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1.1 Introduction

This White Paper developed by the IHE Quality, Research and Public Health (IHE QRPH) Committee in collaboration with the IHE Laboratory (IHE Lab) Committee describes work processes and data information exchange needs for Newborn Screening programs administered by regulatory health authorities. Newborn Screening programs described in the White Paper include newborn bloodspot screening (NBS) and newborn hearing screening (NHS or Early Hearing Detection and Intervention – EHDI). NBS includes screening for metabolic, pulmonary, genetic, hematologic, endocrine disorders and infectious diseases[1] identified by laboratory testing. NHS identifies permanent conductive or sensorineural hearing losses using physiologic testing technologies. NBS and NHS are conducted at the birthing facility within three days of birth, therefore, representing the first two information exchanges between clinical care and public health authorities in the life course of a child.

At the birthing facility, NBS and NHS are included in the routine workflow as part of mandatory procedures or are ordered by the attending physician. Today, there is minimal integration and interoperability across clinical and public health information systems involved in the information exchange with a few examples when integrated clinical and public health NBS and EHDI systems do exist. NBS laboratories often use proprietary standards to transmit information to submitters, primary care providers and state departments of health.

The White Paper describes the work processes of clinicians and public health professionals in NBS and NHS in the electronic information exchange environment based on the input from several state health departments in the US as well as information collected from France, Germany and Austria. Electronic communication of NBS and NHS data between Electronic Health Record Systems (EHR-S), Laboratory Information Management Systems (LIMS) and public health NBS and NHS information systems (NBS-IS and NHS-IS) will help advancing public health's ability to assure that all newborns receive recommended care by reducing manual data entry errors, improving case tracking and follow-up and population-based surveillance for epidemiological purposes.

The objectives of the White Paper are to:

1. identify needs for interoperability between public health and clinical information systems in NBS and NHS domains;
2. inform the development of future IHE integration profiles and content profiles in these domains;
3. provide input for the coordinated work of the IHE QRPH, IHE Lab Committees and other IHE Committees to develop profiles for these domains as well as other future public health profiles; and

[1] MS Watson, MA Lloyd-Puryear, MY Mann, et.al. Newborn screening panel and system. Genetics in Medicine. 2006. 8(5) Supplement: 12S-53S

4. contribute to the national and international health information technology (HIT) standardization efforts for public health.

The target audience for this White Paper includes public health and clinical professionals involved in the NBS and NHS programs, HIT vendors (Electronic Health Record Systems (EHR-S) vendors and public health information systems vendors), members of national and international HIT standards development, harmonization and certification entities including the US Health Information Technology Standardization Panel (HITSP, http://www.hitsp.org) and the US Certification Commission for Health Information Technology (CCHIT, http://www.cchit.org). This White Paper may be particularly of interest to the HITSP Population Perspective Technical Committee that has been working on the development of the interoperability specification for the United States Department of Health and Human Services Office of the National Coordinator Newborn Screening Use Case[2].

1.1.1 Newborn Bloodspot Screening: Overview

NBS is aimed to identify infants who are at risk of particular congenital and hereditary conditions, and who would be likely to benefit from early diagnosis and treatment. In the US, NBS Programs mandated by state legislation are carried out and financed by 50 State health departments. Public health laboratories at the State health departments or commercial laboratories contracted by NBS Programs conduct NBS testing.

In France, NBS is steered by a national non-profit association "l'**A**ssociation **F**rançaise pour le **D**épistage et la **P**révention des **H**andicaps de l'**E**nfant (http://www.afdphe.asso.fr/), which is financed by the national public health insurance. NBS Programs are carried out by 22 regional newborn screening associations that contract with 3 or more laboratories per region, usually regional university hospital laboratories.

In Germany, NBS is a national program carried out by Lands (states) that contract with 10 laboratories over the country (3 commercial and 7 university hospital laboratories).

In Austria, NBS is a national program carried out by one organization. All tests are done by one laboratory. The NBS specimens are collected at the birthing facility within 72 hours of birth and sent to an approved laboratory for analysis[3]. In the US, some States require a second bloodspot testing at 2 weeks of age ordered by the child's primary care provider (pediatrician).

Regulations related to the acquisition and analysis of the NBS specimens, dissemination of screening results, data management and information exchange vary across States in the US and across participating countries. Regulations also vary across States in the US[4] and across countries in term of which disorders are included in the screening panel. Table 1 presents the list of 29 core conditions recommended by the Advisory Committee on Heritable Disorders in Newborns and

[2] US Department of Health and Human Services. Newborn Screening Use Case. URL: http://healthit.hhs.gov/portal/server.pt?open=512&objID=1202&&PageID=15660&mode=2&in_hi_userid=10732&cached=true

[3] Newborn Dried Bloodspot Screening Business Process Analysis. Public Health Informatics Institute. 2008. Page 6-8

[4] US National Screening Status Report. National Newborn Screening and Genetics Resource Center. URL: http://genes-r-us.uthscsa.edu/nbsdisorders.pdf

Children (ACHDNC) and included in the Newborn Screening Saves Lives Act of 2007[1, 5]. In the US, State NBS Programs vary in the disorders included in the NBS panel and may test for from 3 to 62 conditions. Some of these are listed as secondary targets in Table 2 [4]. In France, testing is undertaken for 5 conditions (Table 3).

The NBS specimen is collected via a heel-stick from each newborn and placed as blood spots on the filter paper attached to the NBS Specimen Card (also called NBS Specimen card) that contains submitter information, newborn and family demographic information, and specimen information. NBS Specimen cards' data content and formats vary across States in the US and across countries. In the US, consent for NBS may not be required. In France, parents' consent or consent refusal to genetic testing is recorded on the Card.

Table 1. Core Condition Panel for Newborn Screening in the US Based on the Newborn Screening Saves Lives Act of 2007

Disorders of Organic Acid Metabolism (OA)	Disorders of Fatty Acid Metabolism (FAO)	Disorders of Amino Acid Metabolism (AA)	Hemoglobinopathies (HbPathies)	Others
CORE PANEL				
Isovaleric acidemia (IVA)	Medium-chain acyl-CoA dehydrogenase deficiency (MCAD)	Phenylketonuria (PKU)	Sickle cell anemia (Hb SS)	Congenital hypothyroidism (CH)
Glutaric acidemia type I (GA I)	Very long-chain acyl-CoA dehydrogenase def. (VLCAD)	Maple syrup (urine) disease (MSUD)	Hb S/ β –thalassemia (Hb S/ß-Th)	Biotinidase deficiency (BIOT)
3-hydroxy 3-methyl glutaric aciduria (HMG)	Long-chain 3-OH acyl-CoA dehydrogenase def. (LCHAD)	Homocystinuria (HCY)	Hb S/C disease (Hb S/C)	Congenital adrenal hyperplasia (CAH)
Multiple carboxylase deficiency (MCD) (Holocarboxylase Synthetase deficiency)	Trifunctional protein deficiency (TFP)	Citrullinemia (CIT)		Classic galactosemia (GALT)
Methylmalonic acidemia (mutase) (MUT)	Carnitine uptake defect (CUD)	Argininosuccinic acidemia (ASA)		Hearing loss (HEAR)
3-Methylcrotonyl-CoA carboxylase deficiency (3MCC)		Tyrosinemia type I (TYR I)		Cystic fibrosis (CF)
Methylmalonic acidemia (Cbl A, B)				

[5] Health Resources and Services Administration. Newborn Screening Saves Lives Act of 2008. URL: http://www.hrsa.gov/heritabledisorderscommittee/governance/newbornscreeningsaveslives.htm

Propionic acIdemia (PROP)				
β-Ketothiolase deficiency (BKT)				

Source: MS Watson, MA Lloyd-Puryear, MY Mann, et.al. Newborn screening panel and system. Genetics in Medicine. 2006. 8(5) Supplement: 12S-53S

Table 2. Secondary Targets for Newborn Screening in the US

Disorders of Organic Acid Metabolism (OA)	Disorders of Fatty Acid Metabolism (FAO)	Disorders of Amino Acid Metabolism (AA)	Hemoglobinopathies (HbPathies)	Others
SECONDARY TARGETS				
Methylmalonic acidemia (Cbl C,D)	Short-chain acyl-CoA dehydrogenase deficiency (SCAD)	Benign hyperphenylalaninemia (H-PHE)	Other variant Hb-pathies (including Hb E) (Var Hb)	Galactokinase deficiency (GALK)
Malonic aciduria (MAL)	Glutaric acidemia type II (GA2)	Tyrosinemia type II (TYR II)		Galactose epimerase deficiency (GALE)
Isobutyryl-CoA dehydrogenase deficiency (IBG)	Medium/short-chain 3-OH acyl-CoA dehydrogenase deficiency (M/SCHAD)	Defects of biopterin cofactor biosynthesis (BIOPT [BS])		
2-Methyl 3-hydroxy butyric aciduria (2M3HBA)	Medium-chain ketoacyl-CoA thiolase deficiency (MCKAT)	Argininemia (ARG)		
2-Methylbutyryl-CoA dehydrogenase deficiency (2MBG)	Carnitine palmitoyltransferase II deficiency (CPT II)	Tyrosinemia type III (TYR III)		
3-Methylglutaconic aciduria (3MGA)	Carnitine acylcarnitine translocase deficiency (CACT)	Defects of biopterin cofactor regeneration (BIOPT [REG])		
	Carnitine palmitoyltransferase IA deficiency (liver) (CPT IA)	Hypermethioninemia (MET)		
	Dienoyl-CoA reductase deficiency (DE RED)	Citrullinemia type II (CIT II)		

Source: MS Watson, MA Lloyd-Puryear, MY Mann, et.al. Newborn Screening Panel and System. Genetics in Medicine. 2006. 8(5) Supplement: 12S-53S

Table 3. Core Diseases Screened in France and Corresponding Analytes

Disease	Nature	Incidences	Analyte
Congenital Hypothyroidism	various forms, rarely genetic	1 / 3500	TSH (Thyroid Stimulating Hormone)
Congenital adrenal hyperplasia	genetic, recessive autosomic	1 / 14000	a) 17 Alpha-Hydroxyprogesterone (17-OHP) b) Electrolyte
Cystic fibrosis	genetic, recessive autosomic	1 / 4000	a) Immunoreactive trypsinogen (IRT) b) CFTR mutation/variant panel c) Chloride on sweat
Phenylketonuria	genetic, recessive autosomic	1 / 17000	Phenylalanine
Sickle cell anemia	genetic, recessive autosomic	variable	Hemoglobine S (HbS) depending on population

In the US, the Card with the specimen is mailed or sent by courier from the birthing facility to the designated laboratory (public health department or commercial). In France, NBS cards are first sent to a regional association that then dispatches them to the designated laboratories.

Laboratory data entry personnel (regional newborn screening association staff in France) enter the NBS Specimen Card data into the NBS information system (NBS-IS) that may be integrated with the Laboratory Information Management System (LIMS). The laboratory processes the specimen. Interpretation of the results requires information on maternal history, transfusion status and alimentation type and history that may be missing on the Card when it arrives at the laboratory. This may result in repeat testing that requires tracing a newborn discharged from the birthing facility delaying the diagnosis of potentially life-threatening conditions.

