



Interoperability for Birth Defects Surveillance

A Readiness Assessment Tool

September 2020

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Introduction

The National Center on Birth Defects and Developmental Disabilities (NCBDDD) at the Centers for Disease Control and Prevention (CDC) has partnered with the Public Health Informatics Institute to develop a readiness assessment designed to increase state birth defects program capability to exchange electronic health information with clinical electronic health records systems (EHRs).

The readiness assessment is designed to help birth defects programs gain an understanding of their current system and business processes, agency policies, available resources, existing partnerships, and IT considerations to determine readiness for automated electronic data exchange using health information standards. This readiness assessment tool can help facilitate strategic planning in state/territorial birth defects programs. It provides an approach for birth defects program staff to assess, identify and discuss information needs with internal and external partners.

Participating in this readiness assessment will give birth defects program staff a clearer understanding of success factors and the agency's current capabilities. It also provides guidance on resources to support information needs and greater interoperability with clinical partners.

What the planning activity entails

Interoperability between birth defects surveillance programs and EHRs refers to the ability of different information systems, devices or applications to communicate within and across organizational boundaries; to exchange information accurately, effectively and consistently; and to use the information that has been exchanged to enhance individual and population health.¹ This tool is designed to help birth defects programs assess their readiness to implement automated data exchange using health informatics standards such as HL7 v2 or CDA.

During the readiness assessment, participants will discuss and answer questions organized as below:

- Current system and business processes – The system and processes that the birth defects program uses to achieve its outcomes.
- Leadership and resources – The birth defects program's health information strategy and access to human and financial support for information exchange.
- IT infrastructure – Information technology resources the agency provides to the birth defects program supporting data use and exchange.

For each question in the readiness assessment tool, you will see a range of closed-ended response options that are based on four levels of capability maturity (see Table 1). These levels are adapted from the Capability Maturity Model developed by the Software Engineering Institute at Carnegie Mellon University.² The model describes the progressive stages an organization advances through as it adopts a new process or practice. It is not

¹HIMSS. 2019. *What is Interoperability?* <https://www.himss.org/library/interoperability-standards/what-is-interoperability>.

² Mark Paulk, William Curtis, Mary Beth Chrissis and Charles Weber. *Capability Maturity Model for Software (Version 1.1) (CMU/SEI-93-TR-024)*. Pittsburgh, PA: Software Engineering Institute, Carnegie Mellon University, 1993. <http://resources.sei.cmu.edu/library/asset-view.cfm?AssetID=11955>

uncommon for organizations, even successful ones, to be at relatively low levels of this model. This reflects the organizational challenges that are inevitable with formally establishing new ways of working across an organization and then rigorously evaluating that work.

Table 1. Capability Maturity Model (CMM) Levels (adapted)³

CMM Level Name	General Description
0 - Absent	No capability is evident; “starting from scratch.”
1 - Emergent	Capability is limited to isolated, ad hoc efforts or attempts at repeating successes from earlier initiatives
2 - Defined	Capability is demonstrated by systematic, ongoing efforts underway, but no overall method to measure progress or to ensure coordination.
3 - Optimized	Capability is demonstrated by systematic, ongoing efforts underway with quality improvement activities to align results with guiding vision, strategies and performance metrics.

For each question in this self-assessment instrument, a range of specific response options are provided. The capabilities are stages of growth, with each level serving as a prerequisite for higher levels. Only one response should be selected for each question. Do not choose a given response option if you have not yet achieved all of the prerequisite levels. Each question also includes definitions of key concepts and discussion prompts. The group may find it helpful to review those prior to selection and response, as they can provide a greater understanding of the purpose and the scope of the question. Sample worksheets are included in Appendix 1.

The readiness assessment tool is designed to indicate capabilities for interoperability between birth defects registry surveillance systems and electronic health records (EHRs) while not being too prescriptive in how that interoperability is achieved. As a result, detailed and jurisdiction-specific technical issues are outside the scope of the CMM-based questions.

³ CMM is a registered service mark of Carnegie Mellon University.

Tips for completing the readiness assessment

- Ideally, the birth defects program manager will form a team to collaboratively complete the readiness assessment. Collectively, the team should be knowledgeable of the agency's information technology resources, data use and exchange policies, and the birth defects program. Team members could be staff, external partners or contractors.
- The team should plan to meet and work through each of the three sections and associated questions together, sharing challenges and achievements, coming to consensus on the score, and ideally identifying 1-3 action steps that can help them move closer to readiness or take next steps towards developing electronic data exchange.
- Many questions will likely require conversation and consensus-building to reach agreement on one response option. It's possible that the group may not know the answer to some of the questions. That provides an opportunity for the group or individuals from the group to do additional outreach and investigation.
- The greatest value in conducting such assessments is in the conversations that will occur among participants as you decide what answer to give for each capability. It may well be that this will be the first time that staff from across your health department or program area will have discussed information and information technology as a shared and strategic asset, one of equal importance to all yet one which had not previously been approached in a systematic or coordinated way.
- Scores in the 1 and 2 range are common. When adopting new technologies or processes, few organizations score higher than 3.

