

HITSP Newborn Screening Interoperability Specification

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1.0 INTRODUCTION

This Healthcare Information Technology Standards Panel (HITSP) document is divided into Requirements, Design and Capabilities sections which may be used by analysts, architects and implementers. Analysts might use this document to refer to the requirements of a particular Harmonization Request. Architects and system implementers might refer to this document as the top level architectural specification for a system design while software developers will use the Interoperability Specification as a source of requirements for interoperable information exchange.

The following table details specific sections of this Interoperability Specification (IS) template and how specific sections of this document are targeted to specific readers. Each of the stakeholders listed in this table are more fully defined in a separate appendix. This table is provided as an aid to readers to assist with identifying specific areas of focus. Readers are encouraged to review all sections of this document to further their understanding of HITSP's work.

Table 1-1 Reader's Guide for Interoperability Specification

Document Section	Section Number	Intended Audience	Information Contained
Section 2.0 Requirements	2.1 Synopsis of Requirements	Policy Managers Policy Analysts Executive Leadership	Used to provide an overview (using a scenario-based approach) of the requirements applicable to this document. Readers should start here to learn more about what specific requirements this Interoperability Specification is intended to address
	2.2 – 2.3 Scenarios	Program Managers Policy Analysts Executive Leadership	Each of the scenarios specific to the Interoperability Specification are outlined and described using a HITSP concept known as an Information Exchange Requirement (IER). HITSP uses IER's to outline requirements for HITSP work products
	2.4 System Description	Architects Business Analysts Policy Analysts Program Managers	The systems assigned to the system roles (as defined in the HITSP Capabilities used by this Interoperability Specification) are identified and described here. Readers can learn which systems have been included as part of this HITSP Interoperability Specification
Section 3.0 Design Specification	3.1 Capabilities Used	Architects Business Analysts Development Team	For each Information Exchange Requirement (IER) identified in Section 2.0, a corresponding HITSP Capability is associated and mapped. A reader can review how specific HITSP Capabilities meet information exchange needs. A diagram is also provided to show the interchange of data among systems identified in this Interoperability Specification
	3.2 Capability Orchestration	Architects Development Team	The core of the design in the Interoperability Specification is documented here. This solution shows orchestration of Capabilities to meet the specific Information Exchange Requirements (IER) in Section 3.1. The design also identifies conditions and constraints, as well as any content subsets specific to the solution
Section 4.0 Capability Gaps	4.0 Capability Gaps	Business Analysts Development Team Architects	Gaps specific to Capabilities used as part of this Interoperability Specification are reviewed in this section to determine why specific information exchange requirements may not yet be met or defined. Readers should check this section to track the progress of gap resolution
Section 5.0 Appendix	5.1 Provisional Exchange Content Description	Architects	Supporting information is provided for HITSP exchange content that is identified as provisional (due to gaps identified in the previous section)
	5.2 Provisional Data Requirements	Architects	Supporting information is provided for HITSP data requirements that are associated with provisional exchange content identified in Section 5.1
	5.3 Harmonization Request Traceability	Architects Business Analysts	A complete mapping of information exchange requirements to functional requirements is provided in this section. Readers can trace IER's to underlying Harmonization Request events and actions (in those instances where a Use Case exists) or to functional requirements defined as part of an official standards Harmonization Request



1.1 INTEROPERABILITY SPECIFICATION OVERVIEW

This HITSP Newborn Screening Interoperability Specification describes how to integrate the standards needed to support newborn screening reporting and the associated information exchanges among clinical care settings and public health. This specification is focused on:

- The ability to communicate initial screening results, confirmatory testing orders, and results and information specific to referral and management of the patient
- The ability to report newborn screening information to Public Health
- In order to enable clinical continuity for newborn, all results should be sent electronically to appropriate state newborn screening programs, birthing centers, and primary care of the newborn

1.2 DOCUMENT SCOPE

In addition to the scope defined by the original Harmonization Request, this IS also addresses the newborn screening clinical conditions that are specified by the advisory committee or any U.S. jurisdiction. While this Interoperability Specification enables multiple aspects of newborn screening including follow-up communications, the core requirements of this specification support the minimum necessary to enact reporting of quantitative newborn screening results as a clearly delineated first phase.

The Newborn Screening Use Case (NBS) may be implemented in phases beginning with the highest priority data exchange - the reporting of lab results and integration into the Electronic Health Record (EHR). The reporting of results can be implemented alone with manual entry of NBS test ordering data requirements at the laboratory using information recorded on the manual order form that is attached to the filter paper used to collect the specimen. When electronic test ordering is done, it is not essential to pre-populate the ordering data requirements from other electronic documents such as the birthing summary, if they have not been implemented, and information may be entered directly into the order message or from the newborn EHR. When electronic information is available in the maternal record, available data through data exchange with the newborn record is used, but this is not a pre-requisite to implementing the Newborn Screening Use Case. Similarly, many of the data elements associated with the referrals necessary after an abnormal result are not essential or specific to the Newborn Screening Use Case, but are listed as data requirements because they are used in referral and medical summary documents in other Use Cases. Future releases of this Interoperability Specification may add risk factors to the NBS data elements.

1.3 COPYRIGHT PERMISSIONS

COPYRIGHT NOTICE

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1.4 REFERENCE DOCUMENTS

This section provides a list of key reference documents and background material. These documents can be retrieved from the [HITSP Web Site](#).

Table 1-2 Reference Documents

Reference Documents	Document Description
HITSP Acronyms List	Lists and defines the acronyms used in this document
HITSP Glossary	Provides definitions for relevant terms used by HITSP documents
TN900 – Security and Privacy	TN900 is a reference document that provides the overall context for use of the HITSP Security and Privacy constructs
TN901 - Clinical Documents	TN901 is a reference document that provides the overall context for use of the HITSP Care Management and Health Records constructs
TN903 – Data Architecture	TN903 is a reference document that provides the overall context for use of the HITSP Data Architecture constructs



Reference Documents	Document Description
TN904 – Harmonization Framework and Exchange Architecture	TN904 is a reference document that provides the overall context for use of the HITSP Harmonization Framework and Exchange Architecture constructs
NIH Newborn Screening Codes	This link contains information for constructing HL7 messages for NBS (LOINC and SNOMED codes, answer lists, example message template, etc).

1.5 CONFORMANCE

This section describes the conformance criteria, which are objective statements of requirements that can be used to determine if a specific behavior, function, interface, or code set has been implemented correctly.

1.5.1 CONFORMANCE CRITERIA

For an implementation to claim conformance to a HITSP Interoperability Specification, it must be implemented in its entirety or within a limited scope or subset as defined within the Interoperability Specification, its associated construct specifications, as well as conformance criteria from the selected base and composite standards. A conformant system must be constrained as specified in this Interoperability Specification, and implement all of the required interfaces within the scope, subset or implementation options as described.

1.5.2 CONFORMANCE SCOPING, SUBSETTING AND OPTIONS

HITSP may define the permissibility for system scoping, subsetting or implementation options by which the specification may be implemented in a limited manner. The selected scope, subset or options shall specifically be stated, and implementations must include all requirements within the selected scope, subset or options to claim conformance.

For this Interoperability Specification, conformance may be declared by a participating system for any Capability provided that all declared constraints, conditions and requirements imposed by the Capability and its referenced HITSP constructs are satisfied.

1.5.3 TEST METHODS

HITSP relies on the conformance test methods, test tools and other test-related material produced by, or under the auspices, of standards developers, profiling organizations and Implementation Guide producers as part of its collaborative implementation testing effort. Efforts to produce conformance test methods, tools, etc. may be internal to the organization or provided by an external organization.

An [HIT Implementation Testing and Support](#) Web Site has been developed in collaboration with HITSP, the National Institute of Standards and Testing (NIST), the Certification Commission for Healthcare Information Technology (CCHIT), and the Office of the National Coordinator for Health Information Technology (ONC) to advance conformance and interoperability testing capabilities. This Web Site provides HIT implementers with the necessary resources to support and test their implementation of standards-based health systems.



2.0 REQUIREMENTS

Section 2.0 identifies the requirements from the Harmonization Request for which information exchanges are necessary. The following table details how this section and other sections of the document are targeted to specific readers. Each of the stakeholders listed in this table are more fully defined in a separate appendix. This table is provided as an aid to readers to assist with identifying specific areas of focus. Readers are encouraged to review all sections of this document to further their understanding of HITSP's work.

Table 2-1 Reader's Guide for Section 2.0

Document Section	Section Number	Intended Audience	Information Contained
Section 2.0 Requirements	2.1 Synopsis of Requirements	Policy Managers Policy Analysts Executive Leadership	Used to provide an overview (using a scenario-based approach) of the requirements applicable to this document. Readers should start here to learn more about what specific requirements this Interoperability Specification is intended to address
	2.2 – 2.3 Scenarios	Program Managers Policy Analysts Executive Leadership	Each of the scenarios specific to the Interoperability Specification are outlined and described using a HITSP concept known as an Information Exchange Requirement (IER). HITSP uses IER's to outline requirements for HITSP work products
	2.4 System Description	Architects Business Analysts Policy Analysts Program Managers	The systems assigned to the system roles (as defined in the Capabilities used by this Interoperability Specification) are identified and described here. Readers can learn which systems have been included as part of this Interoperability Specification

2.1 SYNOPSIS OF REQUIREMENTS

The following table describes the information exchange requirements needed to accomplish the Harmonization Request for which information exchange is necessary.

The Newborn Screening Use Case is focused on electronic exchange of information related to newborn screening among ordering clinicians, pediatric clinicians, consumers, Public Health, testing laboratories, and audiology service providers. Newborn screening reporting and information exchanges may also include individual case reporting to Public Health, appropriate registries, and local health service providers.

The scope of this 2009 Use Case is focused on:

- The ability to communicate initial screening results, confirmatory testing orders, and results and information specific to referral and management of the patient
- The ability to report newborn screening information to Public Health

NBS information exchanged to support this Use Case consists of all newborn screening orders, results, and information associated with an order or result. Result information may include normal, abnormal, out of range, and confirmatory results within the domain of hearing, hemoglobin, metabolic, and pulmonary/genetic screening tests. Although endocrine, congenital infections, and other domains such as enzyme disorders are newborn screening domains deemed out of scope in [the original harmonized] Use Case, this Interoperability Specification does not specifically eliminate these conditions.

This Use Case highlights the ability to share de-identified newborn screening information with the clinical research community without requiring additional data collection or data entry. This Use Case also identifies information exchanges that begin with initial newborn screening and extend to include portions of Long Term Follow-Up (LTFU). The information exchanged may include analysis, conditions, hearing tests/results, dates, and other pertinent data. The HITSP Personalized Healthcare Workgroup has developed a newborn screening reference of cross-mappings as a companion document to the Use Case



to facilitate the development of electronic laboratory reports for newborn screening. The document entitled “Newborn Screening Coding and Terminology Guide” is available at the [Newborn Screening Use Case web page](#). Specifics regarding datasets, data elements, and nomenclature considerations are addressed in the Dataset Considerations section of this document, as well as in the Newborn Screening Coding and Terminology Guide.

Recognizing that States may use different processes, require different testing, and gather differing data when conducting NBS, these processes are generalized throughout this Use Case in order to achieve further standardization of information exchange. Further, this document does not prescribe policy or dictate process.

To effectively complete NBS, this Use Case describes some specific information exchanges.

Examples of specific information exchanges:

1. The clinician may receive direction on screening requirements, request patient- or test-specific information, order initial tests, receive results, request second specimens, order confirmatory tests, request referrals/interventions, and report public health cases.
It would be beneficial to clinicians to have electronic communication supporting: the determination of which newborn screening tests are required; the ordering of newborn screening tests; the receipt of newborn screening results; the ordering of genetic/genomic tests (addressed in the 2008 Personalized Healthcare Use Case); the reporting of public health case reports (addressed in the 2008 Public Health Case Reporting Use Case); the requesting of referrals and/or interventions; and the exchange of information to support patient care (addressed in the 2008 Consultations and Transfers of Care Use Case)
2. The Use Case addresses the potential need for the consumer to be informed and educated about the NBS process, the implications of consenting to screening, and the potential need to provide additional information and/or specimens.
Consumers could benefit from better care, which includes earlier appropriate interventions and receiving educational material that is audience-specific and culturally appropriate regarding the screening and/or a suspected or confirmed condition. The communication of standard comprehensive educational information to consumers could result in them providing more relevant information and greater cooperation and receiving better understanding and improved care
3. Public Health may determine and communicate screening requirements, receive and/or process screening orders, receive initial/confirmatory/second specimen results, and track and report long-term outcomes.
Public Health could benefit from electronic communication supporting: the exchange of screening requirements; the receipt of orders; the communication of orders to contracted or third party laboratories; the receipt of laboratory or audiology results; the receipt of Public Health case reports (addressed in the 2008 Public Health Case Reporting Use Case); and the receipt of information for the purposes of determining long-term outcomes
4. The Testing Laboratory and Audiology Services may receive orders, perform tests, and report results including interpretation and referral recommendations.
Testing Laboratory and Audiology Services could benefit from electronic communication supporting: the receipt and processing of orders; the sending of results; the receipt of additional relevant information regarding the patient and family history. This Use Case assumes the developing presence of electronic systems such as Electronic Health Records (EHRs), Laboratory Information Systems (LISs), Public Health Systems/Intermediaries, Audiology Systems, Personally Controlled Health Records, and other local or Web-based solutions that support clinicians, consumers, Public Health, and other healthcare providers while recognizing the issues and obstacles associated with these assumptions



Table 2-2 Description of Information Exchange Requirements

Information Exchange Requirement Number (IER)	Description
IER1	Request & Response PEC-NBS6 – Guideline
IER2	Request & Response PEC-NBS8 - Education Brochure
IER3	Send PEC-NBS8 - Education Brochure
IER4	Send PEC-NBS6 – Guideline
IER5	Publish/Register EC62 Unstructured Data for screening consent, retention of samples, or refusals EHR HIE
IER6	Publish/Register EC30 - Consent Document Component EHR HIE
IER7	Request & Response PEC-NBS15 Newborn Screening Value Sets
IER8	Request & Response PEC-NBS9 - Newborn Record EHR
IER9	Request & Response PEC-NBS4 - Birthing Summary
IER10	Send PEC-NBS9 - Newborn Record
IER11	Send PEC-NBS4 - Birthing Summary
IER12	Send PEC-NBS3 - Lab Order (NBS)
IER13	Request & Response EC24 - Pseudo-identity
IER14	Send PEC-NBS13 - NBS pre-populate form from Birthing Summary
IER15	Publish/Register PEC-NBS9 - Newborn Record
IER16	Send PEC-NBS5 - Hearing Screening Order
IER17	Publish/Register PEC-NBS4 - Birthing Summary
IER18	Query/Retrieve Clinical Data EHR to EHR
IER20	Send EC36 - Lab Result (used when constraint is 'message')
IER21	Publish/Register EC37 - Lab Result (used when constraint is 'document')
IER22	Request & Response EC37 - Lab Result (used when constraint is 'document')
IER23	Send PEC-NBS10 - Hearing Screening Test Results
IER24	Publish/Register EC32 Summary of Care
IER25	Notification EC32 Summary of Care
IER26	Subscribe EC32 Summary of Care
IER27	Request & Response PEC-NBS10 - Hearing Screening Test Results
IER28	IER28 Request & Response Education Materials PHR Public Health
IER29	Send PEC-NBS7 - Antepartum Summary
IER30	Send Family History PHR EHR
IER31	Publish/Register PEC-NBS7 - Antepartum Summary
IER32	Request & Response PEC-NBS7 - Antepartum Summary
IER33	Subscribe PEC-NBS9 - Newborn Record
IER34	Subscribe PEC-NBS4 - Birthing Summary
IER35	Subscribe EC37 - Lab Result (used when constraint is 'document')
IER36	Publish/Register EC62 Unstructured Data for screening consent, retention of samples, or refusals PHR HIE
IER37	Publish/Register EC30 - Consent Document Component PHR HIE
IER38	Publish/Register PEC-NBS10 - Hearing Screening Test Results
IER39	Request & Response EC30 - Consent Document Component
IER40	Request & Response PEC-NBS9 - Newborn Record Public Health
IER41	Send Lab Order Lab
IER42	Send PEC-NBS12 - Request for new Specimen
IER43	Send EC36 - Lab Result (used when constraint is 'message') LIMS
IER44	Send EC32 - Summary of Care
IER45	Send EC36 - Lab Result (used when constraint is 'message') PH
IER46	Send EC48B - Discharge Summary
IER47	Send EC37 - Lab Result (used when constraint is 'document')
IER48	Send EC48a - Referral Summary
IER49	Request & Response EC32 - Summary of Care
IER50	Request & Response EC48B - Discharge Summary
IER51	Publish/Register EC32 - Summary of Care
IER52	Publish/Register Lab Results PH HIE
IER53	Request & Response EC37 - Lab Result (used when constraint is 'document')
IER54	Send PEC-NBS10 - Hearing Screening Test Results PH
IER55	Send PEC-NBS10 - Hearing Screening Test Results EHR



Information Exchange Requirement Number (IER)	Description
IER56	Request & Response PEC-NBS10 - Hearing Screening Test Results PHR
IER57	Request & Response PEC-NBS10 - Hearing Screening Test Results PH
IER58	Publish/Register PEC-NBS10 - Hearing Screening Test Results
IER59	Send EC32 - Summary of Care PH
IER60	Send EC48B - Discharge Summary PH
IER61	Send EC48a - Referral Summary PH
IER62	Request & Response EC32 - Summary of Care EHR
IER63	Request & Response EC48B - Discharge Summary
IER64	Send EC36 Lab Result (used when constraint is 'message') DEV EHR PH
IER65	Send EC36 Lab Result (used when constraint is 'message') PH EHR PH
IER66	Send EC36 Lab Result (used when constraint is 'message') EHR EHR PH

Table 2-3 lists and describes the major subdivisions of a Harmonization Request, called Scenarios.

Table 2-3 Description of Scenarios

Scenario Name	Scenario Description
Ordering and Result Reporting	This scenario covers initial screening both for Newborn Dried Blood Spot (NDBS) and Early Hearing Detection and Intervention (EHDI) and ends with the reporting of results, either within normal limits, or notification of the need for confirmatory testing if results are outside of normal limits
Abnormal and Out of Range Results	This scenario covers the processes in response to an out of range (or abnormal) screening test either from the NDBS or the EHDI

2.2 ORDERING AND RESULT REPORTING SCENARIO

This scenario covers initial screening both for Newborn Dried Blood Spot (NDBS) and Early Hearing Detection and Intervention (EHDI) and ends with the reporting of results, either within normal limits, or notification of the need for confirmatory testing if results are outside of normal limits.