In the case of abnormal results, in the US, the Laboratory typically notifies NBS Program Staff to track the newborn in order to inform the parents and the primary care providers regarding necessary intervention. Alternately the laboratory may contact the submitter (the birthing facility or primary care provider). Primary care providers often state that communicating such information should be their responsibility. However, the primary healthcare provider may not receive timely notification if the information identifying them is missing on the specimen card. Missing information can result in challenges in follow-up and delay in services. In France, the Laboratory notifies the ordering birthing facility and the Referent Physician in a geographic area about abnormal results using a Condition Notification Form. The Referent Physician forwards the notification to the primary care provider or to the family.

In the US, normal results are commonly sent by the Laboratory as hardcopy reports to the ordering birthing facility and State NBS Program or delivered as images (such as PDF) by the LIMS into the State NBS-IS (in France, into regional association NBS-IS). In France, Germany and Austria, no laboratory report is sent back to the birthing facility for normal results. In the US and more and more internationally as well, efforts are being made to standardize reporting of bloodspot results using LOINC codes. The National Library of Medicine has taken a lead role in this effort. Details

can be obtained at http://newbornscreeningcodes-demo.nlm.nih.gov/nb/sc/ or http://www.acmg.net/StaticContent/Moving_NBS/LOINC_AHIC_panel.pdf .

1.1.2 Newborn Hearing Screening (NHS) or Early Hearing Detection and Intervention Screening (EHDI): Overview

In the US, hearing screening is commonly conducted at the birthing facility on a newborn within 72 hours of age at the bedside or in a designated nursery location. NHS may be conducted by nursery personnel, a different hospital department (e.g. audiology) or by contracted staff. NHS results are provided to parents before discharge.

NHS is conducted using non-invasive, objective and automated physiological measures of auditory function. Physiologic measures include otoacoustic emissions (OAEs), either transient (TEOAE) or distortion-product (DPOAE otoacoustic emissions, and/or automated auditory brainstem response (ABR). Both technologies produce easily recordable output in newborns. In response to acoustic stimuli, OAE devices record cochlear responses and ABR devices record neural activity generated in the cochlea, auditory nerve, and brainstem. Depending upon the device used, the cochlear or neural responses may get affected by conditions of the outer and/or middle ear and consequently result in a “failed” screening result even with intact cochlear and/or neural function. Automated screening technologies incorporate statistical response detection algorithms to ensure test consistency and reduce the effects of screener or operator bias in test interpretation. Screening may be conducted in the well-baby nursery using either OAE or automated ABR as the device and may be repeated again if the infant does not pass the initial screening. However, multiple retesting increases both, the possibility of obtaining a false negative screening result. Some programs use a combination of screening technologies (OAE testing for the initial screening followed by an automated ABR for re-screening, i.e., 2-step protocol) to decrease the fail rate at discharge and the subsequent need for outpatient follow-up. With this approach, infants who do not pass the initial OAE screening but subsequently pass the automated ABR test are considered a screening "pass."

The NHS results are submitted to the State NHS Program that calculates the NHS outcomes based on the program-defined rules derived from the state regulations. State regulations vary with regard to NHS screening, data reporting requirements to State NHS Programs and follow-up procedures for abnormal results.

The NHS results are sent to the State in different formats. These include specially designed NHS forms, as fields on the NBS Specimen card or Birth Certificate, as monthly aggregate reports or in electronic format, including stand-alone information systems with web-based interfaces. For States in which birthing facilities submit hearing data on NBS Specimen cards, data are often missing, incomplete, or inaccurate since repeat hearing screening conducted just prior to discharge may not be captured on a NBS Specimen card completed and sent earlier. As a result, the information obtained by NHS/EHDI Programs may be incomplete or may exist only in an estimated or aggregated format. In the US, NBS and NHS/EHDI information systems are generally neither interoperable within a Health Department nor cross-jurisdictional boundaries.

In France, the NHS is done in some birthing facilities experimentally, parallel with NBS. This activity is also monitored/administered by the regional associations separate from blood spot screening. NHS is not universal in France due to cost, which is reported to be higher than the bloodspot screening.

1.2 Open Issues and Questions

1. Regulations related to NBS vary across states in the US and across countries in terms of which disorders are included in the screening panel3. Some jurisdictions in the US require a second bloodspot testing at 2 weeks of age ordered by the child's primary care provider. There is a need for coordination with the IHE Patient Care Coordination (IHE PCC) Committee to utilize the IHE PCC Care Management Profile to document the differing jurisdictional guidelines and the development of the Clinical Decision Support Content Profile for NBS and NHS. (Please see Table 1 above for the 29 target conditions panel for NBS in the United States).
2. The NBS specimen is collected on the filter paper attached to the NBS Specimen card that contains submitter information, newborn and family demographic information, and specimen information. The Card with the specimen is mailed to a designated public health-approved laboratory (public health department, commercial or university-based). NBS Specimen cards' data content and formats vary across states in the US and across countries. In this White Paper, we conducted data mapping across forms from participating states in the US and several European countries. There is a need for the development of the NBS Content Profile that will describe NBS dataset.
3. The NBS and NHS electronic data exchanges depend on the assumption that the Newborn's Electronic Medical Record has been created at the birthing facility's EHR-S. There is a need for collaboration with IHE PCC to develop the Newborn's Birth Record Content Profile that will serve as a basis for pre-population of the NBS and NHS records with the newborn's demographics, mother's demographics, family medical history (risk factors) and other relevant information.
4. Devices: The US Joint Committee on Infant Hearing (JCIH) recommends hospital-based programs utilize either one or both of the two available screening devices to detect sensory (cochlear) hearing loss, i.e., otoacoustic emission (OAE) or automated auditory brainstem response (ABR) testing. Both screening technologies are non-invasive, can be easily used on neonates and infants, and have been successfully used for NHS throughout the world6. There is a need to collaborate with the IHE Device Committee to assure that these devices are specified in the IHE Device Integration Profiles.
5. Considerations should be given to utilization of the common health information exchange infrastructure for NBS, NHS and other public health programs/domains. There is a need to collaborate with the IHE Information Infrastructure (IHE ITI) Committee to assure that public health information exchange needs can be addressed by the IHE ITI Integration Profiles, e.g., Cross-Document Sharing (XDS), Retrieve Form for Data Capture (RFD), Patient Identification Cross-referencing (PIX), Patient Demographic Query (PDQ), Publish/Subscribe, Service-Oriented Architecture, etc.

[6] Joint Committee on Infant Hearing. Year 2007 Position Statement: Principles and Guidelines for Early Hearing Detection and Intervention Programs. Pediatrics 2007; 120; 898-921.

6. There is a need to collaborate with the IHE Lab Domain to assure that Public Health information exchange needs can be addressed by the IHE Lab Technical Framework.

1.3 Closed Issues

None

1.4 Future Considerations

1. Clinical Decision Support Content Profile for NBS and NHS
2. IHE Lab Order Profiles for NBS
3. NBS Screening Content Profile
4. NHS Screening Content Profile
5. Newborn's Birth Record Content Profile
6. Information Technology Infrastructure Integration Profiles

1.5

1.6 Scope

1.6.1 In Scope

NBS and NHS conducted at the birthing facility within72 hours of age prior to dischage are in scope of this White Paper.

1.6.2 Out of scope

The following issues are out of scope of this White Paper;

1. NBS and NHS of babies born premature that may be conducted at older ages in the Neonatal Intensive Care Unit (NICU)
2. Second NBS conducted by the primary care provider at the initial routine care pediatric visit at 2 weeks of age, if such testing is required by jurisdictional regulation.
3. Repeated NBS, if the first specimen is lost or invalid
4. Short-term care follow-up defined as the care process following the notifications of the occurrence of an abnormal test result until the initiation of therapy for a confirmed diagnosis.
5. Long-term care follow-up defined as all care processes that occur from the initiation of therapy following a confirmed diagnosis.
6. Information exchanges between participating actors (EHR-S, LIMS, NBS-IS ans NHS-IS) and Personal Health Record (PHR)
7. Identification of NBS and NHS value sets

1.7 Stakeholders

Newborn Bloodspot Screening. The following stakeholders (business actors) are involved in the NBS:

Healthcare Provider

Birthing Facility

- Specimen Collector (Nurse, Midwife, Hospital Lab Staff, etc.)
- Birthing Facility Staff (Personnel that gather/mail specimens, administrative staff, etc.)
- Clinician (Attending Physician, etc.)

Primary Care Provider

Pediatric Subspecialty Providers such as hematologists, geneticists and endocrinologists among others as needed.

Laboratory Staff

Public Health–Approved/Appointed Laboratory (public health laboratory, contract laboratory, university hospital laboratory, etc.).

- Data Entry Staff
- Laboratory Technician
- Laboratory Result Reporting Staff (Follow-up Coordinators, etc.)

Public Health Staff

NBS Program (State Health Department, NBS Programs (US); National & Regional Associations (France); National Association (Austria, Germany)

- Program Staff (Data Manager, Case Manager, etc.)
- Contracted Case Management / Follow-up Services Staff

Consumer

- Newborn
- Parent/Guardian

The following actors (technical actors) are involved in the NBS:

- Birthing Facility's Electronic Health Record System (**EHR-S**) - *Order Placer/Result Receiver*
- Hospital Laboratory Information Management Systems (**LIMS**) – *Order Tracker*
- Health Information Exchange (**HIE**)
- Laboratory Information Management Systems (**LIMS**) – *Order Filler*
- Public Health NBS Information System (**NBS-IS**) – *Order/Result Tracker* - (State (US)/Regional (France)/National (Austria, Germany)
- Primary Care Provider's **EHR-S** – *Result Receiver and/or Order Placer*
- Personal Health Record System (**PHR-S**) (OUT OF SCOPE)

1.7.1 Newborn Hearing Screening. The following stakeholders (business actors) are involved in the NHS:

Healthcare Provider

Birthing Facility

- Attending Physician
- Hearing Screener
- Screening Supervisor (Birthing Facility's or Contract Staff)

Primary Care Provider (PCP)

Public Health Staff

NHS Program (State Health Department, NHS /EHDI Programs (US); Regional Associations (France)

- Program Staff

The following Actors (technical actors) are involved in the NHS:

- Birthing Facility's Electronic Health Record System (**EHR-S**)
- Health Information Exchange (**HIE**)
- Hearing Screening Device (**HS Device**)
- NHS / EHDI Information System (**NHS/EHDI-IS**)
- Primary Care Provider's **EHR-S**
- Personal Health Record System (**PHR-S**) (OUT OF SCOPE)

2 Use Cases

State, federal and private industry health information technology initiatives in the US and national initiatives in European countries are guiding the evolution of stand-alone information systems involved in newborn screening into interoperable electronic health information exchanges. The Use Case 1: NBS (Table 4) and Use Case 2: NHS/EHDI (Table 5) describe stakeholders, their work processes (flow of events) and data categories generated by these work processes under interoperable electronic health informaton exchanges for NBS and NHS, respectively. These Use Cases were developed with the input from the two State NBS Programs (Alaska, Texas,) and four State NHS Programs (Alaska, Iowa, Maryland and Texas) in the US as well as using information about those programs from France, Germany and Austria. Recognizing the divergent rules, regulations involved in newborn bloodspot and hearing screening, each use case is meant to be a roadmap to shape to meet the requirements of the jurisdictional authority.