Note: The term "agency" is used throughout this readiness assessment and is intended to mean "health department." Since terms such as "agency," "department," "division" and "bureau" mean different things in different jurisdictions, simply translate the word "agency" to mean whatever is most appropriate for your health department and your readiness assessment group.

Section 1: Current system and business processes

Question 1.1 Data exchange capability

Does the birth defects program have the capability to electronically exchange data with partners?

- Level 0 The birth defects program has no capability to send, receive or process electronic messages with partners.
- Level 1 The birth defects program rarely sends and/or receives electronic messages; some manual effort is required to exchange and process the data.
- Level 2 The birth defects program routinely sends and/or receives electronic messages with partners; there is minimal manual effort required to exchange and process the data.
- Level 3 The birth defects program routinely sends and/or receives electronic messages and evaluates data exchange processes.

Key concepts

Data exchange partners refers to entities that send data to or receive data from the program in the course of conducting business or meeting reporting requirements. For the purpose of this assessment, consider partners both internal and external to the agency. **Capability** refers to the ability of the agency to exchange data with partners via standards based electronic messages.

Electronic exchange of data refers to the ability to send, receive and process data that are electronically transferred from one information system to another without manual intervention. Electronically processing information may refer to the ability to accurately match and merge records, reconcile differences and automate de-duplication processes. Generally, this does not include fax, email messages or manually importing static files into a system. Technical capabilities for electronic data exchange might include automated scripts for querying or extracting information from one system and securely transferring it to another via an HL7 message. Data sharing might require enabling legislation or cross-program data use agreements. In some cases, it may be technologically possible to exchange data internally, but policy or programmatic hurdles may exist.

Discussion prompts

- Are any existing data exchanges automated, or do they require significant human intervention? How many manual processes could be automated if sufficient support were available? How much of a priority would that be?
- Is there a high level of human interaction that is required for the data to become usable? Do the electronic messages received utilize established data code set standards, such as SNOMED-CT, LOINC, ICD-10? Do electronic messages received utilize standard message structures, such as HL7 v2 or CDA? Are there processes and policies in place that allow for the integration of data into agency applications? Are practices in place to return information to the sender if needed?
- Which programs in your agency currently receive electronic data from external partners? What standards are used for such exchanges?
- Is your program interested in receiving case reports or case notifications? These terms are defined in the glossary.

Question 1.2 Data exchange partners

Has the birth defects program completed an assessment that identifies existing or potential data exchange partners?

- Level 0 The birth defects program has not undertaken this assessment.
 - Level 1 The birth defects program has made or is making an attempt to conduct this assessment.
 - Level 2 The birth defects program has completed such an assessment.
 - Level 3 The birth defects program has completed an assessment and evaluates data exchange partnerships.
-

Key concepts

Data exchange partner refers to an entity that sends data to or receives data from the agency in the course of conducting business or meeting reporting requirements. For the purpose of this assessment, consider all of the following: data exchange partners that the birth defects program has existing relationships with; potential data exchange partners; and partners both internal and external to the agency.

The **assessment** should include an inventory of current and potential data exchange partners, what data is collected, how it is currently collected and capabilities for future electronic data exchange.

Discussion prompts

- Has your program identified both existing and potential electronic data exchange partners? Which partners are external to your agency? Are the identified partners ready and willing to exchange data with you? Are the identified partners able to exchange data via commonly used data and transport standards?
- What data exchanges would be a high priority, between which programs/entities and for what value? Does a routine process exist within the agency or birth defects program for initiating and operationalizing data exchange with internal partners? Do tools exist to support this exchange (e.g., standardized data use agreements, standard operating procedures, Master Person Index, record matching and merging tools, etc.)?
- Does the birth defects program have an understanding of whether or not facilities in your jurisdiction are using EHRs, and if so, which EHR products they are using?

Question 1.3 Existing data sharing agreements

Has the birth defects program established data sharing agreements with other entities (e.g., healthcare providers, vital records)?

- Level 0 The birth defects program has not established data sharing agreements.
- Level 1 The birth defects program has discussed data sharing with other entities; these discussions may or may not have resulted in data sharing agreements.
- Level 2 The birth defects program has a process it uses to routinely establish data sharing agreements and keep them up-to-date.
- Level 3 The birth defects program has a process to establish data sharing agreements and evaluates this process.

Key concepts

Data sharing agreements are used to establish clear parameters for exchange between organizations. These are written agreements that may include:

- Descriptions of the purpose for the data exchange agreement.
- Identified data elements that will be exchanged and descriptions of allowable use of data.
- Responsibilities of the parties in the agreement.
- Description of the frequency of data exchange.
- Provisions for reporting violations of agreements, including breaches of privacy or security.
- Privacy provisions that describe the circumstances when personally identifiable information may be re-disclosed.
- Security provisions describing who is able to view data, access data or make modifications to data, and how the organization ensures only authorized individuals have access.