After the parents or current guardian(s) receive the appropriate educational material on the screening testing process (ideally during the prenatal period) and are appropriately informed and/or consented, the newborn screening testing is performed. For metabolic testing, a blood specimen is taken, typically in the form of a blood spot on specially designed filter paper. In some instances, this may need to be done at a later time by the pediatric clinician. The blood spot is sent to a testing laboratory which may sub-divide the specimen for testing at other facilities. Results of the metabolic screening are reported to the birthing facility, appropriate public health facilities, the ordering and pediatric clinician, and in some instances the consumer(s) who are notified by either the ordering or pediatric clinician. A second specimen may be required in some states and/or for particular circumstantial reasons.

The hearing test (EHDI) is performed at an audiology center associated with the birthing facility. Results of the hearing test are reported to the birthing facility, appropriate public health facilities, the ordering and pediatric clinician, and in some instances the consumer(s) who are notified by either the ordering or pediatric clinician. Result confirmation may be necessary in certain situations. Upon the communication of normal results, the newborn screening process is complete.

2.2.1 INFORMATION EXCHANGE REQUIREMENTS FOR ORDERING AND RESULTING

Table 2-4 summarizes the relationship between the Exchange Action, Exchange Content, and the Initiating and Responding System(s) along with Exchange Attributes.



Table 2-4 Ordering and Resulting Information Exchange Requirements

IER Number	Exchange Action	Exchange Content	Initiating System	Responding System(s)	Exchange Attribute
IER1	Request & Response	PEC-NBS6 – Guideline	Electronic Health Record (EHR) System	Public Health Information System	
IER19	Request & Response	PEC-NBS6 – Guideline	Personal Health Record (PHR) Systems	Public Health Information System	
IER2	Request & Response	PEC-NBS8 – Education Brochure	Electronic Health Record (EHR) System	Public Health Information System	NOTE: Assume that the Consumer has access to the test results as enabled by HITSP/IS05
IER28	Request & Response	PEC-NBS8 – Education Brochure	Personal Health Record (PHR) Systems	Public Health Information System	NOTE: Assume that the Consumer has access to the test results as enabled by HITSP/IS05
IER3	Send	PEC-NBS8 – Education Brochure	Public Health Information System	Electronic Health Record (EHR) System	Site identifier, subject identifier, visit identifier, study identifier, redacted Newborn Screening document
IER4	Send	PEC-NBS6 – Guideline	Public Health Information System	Electronic Health Record (EHR) System	
IER5	Publish/Register	EC 62 Unstructured Data	Electronic Health Record (EHR) System	Health Information Exchange (HIE)	Consent to Procedure Consent to Retain/Use Test Sample Refusal of Screening Mom/baby authorizations Policy requirement considerations vs. voluntary participation e.g. Texas policy allows for: Screen only, disclose information, refuse
IER36	Publish/Register	EC 62 Unstructured Data	Personal Health Record (PHR) Systems	Health Information Exchange (HIE)	Consent to Procedure Consent to Retain/Use Test Sample Refusal of Screening Mom/baby authorizations Policy requirement considerations vs. voluntary participation e.g. Texas policy allows for: Screen only, disclose information, refuse
IER6	Publish/Register	EC30 – Consent Document Component	Electronic Health Record (EHR) System	Health Information Exchange (HIE)	Consent to share information Mom/Baby consent authorization requirements Policy MAY require EC 26 – Nonrepudiation of Origin Data and/or EC25 – Anonymization Instructions



IER Number	Exchange Action	Exchange Content	Initiating System	Responding System(s)	Exchange Attribute
IER37	Publish/Register	EC30 – Consent Document Component	Personal Health Record (PHR) Systems	Health Information Exchange (HIE)	Consent to share information Mom/Baby consent authorization requirements Policy MAY require EC 26 – Nonrepudiation of Origin Data and/or EC25 – Anonymization Instructions
IER7	Request & Response	PEC-NBS15 – Newborn Screening Value Sets	Electronic Health Record (EHR) System	Health Information Exchange (HIE)	
IER8	Request & Response	PEC-NBS9 – Newborn Record	Electronic Health Record (EHR) System	Electronic Health Record (EHR) System Health Information Exchange (HIE)	GAP: Resolution – anticipate a construct to be delivered in 2010 from IHE PCC – Newborn Discharge Summary PDR-NBS14 Pediatric Demographics DR10 Family History
IER40	Request & Response	PEC-NBS9 – Newborn Record	Public Health Information System	Electronic Health Record (EHR) System Health Information Exchange (HIE)	GAP: Resolution – anticipate a construct to be delivered in 2010 from IHE PCC – Newborn Discharge Summary PDR-NBS14 Pediatric Demographics DR10 Family History
IER9	Request & Response	PEC-NBS4 – Birthing Summary	Electronic Health Record (EHR) System	Electronic Health Record (EHR) System Health Information Exchange (HIE)	NOTE: More applicable for referrals to specialist. Birthing Summary is not readily available today. May be as a pre-existing condition; Birthing PDR-NBS14 Pediatric Demographics DR10 Family History
IER10	Send	PEC-NBS9 – Newborn Record	Electronic Health Record (EHR) System	Electronic Health Record (EHR) System Public Health Information System	PDR-NBS14 Pediatric Demographics DR10 Family History
IER11	Send	PEC-NBS4 – Birthing Summary	Electronic Health Record (EHR) System	Electronic Health Record (EHR) System	PDR-NBS14 Pediatric Demographics DR10 Family History
IER12	Send	PEC-NBS3 – Lab Order (NBS)	Electronic Health Record (EHR) System	Laboratory Information Systems	Need to indicate test qualifiers (first, repeat specimen, or repeat test); PDR-NBS14 Pediatric Demographics
IER41	Send	PEC-NBS3 – Lab Order (NBS)	Laboratory Information Systems	Laboratory Information Systems	Need to indicate test qualifiers (first, repeat specimen, or repeat test); PDR-NBS14 Pediatric Demographics
IER13	Request & Response	EC24 – Pseudo-identity	Electronic Health Record (EHR) System	Health Information Exchange (HIE)	Situations for adoption or child protective situations: pseudonymization/de-identification from mother to baby/baby-to mother



IER Number	Exchange Action	Exchange Content	Initiating System	Responding System(s)	Exchange Attribute
IER14	Send	PEC-NBS13 – NBS pre-populate form from Birthing Summary	Electronic Health Record (EHR) System	Health Information Exchange (HIE) Public Health Information System	HITSP/TP50 RFD Pre-populate; Data Entry NOTE: Only data required for prepopulating the order are required
IER15	Publish/Register	PEC-NBS9 – Newborn Record	Electronic Health Record (EHR) System	HIE	PDR-NBS14 Pediatric Demographics DR10 Family History
IER16	Send	PEC-NBS5 – Hearing Screening Order	Electronic Health Record (EHR) System	Electronic Health Record (EHR) System Hearing Screening System Public Health Information System	In the case that the EHR supporting the hearing screening order is a different system from that servicing the hearing screening activities PDR-NBS14 Pediatric Demographics
IER17	Publish/Register	PEC-NBS4 – Birthing Summary	Electronic Health Record (EHR) System	Health Information Exchange (HIE)	PDR-NBS14 Pediatric Demographics DR10 Family History
IER18	Query/Retrieve	Clinical Data	Personal Health Record (PHR) Systems	Electronic Health Record (EHR) System	
IER20	Send	EC36 – Lab Result (used when constraint is 'message')	Electronic Health Record (EHR) System	Electronic Health Record (EHR) System Public Health	Policy may require Anonymize patient identifiable data (EHDI and NDBS) stage, for Public Health to Public Health communications PDR-NBS14 Pediatric Demographics
IER43	Send	EC36 – Lab Result (used when constraint is 'message')	Laboratory Information Systems	Electronic Health Record (EHR) System Public Health	Policy may require Anonymize patient identifiable data (EHDI and NDBS) stage, for Public Health to Public Health communications PDR-NBS14 Pediatric Demographics
IER45	Send	EC36 – Lab Result (used when constraint is 'message')	Public Health	Electronic Health Record (EHR) System Public Health	Policy may require Anonymize patient identifiable data (EHDI and NDBS) stage, for Public Health to Public Health communications PDR-NBS14 Pediatric Demographics
IER21	Publish/Register	EC37 – Lab Result (used when constraint is 'document')	Laboratory Information Systems	Health Information Exchange (HIE)	PDR-NBS14 Pediatric Demographics
IER52	Publish/Register	EC37 – Lab Result (used when constraint is 'document')	Public Health	Health Information Exchange (HIE)	PDR-NBS14 Pediatric Demographics
IER22	Request & Response	EC37 – Lab Result (used when constraint is 'document')	Electronic Health Record (EHR) System	Health Information Exchange (HIE)	PDR-NBS14 Pediatric Demographics



IER Number	Exchange Action	Exchange Content	Initiating System	Responding System(s)	Exchange Attribute
IER53	Request & Response	EC37 – Lab Result (used when constraint is 'document')	Public Health	Health Information Exchange (HIE)	PDR-NBS14 Pediatric Demographics
IER23	Send	PEC-NBS10 – Hearing Screening Test Results	Hearing Screening System	Electronic Health Record (EHR) System Personal Health Record (PHR) Systems Public Health Information System	Public health interprets information Subscription option PDR-NBS14 Pediatric Demographics DR10 Family History
IER64	Send	EC36 – Lab Result (used when constraint is 'message')	Hearing Screening System	Electronic Health Record (EHR) System Public Health Information System	PDR-NBS14 Pediatric Demographics NOTE: Optional use of Lab Result Message used to communicate hearing screening results
IER54	Send	PEC-NBS10 – Hearing Screening Test Results	Public Health Information System	Electronic Health Record (EHR) System Personal Health Record (PHR) Systems Public Health Information System	Public Health interprets information. Results from Public Health shall include Care Status summary/outcome Policy may require Anonymize patient identifiable data(EHDI and NDBS) for Public Health to Public Health communications Public Health interprets information Subscription option PDR-NBS14 Pediatric Demographics DR10 Family History
IER65	Send	EC36 – Lab Result (used when constraint is 'message')	Public Health Information System	Electronic Health Record (EHR) System Public Health Information System	Results from Public Health shall include Care Status summary/outcome Policy may require Anonymize patient identifiable data(EHDI and NDBS) for Public Health to Public Health communications Public Health interprets information PDR-NBS14 Pediatric Demographics DR10 Family History NOTE: Optional use of Lab Result Message used to communicate hearing screening results
IER55	Send	PEC-NBS10 – Hearing Screening Test Results	Electronic Health Record (EHR) System	Electronic Health Record (EHR) System Personal Health Record (PHR) Systems Public Health Information System	Public Health interprets information. Results from Public Health shall include Care Status summary/outcome Subscription option PDR-NBS14 Pediatric Demographics DR10 Family History



IER Number	Exchange Action	Exchange Content	Initiating System	Responding System(s)	Exchange Attribute
IER66	Send	EC36 – Lab Result (used when constraint is 'message')	Electronic Health Record (EHR) System	Electronic Health Record (EHR) System Public Health Information System	Public Health interprets information. Results from Public Health shall include Care Status summary/outcome PDR-NBS14 Pediatric Demographics DR10 Family History
IER24	Publish/Register	EC32 Summary of Care	Public Health Information System	Health Information Exchange (HIE)	Jurisdictionally Driven – Hearing Screening Outcome PDR-NBS14 Pediatric Demographics DR10 Family History
IER25	Notification	EC32 Summary of Care	Public Health	Electronic Health Record (EHR) System	Abnormal Results Flagged PDR-NBS14 Pediatric Demographics DR10 Family History
IER26	Subscribe	EC32 Summary of Care	Electronic Health Record (EHR) System	Health Information Exchange (HIE)	Policy considerations to assert subscription request may depend upon a relationship with the patient PDR-NBS14 Pediatric Demographics DR10 Family History
IER27	Request & Response	PEC-NBS10 – Hearing Screening Test Results	Electronic Health Record (EHR) System Personal Health Record (PHR) Systems Public Health	Health Information Exchange (HIE)	Subscription option PDR-NBS14 Pediatric Demographics DR10 Family History
IER56	Request & Response	PEC-NBS10 – Hearing Screening Test Results	Personal Health Record (PHR) Systems	Health Information Exchange (HIE)	Subscription option PDR-NBS14 Pediatric Demographics DR10 Family History
IER57	Request & Response	PEC-NBS10 – Hearing Screening Test Results	Public Health	Health Information Exchange (HIE)	Subscription option PDR-NBS14 Pediatric Demographics DR10 Family History
IER29	Send	PEC-NBS7 – Antepartum Summary	Personal Health Record (PHR) Systems	Electronic Health Record (EHR) System	Pediatric Clinician Required NOTE: Priority to Birthing Record Pediatric Clinician if different DR10 Family History
IER31	Publish/Register	PEC-NBS7 – Antepartum Summary	Personal Health Record (PHR) Systems	Health Information Exchange (HIE)	Pediatric Clinician Required NOTE: Priority to Birthing Record Pediatric Clinician if different DR10 Family History
IER32	Request & Response	PEC-NBS7 – Antepartum Summary	Electronic Health Record (EHR) System	Health Information Exchange (HIE)	Pediatric Clinician Required NOTE: Priority to Birthing Record Pediatric Clinician if different Subscription option DR10 Family History



IER Number	Exchange Action	Exchange Content	Initiating System	Responding System(s)	Exchange Attribute
IER33	Subscribe	PEC-NBS9 – Newborn Record	Personal Health Record (PHR) Systems	Health Information Exchange (HIE)	PDR-NBS14 Pediatric Demographics DR10 Family History
IER34	Subscribe	PEC-NBS4 – Birthing Summary	Personal Health Record (PHR) Systems	Health Information Exchange (HIE)	PDR-NBS14 Pediatric Demographics DR10 Family History
IER35	Subscribe	EC37 – Lab Result (used when constraint is 'document')	Personal Health Record (PHR) Systems	Health Information Exchange (HIE)	PDR-NBS14 Pediatric Demographics
IER38	Publish/Register	PEC-NBS10 – Hearing Screening Test Results	Electronic Health Record (EHR) System	Health Information Exchange (HIE)	PDR-NBS14 Pediatric Demographics DR10 Family History
IER58	Publish/Register	PEC-NBS10 – Hearing Screening Test Results	Public Health	Health Information Exchange (HIE)	PDR-NBS14 Pediatric Demographics DR10 Family History
IER39	Request & Response	EC30 – Consent Document Component	Public Health	Health Information Exchange (HIE)	
IER42	Send	PEC-NBS12 – Request for new Specimen	Laboratory Information Systems	Electronic Health Record (EHR) System Personal Health Record (PHR) Systems	Notification This may be indicated using a LOINC code that indicates that a new specimen is required 57718-9 specimen quality of dried bloodspot; In an out of range result, this needs to be handled out of band by clinician-clinician communication

2.3 ABNORMAL AND OUT OF RANGE RESULTS SCENARIO

This scenario covers the processes in response to an out of range (or abnormal) screening test either from the Newborn Dried Blood Spot (NDBS) and Early Hearing Detection and Intervention (EHDI) test. Additional testing may be required when the NDBS result is indeterminate, of insufficient quantity, out of range or abnormal. If known and available, the infant's primary care provider is notified, a family history may be obtained and in certain situations, a sub-specialist or sub-specialist team may be notified. Consultations may take place between any or all of these clinicians and the results of any additional or confirmatory testing are reported back to Public Health. If the results are confirmed, the infant is referred to a specialist where culturally competent or appropriate counseling and education can be initiated.

When the EHDI result is abnormal, similar processes are initiated. A family history is obtained and confirmatory auditory testing is done. An audiology evaluation may involve referral for genetic consultation which may in turn lead to various kinds of genetic testing. Again, consultations may take place between a primary care provider, various specialists and/or the Public Health Department. After confirmation of hearing loss, the audiologist or primary care provider refers the patient to the appropriate specialists and results are reported to Public Health Department.

This scenario also covers clinical management of children with conditions identified by newborn screening, Public Health reporting, program monitoring, and health services. Clinical management is consistent with standard of care and, when available, research derived from outcome data from prior newborn screening.

During the Short Term Follow-up (STFU) period, children may require a variety of medical interventions, which might include emergency management, nutritional therapy, audiology follow-up and/or



management, or other forms of treatment. Pertinent clinical findings must follow patients as they move between clinicians as described in the 2008 Consultations and Transfers of Care Use Case. As described in the Dataset Considerations section of this document, additional information may be needed in addition to the information needs described in previous Use Cases. This is particularly important considering the type of information gathered by newborn screening since much of it has an impact during childhood development.

Long Term Follow-up (LTFU) and outcomes should be reported to Public Health at appropriate intervals. This information is important to determine the effectiveness of newborn screening. Other registries and research organizations may also benefit from receiving this information. Research organizations would receive only de-identified data.

2.3.1 INFORMATION EXCHANGE REQUIREMENTS FOR ABNORMAL AND OUT OF RANGE RESULTS

Table 2-5 summarizes the relationship between the Exchange Action, Exchange Content, and the Initiating and Responding Systems along with Exchange Attributes.