Table 4. Use Case 1: Newborn Bloodspot Screening (NBS)

Use Case Name	Newborn Bloodspot Screening (NBS)
Business Actors (Personnel)	1. Healthcare Provider Birthing Facility Specimen Collector (Nurse, Midwife, Hospital Lab Staff, etc.) Birthing Facility Staff (Personnel that gather/mail specimens, Administrative Staff, etc.) Clinician (Attending Physician, etc.) Primary Care Provider
	2. Laboratory Staff Public Health–Approved/Appointed Laboratory (public health laboratory, contract laboratory, university hospital laboratory, etc.) Data Entry Staff Laboratory Technician Laboratory Result Reporting Staff (Follow-up Coordinators, etc.)
	3. Public Health Staff NBS Program (State Health Department, NBS Programs (US); National & Regional Associations (France); National Association (Austria, Germany) Program Staff (Data Manager, Case Manager, etc.) Contracted Case Management / Follow-up Services Staff
	4. Consumer Newborn Parent/Guardian
Technical Actors (Information Systems)	Birthing Facility's Electronic Health Record System (EHR-S) - *Order Placer/Result Receiver* Hospital Laboratory Information Management Systems (LIMS) – *Order Tracker* Health Information Exchange (HIE) Laboratory Information Management Systems (LIMS) – *Order Filler* Public Health NBS Information System (NBS-IS) – *Order/Result Tracker* - (State (US)/Regional (France)/National (Austria, Germany) Primary Care Provider's EHR-S – *Result Receiver and/or Order Placer* Personal Health Record System (PHR-S) (OUT OF SCOPE)

Flow of Events	Data Categories by Events
1. Birthing Facility	
1.1. EHR-S presents Reminder to Specimen Collector that Newborn is due for NBS	NBS Clinical Decision Support Data, Task Lists
1.2. Specimen Collector explains NBS test to Parent/Guardian and obtains Consent for NBS and Consent for NBS Information Sharing, if needed, from Parent/Guardian NOTE: Consents may be optional in some jurisdictions	*Consents:* 1. Consent or Consent Refusal for NBS and 2. Consent or Consent Refusal for NBS Information Sharing
1.3. Specimen Collector enters Consents or Consent Refusals into EHR-S	
1.4. Specimen Collector enters NBS data into EHR-S; scans barcode from NBS Specimen Card (or enters NBS card ID number) into EHR-S; prints NBS Specimen Label, that contains entered NBS information from EHR-S, and attaches Label to the NBS Specimen Card with filter paper NOTE: Label may also be printed after step 1.5	*Lab Order:* NBS Specimen Card (Label) Data
1.5. Specimen Collector performs heel stick, places blood spots on NBS Specimen Card, and sets specimen to dry	
1.6. Specimen Collector confirms in EHR-S that NBS specimen was collected and creates NBS Lab Order in EHR-S	
1.7. EHR-S sends NBS Lab Order to approved LIMS	
1.8. US - Birthing Facility Staff mails NBS Specimen Card with bloodspots to Laboratory NOTE: In large hospitals in the US, NBS specimens are collected daily from various divisions (birthing facility, outpatient pediatric clinic, NICU). Hospital LIMS (Order Tracker) maintains the log of all NBS specimens to be mailed from hospital to laboratory. In this case, Hospital Laboratory Staff mails specimens to public health-approved Laboratory	
1.9. France - Birthing Facility Staff mails NBS Specimen Card with bloodspots to Regional Association, which dispatches specimens to the regional university hospital Laboratory.	
1.10. EHR-S or Hospital LIMS receives Order Completion Notification from LIMS with reference to NBS Result Report NOTE: May also receive the Order Completion Notification from HIE	*Lab Order=Lab Result:* 1. Order Completion Notification Data 2. NBS Result Report Data 3. Alerts & Task Lists, if Abnormal Results
1.11. EHR-S or Hospital LIMS receive NBS Result Report from LIMS NOTE: May also download NBS Result Report from HIE	
1.12. If Order Completion Notification indicates abnormal results, EHR-S or Hospital LIMS notifies appropriate Clinician to review results NOTE: This may use a forthcoming IHE Alert Profile	
1.13 Birthing Facility Staff receives Notification that NBS Surveillance Reports are available in HIE	*NBS Surveillance:* 1. NBS Surveillance Report Notification 2. NBS Surveillance Reports
1.14 Birthing Facility Staff downloads NBS Surveillance Reports from HIE into EHR-S	
2. Laboratory	
2.1. LIMS receives NBS Lab Order from Birthing Facility's EHR-S	*Lab Order:* NBS Specimen Card Data
2.2. LIMS creates Pending Record for Newborn's NBS specimen, i.e., a queue of "lab orders pending specimen receipt"	***Lab Order:*** NBS Specimen Pending Record Data

2.3. LIMS sends Notification to **NBS-IS** (Order / Result Tracker) that Lab Order was received	***Lab Order:*** NBS Specimen Notification Data
2.4. Laboratory receives NBS Specimen Card with bloodspots from **Birthing Facility** (or Hospital, or Regional Association)	***Lab Order:*** NBS Specimen Card Data
2.5. Data Entry Staff scans barcodes from NBS Specimen Card and verifies NBS Lab Order in **LIMS**	
2.6. Laboratory Technician processes the specimen and captures (enters) the results into **LIMS**	***Lab Result:*** 1. NBS Result Report Data 2. Alerts & Task Lists, if Abnormal Results
2.7. If abnormal results, **Lab Staff** follows up with appropriate notifications or requests for follow-up or re-test, using emergency notification as needed to jurisdictionally defined personnel. **NOTE:** This may use a forthcoming IHE Alert Profile	
2.8. LIMS publishes Newborn's NBS Result Report into **HIE**	
2.9. LIMS sends Order Completion Notification to **Birthing Facility's EHR-S** with reference to NBS Result Report **NOTE**: **LIMS** may send Order Completion Notification to **Hospital's LIMS** – Order Tracker.	***Lab Order=Lab Result:*** Order Completion Notification Data
2.10 LIMS sends Order Completion Notification to **NBS-IS** with reference to NBS Result Report	
2.11 LIMS sends Newborn's NBS Result Report to **EHR-S** or **Hospital's LIMS**	***Lab Result:*** 1. NBS Result Report Data
2.12 LIMS sends Newborn's NBS Result Report to **NBS-IS**	
3. Public Health NBS Program	
3.1. NBS-IS receives Notification of Newborn's Birth Record availability from **HIE**	***Birth Record:*** Notification Data
3.2. NBS-IS downloads Newborn's Birth Record from **HIE** and establishes **Newborn's** NBS Record for Newborn	***NBS Record or Lab Order:*** NBS Specimen Card Data
3.3. NBS-IS receives Notification from **LIMS** that NBS Lab Order was received	***Lab Order:*** NBS Specimen Notification Data
3.4. NBS-IS receives Order Completion Notification from **LIMS** that NBS Result Report was published in **HIE**	***Lab Order=Lab Result:*** *Order Completion Notification Data*
3.5. NBS-IS downloads the NBS Result Report from **HIE**	***Lab Result:*** 1. NBS Result Report Data 2. Alerts & Task Lists, if Abnormal Results
3.6 NBS-IS receives the NBS Result Report from **LIMS**	
3.7 NBS-IS calculates outcome of Newborn's NBS, i.e., determines what follow-up activities are necessary	
3.8. If abnormal results, **NBS-IS** notifies **Program Staff** for appropriate follow-ups. **NOTE:** This may use a forthcoming IHE Alert Profile	
3.9 NBS Program staff initiates appropriate follow-up as required, including emergency notifications	
3.10 NBS Program Staff runs NBS Surveillance Reports periodically as required by jurisdiction in **NBS-IS**	**NBS Surveillance Reports**
3.11 NBS-IS publishes NBS Surveillance Reports in **HIE**	

4. Primary Care Provider	
4.1 Primary Care Provider receives notification from **Birthing Facility** or **Guardian** or **NBS Program Staff** that Newborn's records are available in **HIE** **NOTE**: Notification can be electronic	***Newborn Data***
4.2 Primary Care Provider's EHR-S subscribes to all records related to the **Newborn** in **HIE**	***Lab Result:*** NBS Result Report Data
4.3. Primary Care Provider's EHR-S downloads **Newborn's** NBS Result Report from **HIE**	
4.4. If abnormal results, **Primary Care Provider** is notified by **NBS Program Staff** for appropriate follow-ups. **NOTE:** This may use a forthcoming IHE Alert Profile	***Lab Result:*** Alerts & Task Lists, if Abnormal Results
NOTE: *In the US, some states require mandatory 2nd Newborn Bloodspot Screening during the 1st outpatient visit of the* ***Primary Care Provider*** *at 2 weeks of age. In the case of the 2nd NBS,* ***Primary Care Provider's*** *flow of events will be the same as described above for Birthing Facility's flow of events.*	***Same as above in Birthing Facility section above***
4.5 Primary Care Provider's **EHR-S** receives Notification that NBS Surveillance Reports are available in **HIE**	***NBS Surveillance:*** NBS Surveillance Report Notification
4.6 Primary Care Provider downloads NBS Surveillance Reports from **HIE** into **EHR-S**	***NBS Surveillance:*** NBS Surveillance Reports

Entry Conditions	Newborn is born
	Newborn's Birth Record is created in the **Birthing Facility's EHR-S**
	Newborn's Birth Record is published in **HIE**
Exit Condition	NBS Result Report is uploaded into **NBS-IS**
	NBS Result Report is uploaded into **Birthing Facility's EHR-S** or **Hospital LIMS**
	NBS Result Report is uploaded into **Primary Care Provider's EHR-S**
	NBS Surveillance Report is uploaded into **Birthing Facility's EHR-S**
	NBS Surveillance Report is uploaded into **Primary Care Provider's EHR-S**

Figures 1-1 thru 1-4 provide UML Use Case diagrams of the Newborn Bloodspot Screening from each of the four perspectives.