Discussion prompts

- Has the birth defects program established data sharing agreements with other entities?
- To what degree are data sharing agreements effectively used? Are birth defects program staff trained and supported to execute the development of data sharing agreements? Do they have resources to support the development, execution and monitoring of compliance to data sharing agreements?
- Do program data sharing agreements align with agency policies and procedures?

Question 1.4 Data management and quality assurance procedures

Has the birth defects program adopted procedures for data management and quality assurance?

- Level 0 The birth defects program has not adopted procedures for data management or quality assurance.
 - Level 1 The birth defects program has made attempts to document procedures for data management and quality assurance or has documented procedures that are not followed consistently.
 - Level 2 The birth defects program has documented data management and quality procedures that are followed consistently.
 - Level 3 The birth defects program evaluates compliance with data management and quality assurance procedures.
-

Key concepts

Robust **data management** procedures include systematized plans and processes to collect, retain, protect and enhance the value of data. Security and confidentiality protocols, data use agreements, and applicable statutes or rules may all inform or be included in data management procedures.

Data quality assurance procedures include protocols to assess and ensure the accuracy, completeness, and timeliness of incoming and existing data.

Discussion prompts

- Are data management and data quality assurance procedures documented? If so, are they fully implemented? Do these procedures meet agency requirements?
- Are the processes for data handling evaluated consistently across the health department? Are these findings used to improve upon and expand data management and data quality procedures? Do these findings influence programmatic, operational or IT development decisions?
- Does an information governance plan exist for the agency that establishes clear principles, procedures and accountability for managing information?
- Does the birth defects program have staff dedicated to data quality assurance?

Section 2: Leadership and resources

Question 2.1 Agency information governance

Is your birth defects surveillance program subject to a governance process that guides information systems towards agency objectives?

- Level 0 The agency does not have a governance process.
 - Level 1 The agency has an informal governance process.
 - Level 2 The agency has a formal governance process that is consistently used across the agency.
 - Level 3 The agency has a formal governance process that is evaluated to improve information and information systems decisions.
-

Key concepts

Governance process refers to a formal process for decision-making. This may include a written plan which describes who participates in decision-making; an organized structure, such as a committee or coalition; and how decisions are made. Information system governance processes are intended to ensure that projects align with agency strategy, values, constraints and culture. Governance processes often exist at an agency level, rather than at an individual program level.

Discussion prompts

- Is there a formal information governance plan for the agency?
- Is a formal decision-making process for prioritizing, selecting, procuring and/or developing information systems documented?
- If the birth defects program wanted to embark on a major system change, would you know where and how to begin that process?

Question 2.2 Program informatics vision and strategy

Does the birth defects program have a documented informatics vision and strategy including goals, objectives and measures of success?

- Level 0 The birth defects program has not attempted to develop such a strategy.
 - Level 1 The birth defects program has made or is making a sustained attempt to develop a strategy.
 - Level 2 The birth defects program has a documented informatics vision and strategy.
 - Level 3 The birth defects program has documented an informatics vision and strategy and has established a method to evaluate implementation.
-

Key concepts

Informatics vision refers to a statement of what the birth defects program seeks to achieve as a result of establishing a high level of information capability. The term **strategy** refers to a written “plan of action” for achieving specific goals or outcomes related to the birth defects program’s established information capability.

Discussion prompts

- Does the birth defects program have an “informatics vision”? Does the birth defects program have a written strategy document that specifically seeks to achieve the informatics vision? If so, is that document widely distributed and known by most employees?
- Does the birth defects program have strategies and action steps that address workforce needs, funding, information technology infrastructure and partnership with both internal groups and external organizations?
- Are there established metrics designed to measure progress toward goals? How are data collected and used to measure progress? Are the results broadly shared and discussed with staff, partners and leadership? Do metrics inform decisions and shape interventions?
- Is there any documentation of an agency strategy which supports improved electronic data exchange? Is it mentioned in the agency’s planning documents?
- Is the birth defects program’s information strategy aligned with agency information priorities? Does the strategy have support at the agency level?

Question 2.3 Program informatics assets and needs

Has the birth defects program completed an assessment intended to describe your information assets and information needs, and how interoperability can improve your surveillance approach?

- Level 0 The birth defects program has not undertaken this assessment.
 - Level 1 The birth defects program has made or is making an attempt to conduct this assessment.
 - Level 2 The birth defects program has completed such an assessment.
 - Level 3 The birth defects program has completed an assessment and evaluates information assets and needs.
-

Key concepts

Information assets refer to any definable piece or grouping of information, which is managed and used to bring value to the organization. Typically, information assets are not easily replaceable without significant costs, skills, time and/or other resources. Examples include data sets from surveillance systems and registries, or from surveys or health statistics.