Table 2-5 Abnormal and Out of Range Results Information Exchange Requirements

Information Exchange Requirement Number	Exchange Action	Exchange Content	Initiating System	Responding System(s)	Exchange Attribute
IER1	Request & Response	PEC-NBS6 - Guideline	Electronic Health Record (EHR) System	Public Health Information System	
IER19	Request & Response	PEC-NBS6 - Guideline	Personal Health Record (PHR) Systems	Public Health Information System	
IER2	Request & Response	PEC-NBS8 - Education Brochure	Electronic Health Record (EHR) System	Public Health Information System	
IER4	Send	PEC-NBS6 - Guideline	Public Health Information System	Electronic Health Record (EHR) System	
IER5	Publish/Register	EC62 Unstructured Data	Electronic Health Record (EHR) System	Health Information Exchange (HIE)	Refusal documentation Consent to Procedure Consent to Retain/Use Test Sample Captured as an Unstructured Document Policy requirement considerations vs. voluntary participation e.g. Texas policy allows for: Screen only, disclose information, refuse



IER36	Publish/Register	EC62 Unstructured Data	Personal Health Record (PHR) Systems	Health Information Exchange (HIE)	Refusal documentation Consent to Procedure Consent to Retain/Use Test Sample Captured as an Unstructured Document Policy requirement considerations vs. voluntary participation e.g. Texas policy allows for: Screen only, disclose information, refuse
IER6	Publish/Register	EC30 Consent Document Component	Electronic Health Record (EHR) System	Health Information Exchange (HIE)	Consent to share information. Mom/Baby consent authorization requirements. Policy MAY require EC 26 Nonrepudiation of Origin Data and/or EC25 Anonymization Instructions
IER37	Publish/Register	EC30 Consent Document Component	Personal Health Record (PHR) Systems	Health Information Exchange (HIE)	Consent to share information. Mom/Baby consent authorization requirements. Policy MAY require EC 26 Nonrepudiation of Origin Data and/or EC25 Anonymization Instructions
IER12	Send	PEC-NBS3 – Lab Order (NBS)	Electronic Health Record (EHR) System	Laboratory Information Systems	Need to indicate test qualifiers (first, repeat specimen, or repeat test); PDR-NBS14 Pediatric Demographics
IER41	Send	PEC-NBS3 – Lab Order (NBS)	Laboratory Information Systems	Laboratory Information Systems	Need to indicate test qualifiers (first, repeat specimen, or repeat test); PDR-NBS14 Pediatric Demographics
IER16	Send	PEC-NBS5 – Hearing Screening Order	Electronic Health Record (EHR) System	Electronic Health Record (EHR) System Hearing Screening System Public Health Information System	In the case that the EHR supporting the hearing screening order is a different system from that servicing the hearing screening activities PDR-NBS14 Pediatric Demographics



IER21	Publish/Register	EC37 – Lab Result (used when constraint is 'document')	Laboratory Information Systems	Health Information Exchange (HIE)	PDR-NBS14 Pediatric Demographics
IER52	Publish/Register	EC37 – Lab Result (used when constraint is 'document')	Public Health	Health Information Exchange (HIE)	PDR-NBS14 Pediatric Demographics
IER22	Request & Response	EC37 – Lab Result (used when constraint is 'document')	Electronic Health Record (EHR) System	Health Information Exchange (HIE)	PDR-NBS14 Pediatric Demographics
IER23	Send	PEC-NBS10 – Hearing Screening Test Results	Hearing Screening System	Electronic Health Record (EHR) System Public Health Information System Personal Health Record (PHR) Systems	Public health interprets information Subscription option PDR-NBS14 Pediatric Demographics DR10 Family History
IER64	Send	EC36 – Lab Result (used when constraint is 'message')	Hearing Screening System	Electronic Health Record (EHR) System Public Health Information System	PDR-NBS14 Pediatric Demographics NOTE: Optional use of Lab Result Message used to communicate hearing screening results
IER55	Send	PEC-NBS10 – Hearing Screening Test Results	Electronic Health Record (EHR) System	Electronic Health Record (EHR) System Public Health Information System Personal Health Record (PHR) Systems	Public Health interprets information Subscription option PDR-NBS14 Pediatric Demographics DR10 Family History
IER66	Send	EC36 – Lab Result (used when constraint is 'message')	Electronic Health Record (EHR) System	Electronic Health Record (EHR) System Public Health Information System	Public Health interprets information. Results from Public Health shall include Care Status summary/outcome PDR-NBS14 Pediatric Demographics DR10 Family History
IER24	Publish/Register	PEC-NBS10 – Hearing Screening Test Results	Public Health Information System	Health Information Exchange (HIE)	Jurisdictionally Driven – Hearing Screening Outcome. Require Care status summary/outcome PDR-NBS14 Pediatric Demographics DR10 Family History



IER25	Notification	PEC-NBS10 – Hearing Screening Test Results	Public Health	Electronic Health Record (EHR) System	Abnormal Results Flagged Require Care status summary/outcome PDR-NBS14 Pediatric Demographics DR10 Family History
IER26	Subscribe	PEC-NBS10 – Hearing Screening Test Results	Electronic Health Record (EHR) System	Health Information Exchange (HIE)	Policy considerations to assert subscription request may depend upon a relationship with the patient. Require Care status summary/outcome PDR-NBS14 Pediatric Demographics DR10 Family History
IER27	Request & Response	PEC-NBS10 – Hearing Screening Test Results	Electronic Health Record (EHR) System	Health Information Exchange (HIE)	Require Care status summary/outcome PDR-NBS14 Pediatric Demographics DR10 Family History
IER56	Request & Response	PEC-NBS10 – Hearing Screening Test Results	Personal Health Record (PHR) Systems	Health Information Exchange (HIE)	Require Care status summary/outcome PDR-NBS14 Pediatric Demographics DR10 Family History
IER57	Request & Response	PEC-NBS10 – Hearing Screening Test Results	Public Health Information System	Health Information Exchange (HIE)	Require Care status summary/outcome PDR-NBS14 Pediatric Demographics DR10 Family History
IER29	Send	PEC-NBS7 – Antepartum Summary	Personal Health Record (PHR) Systems	Electronic Health Record (EHR) System	DR10 Family History
IER35	Request & Response	EC37 – Lab Result (used when constraint is 'document')	Personal Health Record (PHR) Systems	Health Information Exchange (HIE)	Subscription option PDR-NBS14 Pediatric Demographics
IER38	Publish/Register	PEC-NBS10 – Hearing Screening Test Results	Electronic Health Record (EHR) System	Health Information Exchange (HIE)	PDR-NBS14 Pediatric Demographics DR10 Family History
IER58	Publish/Register	PEC-NBS10 – Hearing Screening Test Results	Public Health	Health Information Exchange (HIE)	PDR-NBS14 Pediatric Demographics DR10 Family History
IER39	Request & Response	EC30 Consent Document Component	Public Health	Health Information Exchange (HIE)	
IER44	Send	EC32 – Summary of Care	Electronic Health Record (EHR) System	Electronic Health Record (EHR) System Electronic Health Record (EHR) System	PDR-NBS14 Pediatric Demographics DR10 Family History



IER59	Send	EC32 – Summary of Care	Public Health Information System	Electronic Health Record (EHR) System Electronic Health Record (EHR) System	PDR-NBS14 Pediatric Demographics DR10 Family History
IER46	Send	EC48B – Discharge Summary	Electronic Health Record (EHR) System	Electronic Health Record (EHR) System Personal Health Record (PHR) Systems	PDR-NBS14 Pediatric Demographics DR10 Family History
IER60	Send	EC48B – Discharge Summary	Public Health Information System	Electronic Health Record (EHR) System Personal Health Record (PHR) Systems	PDR-NBS14 Pediatric Demographics DR10 Family History
IER47	Send	EC37 – Lab Result (used when constraint is 'document')	Electronic Health Record (EHR) System	Personal Health Record (PHR) Systems	PDR-NBS14 Pediatric Demographics Subscription option
IER48	Send	EC48a – Referral Summary	Electronic Health Record (EHR) System	Electronic Health Record (EHR) System	PDR-NBS14 Pediatric Demographics DR10 Family History
IER61	Send	EC48a – Referral Summary	Public Health Information System	Electronic Health Record (EHR) System	PDR-NBS14 Pediatric Demographics DR10 Family History
IER49	Request & Response	EC32 – Summary of Care	Personal Health Record (PHR) Systems	Health Information Exchange (HIE)	PDR-NBS14 Pediatric Demographics DR10 Family History
IER62	Request & Response	EC32 – Summary of Care	Electronic Health Record (EHR) System	Health Information Exchange (HIE)	PDR-NBS14 Pediatric Demographics DR10 Family History
IER50	Request & Response	EC48B – Discharge Summary	Personal Health Record (PHR) Systems	Health Information Exchange (HIE)	PDR-NBS14 Pediatric Demographics DR10 Family History
IER63	Request & Response	EC48B – Discharge Summary	Electronic Health Record (EHR) System	Health Information Exchange (HIE)	PDR-NBS14 Pediatric Demographics DR10 Family History
IER51	Publish/Register	EC32 – Summary of Care	Electronic Health Record (EHR) System	Health Information Exchange (HIE)	PDR-NBS14 Pediatric Demographics DR10 Family History

2.4 SYSTEM DESCRIPTION

The following table lists systems involved in the above listed scenarios, and identifies the stakeholders served by those involved systems.



Table 2-6 System Names and Descriptions

System Name	System Description	Stakeholders
Electronic Health Record (EHR) System	The Electronic Health Record (EHR) System is a secure, real-time, point-of-care, patient-centric information resource for clinicians	Electronic Health Record (EHR)/Personal Health Record (PHR) System Suppliers Clinicians Healthcare Entities Specialty Healthcare Entities
Health Information Exchange (HIE)	A Health Information Exchange (HIE) is a multi-stakeholder system that enables the exchange and use of health information, in a secure manner, for the purpose of promoting the improvement of health quality, safety and efficiency	Health Information Exchange Organizations
Public Health Information System	An automated and integrated system used to document and address information of interest to public health. Local, state, and federal government organizations and personnel use these systems to help protect and improve the health of their respective constituents. A critical effort under this charge is collecting health information to monitor for the existence of emerging health threats appearing in the population and manage these threats once manifested. Staff of these agencies interacts with the public health information system to verify and validate system indications of public health threats, and to assert acknowledgements that may be required by system processes	Government and Regulatory Agencies Knowledge Suppliers Public Health Agencies Public Health Systems Suppliers Registries Research Entities Social Service Agencies
Laboratory Information Systems	Information system supporting the testing, analysis, and information management for laboratory organizations. Medical laboratories, in either in a hospital or ambulatory environment, which analyze specimens as ordered by clinicians to assess the health status of patients. Laboratories, depending on how they are affiliated with hospitals, can be part of either Individual Healthcare Facilities or Integrated Healthcare Data Suppliers. These systems are responsible for updating interface engine rules and triggers in response to Use Case modifications of requested data feeds.	Laboratory Associations Laboratory Information System (LIS) Suppliers Testing Laboratories
Personal Health Record (PHR) Systems	A healthcare record system used to create, review, annotate and maintain records by the patient or the caregiver for a patient. The PHR may include any aspect(s) of the health condition, medications, medical problems, allergies, vaccination history, visit history or communications with healthcare providers	Personal Health Record (PHR) System Suppliers, Consumers Patients
Hearing Screening System	A System used to measure and record the audiology function of the patient	Audiology Service Providers



3.0 DESIGN SPECIFICATION

Section 3.0 identifies the Capabilities used to meet the requirements identified in Section 2.0 Requirements and describes how to orchestrate this set of Capabilities to meet those requirements. The following table details how this section of the document is targeted to specific readers. Each of the stakeholders listed in this table are more fully defined in a separate appendix. This table is provided as an aid to readers to assist with identifying specific areas of focus. Readers are encouraged to review all sections of this document to further their understanding of HITSP's work.

Table 3-1 Reader's Guide for Section 3.0

Document Section	Section Number	Intended Audience	Information Contained
Section 3.0 Design Specification	3.1 Capabilities Used	Architects Business Analysts Development Team	For each Information Exchange Requirement (IER) identified in Section 2.0, a corresponding Capability is associated and mapped. A reader can review how specific Capabilities meet information exchange needs. A diagram is also provided to show the interchange of data among systems identified in this Interoperability Specification
	3.2 Capability Orchestration	Architects Development Team	The core of the design in the Interoperability Specification is documented here. This solution shows orchestration of Capabilities to meet the specific Information Exchange Requirements (IER) in Section 3.1. The design also identifies conditions and constraints, as well as any content subsets specific to the solution

3.1 CAPABILITIES USED

The table below lists the Capabilities used in this Interoperability Specification, and relates them to the information exchange requirements from Table 2-2 that the Capability satisfies. The information exchanges listed are the relevant information exchanges from the underlying Capability.

Table 3-2 Capabilities Used

Capability	Capability Summary	Capability IE Used	IERs Satisfied
HITSP/CAP119 – Communicate Structured Document	This Capability addresses interoperability requirements that support the communication of structured health data related to a patient in a context set by the source of the document who is attesting to its content. Several document content subsets, structured according to the HL7 CDA standard, are supported by this Capability. The following are examples of the type of structured data that may be used: <ul style="list-style-type: none"> Continuity of Care Document (CCD) Emergency Department Encounter Summary Discharge Summary (In-patient encounter and/or episodes of care) Referral Summary Ambulatory (encounter and/or episodes of care) Consultation Notes History and Physical Personal Health Device Monitoring Document Healthcare Associated Infection (HAI) Report Document Document creators shall support a number of the HITSP specified coded terminologies as defined by specific content subsets specified in this Capability	1– Send Documents	IER8
			IER9
			IER15
			IER17
			IER18
			IER24
			IER25
			IER26
			IER27
			IER31
			IER32
			IER33
			IER34
			IER38
			IER49
			IER50
			IER51
			IER10
			IER11
			IER23



Capability	Capability Summary	Capability IE Used	IEs Satisfied
			IER29
			IER44
			IER46
			IER40
			IER54
			IER55
			IER56
			IER57.
			IER58
			IER59
			IER60
			IER62
			IER63
		2 – Receive Documents	IER8
			IER9
			IER15
			IER17
			IER18
			IER24
			IER25
			IER26
			IER27
			IER31
			IER32
			IER33
			IER34
			IER38
			IER49
			IER50
			IER51
			IER10
			IER11
			IER23
			IER29
			IER44
			IER46
			IER40
			IER54
			IER55
			IER56
			IER57.
			IER58
			IER59
			IER60



Capability	Capability Summary	Capability IE Used	IEs Satisfied
			IER62
			IER63
HITSP/CAP120 – Communicate Unstructured Document	This Capability addresses interoperability requirements that support the communication of a set of unstructured health data related to a patient in a context set by the source of the document who is attesting to its content. Two types of specific unstructured content are supported, both with a structured CDA header: <ul style="list-style-type: none"> • PDF-A supporting long-term archival • UTF-8 text 	1– Send Documents	IER5 IER36
		2 – Receive Documents	IER5 IER36
HITSP/CAP121 – Communicate Clinical Referral Request	This Capability addresses interoperability requirements that support provider-to-provider (clinical) referral request interaction. It allows the bundling of the referral request document with other relevant clinical documents of interest by referencing such documents as shared by other Capabilities such as: HITSP/CAP119 Communicate Structured Document; HITSP/CAP120 Communicate Unstructured Document; or HITSP/CAP133 Communicate Immunization Summary	3 - Send Documents	IER48 IER61
		4 - Receive Documents	IER48 IER61
HITSP/CAP122 – Retrieve Medical Knowledge	This Capability addresses the requirements to retrieve medical knowledge that is not patient-specific based on context parameters. The actual content delivered is not constrained by this Capability; this Capability focuses on providing the mechanism to ask for (query) and receive the medical knowledge	Request and Respond Medical Knowledge	IER1 IER2 IER19 IER28
		Request and Respond Value Set	IER7
HITSP/CAP123 – Retrieve Existing Data	This Capability supports queries for clinical data (e.g., common observations, vital signs, problems, medications, allergies, immunizations, diagnostic results, professional services, procedures and visit history)	Request and Respond Existing Patient Data	IER18
HITSP/CAP126 – Communicate Lab Results Message	This Capability addresses interoperability requirements that support the sending of a set of laboratory test results. Ordering Providers of Care receive results as a laboratory results message. The communication of the order is Out of scope for this Capability. The content of these test results may be either or both: General Laboratory Test Results; Microbiology Test Results This Capability may use content anonymization	Send Lab Result Message	IER20, IER43, IER45
HITSP/CAP127 – Communicate Lab Results Document	This Capability addresses interoperability requirements that support the communication of a set of structured laboratory results related to a patient in a context set by the source of the document who is attesting to its content. Non-ordering Providers of Care access historical laboratory results as documents and "copy-to" Providers of Care may receive document availability notifications to retrieve such lab report documents. Lab Report content creators shall support HITSP specified coded terminologies as defined by specific content subsets specified in this Capability for: General Laboratory Test Results; Microbiology Test Results. This Capability may use content anonymization	Send and Receive Laboratory Report Document	IER21 IER22 IER35 IER47 IER52 IER53



Capability	Capability Summary	Capability IE Used	IEs Satisfied
HITSP/CAP135 – Retrieve and Populate Form	<p>This Capability addresses interoperability requirements to support the upload of specific captured data (e.g. public health surveillance reportable conditions, healthcare associated infection reporting) to Public Health Monitoring Systems and Quality Organizations Systems. The forms presented may be pre-populated by information provided by the clinical or laboratory information systems to avoid manual re-entry. A number of supplemental information variables may be captured from within the user's clinical information system to improve the workflow and timeliness of required reporting. One or more types of form content may be supported:</p> <ul style="list-style-type: none"> • Pre-population for Public Health Case Reports from Structured Documents using CDA • Pre-population for Quality Data from Structured Documents using CDA • No pre-population content <p>Systems may optionally support the means to retrieve request for clarifications</p>	Send Pre-population data	IER14
		Receive Pre-population data	IER14
		Send Pre-populated form	IER14
		Receive Pre-populated form	IER14
HITSP/CAP138 – Retrieve Pseudonym	<p>This Capability addresses interoperability requirements to support a particular type of anonymization that both removes the association with a data subject, and adds an association between a particular set of characteristics relating to the data subject and one or more pseudonyms. This enables a process of supplying an alternative identifier, which permits a patient to be referred to by a key that suppresses his/her actual identification information. The purpose of this Capability is to offer a pseudonymization framework for situations that require the use of specific data without disclosing the specific identity of patients or providers. Pseudo-identifiers are intended to allow accessibility to clinical information, while safeguarding any information that may compromise the privacy of the individual patient or provider. However, unlike anonymization, the alternative identifier key can be used to re-identify the individuals whose data was used</p>	Respond to Pseudonym Request	IER13
		Request Pseudonym	IER13
HITSP/CAP142 – Retrieve Communications Recipient	<p>This Capability addresses interoperability requirements that support access to a directory to identify one or more communication recipients in order to deliver alerts and bi-directional communications (e.g., public health agencies notifying a specific group of service providers about an event). The method and criteria by which individuals are added to a directory is a policy decision, which is Out of scope for this construct</p>	Respond to Personnel White Pages Query	IER3
		Query Personnel White Pages	IER3



Capability	Capability Summary	Capability IE Used	IEs Satisfied
HITSP/CAP143 – Manage Consumer Preference and Consents	This Capability addresses management of consumer preferences and consents as an acknowledgement of a privacy policy. This Capability is used to capture a patient or consumer agreement to one or more privacy policies; where examples of a privacy policy may represent a consent, dissent, authorization for data use, authorization for organizational access, or authorization for a specific clinical trial. This Capability also supports the recording of changes to prior privacy policies such as when a patient changes their level of participation or requests that data no-longer be made available because they have left the region	Send & Receive Unstructured Document	IER6, IER37 IER39
		Request & Response Consent Directives	IER6, IER37 IER39
HITSP/CAP99 – Communicate Laboratory Order Message	This Capability satisfies the information exchange requirements for the sending and receiving of a set of laboratory order, control and status messages. Laboratory orders may be from an inpatient or outpatient (e.g., Clinic, ER, office, etc) environment	Send Laboratory Order	IER12, IER41
		Request and Response Query and Response for Supporting Information	
		Send Pseudonymized Laboratory order	

The following diagram shows how systems use Capabilities to complete the full Interoperability Specification. The diagram is purposely created to be architecturally neutral. In some settings a given system role within a Capability will be filled by more than one system in the Interoperability Specification. In many settings, one system may implement multiple Capabilities as shown in the diagram. There are many potential combinations of systems using these Capabilities in different architectures as discussed in Section 3.2.1 Implementation Variants. The diagram therefore uses one example that includes all systems.