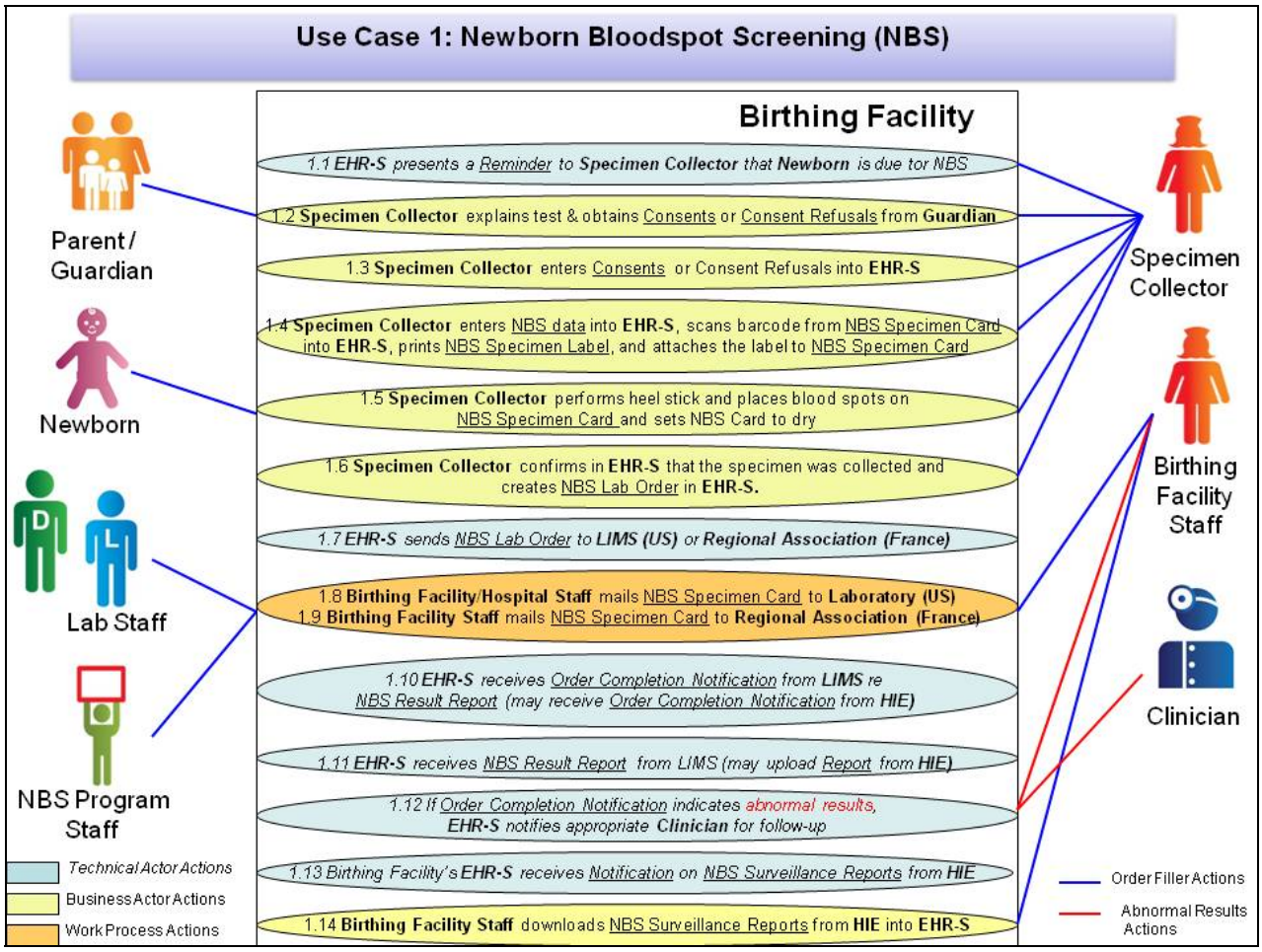

Figure 1-1: UML Use Case Diagram for NBS: Birthing Facility

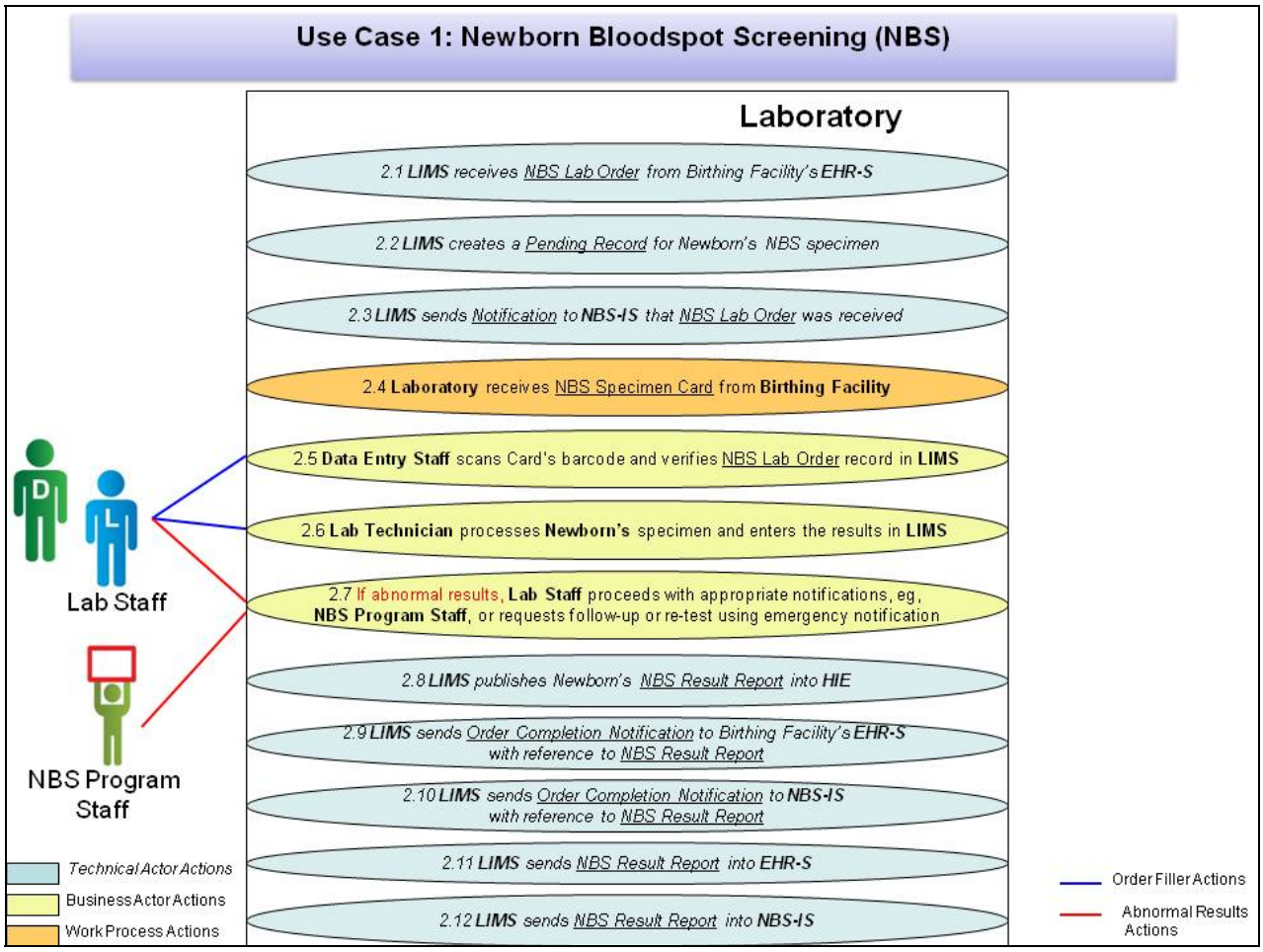

Figure 1-2: UML Use Case Diagram for NBS: Laboratory

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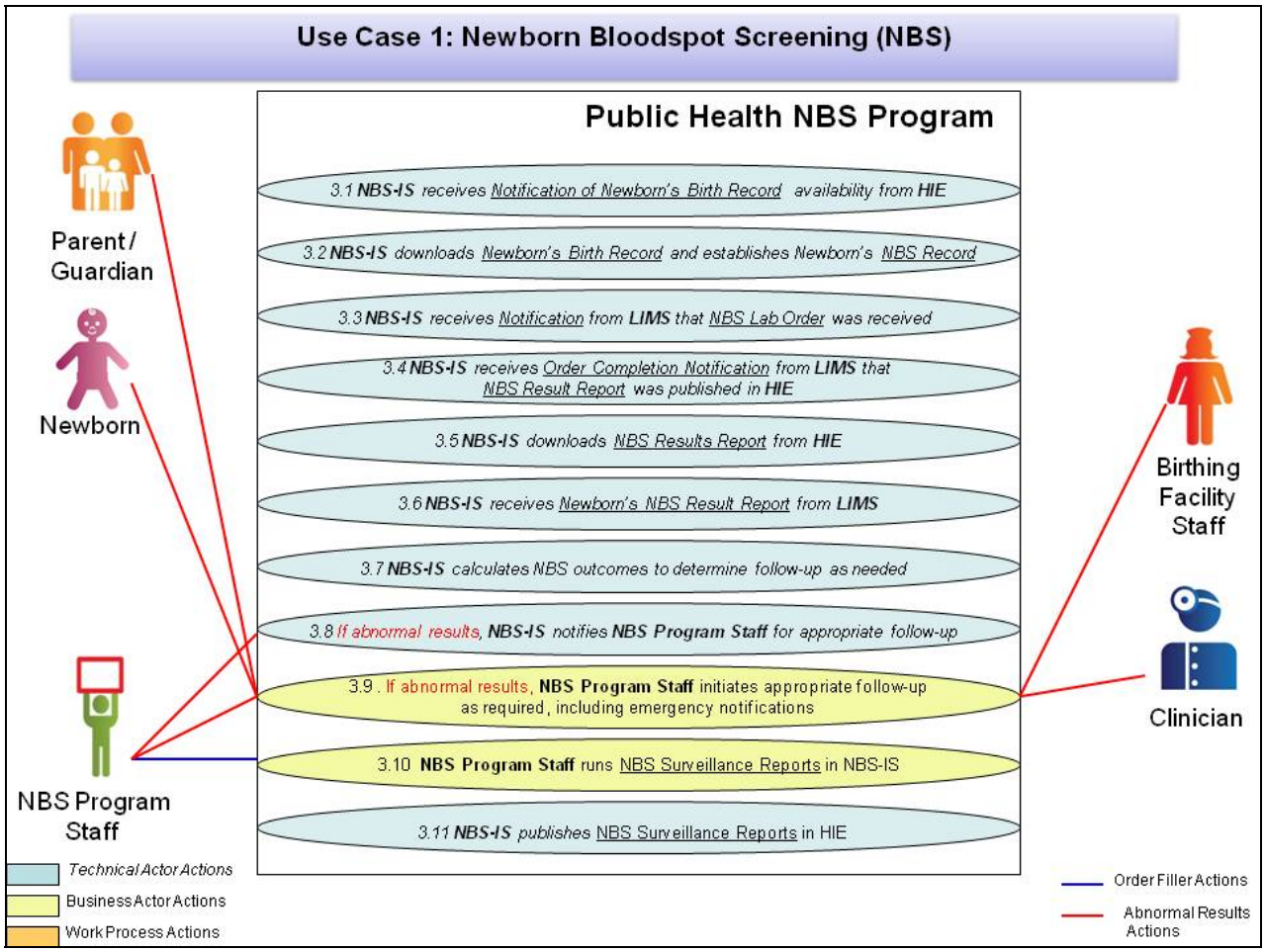