Information needs refer to the data and information that is required for public health practitioners to accomplish work goals and objectives. Examples of work goals for common public health functions might include conduct analysis, inform decisions, perform surveillance activities, confirm a case, manage operations, etc.

Discussion prompts

- Have needs or challenges been identified that could be met by informatics practices? Has the birth defects program considered how to assess these needs? Do gaps between needs and assets or capabilities impact achievement of the vision or strategy?
- Does the birth defects program have sufficient informatics capability to meet current demands for information exchange with internal and external partners? Are there efforts to build internal capabilities in this area?
- Has the birth defects program identified informatics capability enhancement efforts within the agency? Are there other programs with similar needs?

Question 2.4 Program funding

Does the birth defects program have a systematic, sustained approach to funding informatics strategy and/or activities?

- Level 0 The birth defects program has no specific process for funding informatics activities.
 - Level 1 Birth defects program informatics funding is sporadic and not based on a plan.
 - Level 2 The birth defects program routinely plans for informatics funding and can sustain critical informatics functions over time.
 - Level 3 The birth defects program routinely plans for informatics funding and evaluates long-term informatics funding approaches.
-

Key concepts

A sustained approach to funding may include activities undertaken to identify the potential sources of revenue (where will money come from) and how the organization will seek the funds (state or local funds, CDC cooperative agreements, grants, partnerships, monetized services) to support informatics activities. An approach may include development of a funding plan that describes revenue goals and includes measurable objectives or benchmarks, as well as action steps related to the funding strategy. It may also include an analysis of the financial, physical facility and human resources (both staff and volunteer) needs.

Discussion prompts

- What efforts have been made related to a comprehensive funding strategy with associated informatics activities? How effective have these efforts been? How do we ensure that the approach brings value to the birth defects program?
- How stable are the identified funding sources? How diversified?
- Are informatics activities sufficiently funded to achieve the operational goals and objectives? Are there currently or anticipated gaps in funding that require specific strategies?
- Has the agency made efforts to secure informatics funding? Are there opportunities to participate in agency level funding efforts?

Question 2.5 Privacy and confidentiality

Is the birth defects program aware of agency policies and procedures for confidentiality and informed consent that govern data transmitted electronically between electronic health records systems and agency systems?

- Level 0 The agency has not adopted such policies and procedures.
- Level 1 The agency has begun documenting policies and procedures for confidentiality and informed consent, or existing policies and procedures are not followed consistently across the agency.
- Level 2 The agency has written policies and procedures for confidentiality and informed consent policies, and they are generally followed consistently across the agency.
- Level 3 The agency has written confidentiality and informed consent policies and procedures and evaluates adherence to the policies and procedures.

Key concepts

The term **procedures** here is intended to cover the wide range of actions, defined and driven by written policy, needed to ensure privacy protections through appropriate confidentiality and informed consent practices. These mechanisms may include training, policies, procedures, and optimized technology attributes to protect data in electronic environments. Electronic data exchange may require reviewing existing policies to ensure a transition to electronic data exchange will comply with existing confidentiality and consent policies and identify necessary changes.

Discussion prompts

- Are enforceable practices in place to ensure confidentiality and informed consent? Are they adhered to?
- Are processes or procedures in place that allow for measurement of compliance to policies in place? Are the data generated from these procedures used to improve practice?
- Are the policies and procedures regularly reviewed and updated as needed?
- Are staff aware of and understand the jurisdiction's security policies and requirements? Do they know what to do if they suspect a breach?

Question 2.6 Agency interoperability support

Does the birth defects program have access to staff dedicated to leading, implementing and maintaining interoperability projects?

- Level 0 The birth defects program does not have access to staff dedicated to interoperability projects.
 - Level 1 The birth defects program is aware of at least one individual champion supporting interoperability projects.
 - Level 2 The birth defects program has access to established staff to lead, implement and maintain interoperability projects.
 - Level 3 The birth defects program has access to established staff and evaluates how well they guide and maintain interoperability projects.
-

Key concepts

Having experienced informatics professionals who have a demonstrated knowledge of interoperability concepts and standards is an important factor in achieving successful outcomes for interoperability projects. If interoperability is a shared responsibility across agency departments, the level of coordination and support from leadership also plays a significant role for success.

Interoperability between birth defects surveillance programs and EHRs refers to the ability of different information systems, devices or applications to communicate within and across organizational boundaries; to exchange information accurately, effectively and consistently; and to use the information that has been exchanged to enhance individual and population health.

Discussion prompts

- Is there a designated individual or unit that has responsibility for interoperability projects within the agency? If so, do they have sufficient time and other resources to adequately support the projects? Is the scope of the activities limited to internal stakeholders, or does it extend to working with external organizations, such as healthcare providers and other governmental agencies?

Question 2.7 Training

Does the birth defects program staff have opportunities for training on public health informatics or health information technology?

