build multiple EHR-S/EVRS, increasing cost and effort.

Vital records data exchange

Type of barrier	Data providers	Vendors	SHDs	Impacts
-Lack of definitive requirements for data exchange		X (EVRS, EHR-S)		Vendors cite lack of definitive requirements for vital records data exchange with SHDs as barrier for developing EHR-S/EVRS.
-Health information exchanges (HIEs) not robust or consistent from state to state		X (EHR-S, EVRS)		Vendors cite absence of HIEs in some states and inconsistency in HIEs among states as barrier for developing EHR-S/EVRS, and prevents development of single national solution
-Lack of SHD readiness for receiving HL7 messages		X (EHR-S)	X	Fragmented approach to adopting HL7 messaging within SHDs, resulting from absence of cross-program HL7 gateways in SHDs

Certification (general)

Type of barrier	Data providers	Vendors	SHDs	Impacts
-Certification or validation needs to be recognized as social, political, and economic issue rather than technical issue				Certification constitutes multi-faceted issue that needs to be recognized as extending beyond fulfilling technical requirements

Type of barrier	Data providers	Vendors	SHDs	Impacts
-Certification problematic: costly; diverts resources from important development priorities; requires ongoing resources to test new EHR-S components and data elements; data lacking about whether certification improves data quality		X (EHR-S)		Vendors oppose certification for multiple reasons
-Certification does not address complex workflow problems	X (hospitals, physicians)			Skepticism that certification addresses or improves complex workflow issues, such as those with collecting birth record data from multiple sources
-Certification "fatigue"	X (hospitals)	X (EHR-S)		EHR-S vendors find certification requirements burdensome, and feel that ONC "over-reached" in the second stage of meaningful use. Hospitals disappointed with their experiences in using certified EHR-S, due to interoperability limitations in communicating EHR-S data with other hospitals using other EHR-S vendor products
-Certification "frustration"	X (physicians)			Physicians disappointed with functionalities and ease of use of certified EHR-S specifically and EHR-S generally
-SHDs fail to support or encourage certification		X (EHR-S)		
Certification (ONC)				
-ONC certification insufficiently rigorous, leading to inability of some certified EHR-S to communicate or exchange data	X	X (EHR-S, EVRS)		Resistance to certification results from perception of faulty ONC certification processes
-ONC certification managed by NIST expensive and tedious, not consistently appropriate for improving EHR-S		X (EHR-S)		Resistance to certification results from perception of faulty ONC certification processes
-Too many credentialing bodies, with absence of single, stable credentialing body		X (EHR-S)		

Appendix E. Reported facilitators for enhancing EHR-S to generate and exchange data with EVRS[50]

Type of facilitator	Data providers	Vendors	SHDs	Next steps	Impacts
General	[51]	[52]	[53]		
-Common features of widely adopted processes: process has value; process is harmonized				X	Needs to underlie all EHR-S/EVRS planning efforts
Planning and stakeholder engagement					
Planning					
-Planning for EHR-S/EVRS as a systems problem with multiple layers, such as technical, implementation, policy, and political				X	Needs to underlie all EHR-S/EVRS planning efforts
-Developing realistic long-term strategic plan, with intermediate steps, for EHR-S/EVRS development and implementation	X	X	X	X	Constitutes single most essential activity for all stakeholders
-Developing long-term communication plan for EHR-S/EVRS	X	X	X		Constitutes important component of planning process
Stakeholder engagement					
-Engaging EHR-S/EVRS stakeholders through advisory committee	X	X	X	X	Recognizes need to assess, evaluate, and plan for EHR-S/EVRS through involving stakeholders
-Convening vendors, registrars, and data providers to identify barriers and pathways to EHR-S/EVRS	X	X	X	X	Recognizes need to assess, evaluate, and plan for EHR-S/EVRS through involving stakeholders
-Building clinical constituency for EHR-S/EVRS	X (physicians)				Engages crucial stakeholder
-Collaborating with state hospital associations to support vendor development of EHR-S/EVRS	X (hospitals)	X			Engages crucial stakeholder
-Convening session at HIMSS to stimulate vendor development of EHR-S/EVRS		X		X	Engages crucial stakeholder
-Consult with vendors to identify necessary conditions for EHR-S/EVRS success		X			Contributes to understanding of vendor needs

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[50] Based on interviews with 42 experts.

[51] Data providers include prenatal care providers, physicians, medical examiners, hospitals, and funeral homes. Where appropriate, the specific type of provider is specified in individual cells.

[52] Vendors include EVRS vendors, EHR-S vendors, EHR-S/EVRS vendors, and forms managers. Where appropriate, the specific type of vendor is specified in individual cells.