Figure 1-3: UML Use Case Diagram for NBS: Public Health NBS Program

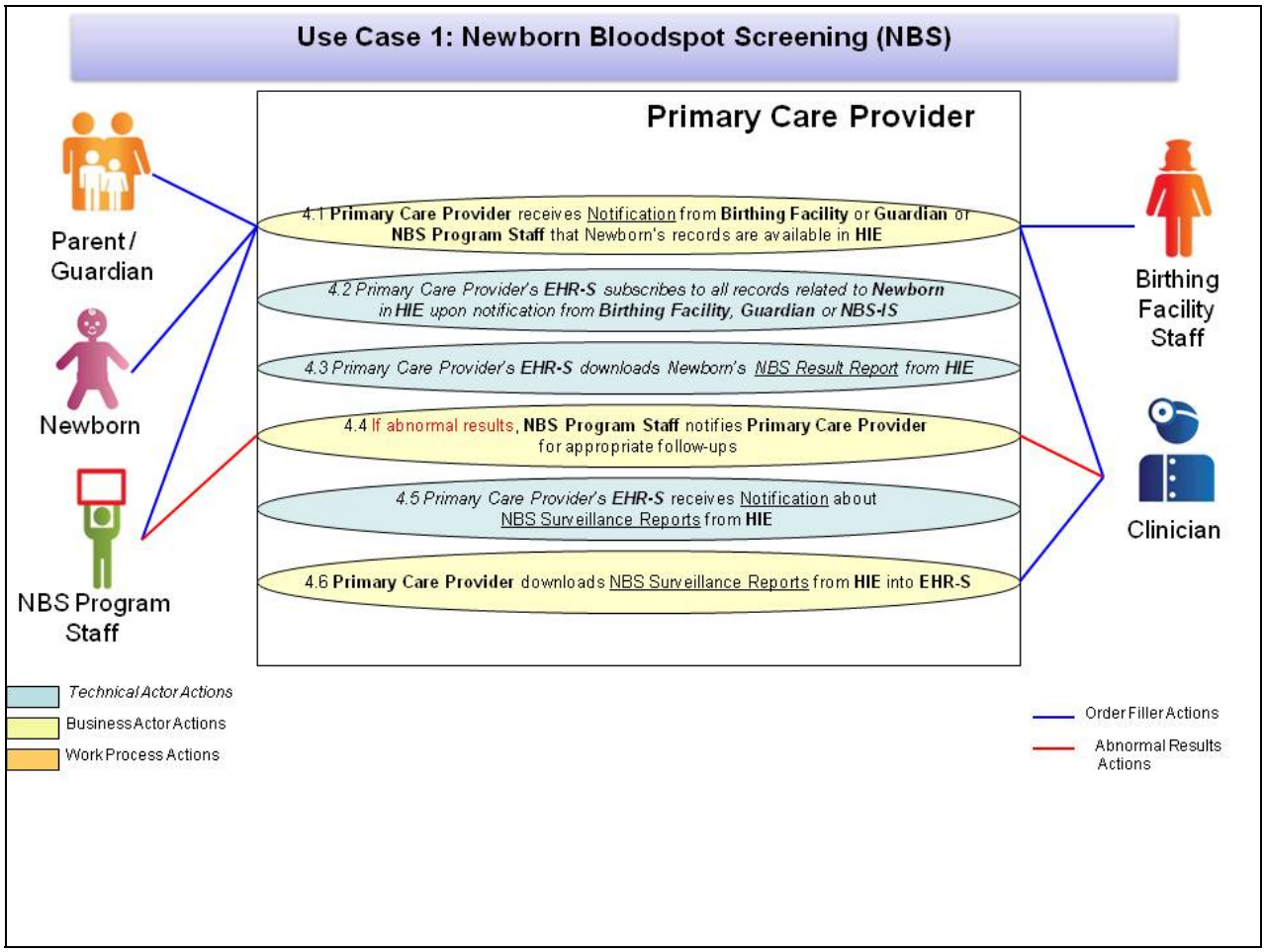

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Figure 1-4: UML Use Case Diagram for NBS: Primary Care Provider

Figures 2-1 thru 2-4 provide UML workflow diagrams of the Newborn Bloodspot Screening from each of the four perspectives.