- Level 0 The birth defects program has no access to such training.
 - Level 1 Policies and practices exist that support birth defects program staff to receive public health informatics or health information technology training; however, these are not known or rarely used.
 - Level 2 Policies and practices exist to support training for birth defects program staff that are used regularly.
 - Level 3 The birth defects program evaluates how staff are trained on public health informatics or health information technology.
-

Key concepts

Public health informatics facilitates the effective use of information and information technology to support public health practice, services and research for the purpose of achieving improved health outcomes.

Health information technology (health IT) makes it possible for healthcare providers to better manage patient care through secure use and sharing of health information. Health IT includes the use of electronic health records (EHRs) instead of paper medical records to maintain people's health information. Training for health IT and informatics may include topics such as terminology, electronic health record (EHRs) and their use within public health, Meaningful Use, roles and responsibilities in managing digital data, change management, project management, and orienting staff members to agency requirements for implementation of applicable policies and procedures. Additional informatics skills and competencies include business process analysis, requirements definition and health information exchange.

Discussion prompts

- Has any assessment of training needs of the workforce related to Health Information Technology (HIT) and/or informatics been conducted? How are training needs identified? Do metrics associated with the provision of training exist? Are policies in place to support professional development, such as flexible schedules or reimbursement to attend training? How are birth defects program staff learning about interoperability?

Section 3: Information technology infrastructure

Question 3.1 Centralized IT and informatics

Does the birth defects program have a relationship with a centralized information technology (IT) unit or services provider (internal or external) to support achievement of informatics goals and objectives?

- Level 0 We do not have an effective strategic relationship with an IT unit or service provider.
- Level 1 We have made isolated, ad hoc efforts to form a partnership with an IT unit or service provider to provide minimal support for program needs and initiatives.
- Level 2 We frequently partner with an IT unit or service provider to support program needs and initiatives.
- Level 3 We have established a strategic partnership with our IT unit and evaluate how well it supports program informatics projects.

Key concepts

Centralized IT unit refers to what might be a separate local or state entity that supports all the other governmental entities, or a centralized IT office within the health department. Evidence of **effective relationships** may include: (1) formally established agreements that outline the nature of services provided by the IT unit to program staff (such as service level agreements); (2) clear decision-making guidance practices described and followed for technology investments, or forums or processes for dispute resolution and other decision making; (3) evidence that each organizational unit is aware of and responsive to the strategies of the other; (4) level and type of end-user engagement and satisfaction with IT services and practices.

Discussion prompts

- Do the birth defects program and IT service providers have an agreement regarding roles/responsibilities, decision-making and service expectations? Do both parties benefit from the relationship? Are they aware of and responsive to each other's strategies and goals? Are end users consulted or engaged in IT decision-making processes?
- Is there a clear process by which the birth defects program can define and communicate its business requirements to IT? Do IT staff see themselves as partners in helping the programs achieve program-level goals and objectives?
- Do formal service level agreements exist? Are they widely known and adhered to?
- Are metrics established to assess user satisfaction? Do the results inform changes in practices, procedures or services?
- Is there a systematic approach to funding information system support, hosting and security?

Question 3.2 Project management

Is the birth defects program aware of agency project management procedures for information technology projects?

- Level 0 The agency has not adopted such procedures.
 - Level 1 The agency has made isolated, ad hoc or periodic efforts to use project management procedures.
 - Level 2 The agency has adopted project management procedures and exercises them routinely.
 - Level 3 The agency has adopted project management procedures and evaluates its procedures to improve project management.
-

Key concepts

In this context, **project management procedures** refer to well-established and consistently-applied methods and strategies designed to accomplish information system project goals within established timelines and budgets. Typical project management components include initiation, planning, execution, monitoring/controlling and close-out. Project managers may also be responsible for coordinating or conducting stakeholder communication and vendor contract management. Adhering to a methodology of project management can help to mitigate risk, maintain timelines and ensure success within a project. This is particularly critical when replacing one information system with another.

Discussion prompts

- Do documented project management processes exist across the agency? Are they well understood? Used routinely?
- Are project management positions and resources (project managers, business analysts) available to the agency?
- Is training available to prepare staff for rigorous project management approaches?
- Is there an approval process for new informatics or IT projects? Is this process transparent and well understood?

Question 3.3 Standards adoption and implementation

Does the birth defects program know of other programs within your agency that are currently using nationally recognized vocabulary, messaging and transport standards?

- Level 0 There are no information systems within the agency that use nationally recognized standards.
- Level 1 There are some information systems within the agency that use nationally recognized standards, but there is no coordination across programs.
- Level 2 The agency coordinates adoption of nationally recognized standards across programmatic information systems.
- Level 3 The agency evaluates the use of nationally recognized standards to improve standards adoption and implementation to meet agency-wide goals.