Figure 3-1 Diagram Showing Capabilities Used Between Systems Part 1

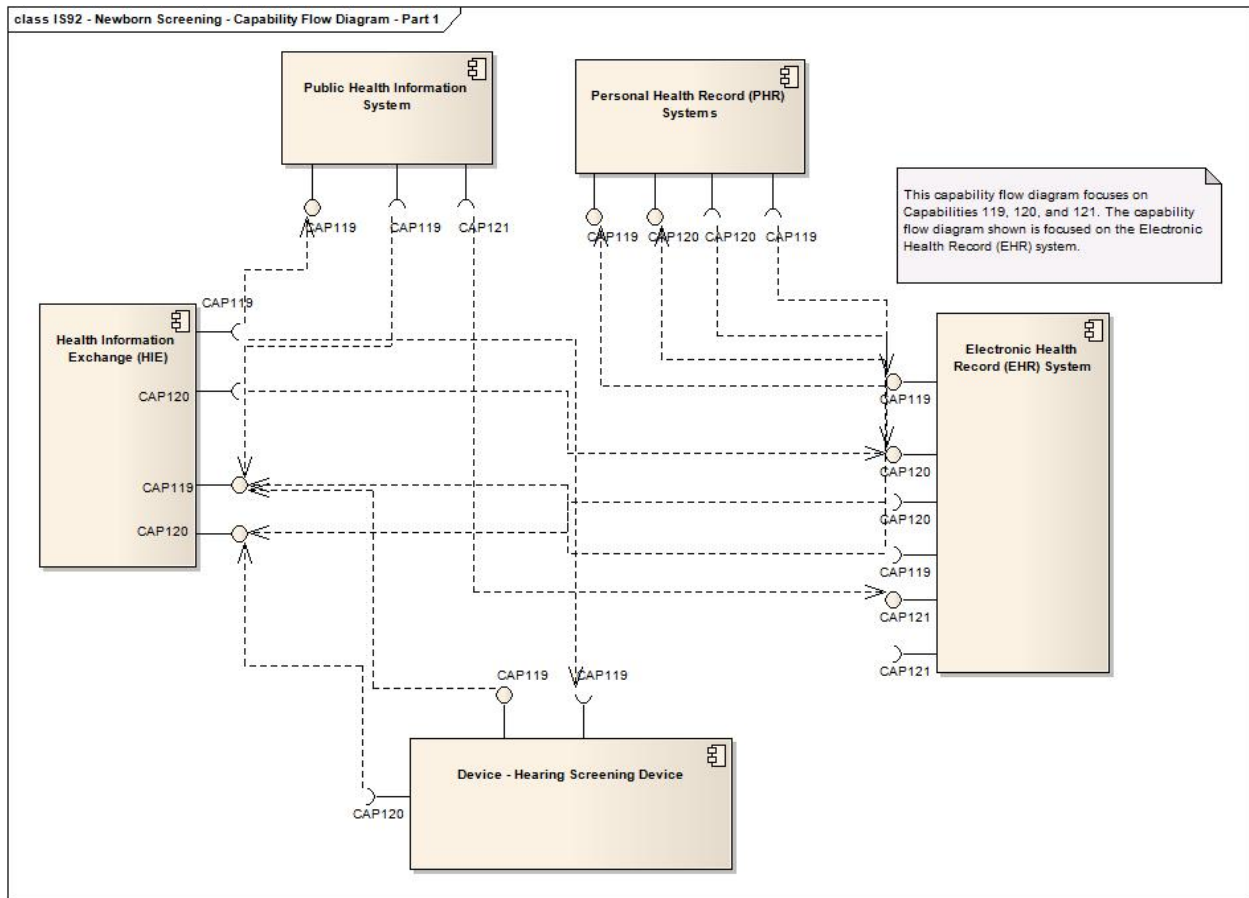


Figure 3-2 Diagram Showing Capabilities Used Between Systems Part 2

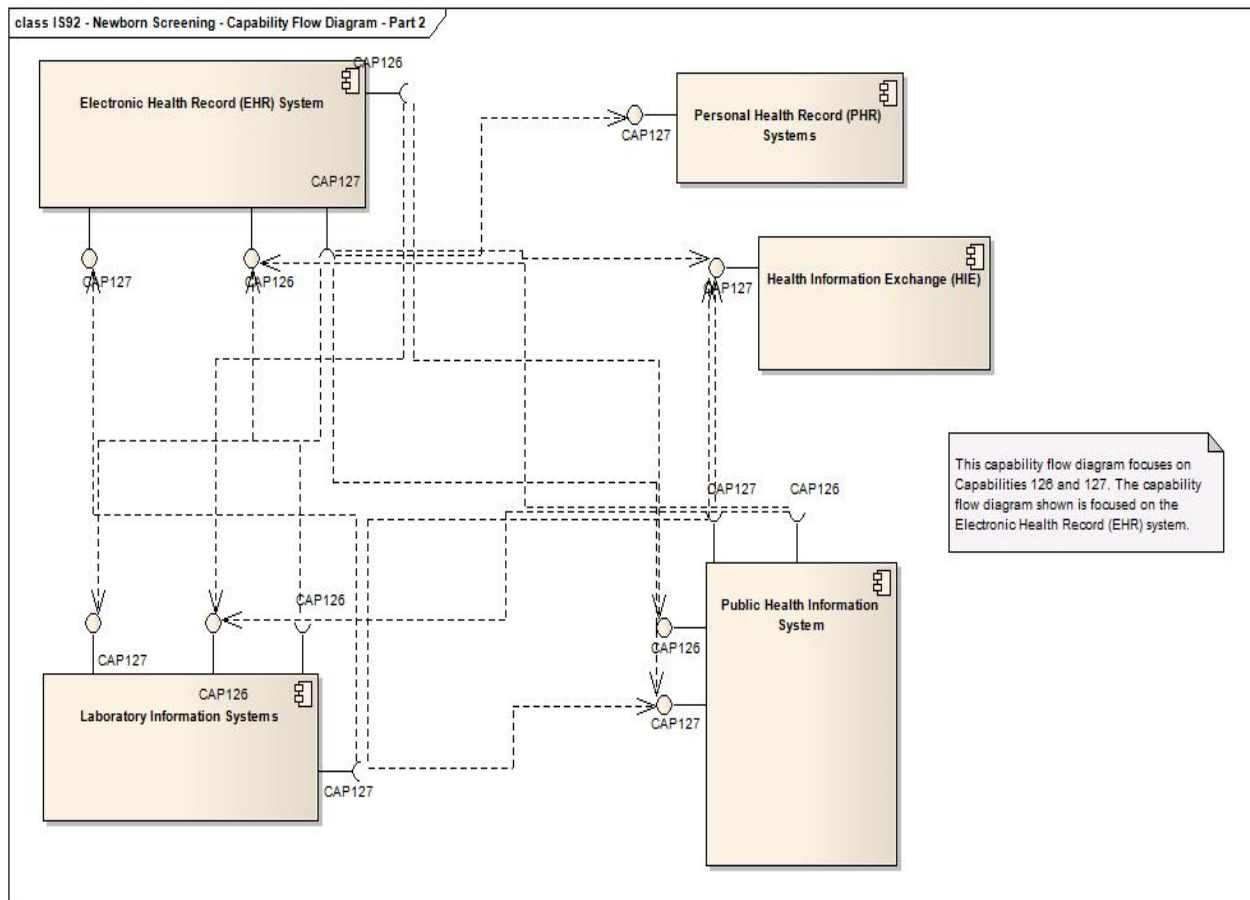


Figure 3-3 Diagram Showing Capabilities Used Between Systems Part 3

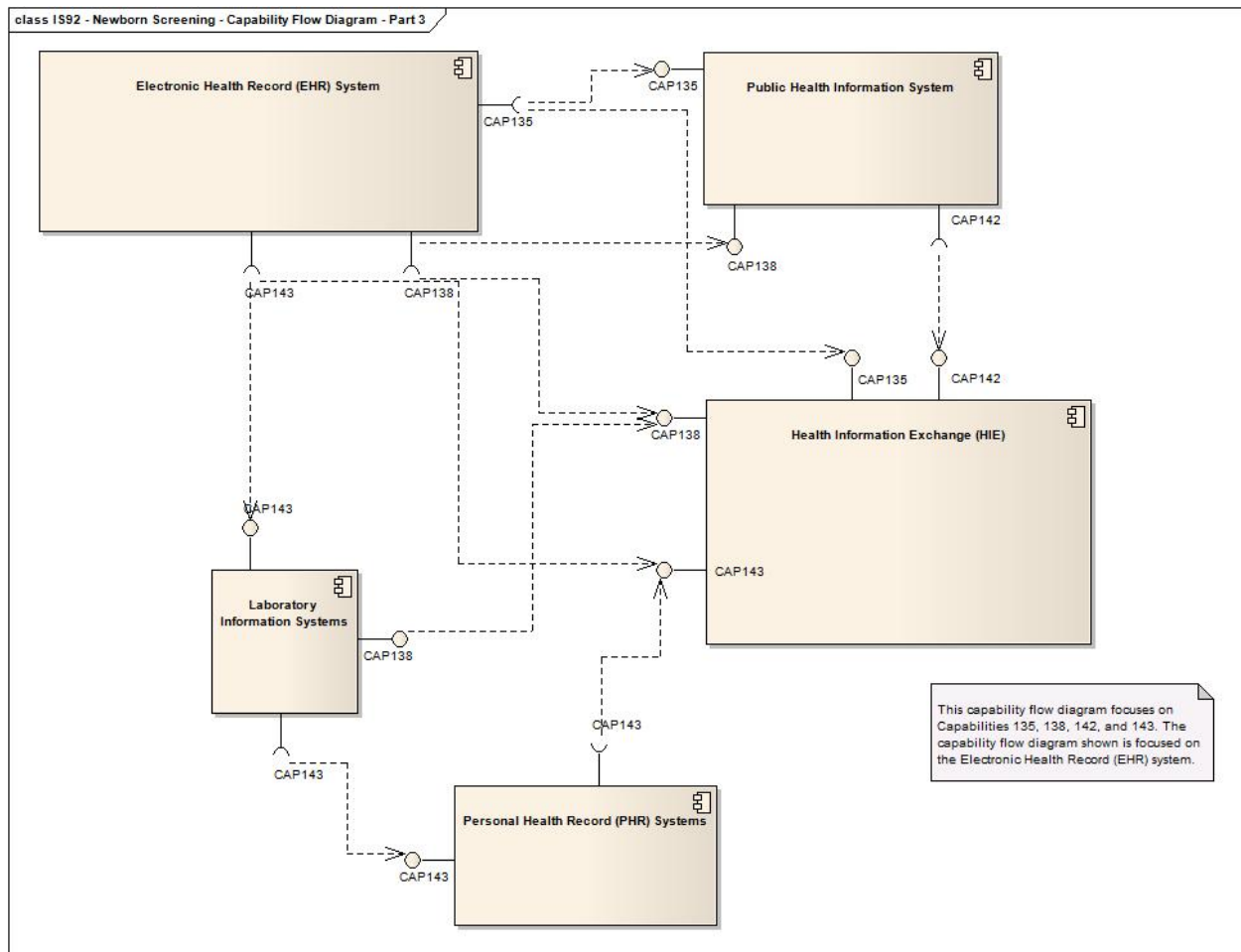
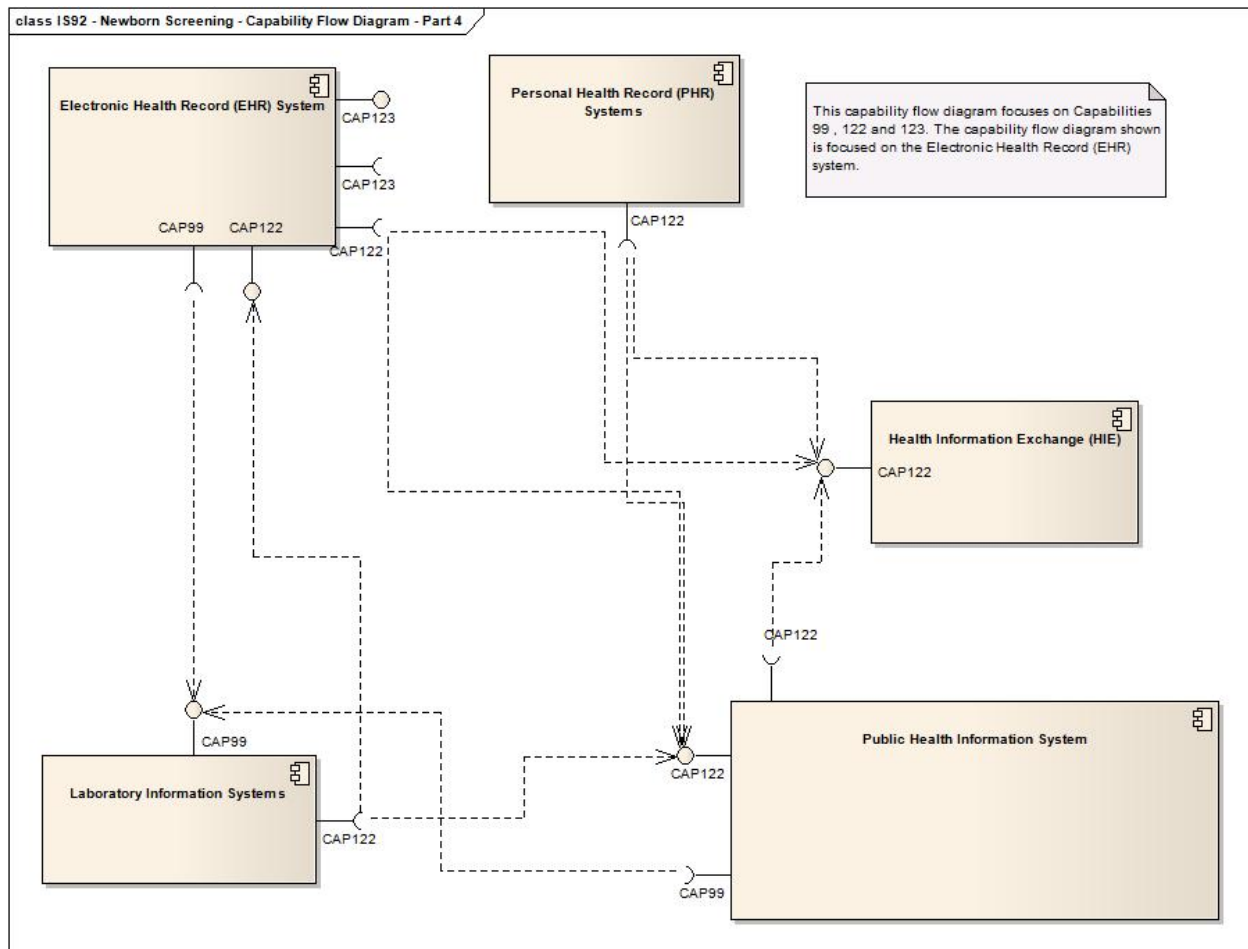


Figure 3-4 Diagram Showing Capabilities Used Between Systems Part 4



3.2 CAPABILITY ORCHESTRATION

This section describes how the Capabilities identified above are orchestrated to achieve the aims of the Harmonization Request (such as a Use Case) addressed by this Interoperability Specification. The orchestration identifies systems that fill the system roles in the Capabilities to achieve the desired data flows.

Table 3-3 lists the Orchestration of Capabilities by system to meet the information exchange requirements described in Section 2.0. Subsets of these systems perform information exchanges according to one or more of the Capabilities identified in this specification. The Capabilities are annotated on the diagrams. The in-scope requirements are supported by Capabilities either previously specified by HITSP or new Capabilities introduced in this section. Optionality is expressed as Required (R), Optional (O) or Conditional (C). If the optionality is Conditional, the applicable conditions are given in Table 3-4 below.