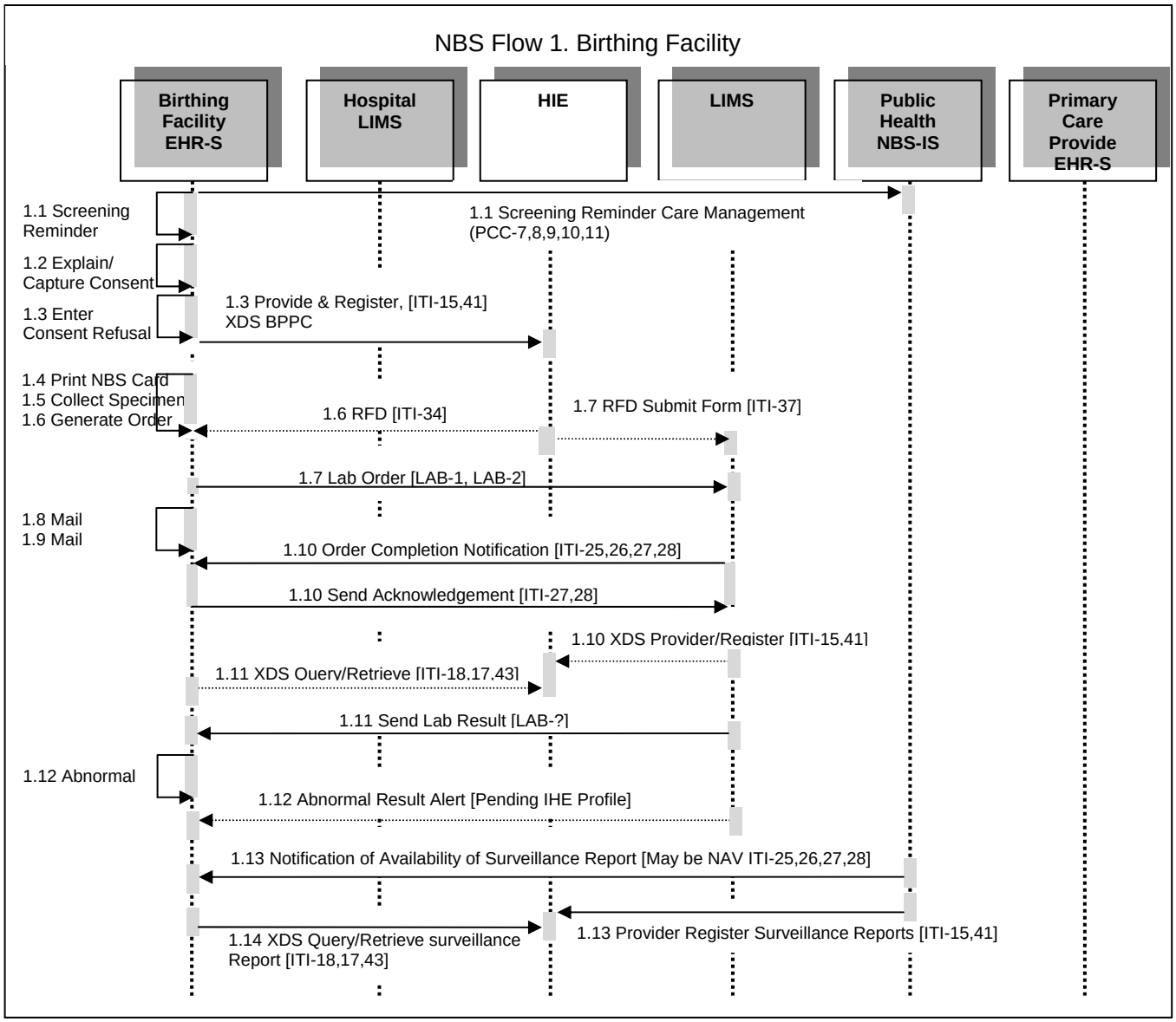

Figure 2-1: UML Workflow Diagram for NBS: Birthing Facility

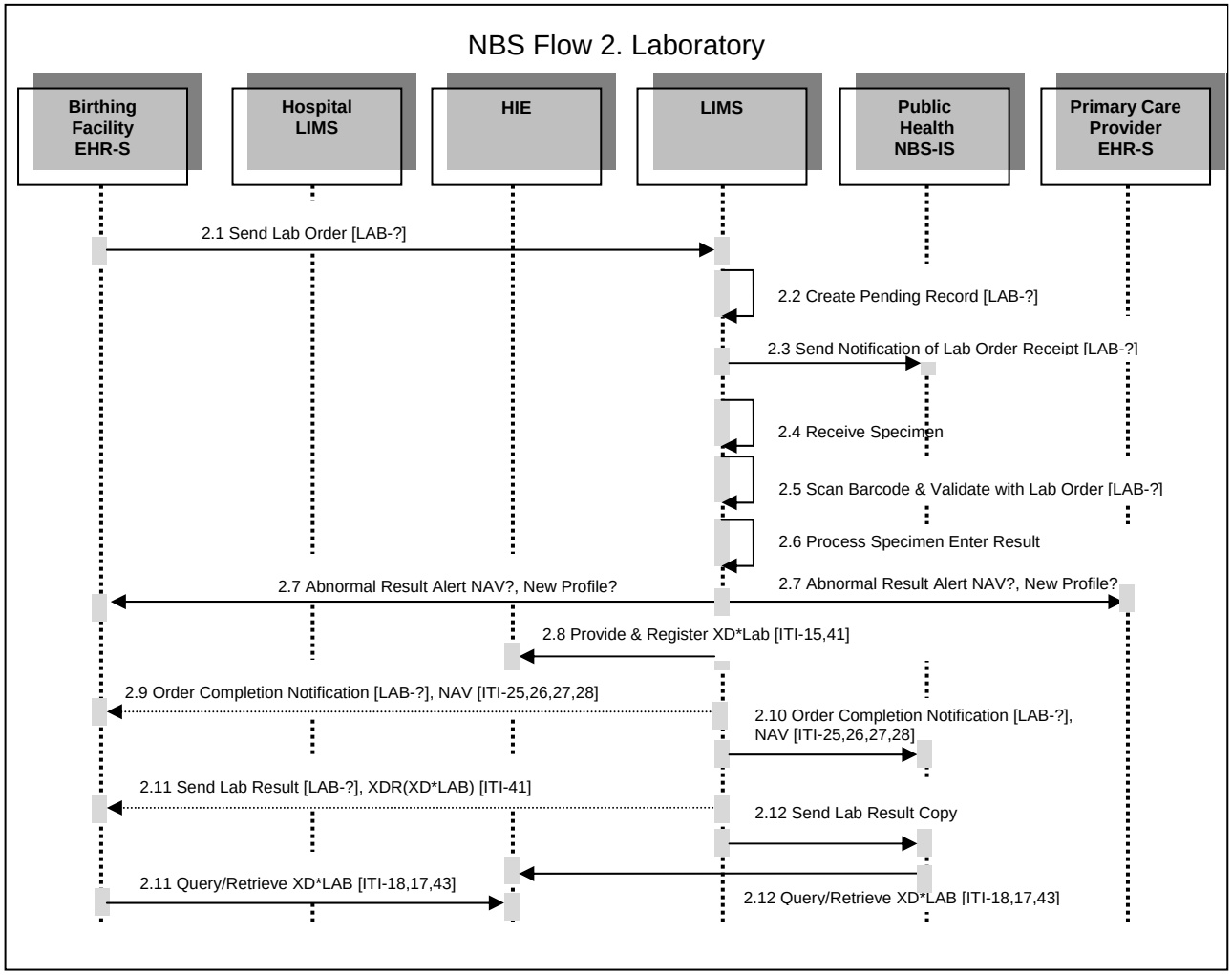

Figure 2-2: UML Workflow Diagram for NBS: Laboratory

375

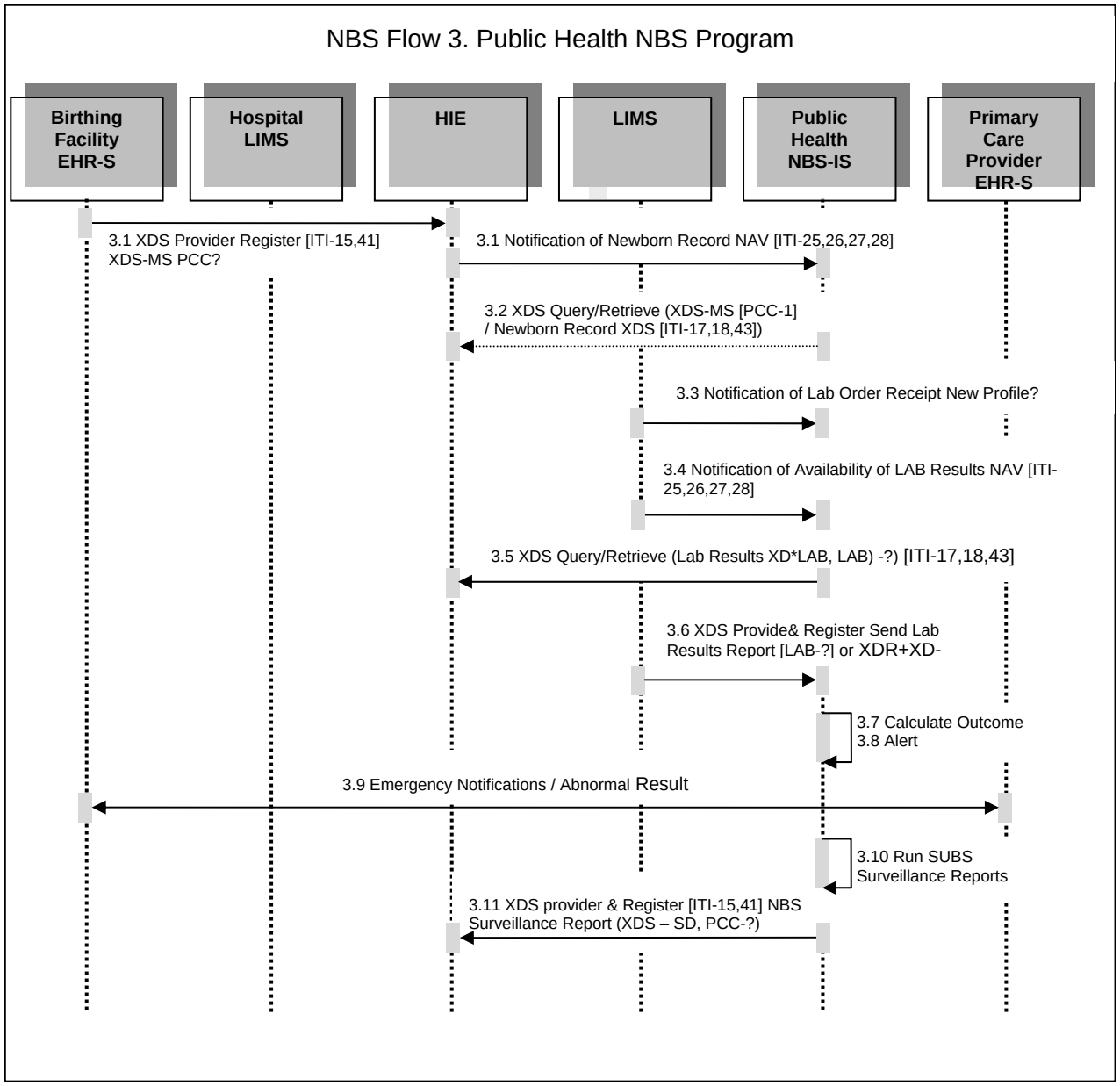

Figure 2-3: UML Workflow Diagram for NBS: Public Health NBS Program

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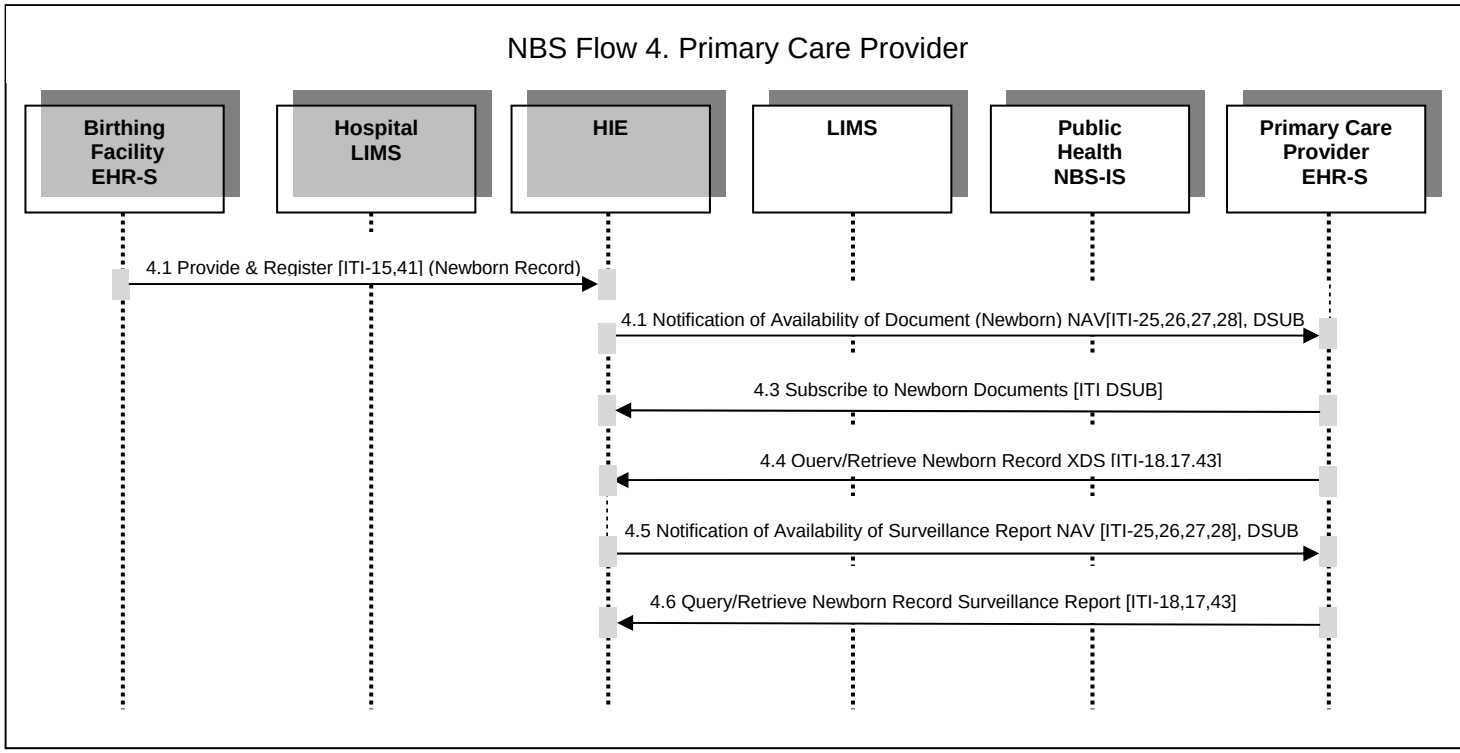


Figure 2-4: UML Workflow Diagram for NBS: Primary Care Provider

385 **Table 5. Use Case 2: Newborn Hearing Screening / Early Hearing Detection & Intervention (NHS/EHDI))**

Use Case Name	Newborn Hearing Screening / Early Hearing Detection & Intervention (NHS/EHDI)
Business Actors (Personnel)	**A. Healthcare Provider** Birthing Facility • Attending Physician • Hearing Screener • Screening Supervisor (Birthing Facility's or Contract Staff) Primary Care Provider (PCP)
	B. Public Health Staff NHS / EHDI Program (State Health Department, NHS Programs (US); Regional Associations (France) • Program Staff
	C. Consumer • Newborn • Parent/Guardian
Technical Actors (Information Systems)	• Birthing Facility's Electronic Health Record System (**EHR-S**) • Health Information Exchange (**HIE**) • Hearing Screening Device (**HS Device**) • NHS / EHDI Information System (**NHS/EHDI-IS**) • Primary Care Provider's **EHR-S** • Personal Health Record System (**PHR-S**) (OUT OF SCOPE)

Flow of Events	Data Categories by Events
1. Birthing Facility	
1.1 EHR-S presents a Reminder to **Hearing Screener** that Newborn is due for NHS	NHS Clinical Decision Support Data, Task Lists
1.2 Hearing Screener explains the NHS test to **Parent/Guardian** and obtains Consent for NHS and Consent for NHS Information Sharing, if needed, from **Parent/Guardian** **NOTE**: Consents may be optional in some jurisdictions	***Consents:*** 1. Consent or Consent Refusal for NHS and 2. Consent or Consent Refusal for NHS Information Sharing
1.3 Hearing Screener enters Consents or Consent Refusals into **EHR-S or NHS IS** **NOTE:** This step can be also performed after Step 1.6	
1.4 Hearing Screener enters jurisdictionally required NHS data (risk factors, family history information) into **EHR-S or NHS-IS** **NOTE:** This step can be also performed after Step 1.6	HS Data
1.5 Hearing Screener uses an approved **HS Device** and scans barcode or enters Newborn ID into **HS Device**	***NHS Device:*** Device Data Newborn ID Data
1.6 Hearing Screener performs the test using approved **HS Device** **NOTE:** Test may be repeated before Newborn is discharged	***NHS Results:*** 1. NHS Result Report Data 2.NHS Outcome Report Notification Data 3.NHS Outcome Report Data 4. Alerts & Task Lists, if
1.7 HS Device sends HS Results **to EHR-S or NHS-IS** as jurisdictionally required	
1.8 EHR-S may publish HS Results Report to **HIE**	