Key concepts

Vocabulary, messaging and transport standards support efficient development and interoperability for health information exchange. Adopting nationally recognized standards where available can decrease the time and resources needed for software development and for building interfaces and supporting connectivity. Use of standards for data elements such as race and gender/ethnicity also make it easier to “pool” data sets for a more meaningful and larger picture of community health. Examples of nationally recognized standards for vocabulary include CVX, CPT, ICD, LOINC and SNOMED. **Messaging standards** like HL7 v2 and CDA often call for the use of specific vocabulary standards; for electronic laboratory messages, LOINC and SNOMED codes are recommended for tests and results, while immunization messages recommend CVX and ICD codes for vaccines and administration methods. **Transport standards** direct how messages should be sent between systems, for example SOAP web-services, secure FTP or VPN, or direct secure messaging.

Discussion prompts

- Are there other programs within your agency that are exchanging electronic data using HL7 messaging standards?
- Are standards considered and, when possible, implemented for new systems or modules?
- Does the agency support discussions or exchange of information about established and emerging standards, both locally and nationally? When the agency does adopt standards as described in standards organizations’ implementation guides, does the agency typically adhere to that guidance or deviate from it?
- Is there a venue to explore the value and cost of incorporating nationally recognized standards for systems that are not currently using them?

Question 3.4 IT test environment

Does the birth defects program have access to IT testing environments for end users and program staff?

- Level 0 The birth defects program does not have access to an IT testing environment.
 - Level 1 The birth defects program or agency is implementing access to an IT testing environment.
 - Level 2 The birth defects program has access to an IT testing environment to test electronic messages incoming or outgoing to external partners.
 - Level 3 The birth defects program evaluates its IT testing environment's ability to test incoming or outgoing electronic messages.
-

Key concepts

A test environment is considered a best practice as part of information system design and maintenance, and is intended to be a collaborative process between the software developer, other members of the IT team, and the system owners and end users. A typical software development process would provide a test environment (sometimes referred to as a “playground” or “sandbox”) in which end users or other members of the development team can safely try out new enhancements prior to “going live.” Such a practice allows errors in the code to be identified early, reducing risk of adversely affecting the program or agency during a large-scale implementation. In addition, developers may make modifications to the way the screens appear to users or how data is displayed. Usability/user experience and support for efficient end-user workflows are increasingly seen as critical to ensuring high quality data and successful interoperability.

Discussion prompts

- Does the agency or central IT support any type of environment in which program/non-technical/end-user staff can try out features of software prior to release or implementation? Are end users queried about preferences for the system design elements that affect or support users (usability testing)?

Question 3.5 Enterprise architecture

Does the birth defects program have access to agency-supported enterprise-level/cross-agency shared services such as a provider or facility registry, master patient index or message integration services to facilitate information exchange?

- Level 0 Programs within the agency do not share any services.
- Level 1 Programs within the agency are considering sharing services or are in the process of implementing key shared services across the agency.
- Level 2 Programs are actively sharing services across the agency.
- Level 3 The agency evaluates the quality and utility of shared services.

Key concepts

The key concept of **shared services** contributes to the capability of an enterprise view of information and the technology supports to operationalize this concept. A **provider or facility registry** refers to a centralized registry of individual providers (such as physicians, nurse practitioners, audiologists, psychologists) and/or healthcare, social services and other facilities (restaurants, child care centers, nursing homes, mental health facilities, clinics or hospitals). A **master patient index (MPI)** is a database that includes information about the individuals who have received services including contact information and specific services received. MPI and facility or provider registries enable integration of records that can serve public health departments to conduct surveillance, support emergency preparedness activities and track outbreaks. **Message integration services** support the capability to enable the flow of information between disparate information systems. For example, programs may use institutional coding formats that would need to be translated to standard coding formats like LOINC, SNOMED or HL7 to send that data to a healthcare facility.

Shared or centralized services that are leveraged across an agency can allow programs to access resources and tools they may not otherwise be able to implement. Shared services can also facilitate a uniform and standards-based adoption of programmatic functions, while supporting common goals and processes.

Discussion prompts

- How many programs are managing data from the same hospitals, clinics, dental offices, pharmacies, other local health departments and others? Are there processes or information systems/databases that document the location and types of facilities in the agency's jurisdiction? How are name or address changes of clinics, etc., maintained across programs and kept in sync? How are they kept in sync with the various healthcare professional licensing boards?
- Are there any active health information exchanges (HIEs) in your jurisdiction? How do these HIEs engage with the birth defects program and/or other programs within the agency?

Score sheets

Instructions

1. Within the group, participants take turns reading a question, then offer their opinion on the most appropriate score and why.
2. The other participants then offer their opinion on the program's score.
3. After discussion and consideration, the group then comes to a consensus score, which is recorded on the worksheet.
4. The participants then briefly discuss possible next steps that would build on current capabilities and address current challenges, needs or deficiencies. These action steps can also be recorded on the worksheet.