Table 3-3 Orchestration of Capabilities by System

System	Capability	System Role	System Role Option	Condition
Electronic Health Record (EHR) System	HITSP/CAP119 – Communicate Structured Document	Document Source	R	R
	HITSP/CAP119 – Communicate Structured Document	Document Consumer	R	R



System	Capability	System Role	System Role Option	Condition
	HITSP/CAP120 – Communicate Unstructured Document	Document Source	R	R
	HITSP/CAP120 – Communicate Unstructured Document	Document Consumer	R	R
	HITSP/CAP121 – Communicate Clinical Referral Request	Referral Dispatcher	O	
	HITSP/CAP121 – Communicate Clinical Referral Request	Referral Requestor	O	
	HITSP/CAP122 – Retrieve Medical Knowledge	Knowledge Requestor	O	C[108]
	HITSP/CAP122 – Retrieve Medical Knowledge	Value Set Consumer	O	
	HITSP/CAP123 – Retrieve Existing Data	Clinical Data Consumer	O	
	HITSP/CAP123 – Retrieve Existing Data	Clinical Data Source	O	
	HITSP/CAP126 – Communicate Lab Results Message	Result Receiver	O	C[102]
	HITSP/CAP126 – Communicate Lab Results Message	Result Sender	O	
	HITSP/CAP127 – Communicate Lab Results Document	Document Sender	O	
	HITSP/CAP126 – Communicate Lab Results Message	Document Receiver	O	C[102]
	HITSP/CAP135 – Retrieve and Populate Form	Form Filler	O	C[103]
	HITSP/CAP138 – Retrieve Pseudonym	Patient Identity Source	O	C[104]
	HITSP/CAP143 – Manage Consumer Preference and Consents	Document Sender	R	
	HITSP/CAP143 – Manage Consumer Preference and Consents	Document Receiver	R	
	HITSP/CAP 99 – Communicate Laboratory Orders	Order Placer	O	C[109]
	HITSP/CAP XXX – Communicate Procedure Orders	See Capability Gaps	R	
	HITSP/CAP XXX – NEW Communicate Device Results Data (PCD – Devices)	See Capability Gaps	O	C[105]
Health Information Exchange (HIE)	HITSP/CAP119 – Communicate Structured Document	Document Registry	O	C[109]
	HITSP/CAP119 – Communicate Structured Document	Document Repository	O	C[101]
	HITSP/CAP120 – Communicate Unstructured Document	Document Registry	O	C[109]
	HITSP/CAP120 – Communicate Unstructured Document	Document Repository	O	C[101]
	HITSP/CAP122 – Retrieve Medical Knowledge	Value Set Repository	O	
	HITSP/CAP127 – Communicate Lab Results Document	Document Registry	O	C[109]



System	Capability	System Role	System Role Option	Condition
	HITSP/CAP127 – Communicate Lab Results Document	Document Repository	O	C[101]
	HITSP/CAP135 – Retrieve and Populate Form	Form Manager	O	
	HITSP/CAP135 – Retrieve and Populate Form	Form Receiver	O	
	HITSP/CAP135 – Retrieve and Populate Form	Form Archiver	O	
	HITSP/CAP138 – Retrieve Pseudonym	Pseudonymization Services	O	C[104]
	HITSP/CAP142 – Retrieve Communications Recipient	Personnel White Pages Directory	O	
	HITSP/CAP143 – Manage Consumer Preference and Consents	Document Registry	O	C[109]
	HITSP/CAP143 – Manage Consumer Preference and Consents	Document Repository	O	C[101]
	HITSP/CAP XXX – Communicate Procedure Orders	See Capability Gaps	R	
Public Health Information System	HITSP/CAP119 – Communicate Structured Document	Document Source	O	C[102]
	HITSP/CAP119 – Communicate Structured Document	Document Consumer	O	C[102]
	HITSP/CAP121 – Communicate Clinical Referral Request	Referral Dispatcher	O	
	HITSP/CAP122 – Retrieve Medical Knowledge	Knowledge Resource	O	
	HITSP/CAP122 – Retrieve Medical Knowledge	Value Set Repository	O	
	HITSP/CAP126 – Communicate Lab Results Message	Result Receiver	O	C[102]
	HITSP/CAP126 – Communicate Lab Results Message	Result Sender	O	
	HITSP/CAP127 – Communicate Lab Results Document	Document Sender	O	
	HITSP/CAP127 – Communicate Lab Results Document	Document Receiver	O	C[102] C[112]
	HITSP/CAP135 – Retrieve and Populate Form	Form Manager	O	
	HITSP/CAP135 – Retrieve and Populate Form	Form Receiver	O	
	HITSP/CAP135 – Retrieve and Populate Form	Form Archiver	O	
	HITSP/CAP138 – Retrieve Pseudonym	Patient Identity Source	O	C[104]
	HITSP/CAP142 – Retrieve Communications Recipient	Personnel White Pages Consumer	O	
	HITSP/CAP143 – Manage Consumer Preference and Consents	Document Sender	R	
	HITSP/CAP143 – Manage Consumer Preference and Consents	Document Receiver	R	



System	Capability	System Role	System Role Option	Condition
	HITSP/CAP 99 – Communicate Laboratory Orders	Order Placer	O	C[110]
	HITSP/CAP XXX – Communicate Procedure Orders	See Capability Gaps	O	C[107]
	HITSP/CAP XXX – NEW Communicate Device Results Data (PCD – Devices)	See Capability Gaps	O	C[105]
Laboratory Information Systems	HITSP/CAP122 – Retrieve Medical Knowledge	Value Set Consumer	O	
	HITSP/CAP126 – Communicate Lab Results Message	Result Receiver	O	
	HITSP/CAP126 – Communicate Lab Results Message	Result Sender	O	C[102]
	HITSP/CAP127 – Communicate Lab Results Document	Document Sender	O	C[102] C[111]
	HITSP/CAP127 – Communicate Lab Results Document	Document Receiver	O	
	HITSP/CAP138 – Retrieve Pseudonym	Patient Identity Source	O	C[104]
	HITSP/CAP143 – Manage Consumer Preference and Consents	Document Sender	R	
	HITSP/CAP143 – Manage Consumer Preference and Consents	Document Receiver	R	
	HITSP/CAP 99 – Communicate Laboratory Orders	Order Filler	O	
Personal Health Record (PHR) Systems	HITSP/CAP119 – Communicate Structured Document	Document Source	O	C[102]
	HITSP/CAP119 – Communicate Structured Document	Document Consumer	O	C[102]
	HITSP/CAP120 – Communicate Unstructured Document	Document Source	O	
	HITSP/CAP120 – Communicate Unstructured Document	Document Consumer	O	
	HITSP/CAP122 – Retrieve Medical Knowledge	Knowledge Requestor	O	C[108]
	HITSP/CAP127 – Communicate Lab Results Document	Document Receiver	O	
	HITSP/CAP143 – Manage Consumer Preference and Consents	Document Sender	R	
	HITSP/CAP143 – Manage Consumer Preference and Consents	Document Receiver	R	
Device – Hearing Screening Device	HITSP/CAP119 – Communicate Structured Document	Document Source	R	
	HITSP/CAP119 – Communicate Structured Document	Document Consumer	R	
	HITSP/CAP120 – Communicate Unstructured Document	Document Consumer	R	
	HITSP/CAP XXX – Communicate Procedure Orders	See Capability Gaps	R	



System	Capability	System Role	System Role Option	Condition
	HITSP/CAP XXX – NEW Communicate Device Results Data (PCD – Devices)	See Capability Gaps	R	

Optionality Legend: “R” for Required, “O” for Optional, or “C” for Conditional

Table 3-4 below lists the conditions applicable to the orchestration (see above table) of the Capabilities engaged in this Interoperability Specification.

Table 3-4 Conditions

Condition Code	Condition Description
C[101]	Conditional on HIO model (e.g. Federated, centralized, hybrid)
C[102]	Shall support at least one of these Capabilities
C[103]	Implementation environment may require the pre-population of forms from Birthing Summary
C[104]	Required where pseudonymization is required by the jurisdiction or information sharing agreements
C[105]	Implementation environment may require where device sends hearing screening results
C[106]	Shall support HITSP/CAP136 or HITSP/CAP119 with NAV
C[107]	Required where Public Health Initiates Screening Referrals
C[108]	Knowledge Consumer may be used to retrieve guideline and educational material. Email or Web-based retrieval alternatives may be use. At least one of these methods must be supported. Jurisdiction implementations may require the use of one or more methods
C[109]	For document sharing, at least one Registry Shall exist.
C[110]	May be used where Public Health manages orders for laboratory screening
C[111]	Should Support Publish Document Through Share or Notification of Document Availability Document Sharing Environment

3.2.1 IMPLEMENTATION VARIANTS

None apply.

Table 3-5 lists a number of general constraints applicable to this specification. They include assumptions, a number of pre-conditions and post-conditions as well as external trigger events that play a critical role in implementing this specification.

Table 3-5 Orchestration Constraints

Constraint ID	Constraint	Type of Constraint
1	Assume that the Consumer has access to the test results as enabled by HITSP/IS05	Assumption
2	It is expected that initial newborn screening will typically occur in hospital settings rather than provider offices. Subsequent screening will be likely to happen in the outpatient clinician office setting	Assumption
3	Home birth, birth center and hospital need to be considered for the initial screening (i.e., midwifery needs to be included in the analysis)	Assumption
4	For document sharing, a registry is present	Assumption
5	Government and Regulatory Agencies are part of Public Health for this Use Case	Assumption
6	Research Entities and Social Service Agencies are part of public health for this Use Case NOTE: there are no direct Use Case interactions so these Use Case stakeholders could be removed	Assumption
7	In the case of a home birth, an audiologist is not present. It needs to be determined who creates the EHR and who is responsible	Assumption
8	Protocols may differ in midwifery facilities - could be part of the guideline or advice	Assumption
9	Screening done by birth hospital and can be sent to Public Health	Assumption



Constraint ID	Constraint	Type of Constraint
10	Nursery care or the hospital service that is fulfilling the order, rather than auditory services facilities are sending results - results from the birthing facility EHR to Public Health; also birthing facility communicates results to parents and other providers	Assumption
11	Results are transmitted directly to EHDI program (Early Hearing Detection and Intervention)	Assumption
12	Need to associate multiple results with the same child before computing aggregate statistics	Assumption
13	This is the only way that Public Health receives the screening results; resolution of duplicates needed in this case	Assumption
14	Electronic Birth Certificate (EBC) - is a request for the legal birth certificate document to be created hospital-of-birth ->Public Health ->vital records+screening program. This is addressed in HITSP/IS91 Maternal and Child Health	Assumption
15	In the case of a commercial lab or involvement of another state, there may be delay to hearing screening resulting from binding to lab testing pathway	Assumption
16	In the case of a commercial lab or involvement of another state, there may be delay to hearing screening resulting from binding to lab testing pathway	Assumption
17	Policies and requirements are the same concept as a protocol/guideline - could take advantage of CDS, but would not drive the development of these	Assumption
18	HITSP/T81-Retrieval of Medical Information is a possibility - but this is overkill as the guidelines are relatively static	Assumption
19	Policies change - many not in years, some may be annual	Assumption
20	Need for identifying the physician providing care - pediatrician may be family practitioner or other specialist	Assumption
21	Need to align the concepts for Medical home for the infant	Assumption
22	Pseudonymize and anonymize pertains to research, not Public Health registries	Assumption
23	Laboratory order is communicated from a source with an EHR	Assumption
24	Public health would need to be informed as well	Assumption
25	Most hospitals do not have audiology services – it is the nursery or volunteer staff that conducts the screening	Assumption
26	Most hospitals do not have audiology services – it is the screening personnel (e.g. nursery or volunteer staff) that reports the results	Assumption
27	The last screening test is the test reported or may be driven by the state protocol	Assumption
28	Hospital may do multiple screening tests in the hospital	Assumption
29	Vital records data requirements: do not need clinical results, but many states are using this approach	Assumption
30	Anticipate that bureau of vital statistics requirements will be described in the MCH Use Case	Assumption
31	Audiologist are not yet in the picture – this is the hospital screening staff that will inform either the clinician directly and/or State Department of Public Health which may contact clinician	Assumption
32	Assume that this is 'Other' online source – only the communication partners differ between 8.1.1.2 and 8.1.1.3	Assumption
33	Assume family history is for the purpose of risk factor monitoring and possibly for repeat test recommendations/orders	Assumption
34	Policy decisions are Out of scope	Assumption
35	Assume that there may be a gap in information detail on what was originally collected for the mother	Assumption
36	Family history gathering may have been captured for a different purpose	Assumption
37	Assume that this is a repeat AND/OR confirmatory tests	Assumption
38	Assume this may instead be a referral for EHDI	Assumption



Constraint ID	Constraint	Type of Constraint
39	Confirmatory may or may not be a repeat of the same test	Assumption
40	In some cases the care giver may send the specimen to the lab – assume this is Out of scope	Assumption
41	By most policy, it is not the pediatric clinician that files this report but the audiologist listed in action 8.1.8.2, but reporting is valid for metabolic or genetic	Assumption
42	This may support birth defects registry reporting where a registry exists	Assumption
43	Implication that the emergency care staff has access to the results, medical summaries	Assumption
44	The condition is identified	Assumption
45	If diagnosis, may be a plan of care	Assumption
46	This includes the Public Health STFU	Assumption
47	Any reference to services referral is covered in the HITSP Maternal and Child Health IS	Assumption
48	Any Long-term follow-up is outcome assessment – this is covered in the Quality IS	Assumption
49	This includes the Public Health STFU	Assumption
50	Any reference to services referral is covered in the HITSP Maternal and Child Health IS	Assumption
51	Any Long-term follow-up is outcome assessment – this is covered in the Quality IS	Assumption
52	This includes the Public Health STFU	Assumption
53	Any reference to services referral is covered in the HITSP Maternal and Child Health IS	Assumption
54	Any Long-term follow-up is outcome assessment – this is covered in the Quality IS	Assumption
55	This may not be covered in the Use Case given the age group constraining imposed by the Use Case and/or the IS implementation. Also considerations of well child care and not abnormal results may pertain	Assumption
56	Based upon jurisdiction policy and disclosure protocols, the results are made available to the patient PHR	Assumption
57	Based upon jurisdiction policy and disclosure protocols, the results are made available to the patient PHR	Assumption
58	Family genetic/genomic information is part of the risk factor	Assumption
59	Assume that they are informing the patient's family as the patient is a newborn	Assumption
60	LTFU requirements are addressed by other Use Cases and should not be part of this IS	Assumption
61	Policy subject to 'part C' of individual with disabilities education act	Assumption
62	Tracking may include e.g. number of births vs. number of screening	Assumption
63	Including Hospital Screening Results	Assumption
64	These communications may come from public health or from other clinicians/organizations	Assumption
65	May go to Public Health	Assumption
66	Support the technical measures to ensure Security and Privacy of consumer/patient health information	Pre-condition
67	Authentication service to authenticate requestors and/or data submissions from various locations	Pre-condition
68	Security and Privacy policies, procedures and practices are commonly implemented to support acceptable levels of consumer/patient security and privacy	Pre-condition
69	Legal and governance issues regarding data access authorizations, data ownership, and data use are in effect	Pre-condition
70	Support the following HITSP Security and Privacy constructs: HITSP/C19 – Entity Identity Assertion HITSP/T16 – Consistent Time – Maintain time HITSP/T17 – Secured Communication Channel – Authenticate node HITSP/T15 – Collect and Communicate Security Audit Trail – Record audit event in repository HITSP/TP30 – Manage Consent Directives – Capture/Request consent directive HITSP/TP20 – Access Control – Access control request	Pre-condition



Constraint ID	Constraint	Type of Constraint
71	Child is born and new electronic health records are established for the newborn at the birthing facility, health department, medical home, EHR	Pre-condition
72	Initial screening results are known	Pre-condition
73	The jurisdiction for the child is known	Pre-condition
74	Newborn Screening protocols are defined by the jurisdiction	Pre-condition
75	Pre-requisite: Dependency that EHR has already communicated notification of birth of the child (see Maternal and Child Health (MCH) Use Case)	Pre-condition
76	Results are entered and available to the patient EHR, hospital of birth, medical home, PHR, specialty providers, and public health record	Post-condition
77	Follow-up results are entered and available to the patient EHR, hospital of birth, medical home, PHR, specialty providers, and public health record	Post-condition
78	Registration or referral for Long-term care follow-up (e.g. Dietary management, early intervention)	Post-condition
79	Initiate long-term care management	Post-condition
80	Enabling ongoing monitoring of screening effectiveness and care quality/outcomes	Post-condition
81	New screening techniques or policies are recommended	Trigger
82	New screening policies and requirements are available	Trigger
83	A child is born	Trigger
84	Information not maintained by the EHR is available to the EHR for augmentation (e.g. Risk factor information from the mother's record)	Trigger
85	Electronic consent is gather from the patient caregiver	Trigger
86	Clinical conditions indicate that the child is stable and ready for the hearing screening test	Trigger
87	Specimen has been collected and order detail captured	Trigger
88	Clinical conditions or policy dictates second screening	Trigger
89	Results are available for communication	Trigger
90	Family history and consent is available from caregiver	Trigger
91	Clinical conditions or policy dictates repeat screening or confirmation	Trigger
92	Jurisdiction policy dictates that reporting to public health is required	Trigger
93	Clinical conditions or jurisdiction policy dictates referrals and short-term follow-up	Trigger

3.2.2 CONSTRAINTS ON REQUIRED CAPABILITIES

This section describes the constraints that further limit the Capabilities that are used by this Interoperability Specification.



Table 3-6 Additional Constraints on Required Capabilities

Constraint ID	Data Element	Capability	Constraint	Constraint Type	Purpose (Reason for this constraint)
3	Demographics	HITSP/CAP-119	SHALL use Pediatric Option for Patient Identification (TP22, T23, T24)	General	Enable support for newborn identity resolution C154-[DE-18.18-1] Components of a Genetic Laboratory Test SHALL be coded as specified in HITSP/C80 Section 2.2.3.11 Genetic Testing
4	Demographics	HITSP/CAP-127	SHALL use Pediatric Option for Patient Identification (TP22, T23, T24)	General	Enable support for newborn identity resolution C154-[DE-18.18-1] Components of a Genetic Laboratory Test SHALL be coded as specified in HITSP/C80 Section 2.2.3.11 Genetic Testing
5	Lab Order	HITSP/CAP-99	SHALL support lab order value sets	General	Enable appropriate semantic expression for newborn screening orders
6	Lab Order	HITSP/CAP-126	SHALL support lab order value sets	General	Enable appropriate semantic expression for newborn screening results



Constraint ID	Data Element	Capability	Constraint	Constraint Type	Purpose (Reason for this constraint)
7	Lab Results	HITSP/CAP-127	SHOULD report the quantitative results along with impression results and use SNOMED for diagnosis of relevance Quantitative results SHOULD be included along with the impression to support the interpretation Value subset SHALL be selected as specified by the AHIC newborn screening panel (http://newbornscreeningcodes.nlm.nih.gov/constructingNBSHL7messages) which includes quantitative codes and interpretation by condition Support Anonymize	General	Enable appropriate semantic expression for newborn screening results
8	Imaging Results	HITSP/CAP-128	SHOULD report the quantitative results along with impression results and use SNOMED for diagnosis of relevance Quantitative results SHOULD be included along with the impression to support the interpretation Value subset SHALL be selected as specified by the AHIC newborn screening panel (http://newbornscreeningcodes.nlm.nih.gov/constructingNBSHL7messages) which includes quantitative codes and interpretation by condition Support Anonymize	General	Enable appropriate semantic expression for newborn screening results
9	Lab Orders	HITSP/CAP-99	C163 SHALL include the NK1 segment which SHALL be populated with Parent's demographic data: Mother's information Mother's Name Mother's Birthdate Mother's Phone Mother/Caregiver Address, City, State, Zip code County Mother's Maiden Name Mother's SSN Primary Language Father's information where known		
10	Results Module	HITSP/CAP 119	All NBS summary documents (C48 and C32) SHALL populate sections 2.2.1.2 Results with newborn hearing screening results and Newborn Bloodspot Results		



4.0 CAPABILITY GAPS

Section 4.0 identifies gaps not met by existing Capabilities but needed to achieve the aims of the Harmonization Request for which this Interoperability Specification is written. This includes overlaps in Capabilities as well. The following table details how this section of the document is targeted to specific readers. Each of the stakeholders listed in this table are more fully defined in a separate appendix. This table is provided as an aid to readers to assist with identifying specific areas of focus. Readers are encouraged to review all sections of this document to further their understanding of HITSP's work.