[53] SHD = State health departments

Type of facilitator	Data providers	Vendors	SHDs	Next steps	Impacts
Business case and marketing					
-Developing viable business case for data providers, vendors, and SHDs to design, develop, and implement EHR-S/EVRS, including value of data that would be available for various uses	X	X	X	X	Provides empirical basis and possible incentives for working on EHR-S/EVRS interaction
National and state policies					
Mandates and incentives					
-Providing incentives for EHR-S/EVRS development and implementation	X (hospitals)	X	X		Enhances business case for data providers, vendors, SHDs
-Facilitating development and implementation of EHR-S/EVRS standards and certification through CDC funding		X	X		Enhances business case for vendors and SHDs
-Adding PHAB requirements for use of EHR-S/EVRS by SHDs			X		Enhances business case for SHDs
-Mandating SHD use of EHR-S/EVRS in VSCP		X	X		Increases EHR-S/EVRS market for vendors
-Mandating use of EHR-S/EVRS by data providers	X (hospitals)				Increases EHR-S/EVRS market for vendors
State variability					
-Minimizing periodic changes in U.S. standard certificates		X			Reduces costs for EHR-S and EVRS vendors in maintaining their systems
-Surveying and then eliminating jurisdictional variation in birth, death, and fetal death requirements		X			Reduce costs for EHR-S and EVRS vendors in developing and maintaining systems for different VR jurisdictions, and addresses major vendor concern
Data quality					
-Configuring EHR-S/EVRS to support quality improvement programs	X (hospitals, physicians)	X			Increases utility of EHR-S/EVRS for data providers
-Identifying birth and death data items most likely to have conflicting EHR-S data	X (hospitals, physicians)	X (EHR-S)			Addresses physician concerns about EHR-S/EVRS data quality
Workflows					
-Surveying data provider workflows to identify current inefficiencies and potential improvements feasible with and without EHR-S/EVRS	X (physicians, hospitals)				Identifies potential targets for improving data collection for vital records; generates data for business case
-Surveying data provider workflows to identify potential costs and benefits of EHR-S/EVRS implementation	X (hospitals, physicians)	X (EHR-S)			Facilitates more functional and efficient EHR-S design and exchange of data with EVRS, and generates data for business case

Type of facilitator	Data providers	Vendors	SHDs	Next steps	Impacts
-Surveying jurisdictional vital records workflows to identify common elements and current inefficiencies and potential costs and benefits of EHR-S/EVRS implementation		X	X		Facilitates more functional and efficient EHR-S design and exchange of data with EVRS, and generates data for business case

Health information technology

EHR-S/EVRS design

Type of facilitator	Data providers	Vendors	SHDs	Next steps	Impacts
-Conceptualizing EHR-S/EVRS solutions not requiring separate configurations for all EHR-S and EVRS now operating in all vital records jurisdictions		X		X	Increases simplicity and cost-effectiveness of vendor development of EHR-S/EVRS
-Surveying OB-GYNs, pediatricians, and neonatologists to identify most useful structured data items in EHR-S and HL7, and determining their utility for EHR-S/EVRS	X (physicians)				Meets major physician concern and potentially increases clinical support for EHR-S/EVRS
-Identifying any birth record items regarded as unclear or insufficiently specific by OB-GYNs, pediatricians and neonatologists, prior to designing EHR-S/EVRS	X (physicians)				Meets major physician concern and potentially increases clinical support for EHR-S/EVRS
- Developing and embedding "SMART apps" within the EHR-S to collect VR data within context of clinical workflow and then "packaging" and transferring data to SHD (EVRS)	X (physicians)	X (EHR-S)			Reduce EHR-S vendor time and resources needed to develop VR functionality within EHR-S, and eliminates need for providers to work with separate EHR-S and EVRS
-Using form managers to facilitate collection of data from the EHR-S and to address interoperability issues between EHR-S and EVRS		X (EHR-S)			Reduce EHR-S vendor time and resources needed to develop VR functionality within EHR-S
-Recognizing role of clerks in EVRS process and evaluating potential role in EHR-S/EVRS design, implementation, and process	X (hospitals)	X			Engages and builds on knowledge of essential stakeholder
-Implementing EHR-S/EVRS pilot projects for births, deaths, and fetal deaths with planned implementation variation and common metrics	X	X	X	X	Assesses feasibility of specific methods for gathering vital records data, and provides essential data for business case
-Developing bi-directional EHR-S/EVRS to meet clinical needs	X (hospitals, physicians)	X			Increases utility of EHR-S/EVRS for data providers
-Designing EHR-S/EVRS to minimize double entry of data	X				Meets important data provider concern
-Designing EHR-S/EVRS to minimize unstructured data		X	X		Facilitates exchange of data between EHR-S and EVRS and reduces SHD queries of data providers by providing structured VR data within EHR-S, which conforms with NCHS and EVRS edit specifications
-Developing EHR-S/EVRS products for top ten EHR-S vendors		X			Increases simplicity and cost-effectiveness of vendor development of EHR-S/EVRS