Current system and business processes worksheet

Question	Score	Notes/findings
Question 1.1 Data exchange capability		
Question 1.2 Data exchange partners		
Question 1.3 Existing data sharing agreements		
Question 1.4 Data management and quality assurance procedures		

Leadership and resources worksheet

Question	Score	Notes/findings
Question 2.1 Agency information governance		
Question 2.2 Program informatics vision and strategy		
Question 2.3 Program informatics assets and needs		
Question 2.4 Program funding		

Question	Score	Notes/findings
Question 2.5 Privacy and confidentiality		
Question 2.6 Agency interoperability support		
Question 2.7 Training		

Information technology infrastructure worksheet

Question	Score	Notes/findings
Question 3.1 Centralized IT and informatics		
Question 3.2 Project management		
Question 3.3 Standards adoption and implementation		
Question 3.4 IT test environment		

Question	Score	Notes/findings
Question 3.5 Enterprise architecture		

Next steps

After completing the assessment, review your responses and potential action steps that you have identified. It may be helpful to prioritize next steps based on identified needs or program goals. If your scores are mostly zeros and ones, you may want to prioritize planning activities such as assessments and identifying resources. If your scores are mostly twos and threes, you may want to prioritize activities such as developing a plan and timeline for interoperability. The next section is intended to help you translate your scores into potential next steps. These next steps are suggestions and can be adapted to meet program needs.

Score interpretation

Current system and business processes

If your score is mostly zeroes and ones, you may want to prioritize assessing your current state.

- Document and assess your current business process and workflows.
 - What is the current functionality of your birth defects registry? What are your current business processes and workflow?
 - What major business process changes should be considered (i.e., moving from manual entry to automated entry or from receiving intermittent case notifications to continuous case notifications)?
 - What are your surveillance goals?
- Assess your data exchange partners to determine their level of interest and electronic data exchange capabilities.
 - Who are your current data exchange partners? Are they exchanging data with other programs in your agency? Are there existing data sharing networks that can be leveraged?
 - How will you address provider concerns?

If your score is mostly twos and threes, you may want to prioritize assessing your data exchange approach and partners.

- Reach out to other programs within your agency to determine how they are implementing interoperability.
 - Which programs have implemented electronic data exchange?
- Develop exchange specifications/implementation guide so providers understand what is needed to participate.
 - Does your program plan to receive case reports or case notifications?
 - What data are needed from the EHR to meet surveillance goals? Are those data currently captured in the EHR?
- Meet with your agency legal team to discuss any implications for data sharing agreements.
 - Will electronic data exchange require new data use agreements, or can existing agreements be used or adapted?

Leadership and resources

If your score is mostly zeroes and ones, you may want to prioritize understanding how interoperability aligns with your agency's priorities and developing the value case.

- Review your agency's priorities and goals and identify initiatives that your program can support or leverage. Consider how to tie what your agency leadership cares about most into your value case.
 - How do your program's goals align with your agency's priorities?
 - Does your program have leadership support (executive, IT, etc.) to support this change?
 - How can your program best articulate the value case for agency leadership? To relevant advocacy or opposition groups?

If your score is mostly twos and threes, you may want to prioritize developing your value case and securing resources for implementation.

- Develop a compelling value case to secure leadership support and justify resources.
 - What is the public health need or problem, and why should this be considered a priority?
 - To what extent do healthcare organizations have the needed information, and how likely is it to be in an EHR system?
 - Are there other jurisdictional priorities that this program can support or leverage?
 - What are the estimated costs?
- Identify other programs making progress towards electronic data exchange or agency-level funding initiatives.
 - How are other programs funding electronic data exchange?
 - How will the birth defects program fund electronic data exchange? Does your program have the capacity (including financial and human resources) to support this effort for the long term?

IT Infrastructure

If your score is mostly zeroes and ones, you may want to prioritize assessing your IT resources and technical needs

- Work with IT staff to determine supported approaches for electronic data exchange throughout the agency.
 - What programs are currently participating in electronic data exchange? What standards are currently supported?

If your score is mostly twos and threes, you may want to prioritize strategizing an IT approach.

- Determine system requirements.

- What data elements are needed to achieve your surveillance system goals? Which data elements are highest priority?
- Review your business processes and define what the system must accomplish.
- Work with IT staff to determine technical options.
 - What is the pathway between systems? Would there be a straight exchange over an agreed transport protocol or with an HIE/HIN?
 - What are the vocabulary, messaging and transport standards required for the systems involved?

Appendix 1 includes a sample template for beginning an action plan. This template can be used to begin planning additional actions as follow up from the readiness assessment.

As you review the results of the readiness assessment, you may identify areas where additional information or guidance is needed. Additional resources are included below to provide guidance relevant to each section of the readiness assessment. At the time this assessment was drafted, new federal policies were in development that may impact your approach to interoperability, including the Trusted Exchange Framework and Common Agreement (TEFCA) and the Medicare Access and CHIP Reauthorization Act (MACRA). Please be aware of these and related policies that may impact your progress.

Resources

Current systems and business processes:

Resources related to electronic data exchange and data sharing agreements can be found at phii.org/ehrtoolkit.