1.9 If abnormal, **EHR staff or NHS program staff** notify appropriate Clinicians as jurisdictionally required **Notification may be electronic**	Abnormal Results
1.10 EHR-S receives Notification that HS Outcome Report is available in **HIE**	
1.11 Birthing Facility Staff downloads HS Outcome Report from **HIE** into **EHR-S. Report download into EHR-S can be automatic.**	
1.12 Hearing Screener communicates HS outcomes to **Guardian** and provides information /education about follow-up care	***NHS Education:*** HS Health Education Documents
1.13 EHR-S receives Notification that Birthing Facility's HS Surveillance Reports are available in **HIE**	***NHS Surveillance:*** 1. NHS Surveillance Report Notification Data 2. NHS Surveillance Reports Data
1.14 Birthing Facility Staff downloads HS Surveillance Reports from **HIE** into **EHR-S**	
2. Hearing Screening Device	
2.1 HS Device generates HS Results for Newborn	HS Results Data
2.2 HS Device sends HS Results to **EHR-S**	
2.3 HS Device sends HS Results to **NHS/EHDI-IS** to calculate Newborn's HS Outcomes	
3. NHS/EHDI Program	
3.1. NHS/EHDI-IS receives Notification of Newborn's Birth Record availability from **HIE** **NOTE**: NHS/EHDI-IS may receive Notification of Newborn's Birth Record from Birthing Facility's **EHR-S**	***Birth Record:*** *Notification Data*
3.2. NHS/EHDI-IS downloads Newborn's Birth Record and establishes NHS Record for Newborn	***NHS Record***
3.3 NHS/EHDI-IS receives Notification that HS Results Report is available in **HIE**	***NHS Results:*** 1. NHS Result Report Data 2. NHS Result Report Notification Data 3. NHS Outcome Report Data 4. Alerts & Task Lists, if Abnormal Results
3.4 NHS/EHDI-IS downloads HS Results Report from **HIE**	
3.5 NHS/EHDI-IS matches HS Results Report from **EHR-S or HS Device** with the NHS Record and calculates HS Outcome Report for the Newborn including appropriate follow-up activities	
3.6. Alternative flow: NHS/EHDI-IS receives HS Results from **HS Device**	
3.7 NHS/EHDI-IS matches HS Results from HS Device with NHS Record and calculates HS Outcome Report for the Newborn including appropriate follow-up activities	
3.8 NHS/EHDI-IS publishes HS Outcome Report to **HIE**	
3.9 If abnormal results, **NHS/EHDI-IS** notifies **Program Staff** for appropriate follow-ups	
3.10 Program Staff runs HS Surveillance Reports periodically as	***HS Surveillance Reports***

required by jurisdiction in **NHS/EHDI-IS**	
3.11 NHS/EHDI-IS publishes HS Surveillance Reports into **HIE**	
4. Primary Care Provider	
4.1 Primary Care Provider receives Notification from **Birthing Facility** or **Guardian** or **Program Staff** that Newborn's records are available in **HIE** **NOTE**: Notification can be electronic	***Newborn Records:*** Notification Data
4.2 EHR-S subscribes to all records related to Newborn in **HIE**	***NHS Results:*** 1. NHS Outcome Report Data 2. Alerts & Task Lists, if Abnormal Results
4.3. EHR-S downloads Newborn's HS Outcome Report from **HIE**	
4.4. If abnormal results, **Primary Care Provider** is notified by **NHS Program Staff** for appropriate follow-ups **NOTE:** This may use a forthcoming IHE Alert Profile	
4.5 EHR-S receives Notification that HS Surveillance Reports are available in **HIE**	***NHS Surveillance:*** 1. NHS Surveillance Report Notification Data 2. NHS Surveillance Reports Data
4.6 Primary Care Provider downloads HS Surveillance Reports from **HIE** into **EHR-S**	

Entry Conditions	Newborn is born
	Newborn's Birth Record is created in the **Birthing Facility's EHR-S**
	Newborn's Birth Record is published in **HIE**
Exit Conditions	Newborn's HS Result Report is uploaded into **NHS-IS**
	Newborn's HS Outcome Report is uploaded into **Birthing Facility's EHR-S**
	Newborn's HS Outcome Report is uploaded into **Primary Care Provider EHR-S**
	NHS Surveillance Report is uploaded into **Birthing Facility's EHR-S**
	NHS Surveillance Report is uploaded into **Primary Care Provider EHR-S**

Figures 3-1 thru 3-4 provides UML Use Case diagrams of the Newborn Hearing Screening/Early Hearing Detection & Intervention (NHS/EHDI) from each of the four perspectives.

390

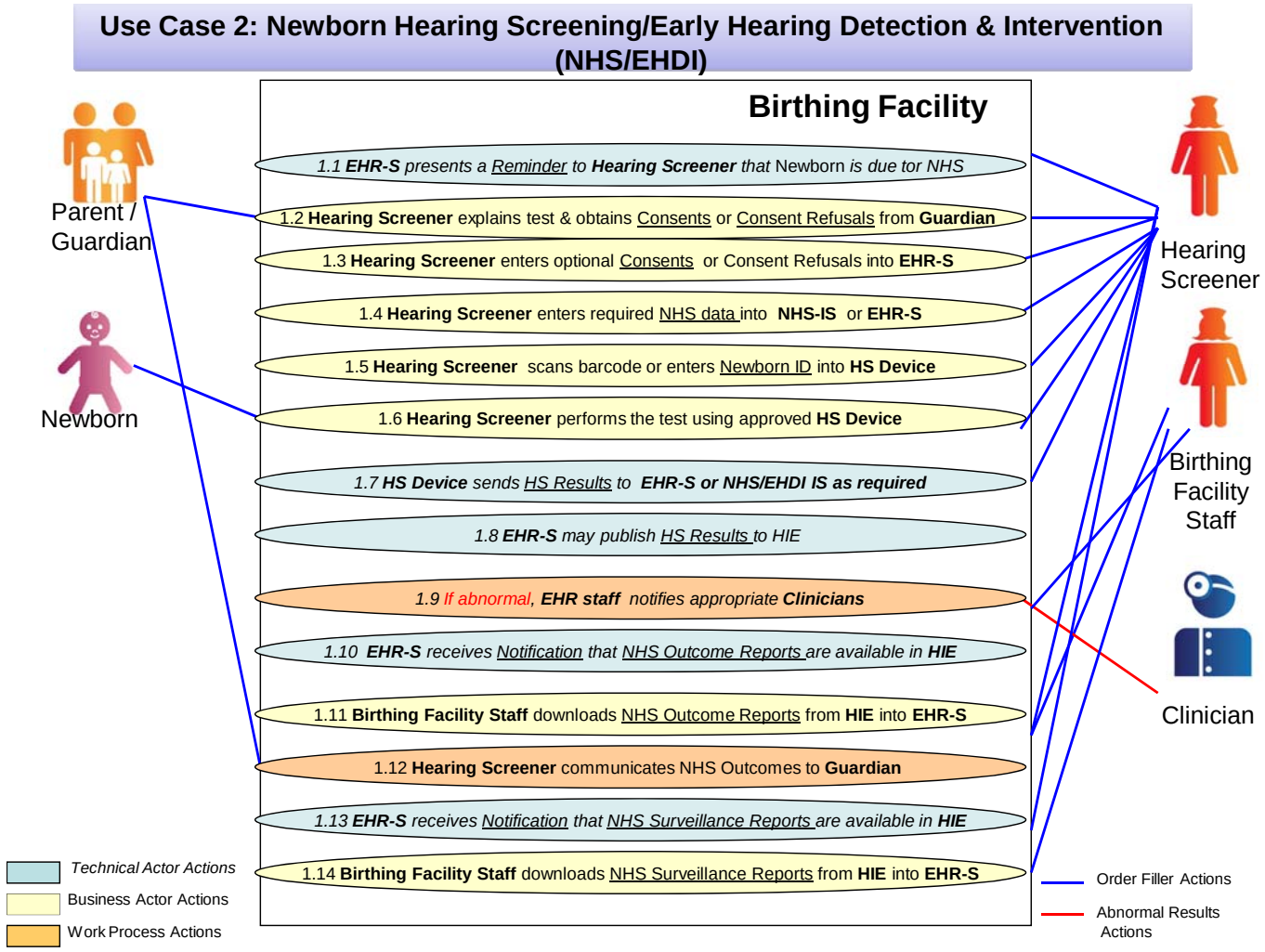
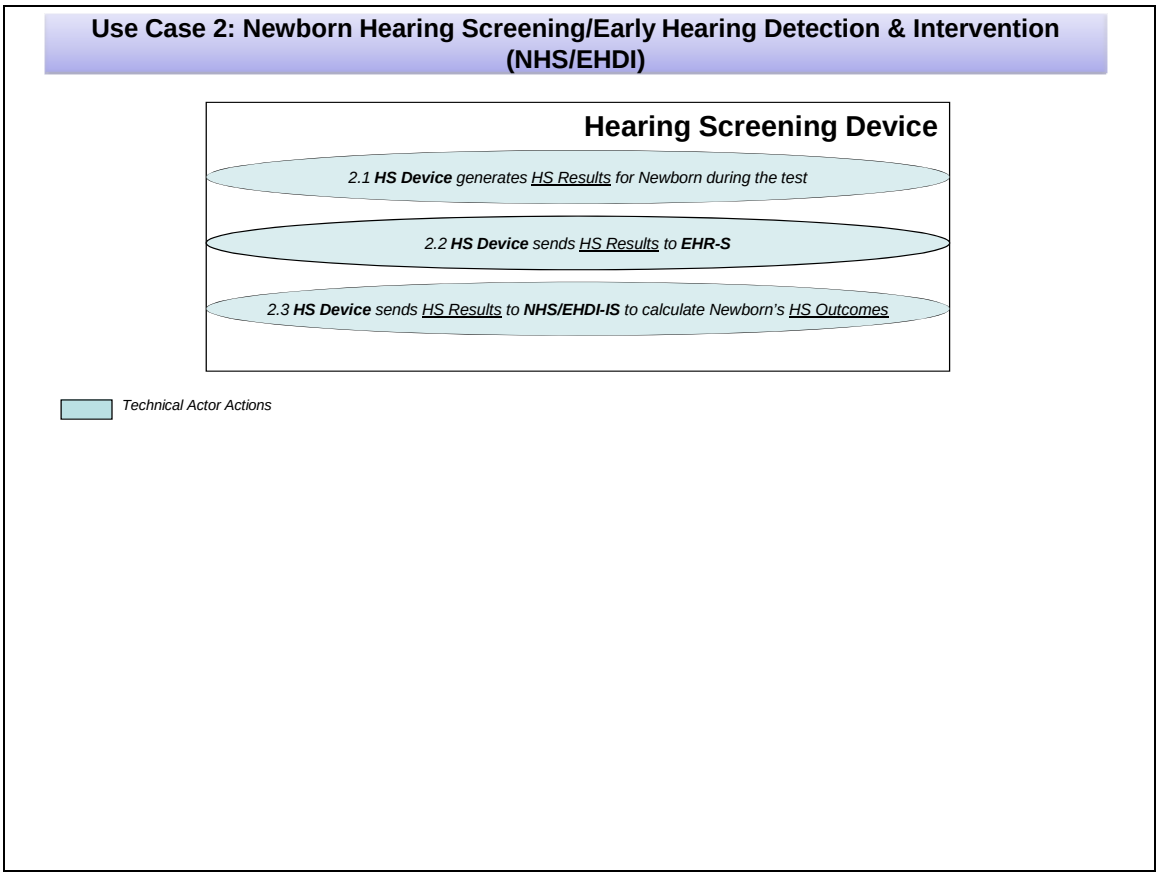