Type of facilitator	Data providers	Vendors	SHDs	Next steps	Impacts
-Compiling and comparing data items on state certificates with IHE standards and HL7, compare with U.S. standard certificates		X	X		Reduces EHR-S vendor time and resources needed to develop VR functionality within EHR-S
-Developing single national platform and/or third party application for EHR-S/EVRS		X	X		Increases simplicity and cost-effectiveness of vendor development of EHR-S/EVRS and reduces need for SHDs to work with multiple EHR-S
-Developing single SHD cross-program patient identification standards for use by data providers	X (hospitals)	X (EHR-S)			Facilitates efforts of EHR-S vendors to build EHR-S to exchange data with multiple SHD programs
-Developing single SHD cross-program data provider interface for EHR-S	X (hospitals)	X (EHR-S)			Reduces EHR-S vendor costs for developing multiple interfaces by having a single SHD interface for receiving EHR-S data
EHR-S/EVRS implementation					
-Learning from mistakes of EHR-S implementation	X	X (EHR-S)	X		Anticipates and reduces problems in developing and implementing EHR-S/EVRS
-Drafting EHR-S/EVRS implementation guides		X	X		Eases and increases uniformity of EHR-S/EVRS implementation
-Leveraging tools, such as those provided to states by CDC for immunization and cancer registries, to facilitate implementation of EHR-S components for EVRS		X			Eases and increases uniformity of EHR-S/EVRS implementation
Vital records data exchange					
-Using health information exchanges (HIEs) where available to broker EHR-S/EVRS data exchange to SHDs		X	X		Reduces EHR-S and EVRS development costs and facilitates interoperability
-Developing realistic long-term plan (10-15 years) for SHD implementation of HL7		X	X	X	Constitutes essential component of EHR-S/EVRS planning efforts
-Developing single national approach for SHD cross-program approach to HL7 implementation		X	X		Reduces EHR-S vendor and SHD development costs and facilitates interoperability of EHR-S with SHD, including EVRS
-Providing CDC support for SHD-VR adoption of HL7		X	X		Increases likelihood that SHD will develop ability to receive and send HL7 messages
-Providing CDC support for SHD HL7 implementation			X		Increases likelihood that SHD will develop ability to receive and send HL7 messages
Certification					
-Learning from perceived problems of Meaningful Use certification		X			Meets major vendor concern

Type of facilitator	Data providers	Vendors	SHDs	Next steps	Impacts
-Preceding EHR-S/EVRS certification by certifying EVRS compliance with standard data items, messaging, and interface requirements		X			Ensuring that EVRS can send, receive, and process standard messages
-Exploring other conformity assessment options as alternatives to certification		X			Addresses major vendor concern
-Developing certification and/or other conformity assessment tiers		X			Addresses major vendor concern
-Limiting EHR-S/EVRS certification to U.S. standard certificate data items		X			Increases simplicity and cost-effectiveness of vendor development and certification of EHR-S/EVRS
-Leveraging related certification and/or other conformity assessment activities in certifying EHR-S/EVRS		X			Addresses vendor concern and simplifies certification and/or other conformity assessment efforts
-Including vital records registries as Meaningful Use public health registry	X (hospitals)	X	X		Represents huge incentive for vendor and provider participation
-Positioning certification of EHR-S/EVRS as marketing advantage for vendors		X			Represents incentive for vendors

Appendix F. Examples of Activities Required to Complete Different Routes for Enhancing EHR-S to Generate and Exchange Data with EVRS

	Route[54] [55]					
	1	2	3	4	5	6
Planning and Stakeholder Engagement						
Describe need for trip	●	●	●	●	●	●
Determine stakeholder VR data needs	●	●	●	●	●	●
Determine stakeholder VR system concerns	●	●	●	●	●	●
Policy						
Revise U.S. standard certificates			☉	☉	☉	☉
Revise state certificates				☉	●	●
Workflows						
Describe current VR processes		●	●	●	●	●
Modify workflow for VR processes		●	●	●	●	●
Design and Development						
Add VR data items to EHR				☉	●	☉
Enter VR data via EHR			●	●	●	●
Build NCHS VR edit specifications into EHR-S					●	●
Embed NCHS VR edit specifications into EHR-S via EVRS			●			
Adopt or use HL7 FHIR or similar technology[56]			●	☉		
Employ form manager or similar technology					☉	☉
Build SHD HL7 gateway				☉	●	●
Build HIE capacity for VR data exchange				☉	☉	☉
Test system and assess results			●	●	●	●
Implementation						
Train staff and provide support for implementation		●	●	●	●	●
Implement and test system(s) in production environment			●	●	●	●
Support ongoing VR systems operations	●	●	●	●	●	●
Monitor performance of VR system	●	●	●	●	●	●
Evaluation						
Periodically evaluate and modify VR system to ensure optimal performance	●	●	●	●	●	●
Certification or Conformity Assessment						
Assess or Certify EHR-S				☉	☉	☉
Assess or Certify EVRS	☉	☉	☉	☉		