Table 4-1 Reader's Guide for Section 4.0

Document Section	Section Number	Intended Audience	Information Contained
Section 4.0	4.0 Capability Gaps	Business Analysts Development Team Architects	Gaps specific to Capabilities used as part of this Interoperability Specification are reviewed in this section to determine why specific information exchange requirements may not yet be met or defined. Readers should check this section to track the progress of gap resolution

The following table identifies gaps not met by or overlapping with existing Capabilities as described above.

Table 4-2 Capability Gaps

IER Gap Description	Responsible HITSP TC	Design Approach	Required Standards Now Unavailable for Constructs	SDO Working on Unavailable Standards	Expected Availability
IER16 Send Hearing Screening Orders: Communicate Procedure Orders	Care Management and Health Records	Initiate Further Capability development in HITSP for generalized orders for any procedure	Terminology	LOINC, HITSP (General Procedure Order Capability)	Pending HITSP CMHR General Procedure Order Evaluations
IER23 Send Hearing Screening Results from Hearing Screening Device: Communicate Device Results Data (PCD – Devices)	Care Management and Health Records	Reference the HITSP Capabilities pending for Patient Care Device Results	Specification	HITSP (Device Capability)	Pending Patient Care Device/RMON Capability development
IER8 Request & Response Newborn Record EHR: Not currently profiled as a standard CDA document	Care Management and Health Records	Anticipate a construct to be delivered in 2010 from IHE PCC – Newborn Discharge Summary Provide requirements Monitor and participate Develop construct with constraints as needed	Specification	IHE	August 2010
IER9 Request & Response Birthing Summary EHR: Not currently profiled as a	Care Management and Health Records	Anticipate a construct to be delivered in 2010 from IHE PCC – Newborn Discharge Summary Provide requirements Monitor and participate Develop construct with constraints as needed	Specification	IHE	August 2010



standard CDA document					
IER16 Send PEC-NBS5 - Hearing Screening Order: No current standard for hearing screening order	Care Management and Health Records	Further CMHR Review SDO Referral as appropriate Provide requirements Monitor and participate Develop construct with constraints as needed	Specification, Terminology	HL7, LOINC, SNOMED-CT	Pending HITSP CMHR General Procedure Order Evaluations
IER12, IER41 Send PEC-NBS3 - Lab Order (NBS): PDR-NBS3, the only field that does not have a clear approach to coding of answer sets in LOINC is the feeding type, status, or history that requires multiple responses	Population Perspective TC	Suggestion: recommend resolution in IHE as part of the newborn discharge summary and that answer value set can be used for NBS ordering. Recommend NLM add LOINC codes for the NBS order data to their Newborn Screening Codes database in the near future and most of these fields are already defined in the HL7 messages and in IHE pediatric demographics http://newbornscreeningcodes.nlm.nih.gov/constructingNBSHL7messages	Specification	IHE, LOINC	August 2010
IER14 Send PEC-NBS13 - NBS pre-populate form from Birthing Summary: PDR-NBS3, the only field that does not have a clear approach to coding of answer sets in LOINC is the feeding type, status, or history that requires multiple responses	Population Perspective TC	Suggestion: recommend resolution in IHE as part of the newborn discharge summary and that answer value set can be used for NBS ordering. Recommend NLM add LOINC codes for the NBS order data to their Newborn Screening Codes database in the near future and most of these fields are already defined in the HL7 messages and in IHE pediatric demographics http://newbornscreeningcodes.nlm.nih.gov/constructingNBSHL7messages	Specification, Terminology	IHE, LOINC	August 2010
IER16 Send PEC-NBS5 - Hearing Screening Order: PDR-NBS3, the only field that does not have a clear approach to coding of answer sets in LOINC is the feeding type, status, or history that requires multiple responses	Population Perspective TC	Suggestion: recommend resolution in IHE as part of the newborn discharge summary and that answer value set can be used for NBS ordering. Recommend NLM add LOINC codes for the NBS order data to their Newborn Screening Codes database in the near future and most of these fields are already defined in the HL7 messages and in IHE pediatric demographics http://newbornscreeningcodes.nlm.nih.gov/constructingNBSHL7messages	Specification, Terminology	IHE, , LOINC	August 2010
Implementation GAP: We need OIDs for NBS screening Labs.	Population Perspective TC	This is an implementation concern. Refer recommendation to APhL and National Newborn Screening and Genetics Resource Center to facilitate OID applications.	Code Set	HL7	August 2010



The receiver (e.g. PH) would also need an HL7 OID. The sender can't be empty.					
IER12, IER41 Send PEC-NBS3 - Lab Order (NBS): – value set for feeding, hyperalimentation	Population Perspective TC	Need to work with NLM and Vocabulary SDOs to identify and specify the code sets	Code Set	LOINC, SNOMED- CT	Unknown



5.0 APPENDIX

The following section includes relevant materials referenced throughout this document. The following table details how this section of the document is targeted to specific readers. Each of the stakeholders listed in this table are more fully defined in a separate appendix. This table is provided as an aid to readers to assist with identifying specific areas of focus. Readers are encouraged to review all sections of this document to further their understanding of HITSP's work.

Table 5-1 Reader's Guide for Section 5.0

Document Section	Section Number	Intended Audience	Information Contained
Section 5.0	5.1 Provisional Exchange Content Description	Architects	Supporting information is provided for HITSP exchange content that is identified as provisional (due to gaps identified in the previous section)
	5.2 Provisional Data Requirements	Architects	Supporting information is provided for HITSP data requirements that are associated with provisional exchange content identified in Section 5.1
	5.3 Harmonization Request Traceability	Architects Business Analysts	A complete mapping of information exchange requirements to functional requirements is provided in this section. Readers can trace IER's to underlying Harmonization Request events and actions (in those instances where a Use Case exists) or to functional requirements defined as part of an official standards Harmonization Request

[NLM Newborn Screening Codes](#), this link contains information for constructing HL7 messages for NBS (LOINC and SNOMED codes, answer lists, example messages templates, etc).

5.1 PROVISIONAL EXCHANGE CONTENT DESCRIPTIONS

The exchange content descriptions answer one or more data requirements, and map to existing or planned HITSP constructs. In this section, any provisional exchange content descriptions identified for IERs that address gaps are described.

The Newborn Screening Use Case may be implemented in phases beginning with the highest priority data exchange which is the reporting of the lab results and integration into the EHR. The reporting of results can be implemented alone with manual entry of the NBS test ordering data requirements at the laboratory using information recorded on the manual order form that is attached to the filter paper used to collect the specimen. When electronic test ordering is done, it is not essential to pre-populate the ordering data requirements from other electronic documents such as the birthing summary, if they have not been implemented, and information may be entered directly into the order message or from the newborn EHR. When electronic information is available in the maternal record, it is use all available data through data exchange with the newborn record, but this is not an essential pre-requisite to implementing the Newborn Screening Use Case. Similarly, many of the data elements associated with the referrals necessary after an abnormal result are not essential or specific to the Newborn Screening Use Case, but are listed as data requirements because they are used in referral and medical summary documents in other Use Cases.



Table 5-2 Exchange Content Descriptions

Exchange Content Identifier	Exchange Content Name	Exchange Content Definition	Data Requirements
EC48A	Referral Summary	Document-based patient encounter data (excluding laboratory, radiology)	DR31 Problem List DR02 Advance Directives DR03 Allergies and Other Adverse Reactions DR23 Medications DR10 Family History DR11 Functional Status DR14 History of Present Illness DR18 Immunizations DR21 List of Surgeries DR22 Medical Equipment DR27 Personal Information DR26 Payers DR34 Review of Systems DR28 Physical Examination DR29 Plan of Care DR33 Reason for Referral DR07 Diagnostic Results DR13 History of Past Illness DR35 Social History DR37 Vital Signs
EC24	EC 24 - Pseudo-identity		PDR-NBS14 Pediatric Demographics
EC30	EC30 - Consent Document Component		
EC32	Summary of Care	Describes the document content summarizing a consumer's registration, medication and health data information	DR02 Advance Directives DR03 Allergies and Other Adverse Reactions DR06 Comment DR31 Problem List DR09 Encounters DR12 Healthcare Providers DR18 Immunizations DR19 Information Source DR26 Payers DR20 Language Spoken DR23 Medications DR27 Personal Information DR29 Plan of Care DR30 Pregnancy DR32 Procedure DR36 Support DR37 Vital Signs
EC36			Require LOINC, Analyte quantitative result and units. NOTE: All results, should be sent electronically to appropriate state newborn screening programs, birthing centers, and primary care of the newborn
EC37			Require LOINC, Analyte quantitative result and units. NOTE: All results, should be sent electronically to appropriate state newborn screening programs, birthing centers, and primary care of the newborn



Exchange Content Identifier	Exchange Content Name	Exchange Content Definition	Data Requirements
EC48B	Discharge Summary	A discharge summary is a type of medical summary	DR31 Problem List DR01 Admission Medications History DR15 Hospital Admission Diagnosis DR02 Advance Directives DR03 Allergies and Other Adverse Reactions DR08 Discharge Diagnosis DR38 Discharge Diet DR17 Hospital Discharge Medications DR07 Diagnostic Results DR11 Functional Status DR14 History of Present Illness DR16 Hospital Course DR22 Medical Equipment DR27 Personal Information DR28 Physical Examination DR29 Plan of Care DR13 History of Past Illness DR34 Review of Systems DR24 Medications Administered DR37 Vital Signs
EC62	Unstructured Data	Used to capture and store patient identifiable, unstructured document content, such as text, PDF, and images rendered in PDF	Document Metadata DR58 Unstructured Data Content
EC66	Value Set	Used to communicate value sets	Newborn Screening Value Sets

5.2 PROVISIONAL DATA REQUIREMENTS

In this section, any provisional data requirement descriptions identified for provisional exchange contents listed above are described.

The Newborn Screening Use Case may be implemented in phases beginning with the highest priority data exchange which is the reporting of the lab results and integration into the EHR. The reporting of results can be implemented alone with manual entry of the NBS test ordering data requirements at the laboratory using information recorded on the manual order form that is attached to the filter paper used to collect the specimen. When electronic test ordering is done, it is not essential to pre-populate the ordering data requirements from other electronic documents such as the birthing summary, if they have not been implemented, and information may be entered directly into the order message or from the newborn EHR. When electronic information is available in the maternal record, it is use all available data through data exchange with the newborn record, but this is not an essential pre-requisite to implementing the Newborn Screening Use Case. Similarly, many of the data elements associated with the referrals necessary after an abnormal result are not essential or specific to the Newborn Screening Use Case, but are listed as data requirements because they are used in referral and medical summary documents in other Use Cases.



Table 5-3 Data Requirements

Data Requirement Number (DR)	Description	Data
PDR-NBS5	Hearing Screening Order	<ul style="list-style-type: none"> • PDR-NBS3 • Demographics • DR25 • NICU • Mother's education <p>NOTE: LOINC codes newly developed For Ordering a procedure/test</p> <ul style="list-style-type: none"> • May be an HL7 message NICU and mother's education <p>Should align with HITSP Orders Data Requirements</p> <p>NOTE: Not needed in most current environments there is a standing order</p>
PDR-NBS3	NBS Lab Order ¹	<p>Ordering information</p> <ul style="list-style-type: none"> • State (where screening is performed) • Pre-Printed Unique Filter Paper Number (Barcoded) • Placer (Hospital) Order Number • Filler (Laboratory) Accession Number (added by the laboratory) • Blood Draw Date/Time • Initial/Repeat • Filter Paper Number of Initial Test • Hospital/Submitter information (NPI code, name, address, phone) • Newborn Screening Lab information (code, name, address) • Ordering Physician (NPI, name) • Submitter's Initials (to identify the person who drew the blood) <p>Patient (baby's) information</p> <ul style="list-style-type: none"> • Baby's name • Multiple birth information (qualifies the name) • Baby's aliases (other previous names) • Date/Time of Birth • Baby's Gender

- ¹ Newborn screening is ordered as a single test panel and the composition of the panel depends on which tests are mandated in the state where the tests is performed, but it is always based on the 29 test core panel proposed by the American College of Medical Genetics (ACMG) and recommended by the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC). Identifying the state where the test is performed on the order will be used to define the specific newborn screening panel that is ordered
- Some public health laboratories that perform newborn screening are not required to be CLIA certified and do not have CLIA identifiers. It will be necessary to have an alternate laboratory identifier for all newborn screening laboratories
- Nearly all of the fields on the NBS Lab Order should be considered optional because each state specifies which fields appear on the filter paper order form and are required for mandated newborn screening in that state
- The fields listed above represent the most prevalent and frequently used fields. The ability to accommodate additional fields as needed by limited numbers of states can be accommodated through general purpose LOINC codes for additional fields
- The fields listed on the NBS Lab Order are usually echoed back to the clinician as part of the laboratory test results report to assist in interpreting the results or locating the patient
- The NBS Lab Order is intended to align with HITSP Orders Data Requirements for Lab Orders and many of these interactions have been detailed in the 2008 General Lab Orders Use Case
- The National Library of Medicine maintains a Newborn Screening Codes Web Site that will maintain the LOINC codes and SNOMED codes that were provided in the Newborn Screening Coding and Terminology Guide that was developed as a companion to the Newborn Screening Use Case with periodic review by the ACHDNC
- Reporting the results of newborn hearing screening on the dried blood spot filter paper form is not an ideal practice and separate reporting of the results to public health by the person performing the test should be encouraged. The option to include the hearing results on the blood spot order is included because several states still follow this practice and the data should be sent this way only if there is no alternative



Data Requirement Number (DR)	Description	Data
		<ul style="list-style-type: none"> • Baby's Race and Ethnicity • Baby's Medical Record Number • Birth Hospital (NPI code or code for Home Birth) • Birth Weight • Weight at time of sample (where required) • Gestational age at birth Transfusion given y/n • Feeding Type or Status (coded) <p>Mother's information</p> <ul style="list-style-type: none"> • Mother's Name • Mother's Birthdate • Mother's Phone • Mother/Caregiver Address, City, State, Zip code • County • Mother's Maiden Name <p>Baby's physician information</p> <ul style="list-style-type: none"> • Baby's Physician Name (primary care) • Physician Phone • Physician Id (NPI) <p>Additional fields as required by individual states (examples)</p> <p>Mother's SSN</p> <p>Father's information</p> <ul style="list-style-type: none"> • Father's Name • Father's Birthdate • Father's Phone • Father's Address, City, State, Zip code, County • Family history of specific conditions • Primary Language <p>NOTE: Standard panel is 29 tests; over 5-69 tests that can be done; American College of Medical Genetics (ACMG)</p> <p>NOTE: Intended to align with HITSP Orders Data Requirements for Lab Orders</p> <p>See PHII Implementation Guide for sending lab results to ordering clinicians</p> <p>See Newborn Screening Coding and Terminology Guide.</p> <p>See 2008 General Lab Orders Use Case</p>
PDR-NBS10	Hearing Screening Test Results	<ul style="list-style-type: none"> • Test Interpretation Required (DR07) • Care Plan (Public Health Instructions for patient) • May be produced as an Unstructured Document (DR58) <p>Hearing Screening Information</p> <ul style="list-style-type: none"> • Results of hearing screening (pass/refer for left, right, or both ears, method used) • Reason hearing screening was not done • NICU stay (changes requirements for hearing testing) • Antibiotics • Mother's education level • Other hearing loss risk factors
PDR-NBS4	Birthing Data	<ul style="list-style-type: none"> • Labor and Delivery Admission History and Physical • Labor and Delivery Summary • Maternal Discharge Summary • Antepartum Information • Delivery event information • Pediatric clinician • Encounter Date • Patient Information (DOB, age, gender, resident zip code, state of residence) • Date/time of last record update



Data Requirement Number (DR)	Description	Data
		<ul style="list-style-type: none"> • Linkage between Mom/Baby records <p>NOTE: Data attained from this and other sources (Antepartum Summary, Birth Event Record, Laboratory Results, Audiology Results, Laboratory Orders, Hearing Screening Orders) must support the following public health monitoring assessments: should support 1) tracking and estimating screening rates for both NDBS and EHDI, 2) tracking and confirmation of completion of all recommended confirmatory or diagnostic testing for both NDBS and EHDI, 3) tracking and confirmation of clinical or early intervention service delivery, 4) tracking the number of infants with conditions identified with newborn screening, 5) measuring rates of false positives, and 6) maybe using data to evaluate selection of cut-off points for normal or within/out of range results</p>
PDR-NBS6	Structured Guideline Data	<p>GAP</p> <ul style="list-style-type: none"> • Presentation Preserving format • Screening guidelines, • Management and testing guidelines (e.g.pre-natal screening guidelines, timing for testing, possibly guidelines for management of pregnancy complications) • Emergency Management of identified condition • ACMG • ACT sheet, care plan for conditions – data requirements • State protocol • Abnormal results care guidelines
PDR-NBS7	Antepartum Data	<ul style="list-style-type: none"> • Antepartum History and Physical • Antepartum Laboratory • Antepartum Education • Pediatric clinician • Maternal age • Maternal occupation • Medical history • Menstrual history • Pregnancy history • Genetic screenings • Risk factors <p>NOTE: Data attained from this and other sources (Antepartum Summary, Birth Event Record, Laboratory Results, Audiology Results, Laboratory Orders, Hearing Screening Orders) must support the following public health monitoring assessments: should support 1) tracking and estimating screening rates for both NDBS and EHDI, 2) tracking and confirmation of completion of all recommended confirmatory or diagnostic testing for both NDBS and EHDI, 3) tracking and confirmation of clinical or early intervention service delivery, 4) tracking the number of infants with conditions identified with newborn screening, 5) measuring rates of false positives, and 6) maybe using data to evaluate selection of cut-off points for normal or within/out of range results</p>
PDR-NBS8	Structured Education Material	GAP
PDR-NBS9	Newborn Clinical Data	<ul style="list-style-type: none"> • Newborn Birth Attributes • NICU Attributes • Prenatal Attributes • Pediatric clinician • Encounter Date • Patient Information (DOB, age, gender, resident zip code,