Agency policies and resources

The Informatics-Savvy Health Department toolkit can be found at phii.org/infosavvy and includes tools such as:

- Developing a Strategic Informatics Roadmap (strategic and operational planning)
- Information Governance for Public Health (guidance for collection, management, uses, exchange and release of information)

Other useful toolkits available on PHII's website include:

- Public Health Informatics Profile Toolkit (needs assessment): phii.org/PHI-Toolkit
- Reframing Public Health Informatics: A Communications Toolkit (evidence based framing recommendations and sample communications to talk about informatics): <https://phii.org/informatics-communication-toolkit>
- CMS 90-10 Funding Toolkit - <https://www.phii.org/medicaid-90-10-toolkit>

Medicare Access and CHIP Reauthorization Act (MACRA) and the Merit-based Incentive Payment System (MIPS) - <https://www.healthit.gov/topic/meaningful-use-and-macra/meaningful-use-and-macra>

Promoting Interoperability (formerly Meaningful Use) - <https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/index.html?redirect=/EHRIncentivePrograms/>

Information technology infrastructure

Office of the National Coordinator, Interoperability Standards Advisory: Best Available Standards and Implementation Specifications - <https://www.healthit.gov/isa/>

Trusted Exchange Framework and Common Agreement (TEFCA) - <https://www.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement>

HIMSS HIE Toolkit for Public Health: <https://www.himss.org/public-health-hie-toolkit>

Collaborative Requirements Development Methodology: <https://www.phii.org/crdm>

Resources related to technical approaches and data exchange implementation can be found at <https://phii.org/ehrtoolkit>.

Appendix 1: Beginning an action plan

Beginning an action plan

Instructions: Review the action steps identified on the worksheet and select at least three action steps that can be implemented within the next 12 months.

<p>Action steps</p> <p>What next step will help you progress?</p>	<p>Timeframe</p> <p>In how many weeks/by what date do you intend to have this action completed?</p>	<p>Information/ resources needed</p> <p>What information or resources do you need to support these action steps?</p>	<p>Collaboration</p> <p>Who will you work with or through on this action step?</p>

Appendix 2: Glossary

Case report refers to information provided to a public health agency that can be used to identify and document an incidence of a reportable condition.

Case notification refers to information provided to a public health agency that can be used to identify an incidence of a reportable condition but will require additional information gathering to complete a case report.

Centralized IT unit refers to what might be a separate local or state entity that supports all the other governmental entities, or a centralized IT office within the health department.

Data exchange partner refers to an entity that sends data to or receives data from the agency in the course of conducting business or meeting reporting requirements.

Data management procedures include systematized plans and processes to collect, retain, protect and enhance the value of data. Security and confidentiality protocols, data use agreements, and applicable statutes or rules may all inform or be included in data management procedures.

Data quality assurance procedures include protocols to assess and ensure the accuracy, completeness and timeliness of incoming and existing data.

Data sharing agreements are used to establish clear parameters for exchange between organizations.

Electronic exchange of data refers to the ability to send, receive and process data that are electronically transferred from one information system to another without manual intervention.

Governance process refers to a formal process for decision-making. This may include a written plan which describes who participates in decision-making; an organized structure, such as a committee or coalition; and how decisions are made.

Information assets refer to any definable piece or grouping of information, which is managed and used to bring value to the organization.

Information needs refer to the data and information that is required for public health practitioners to accomplish work goals and objectives.

Informatics vision refers to a statement of what the birth defects program seeks to achieve as a result of establishing a high level of information capability.

Information systems are a combination of hardware, software, infrastructure and trained personnel organized to facilitate planning, control, coordination and decision-making in an organization.

Message integration services support the capability to enable the flow of information between disparate information systems.

Master patient index (MPI) is a database that includes information about the individuals who have received services including contact information and specific services received.

Messaging standards like HL7 v2 and CDA often call for the use of specific vocabulary standards; for electronic laboratory messages, LOINC and SNOMED codes are recommended for tests and results, while immunization messages recommend CVX and ICD codes for vaccines and administration methods.

Provider or facility registry refers to a centralized registry of individual providers (such as physicians, nurse practitioners, audiologists, psychologists) and/or healthcare, social services and other facilities (restaurants, child care centers, nursing homes, mental health facilities, clinics or hospitals).

Public health informatics facilitates the effective use of information and information technology to support public health practice, services and research for the purpose of achieving improved health outcomes.

Standardized project management procedures refer to well-established and consistently-applied methods and strategies designed to accomplish information system project goals within established timelines and budgets.

Strategic plan refers to a written “plan of action” for achieving specific goals or outcomes related to the agency’s established information capability. This includes information systems and information management.

Test environment is considered a best practice as part of information system design and maintenance, and is intended to be a collaborative process between the software developer, other members of the IT team, and the system owners and end users. A typical software development process

would provide a test environment (sometimes referred to as a “playground” or “sandbox”) in which end users or other members of the development team can safely try out new enhancements prior to “going live.”

Transport standards direct how messages should be sent between systems, for example SOAP web-services, secure FTP or VPN, or direct secure messaging.