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[54] Legend: ● = Yes; ☉ = Maybe

[55] Routes:

    1 = Continue current VR processes

    2 = Improve workflow for current VR processes

    3 = Provide direct user access to EVRS from EHR-S

    4 = Collect data for EVRS using applications that run within EHR-S

    5 = Develop EHR-S module to collect and transmit VR data

    6 = Extract available VR data from EHR-S and complete form manually

[56] Technology that allows access to web applications or services directly from the EHR-S interface

Appendix G. Figures used in report

Figure 1. Current Birth and Fetal Death Registration Process and Possible Routes for Using EHRS to Generate and Exchange Data with EVRS
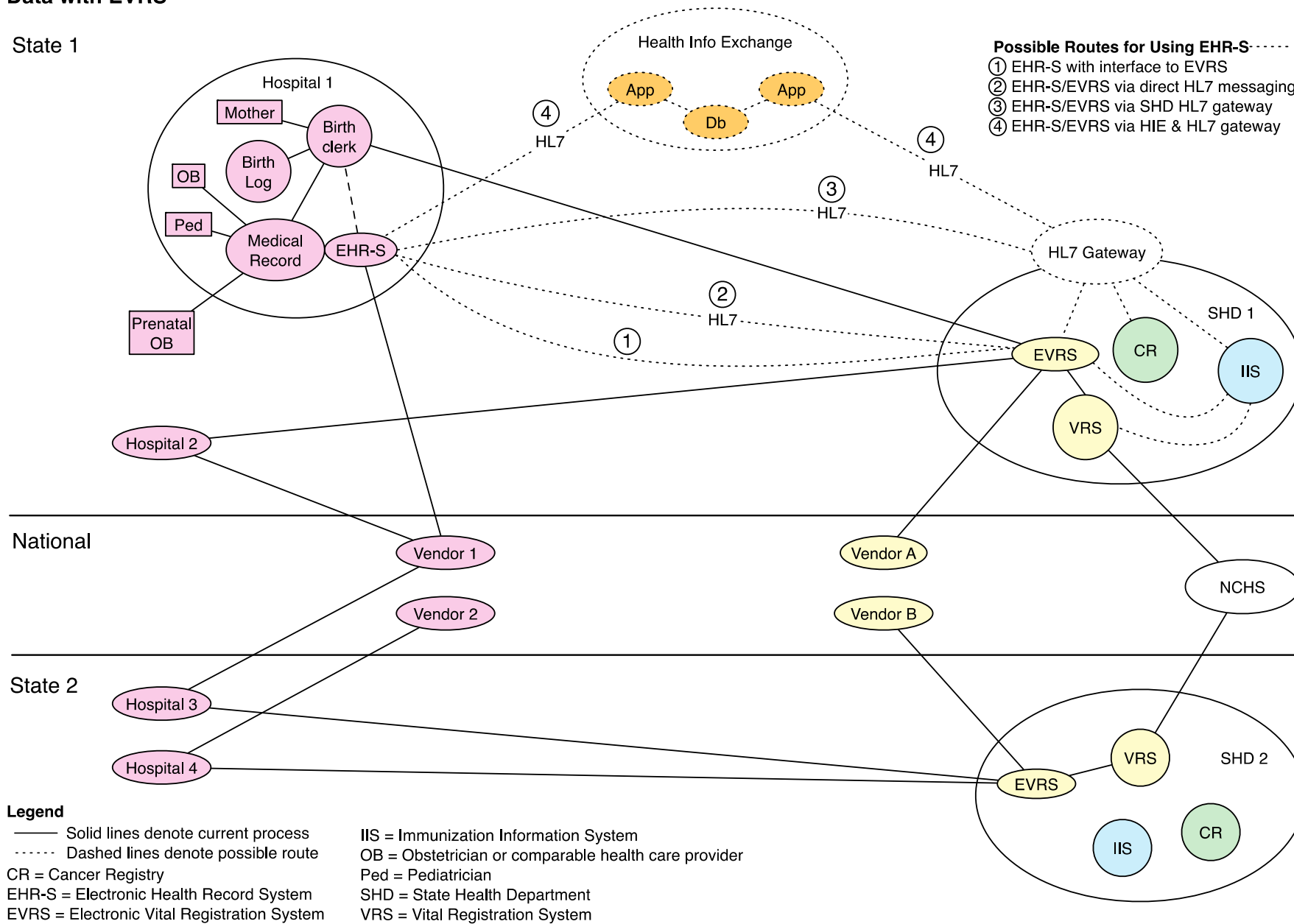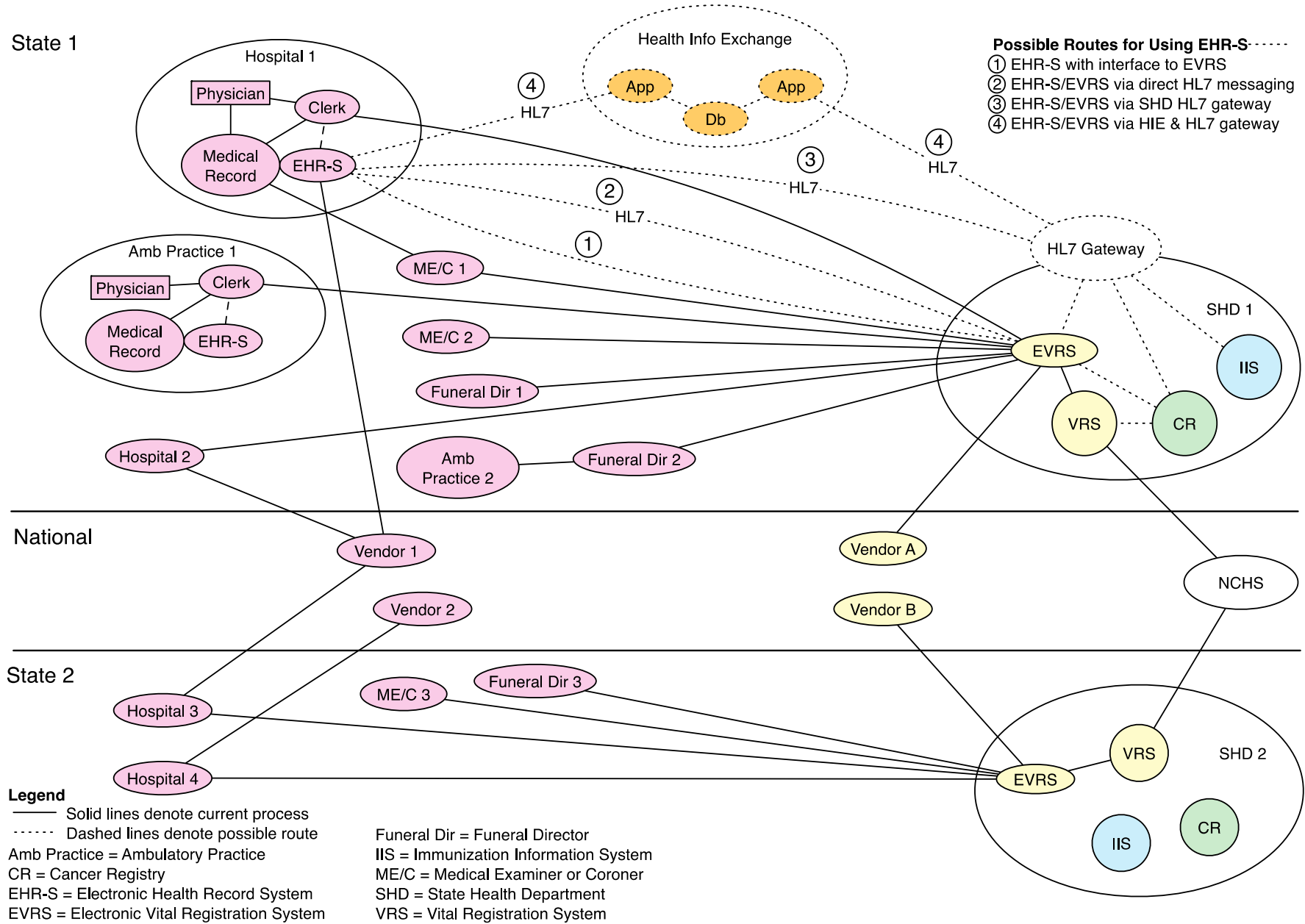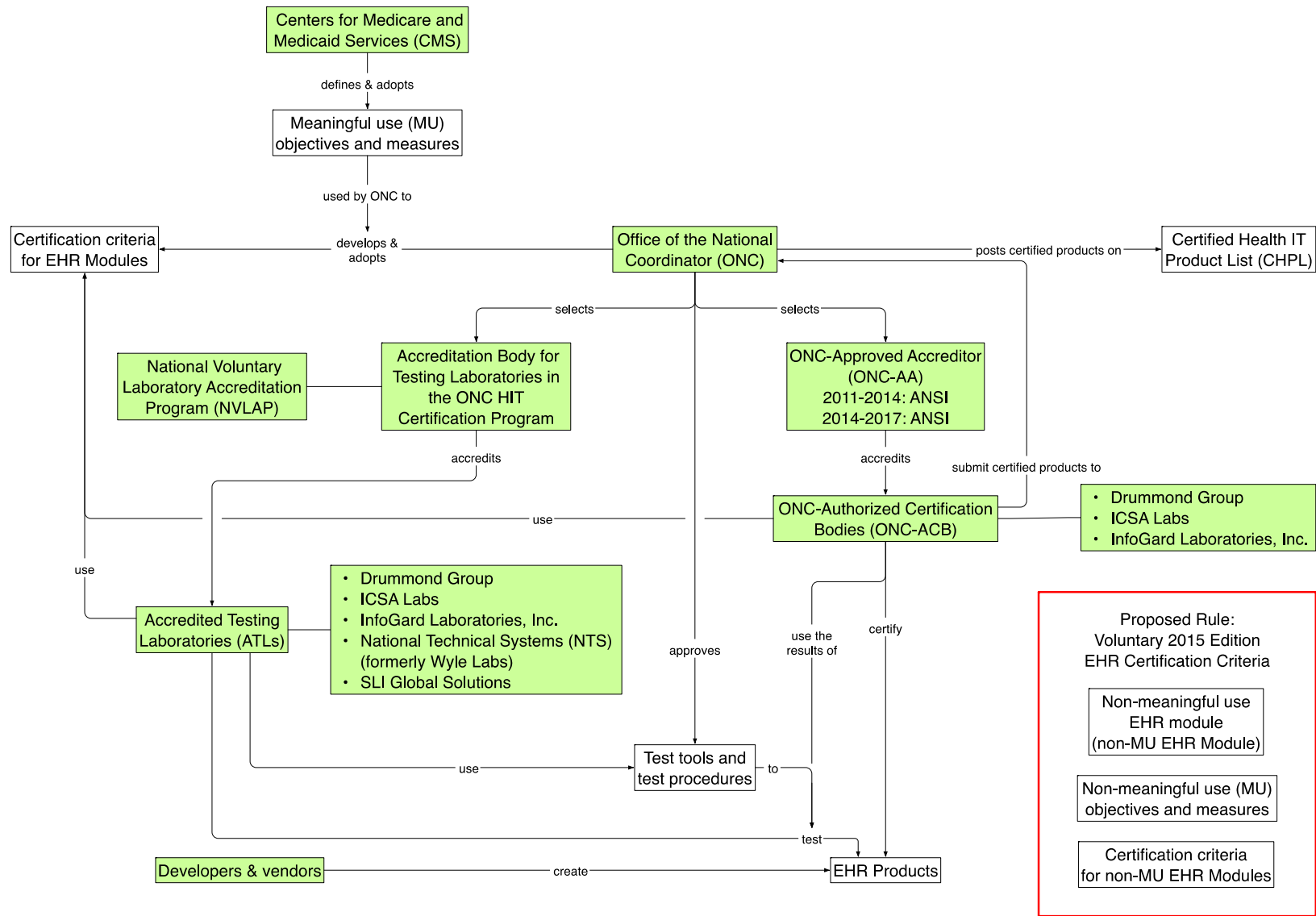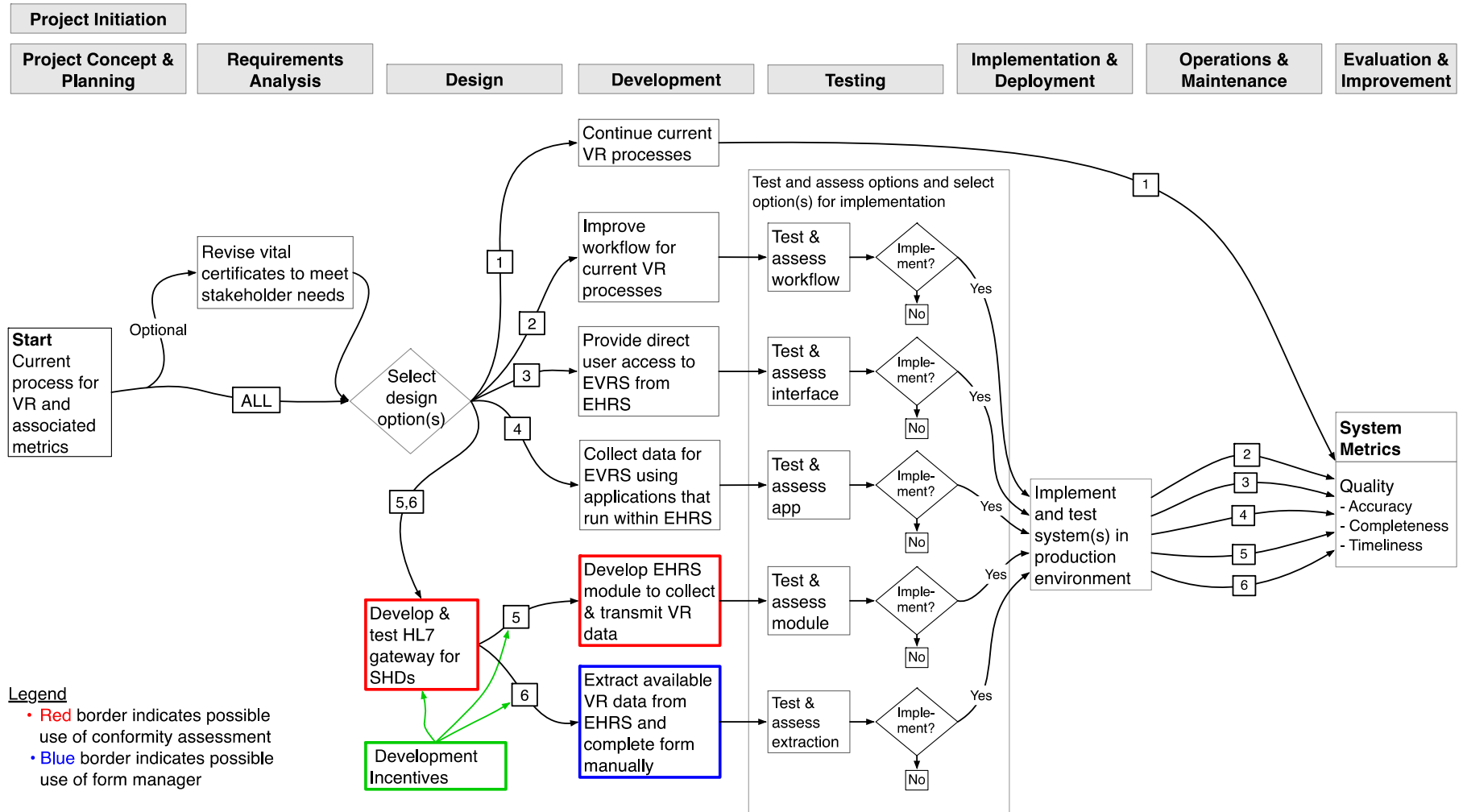
Figure 2. Current Death Registration Process and Possible Routes for Using EHRS to Generate and Exchange Data with EVRS