Data Requirement Number (DR)	Description	Data
		<p>state of residence)</p> <ul style="list-style-type: none"> • Date/time of last record update • Linkage between Mom/Baby records <p>NOTE: Data attained from this and other sources (Antepartum Summary, Birth Event Record, Laboratory Results, Audiology Results, Laboratory Orders, Hearing Screening Orders) must support the following public health monitoring assessments: should support 1) tracking and estimating screening rates for both NDBS and EHDI, 2) tracking and confirmation of completion of all recommended confirmatory or diagnostic testing for both NDBS and EHDI, 3) tracking and confirmation of clinical or early intervention service delivery, 4) tracking the number of infants with conditions identified with newborn screening, 5) measuring rates of false positives, and 6) maybe using data to evaluate selection of cut-off points for normal or within/out of range results</p>
PDR-NBS11	Screening Refusal	<ul style="list-style-type: none"> • Procedure or Test to be performed • Risks disclosed • Consent Refusal • Authorized by
PDR-NBS12	New Specimen Request	GAP
PDR-NBS13	NBS Pre-op	<p>DR25</p> <p>PDR-NBS3 NBS Lab Order</p>
PDR-NBS14	Pediatric Demographics	<ul style="list-style-type: none"> • Patient Name: First, Middle, Last • Patient Alias Name: First, Middle, Last • Patient Address • Patient Phone Number • Patient Identifier • Patient Birth Date • Patient Sex • Patient Race • Patient Ethnicity • Patient Primary Language • Patient Multiple Birth Indicator • Patient Multiple Birth Order • Patient Birth Registration Number • Patient Birth State/Country • Patient Birthing Facility • Mother's Name: First, Middle, Last • Mother's Maiden Name • Mother's SSN • Father's Name: First, Middle, Last • Father's SSN • Insurance Plan • Insurance Company • Immunization Services Funding Eligibility • Next of Kin Relationship • Next of Kin Address • Next of Kin Telephone • Next of Kin DOB • Last Update Time/Date • Last Update Facility
PDR-NBS1	Consent for Procedure	<ul style="list-style-type: none"> • Procedure or Test to be performed • Risks disclosed • Consent Refusal



Data Requirement Number (DR)	Description	Data
		<ul style="list-style-type: none"> • Authorized by • Effective Date/Time • Expiration Date/Time • Signature
PDR-NBS2	Consent to retain sample	<ul style="list-style-type: none"> • Sample type • Sample uses permitted • Authorized by
DR01	Admission Medications History: Contains information about the relevant medications of a patient prior to admission to a facility	2.2.1.13 Admission Medications Section
DR02	Advance Directives: Contains information that defines the patient's expectations and requests for care along with the locations of the documents	2.2.1.16 Advance Directives Section
DR03	Allergies and Other Adverse Reactions: Contains data on the substance intolerances and the associated adverse reactions suffered by the patient	2.2.1.2 Allergies and Other Adverse Reactions Section
DR06	Comment: Contains a comment to be supplied for any other data requirement	2.2.2.11 Comment
DR07	Diagnostic Results: Contains information about the results from diagnostic procedures the patient received	2.2.1.22 Diagnostic Results Section
DR08	Discharge Diagnosis: Contains information about the conditions identified during the hospital stay that either need to be monitored after discharge from the hospital and/or where resolved during the hospital course	2.2.1.11 Discharge Diagnosis Section
DR09	Encounters: Contains information describing the patient history of encounters. At a minimum, includes current and pertinent historical encounters, and may include a full encounter history	2.2.1.27 Encounters Section
DR10	Family History: Contains information about the genetic family members, to the extent that they are known, the diseases they suffered from, their ages at death, and other relevant genetic information	2.2.1.25 Family History
DR11	Functional Status: Provides information about the capability of the patient to perform acts of daily living	2.2.1.9 Functional Status Section
DR12	Healthcare Providers: Contains the healthcare providers involved in the current or pertinent historical care of the patient	2.2.2.4 Healthcare Provider
DR13	History of Past Illness: Contains data about problems the patient suffered in the past	2.2.1.4 History of Past Illness Section
DR14	History of Present Illness: Contains information about the sequence of events preceding the patient's current complaints	2.2.1.7 History of Present Illness Section
DR15	Hospital Admission Diagnosis: Contains information about the primary reason for admission to a hospital facility	2.2.1.10 Hospital Admission Diagnosis Section
DR16	Hospital Course: Contains information about of the sequence of events from admission to discharge in a hospital facility	2.2.1.21 Hospital Course Section
DR17	Hospital Discharge Medications: Contains information about the relevant medications ordered for the patient for use after discharge from the hospital	2.2.1.14 Hospital Discharge Medications Section
DR18	Immunizations: Contains information describing the immunizations administered to the patient	2.2.1.17 Immunizations Section



Data Requirement Number (DR)	Description	Data
DR19	Information Source: Contains information about the original author to be supplied and for a reference to the original document to be provided	2.2.2.10 Information Source
DR20	Language Spoken: Contains the primary and secondary languages of communication for the patient	2.2.2.2 Language Spoken
DR21	List of Surgeries: Provides a list of surgeries the patient has received	2.2.1.8 List of Surgeries Section
DR22	Medical Equipment: Contains information describing a patient's implanted and external medical devices and equipment that their health status depends on, as well as any pertinent equipment or device history	2.2.1.28 Medical Equipment Section
DR23	Medications: Description of the relevant medications for the patient, e.g. An ambulatory prescription list	2.2.1.12 Medications Section
DR24	Medications Administered: Contains information about the relevant medications administered to a patient during the course of an encounter	2.2.1.15 Medications Administered Section
DR25	Orders	
DR26	Payers: The Payers Section contains data on the patient's payers, whether a 'third party' insurance, self-pay, other payer or guarantor, or some combination - At a minimum, the patient's pertinent current payment sources should be listed	2.2.1.1 Payers Section
DR27	Personal Information: Contains the name, address, contact information, personal identification information, ethnic and racial affiliation and marital status of the subject person	2.2.2.1 Personal Information
DR28	Physical Examination: Contains information describing the physical findings	2.2.1.18 Physical Examination Section
DR29	Plan of Care: Contains information about the expectations for care to be provided including proposed interventions and goals for improving the condition of the patient. A plan of care section varies from the assessment and plan data requirements in that it does not include a physician assessment of the patient condition	2.2.1.24 Plan of Care Section
DR30	Pregnancy: Contains a coded entry indicating whether the patient is currently pregnant	2.2.2.9 Pregnancy
DR31	Problem List: Contains data on the problems currently being monitored for the patient	2.2.1.3 Problem List Section? 2.2.2.7 Condition
DR32	Procedure: Contains a coded entry indicating a procedure performed on a patient	2.2.2.17 Procedure
DR33	Reason for Referral: Contains information about the reason that the patient is being referred	2.2.1.6 Reason for Referral Section
DR34	Review of Systems: Contains information describing patient responses to questions about the function of various body systems	2.2.1.20 Review of Systems Section
DR35	Social History: Contains information about the person's beliefs, home life, community life, work life, hobbies, and risky habits	2.2.1.26 Social History Section
DR36	Support: Contains the patient's sources of support, such as immediate family, relatives and guardian at the time as the summarization is generated. Support information also includes next of kin, caregivers and support organizations. At a minimum, key support contacts relative to healthcare	2.2.2.3 Support



Data Requirement Number (DR)	Description	Data
	decisions, including next of kin, should be included. Support providers may include providers of healthcare related services, such as a personally controlled health record, or registry of emergency contacts	
DR37	Vital Signs: Contains information documenting the patient vital signs	2.2.2.14 Vital Sign
DR38	Discharge Diet	
DR58	Unstructured Data Content	
	Message Header Content	
PDR 50	Fully Coded Lab Result Content	

5.3 HARMONIZATION REQUEST TRACEABILITY

This section describes the traceability to the Harmonization Request for which this Interoperability Specification is written. The traceability may be described in terms of events and actions, or in terms of functional requirements.

The Newborn Screening Use Case may be implemented in phases beginning with the highest priority data exchange which is the reporting of the lab results and integration into the EHR. The reporting of results can be implemented alone with manual entry of the NBS test ordering data requirements at the laboratory using information recorded on the manual order form that is attached to the filter paper used to collect the specimen. When electronic test ordering is done, it is not essential to pre-populate the ordering data requirements from other electronic documents such as the birthing summary, if they have not been implemented, and information may be entered directly into the order message or from the newborn EHR. When electronic information is available in the maternal record, it is use all available data through data exchange with the newborn record, but this is not an essential pre-requisite to implementing the Newborn Screening Use Case. Similarly, many of the data elements associated with the referrals necessary after an abnormal result are not essential or specific to the Newborn Screening Use Case, but are listed as data requirements because they are used in referral and medical summary documents in other Use Cases.

This table relates the events of a Harmonization Request to the actions taken and information exchanges required.

Table 5-4 Harmonization Request Events and Actions Analysis Table

Event	Action	Information Exchange Requirement(s) (includes security requirements)
7.1.1 Event: Receive and Utilize Screening Policies & Requirements	7.1.1.1 Receive and use information regarding newborn screening to manage screening program	IER1 Request & Response Guideline data
	7.1.1.2 Utilize information for patient education 7.1.1.3 Inform patients and/or obtain consent from parents/current guardian(s)	IER4 Send Guideline data
		IER2 Request & Response Education Brochure
		IER3 Send Education Brochure
		IER5 Publish/Register Unstructured Data (Refusal documentation, Consent to Procedure, Consent to Retain/Use Test Sample) EHR HIE
		IER36 Publish/Register Unstructured Data (Refusal documentation, Consent to Procedure, Consent to Retain/Use Test Sample) PHR HIE
		IER6 Publish/Register Patient Consent EHR
		IER37 Publish/Register Patient Consent PHR
7.1.2 Gather and Augment EHR Information	7.1.2.1 Obtain key pieces of information	IER8 Request & Response Newborn Record



Event	Action	Information Exchange Requirement(s) (includes security requirements)
		IER9 Request & Response Birthing Summary
		IER9 Request & Response Birthing Summary
		IER10 Send Newborn Record
		IER11 Send Birthing Summary
		IER12 Send Lab Order EHR
		IER13 Request & Response Pseudo-identity
		IER14 Send Birthing Summary Pre-populate
		IER14 Send Birthing Summary Pre-populate
		IER10 Send Newborn Record to public health
		IER15 Publish/Register Newborn Record to HIE
		IER17 Publish/Register Birthing Summary
		IER40 Request & Response Newborn Record to public health
		IER7 Request & Response Newborn Screening Value Sets
		IER18 Query/Retrieve Clinical Data EHR EHR
		IER41 Send Lab Order Lab
7.1.3a Order Hearing test(s)	7.1.3a.1 A clinician at the birthing facility orders EHDI testing	IER16 Send Hearing Screening Order
		IER16 Send Hearing Screening Order EHR ADEV
7.1.3b Order NDBS screening test(s)	7.1.3b.1 A clinician at the birthing facility orders NDBS testing	IER12 Send Lab Order EHR LIMS
		IER41 Send Lab Order Lab
7.1.4 Collect Specimen(s)	7.1.4.1 A clinician obtains blood and prepares the dried blood spot.	No Interoperability Requirement
	7.1.4.1a Specimen obtained at a non-standard time, due to medical or logistical reasons	No Interoperability Requirement
7.1.5 Communicate Order and Send Specimen	7.1.5.1 Specimen and order information are sent to either the testing laboratory or Public Health	IER12 Send Lab Order EHR LIMS
		IER41 Send Lab Order LIMS LIMS
		No interoperability Requirement
7.1.6 Perform Second Screening Specimen Requirements	7.1.6.1 Second specimen collected.	No Interoperability Requirement
	7.1.6.2 Second specimen follows similar pathway to initial specimen	IER12 Send Lab Order EHR LIMS
		IER41 Send Lab Order Lab LIMS
	7.1.6.3 Second hearing screen is ordered	IER16 Send Hearing Screening Order EHR
		IER16 Send Hearing Screening Order EHR Device
		No interoperability Requirement
7.1.7 Receive Results	7.1.7.1 Clinician or birthing facility receives test results	IER43 Send Lab Results LIMS EHR
		IER21 Publish/Register Lab Results LIMS HIE
		IER22 Request & Response Lab Results EHR HIE
		IER52 Publish/Register Lab Results PH HIE
		IER43 Send Lab Results LIMS PH
		IER22 Request & Response Lab Results Public Health HIE



Event	Action	Information Exchange Requirement(s) (includes security requirements)
		IER55 Send Hearing Screening Test Results EHR
		IER66 Send EC36 Lab Result (used when constraint is 'message') EHR EHR PH
		IER23 Send Hearing Screening Test Results DEV Public Health
		IER64 Send EC36 Lab Result (used when constraint is 'message') DEV EHR PH
		IER24 Publish/Register EC 32 Summary of Care Public Health HIE
		IER25 Notification EC 32 Summary of Care Public Health EHR
		IER26 Subscribe EC 32 Summary of Care EHR HIE
		IER54 Send EC 32 Summary of Care Public Health EHR
		IER65 Send EC36 Lab Result (used when constraint is 'message') PH EHR PH
		IER27 Request & Response EC 32 Summary of Care EHR HIE
		IER25 Notification EC 32 Summary of Care Public Health EHR
		IER7 Request & Response Newborn Screening Value Sets
7.2.1 Receive Information Per Policies.	7.2.1.1 Consumer receives information regarding policies	IER28 Request & Response Education Materials PHR Public Health
		IER2 Request & Response Education Materials EHR Public Health
		IER19 Request & Response Guideline PHR Public Health
7.2.2 Provide Consent and Requested Information, if required by state	7.2.2.1 Consumer is informed and may provide consent for screening tests	IER28 Publish/Register Screening Refusal PHR HIE
		IER5 Publish/Register Unstructured Data (Refusal documentation, Consent to Procedure, Consent to Retain/Use Test Sample) PHR HIE
		IER36 Publish/Register Unstructured Data (Refusal documentation, Consent to Procedure, Consent to Retain/Use Test Sample) EHR HIE
		IER37 Publish/Register Patient Consent PHR HIE
	7.2.2.2 Consumer provides other requested information	IER29 Send Pediatric Clinician PHR EHR
		IER31 Publish/Register Pediatric Clinician PHR HIE
		IER32 Request & Response Pediatric Clinician EHR HIE
		IER33 Request & Response Newborn Record PHR HIE
		IER34 Request & Response Birth event record PHR HIE
		IER56 Request & Response Hearing Screening Test Results record PHR HIE
		IER35 Query/Lab Result PHR HIE



Event	Action	Information Exchange Requirement(s) (includes security requirements)
7.3.1 Determine & Communicate Screening Policies & Requirements	7.3.1.1 Public Health determines newborn screening policies and requirements	IER1 Request & Response Guideline data
		IER19 Request & Response Guideline data
		IER 2 Request & Response Education Brochure
7.3.2 Receive Order and Specimen	7.3.2.1 Public Health receives the testing order(s)	IER56 Send Laboratory Order EHR Public Health
		IER16 Send Audiology test Order EHR Public Health
7.3.3 Receive EHDI Results	7.3.3.1 Results of the EHDI are received by Public Health	IER23 Send Hearing Screening Test Results DEV Public Health
		IER64 Send EC36 Lab Result (used when constraint is 'message') DEV EHR PH
		IER38 Publish/Register Hearing Screening Test Results EHR HIE
		IER57 Request & Response Hearing Screening Test Results Public Health HIE
	7.3.3.1a EHDI results are received with the NDBS specimen and testing order	IER56 Send Laboratory Order EHR Public Health
		IER23 Send Hearing Screening Test Results DEV PH
		IER64 Send EC36 Lab Result (used when constraint is 'message') DEV EHR PH
	7.3.3.1b EHDI results are noted on the birth certificate	Refer to HITSP/IS91-Maternal and Child Health For Vital Statistics communications
	7.3.3.1c EHDI results are received at the time of the NDBS results	IER22 Request & Response Lab Results EHR HIE
		IER43 Send Lab Results LIMS Public Health
		IER22 Request & Response Lab Results Public Health HIE
		IER23 Send Hearing Screening Test Results DEV Public Health
		IER64 Send EC36 Lab Result (used when constraint is 'message') DEV EHR PH
		IER38 Publish/Register Hearing Screening Test Results EHR HIE
		IER57 Request & Response Hearing Screening Test Results Public Health HIE
		IER7 Request & Response Newborn Screening Value Sets
7.3.4 Receive NDBS Lab Results	7.3.4.1 Public Health department receives the results of the NDBS testing	IER22 Request & Response Lab Results EHR HIE
		IER43 Send Lab Results LIMS Public Health
		IER53 Request & Response Lab Results Public Health HIE
		IER7 Request & Response Newborn Screening Value Sets
	7.3.4.1a Public Health department receives results from birthing facility	IER22 Request & Response Lab Results EHR HIE
		IER53 Request & Response Lab Results Public Health HIE



Event	Action	Information Exchange Requirement(s) (includes security requirements)
		IER20 Send Lab Results EHR Public Health
		IER7 Request & Response Newborn Screening Value Sets
7.3.5 Incorporate Results into Public Health System	7.3.5.1 Results are incorporated into the Public Health system	No Interoperability requirement – edge system function
	7.3.5.2 Results are sent to research entities or other Public Health registries or organizations	IER54 Send Hearing Screening Test Results Public Health
		IER65 Send EC36 Lab Result (used when constraint is 'message') PH EHR PH
		IER20 Send Lab Results PH
		IER58 Publish/Register Hearing Screening Test Results
		IER21 Publish/Register Lab Test Results
		IER52 Publish/Register Lab Results PH HIE
		IER27 Request & Response Audiology Results
		IER53 Request & Response Lab Results
		IER39 Request & Response Patient Consent Public Health HIE
		IER7 Request & Response Newborn Screening Value Sets
7.4.1 Receive Order and Specimen	7.4.1.1 Testing laboratory receives order and NDBS specimen from birthing facility	IER12 Send Lab Order
		IER41 Send Lab Order Lab LIMS
		IER14 Send Birthing Summary Pre-populate
		IER14 Send Birthing Summary Pre-populate
		IER40 Request & Response Patient Identity LIMS HIE
	7.4.1.1a Testing laboratory receives order and NDBS specimen from clinician outside the hospital setting	IER12 Send Lab Order EHR
		IER41 Send Lab Order Lab LIMS
		IER14 Send Birthing Summary Pre-populate
		IER14 Send Birthing Summary Pre-populate
	7.4.1.2 Specimen is accessioned	IER12 Send Lab Order
		IER41 Send Lab Order Lab LIMS
	7.4.1.2a Specimen is deemed inadequate for testing	IER42 Send request new specimen LIMS EHR
		IER42 Send request new specimen LIMS PHR
		IER43 Send Lab Results LIMS EHR
		IER21 Publish/Register Lab Results LIMS HIE
		IER22 Request & Response Lab Results EHR HIE
		IER7 Request & Response Newborn Screening Value Sets
7.4.2 Perform Testing & Report Results	7.4.2.1 The laboratory performs the tests	No interoperability requirement
	7.4.2.2 The lab reports the results	IER43 Send Lab Results LIMS EHR
		IER21 Provider/Register Lab Results LIMS HIE
		IER22 Request & Response Lab Results EHR HIE



Event	Action	Information Exchange Requirement(s) (includes security requirements)
		IER7 Request & Response Newborn Screening Value Sets
7.5.1 Receive EHDI Order 7.5.2 Perform Testing & Report Results	7.5.1.1 Audiology receives order for EHDI	IER16 Send Hearing Screening Order
		IER16 Send Hearing Screening Order EHR ADEV
		IER1 Request & Response Guideline data
		IER19 Request & Response Guideline data
	7.5.2.1 Audiology performs testing in a facility associated with the hospital or birthing center	No interoperability requirements
	7.5.2.2 EHDI results are reported by Audiology	IER55 Send Hearing Screening Test Results EHR
		IER66 Send EC36 Lab Result (used when constraint is 'message') EHR EHR PH
		IER23 Send Hearing Screening Test Results DEV Public Health
		IER64 Send EC36 Lab Result (used when constraint is 'message') DEV EHR PH
		IER24 Publish/Register EC 32 Summary of Care Public Health HIE
		IER25 Notification EC 32 Summary of Care Public Health EHR
		IER26 Subscribe EC 32 Summary of Care EHR HIE
		IER54 Send EC 32 Summary of Care Public Health EHR
		IER65 Send EC36 Lab Result (used when constraint is 'message') PH EHR PH
		IER27 Request & Response EC 32 Summary of Care EHR HIE
		IER25 Notification EC 32 Summary of Care Public Health EHR
		IER1 Request & Response Guideline data
		IER19 Request & Response Guideline data
	7.5.2.2a Second test is required	IER16 Send Hearing Screening Order
		IER16 Send Hearing Screening Order EHR ADEV
		IER1 Request & Response Guideline data
		IER19 Request & Response Guideline data
8.1.1 Receive Abnormal or Out of Range Results and Educational Materials	8.1.1.1 Clinician receives out of range result	IER43 Send Lab Results LIMS EHR
		IER21 Publish/Register Lab Results LIMS HIE
		IER22 Request & Response Lab Results EHR HIE
		IER55 Send Hearing Screening Test Results EHR
		IER66 Send EC36 Lab Result (used when constraint is 'message') EHR EHR PH
		IER23 Send Hearing Screening Test Results DEV Public Health
		IER64 Send EC36 Lab Result (used when constraint is 'message') DEV EHR PH
		IER24 Publish/Register EC 32 Summary of Care Public Health HIE



Event	Action	Information Exchange Requirement(s) (includes security requirements)
		IER25 Notification EC 32 Summary of Care Public Health EHR
		IER26 Subscribe EC 32 Summary of Care EHR HIE
		IER54 Send EC 32 Summary of Care Public Health EHR
		IER65 Send EC36 Lab Result (used when constraint is 'message') PH EHR PH
		IER27 Request & Response EC 32 Summary of Care EHR HIE
		IER25 Notification EC 32 Summary of Care Public Health EHR
		IER1 Request & Response Guideline data
		IER7 Request & Response Newborn Screening Value Sets
	8.1.1.2 Clinician receives information from Public Health	IER 2 Request & Response Education Brochure
		IER1 Request & Response Guideline data
	8.1.1.3 Clinician obtains information from an online source	IER 2 Request & Response Education Brochure
8.1.2 Gather Detailed Family History	8.1.2.1 Gather detailed family history from the consumer by consultative interview	IER30 Send Family History PHR EHR
		IER77 Publish/Register Family History PHR HIE
		IER43 Request & Response Family History EHR HIE
		IER29 Send Family History PHR EHR
		IER77 Publish/Register Family History PHR HIE
		IER43 Request & Response Family History EHR HIE
		IER1 Request & Response Guideline data
		IER19 Request & Response Guideline data
	8.1.2.2 Gather detailed family history using electronic tools	IER30 Send Family History PHR EHR
		IER77 Publish/Register Family History PHR HIE
		IER43 Request & Response Family History EHR HIE
		IER29 Send Family History PHR EHR
		IER77 Publish/Register Family History PHR HIE
		IER43 Request & Response Family History EHR HIE
		IER1 Request & Response Guideline data
		IER19 Request & Response Guideline data
8.1.3 Order Repeat Specimen and Confirmatory Test(s)	8.1.3.1 A repeat specimen or repeat audiological evaluation is ordered	IER44 Send Patient Clinical Information EHR
		IER46 Send Patient Encounter/Discharge Summary EHR EHR
		IER48 Send Referral/Consult Request
		IER16 Send Hearing Screening Order
		IER12 Send Lab Order



Event	Action	Information Exchange Requirement(s) (includes security requirements)
		IER41 Send Lab Order Lab LIMS
		IER7 Request & Response Newborn Screening Value Sets
	8.1.3.2 The pediatric clinician consults with a specialist	IER44 Send Patient Clinical Information EHR
		IER46 Send Patient Encounter/Discharge Summary EHR
8.1.4 Collect specimen(s)	8.1.4.1 Clinician obtains specimen for confirmatory test(s)	No Interoperability requirement
8.1.5 Communicate Order and Send Specimen	8.1.5.1 The order is communicated along with any specimens collected	IER16 Send Hearing Screening Order
		IER12 Send Lab Order
		IER41 Send Lab Order Lab LIMS
8.1.6 Receive Results	8.1.6.1 The clinician receives confirmatory results from the testing laboratory or auditory services	See 7.5.2.2
	8.1.6.2 The clinician receives additional information	IER1 Request & Response Guideline data
		IER2 Request & Response Education Brochure
	8.1.6.3 The clinician refers the consumer to a specialist	IER44 Send Patient Clinical Information EHR
		IER46 Send Patient Encounter/Discharge Summary EHR
		IER48 Send Referral/Consult Request
		IER51 Publish/Register Patient Clinical Information EHR HIE
		IER93 Publish/Register Patient Encounter/Discharge Summary EHR HIE
		IER62 Request & Response Patient Clinical Information EHR HIE
		IER63 Request & Response Patient Encounter/Discharge Summary EHR HIE
	8.1.6.4 Confirmatory genetic testing is done	IER12 Send Lab Order
		IER41 Send Lab Order Lab
	8.1.6.5 Further testing is done to identify genetic subtypes	IER12 Send Lab Order
		IER41 Send Lab Order Lab
8.1.7 Public Health Case Reporting	8.1.7.1 Pediatric clinician files Public Health case report	Refer to HITSP/IS11 Public Health Case Reporting Interoperability Specification
8.1.8 Request Referral & Place Intervention Orders	8.1.8.1 Consumer is referred for education and counseling for a genetic disorder	IER44 Send Patient Clinical Information EHR
		IER46 Send Patient Encounter/Discharge Summary EHR EHR
	8.1.8.2 Consumer is referred for education and counseling for an abnormal confirmatory hearing test	IER44 Send Patient Clinical Information EHR
		IER46 Send Patient Encounter/Discharge Summary EHR EHR
	8.1.8.3 Emergency management is required	IER44 Send Patient Clinical Information EHR
		IER46 Send Patient Encounter/Discharge Summary EHR EHR
		IER1 Request & Response Guideline data
	8.1.8.4 Nutritional intervention is required	IER35 Request & Response Lab Result PHR HIE



Event	Action	Information Exchange Requirement(s) (includes security requirements)
		IER47 Send Lab Results EHR PHR
		IER1 Request & Response Guideline Data
		IER19 Request & Response Guideline data
		IER2 Request & Response Education Brochure
		IER1 Request & Response Guideline PHR Public Health
		IER49 Request & Response Patient Clinical Information PHR HIE
		IER50 Request & Response Patient Encounter/Discharge Summary PHR HIE
		IER46 Send Patient Encounter/Discharge Summary EHR PHR
		IER62 Send Patient Clinical Information EHR
		IER7 Request & Response Newborn Screening Value Sets
8.1.9 Short Term and Long Term Follow-Up	8.1.9.1 Children with various disorders require periodic follow-up visits	IER38 Publish/Register Hearing Screening Test Results EHR HIE
		IER22 Request & Response Lab Results EHR HIE
		IER1 Request & Response Guideline data
		IER19 Request & Response Guideline data
		IER2 Request & Response Education Brochure
		IER51 Publish/Register Patient Clinical Information EHR HIE
		IER93 Publish/Register Patient Encounter/Discharge Summary EHR HIE
		IER62 Request & Response Patient Clinical Information EHR HIE
		IER63 Request & Response Patient Encounter/Discharge Summary EHR HIE
		IER7 Request & Response Newborn Screening Value Sets
	8.1.9.2 Families are referred for education and/or social services	IER35 Request & Response Lab Result PHR HIE
		IER56 Request & Response Hearing Screening Test Results record PHR HIE
		IER47 Send Lab Results EHR PHR
		IER55 Send Audiology Results EHR PHR
		IER66 Send EC36 Lab Result (used when constraint is 'message') EHR EHR PH
		IER1 Request & Response Guideline Data
		IER19 Request & Response Guideline data
		IER2 Request & Response Education Brochure
		IER1 Request & Response Guideline PHR Public Health
		IER49 Request & Response Patient Clinical Information PHR HIE
		IER50 Request & Response Patient Encounter/Discharge Summary PHR HIE



Event	Action	Information Exchange Requirement(s) (includes security requirements)
		IER46 Send Patient Encounter/Discharge Summary EHR PHR
		IER62 Send Patient Clinical Information EHR
		IER7 Request & Response Newborn Screening Value Sets
	8.1.9.3 Continue to monitor patient for LTFU activities	See 8.1.9.2
8.2.1 Provide Detailed Family History and Any Appropriate Consent	8.2.1.1 Parents or current guardian(s) provide detailed family history and consent for confirmatory testing	See 7.1.1.3, 7.2.2.1, 8.1.2.2
8.2.2 Confirmatory Testing	8.2.2.1 Patient provides a blood specimen for confirmation of the blood spot screening test result	See 7.1.6.1, 7.1.6.2, 7.1.7.1
		IER1 Request & Response Guideline data
		IER19 Request & Response Guideline data
		IER 2 Request & Response Education Brochure
8.2.3 Confirmatory Audiology Evaluation	8.2.3.1 Infant undergoes confirmatory hearing test	See 7.1.6.3
		IER1 Request & Response Guideline data
		IER19 Request & Response Guideline data
		IER 2 Request & Response Education Brochure
8.2.4 Receive Clinical Interventions and Support Services	8.2.4.1 Consumer receives referrals for interventions, treatments and other support services	See 8.1.6.3, 8.1.8.1, 8.1.8.2, 8.1.8.3, 8.1.8.4, 8.1.9.1, 8.1.9.2
8.3.1 Collect and Distribute Disorder Information	8.3.1.1 Public Health collects data regarding disorders	See 7.3.1.1, 7.3.2.1, 7.3.3.1, 7.3.3.1a, 7.3.3.1c, 7.3.4.1, 7.3.4.1a, 7.3.5.2
	8.3.1.2 Condition information is made available to clinicians	IER24 Publish/Register EC 32 Summary of Care PH HIE
		IER25 Notification EC 32 Summary of Care Public Health EHR
		IER26 Subscribe EC 32 Summary of Care EHR HIE
		IER54 Send EC 32 Summary of Care Public Health EHR
		IER65 Send EC36 Lab Result (used when constraint is 'message') PH EHR PH
		IER27 Request & Response EC 32 Summary of Care EHR HIE
		IER25 Notification EC 32 Summary of Care Public Health EHR
		IER1 Request & Response Guideline Data
		IER 2 Request & Response Education Brochure
8.3.2 Receive Detailed Family History	8.3.2.1 Public Health receives the detailed family history	IER49 Request & Response Patient Clinical Information
		IER60 Send Patient Encounter/Discharge Summary Public Health EHR
8.3.3 Receive Confirmatory Result Information	8.3.3.1 Public Health receives the case report.	Refer to HITSP/IS11 for all requirements
8.3.4 Request Referral & Place Intervention Orders	8.3.4.1 Public Health requests a referral	IER59 Send Patient Clinical Information Public Health EHR
		IER60 Send Patient Encounter/Discharge Summary Public Health EHR



Event	Action	Information Exchange Requirement(s) (includes security requirements)
		IER61 Send Referral/consult request Public Health EHR
		IER23 Send Audiology Results
		IER64 Send EC36 Lab Result (used when constraint is 'message') DEV EHR PH
		IER45 Send Lab Results Public Health EHR
		IER62 Request & Response Patient Clinical Information EHR HIE
		IER63 Request & Response Patient Encounter/Discharge Summary EHR HIE
		IER22 Request & Response Lab Results EHR HIE
		IER27 Request & Response EC 32 Summary of Care EHR HIE
		IER7 Request & Response Newborn Screening Value Sets
8.3.5 Conduct Long Term Follow-Up IER01 Provide authorization and consent	8.3.5.1 Public Health conducts LTFU of the screening results	No new requirements – see MCH and HITSP/IS06
	8.3.5.2 Track outcomes through registries	Edge system function
	8.3.5.3 Hearing evaluation follow-up	See 7.1.1.3, 7.2.2.1,
	8.3.5.4 Information is used to track key parameters of the newborn screening process	Edge system function fed through exchanges and data collected in 7.3.1.1, 7.3.2.1, 7.3.3.1, 7.3.3.1a, 7.3.3.1c, 7.3.4.1, 7.3.4.1a, 7.3.5.2
	8.3.5.5 Results of newborn screening programs reported back to healthcare providers and consumers	See 7.1.7.1
		IER35 Request & Response Lab Result PHR HIE
		IER56 Request & Response Hearing Screening Test Results record PHR HIE
		IER47 Send Lab Results EHR PHR
		IER55 Send Audiology Results EHR PHR
		IER66 Send EC36 Lab Result (used when constraint is 'message') EHR EHR PH
	8.3.5.5a Public Health focuses on unconventional situations	See 8.1.6.3, 8.1.8.1, 8.1.8.2, 8.1.8.3, 8.1.8.4, 8.1.9.1, 8.1.9.2
		IER53 Request & Response Lab Results Public Health HIE
		IER57 Request & Response Hearing Screening Test Results Public Health HIE
		IER7 Request & Response Newborn Screening Value Sets
8.4.1 Receive Order & Specimen	8.4.1.1 Testing laboratory receives order and blood specimen from pediatric clinician	See 7.1.3b.1
	8.4.1.2 Specimen is accessioned	Edge system function – accession number association
8.4.2 Perform Testing & Report Results	8.4.2.1 The laboratory performs the tests	No interoperability requirement
	8.4.2.2 Results are reported	See 7.1.7.1
8.5.1 Receive Order	8.5.1.1 Audiology services receive the order for a confirmatory test	See 7.1.6.3



Event	Action	Information Exchange Requirement(s) (includes security requirements)
8.5.2 Perform Testing & Report Results	8.5.2.1 Audiology services perform testing	No interoperability requirement
	8.5.2.2 Results are reported to ordering clinician	IER55 Send Hearing Screening Test Results EHR
		IER66 Send EC36 Lab Result (used when constraint is 'message') EHR EHR PH
		IER23 Send Hearing Screening Test Results DEV Public Health
		IER64 Send EC36 Lab Result (used when constraint is 'message') DEV EHR PH
		IER24 Publish/Register EC 32 Summary of Care Public Health HIE
		IER25 Notification EC 32 Summary of Care Public Health EHR
		IER26 Subscribe EC 32 Summary of Care EHR HIE
		IER54 Send EC 32 Summary of Care Public Health EHR
		IER65 Send EC36 Lab Result (used when constraint is 'message') PH EHR PH
		IER27 Request & Response EC 32 Summary of Care EHR HIE
		IER25 Notification EC 32 Summary of Care Public Health EHR
	8.5.2.3 Audiologist makes appropriate referrals	See 8.1.8.2



6.0 DOCUMENT UPDATES

The following sections provide the details of updates made to this document.

6.1 NOVEMBER 9, 2009

No changes. This is the first published version of the document.

6.2 JANUARY 18, 2010

Updated to HITSP Interoperability Specification Template version 2.0

The changes in this cycle address the following comments:

- 8802 8061, 8541, 8546, 8552, 8628, 8644, 8909, 8911, 8912, 8916, 8922, 8924, 8927, 8929, 8930, 8935, 8938, 8943, 8946, 8950, 9377, 9378, 9379, 9380, 9381, 9382

The full text of the comments along with the Technical Committee's disposition can be reviewed on the [HITSP Public Web Site](#).

6.3 JANUARY 25, 2010

Upon approval by the HITSP Panel on January 25, 2010, this document is now Released for Implementation.