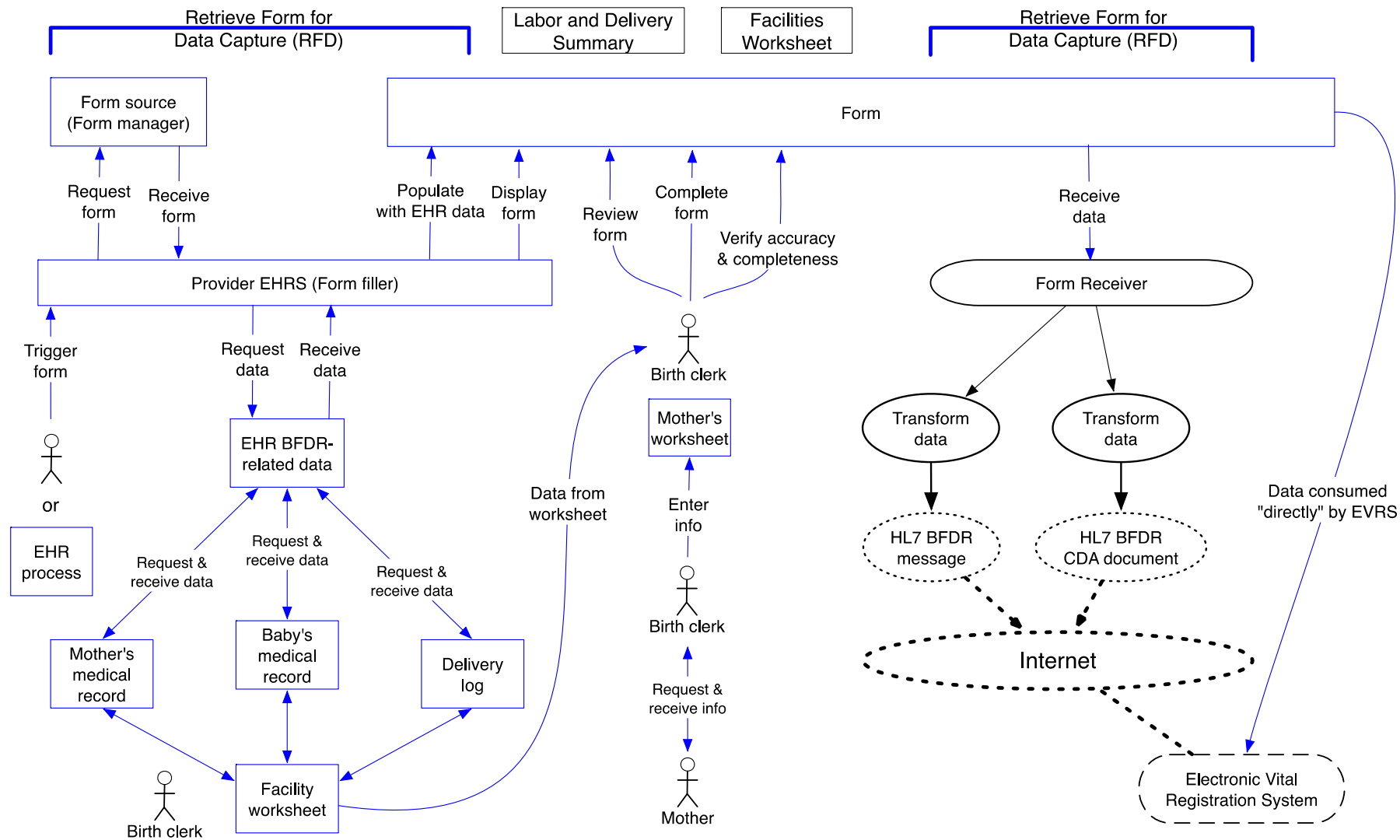
Figure 3. USDHHS Office of the National Coordinator for Health Information Technology Certification Program for Meaningful Use of Health Information
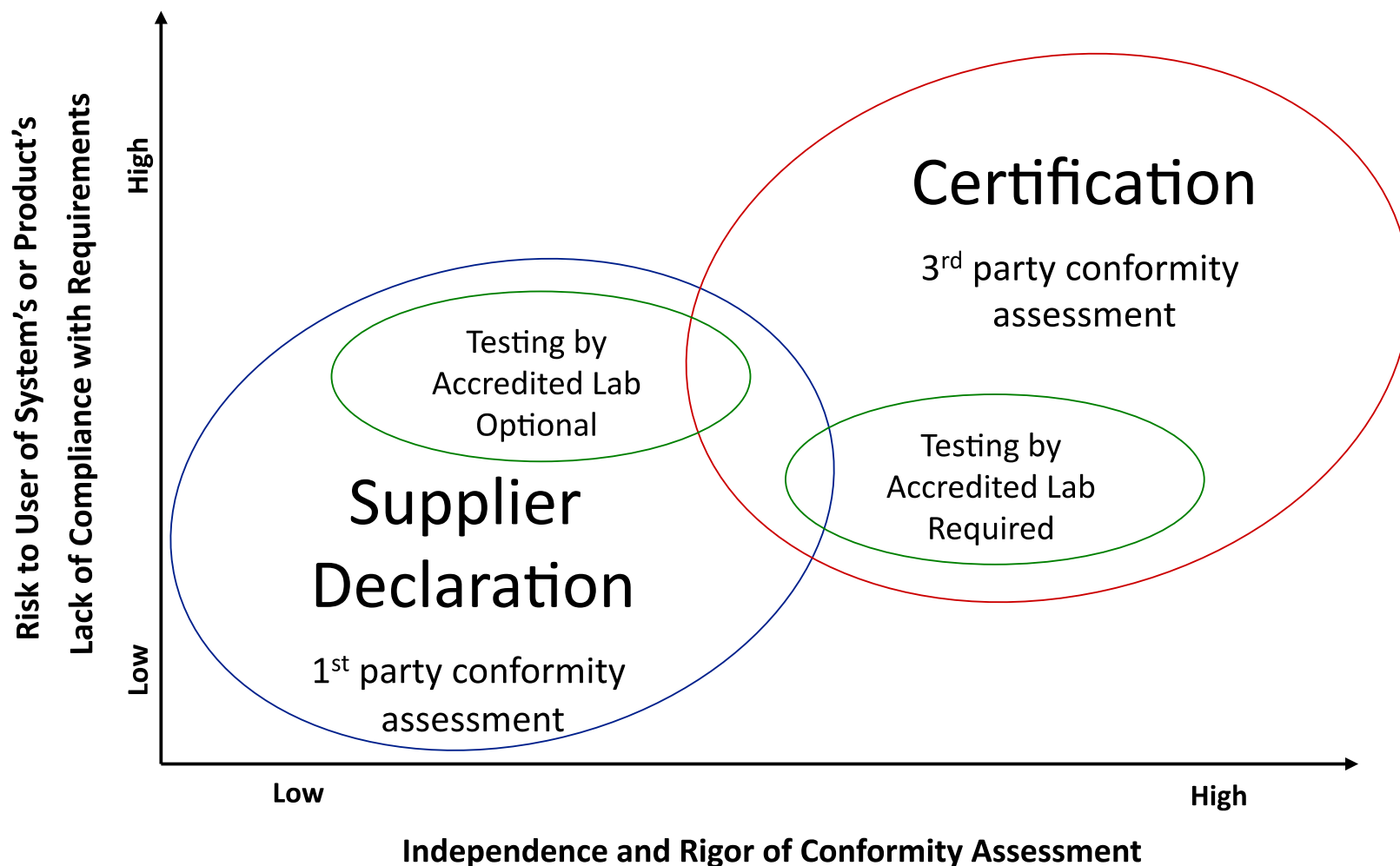
Figure 4. Routes for Enhancing EHRS to Generate and Exchange Data with EVRS

Figure 5. Use of Retrieve Form for Data Capture (RFD) to Facilitate Birth Registration

Figure 6. Risk and Conformity Assessment: How Much Confidence is Needed?

Adapted from Carnahan L. National Institute of Standards and Technology, 2015

Figure 7. Routes for Conformity Assessment of EHRS to Generate And Exchange Data With EVRS