Figure 3-1: UML Use Case Diagram for NHS/EHDI: Birthing Facility



395 Figure 3-2: UML Use Case Diagram for NHS/EHDI: Hearing Screening Device

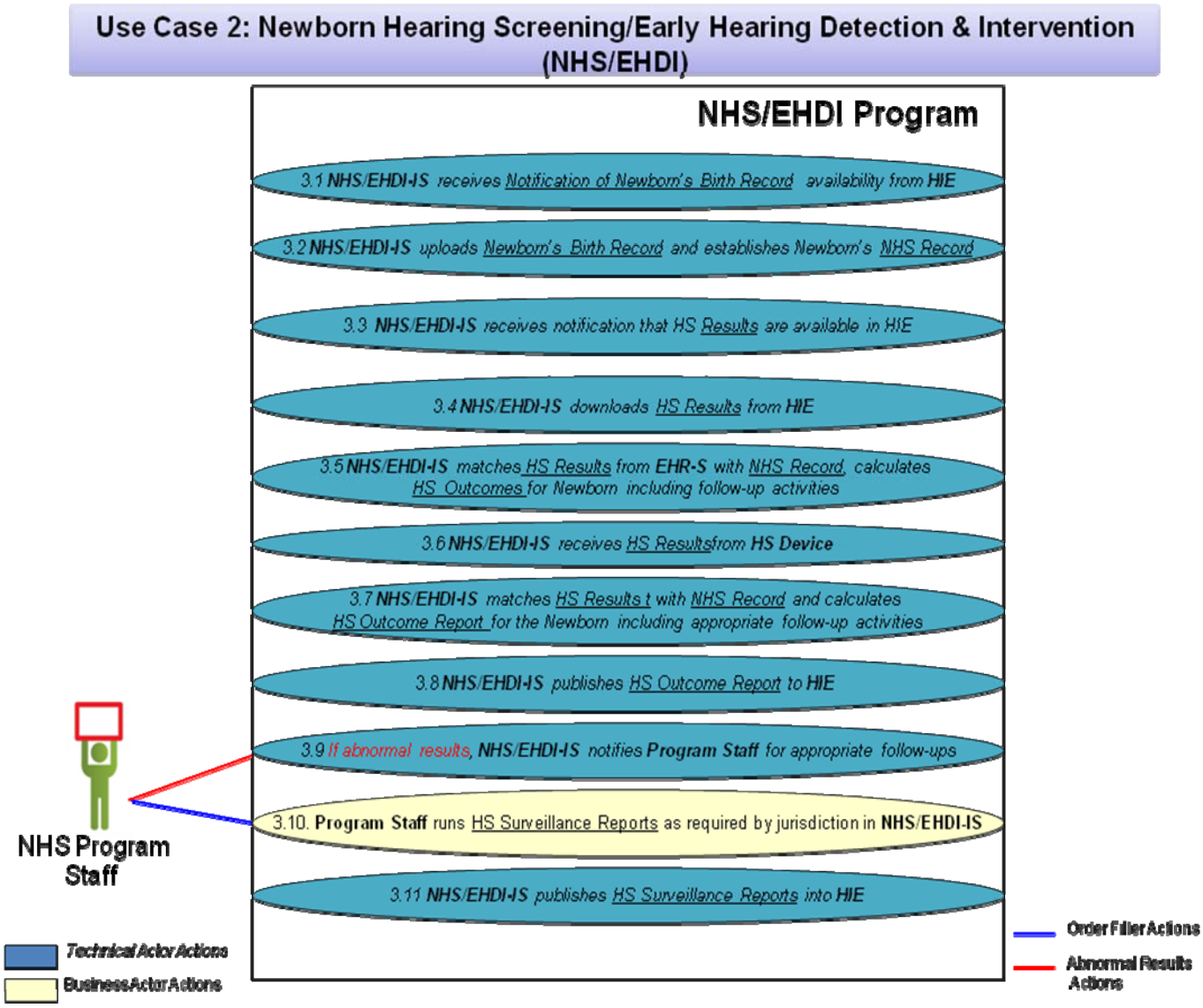


Figure 3-3: UML Use Case Diagram for NHS/EHDI: NHS/EHDI Program

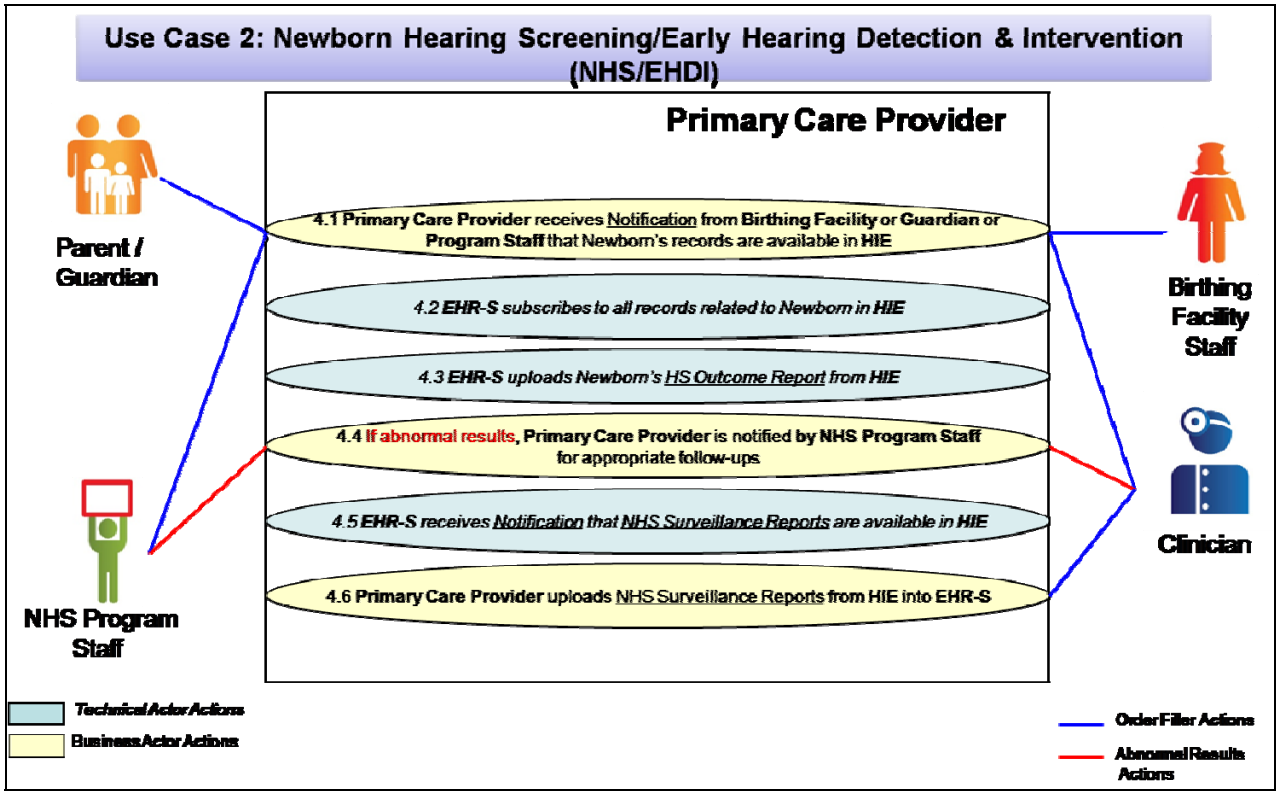


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Figure 3-4: UML Use Case Diagram for NHS/EHDI: Primary Care Provider

Figures 4-1 thru 4-4 provides UML workflow diagrams of the Newborn Hearing Screening from each of the four perspectives.

410

Figure 4-1: UML Workflow Diagram for NHS/EHDI: Birthing Facility

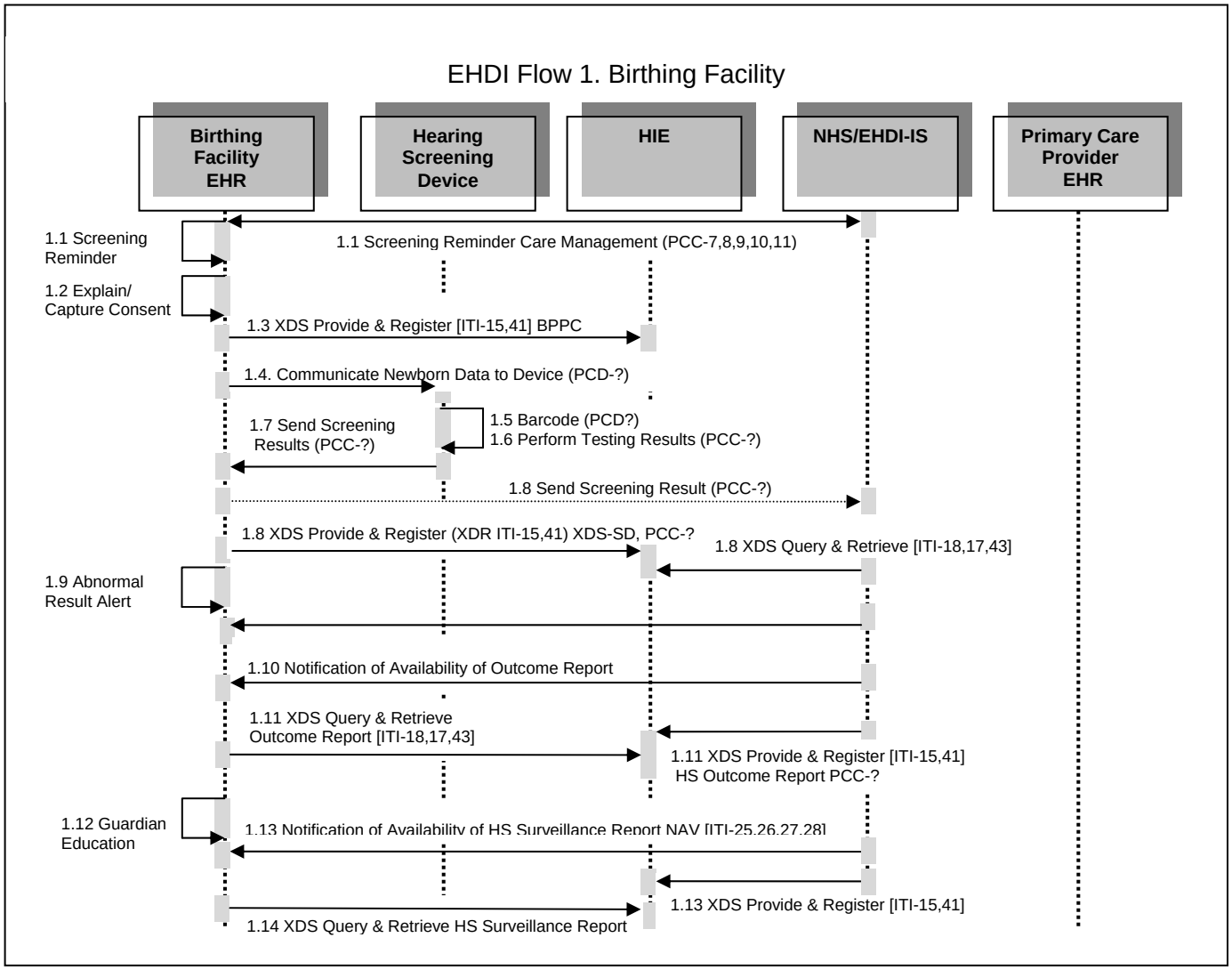

Figure 3-4: UML Use Case Diagram for NHS/EHDI: Primary Care Provider

415

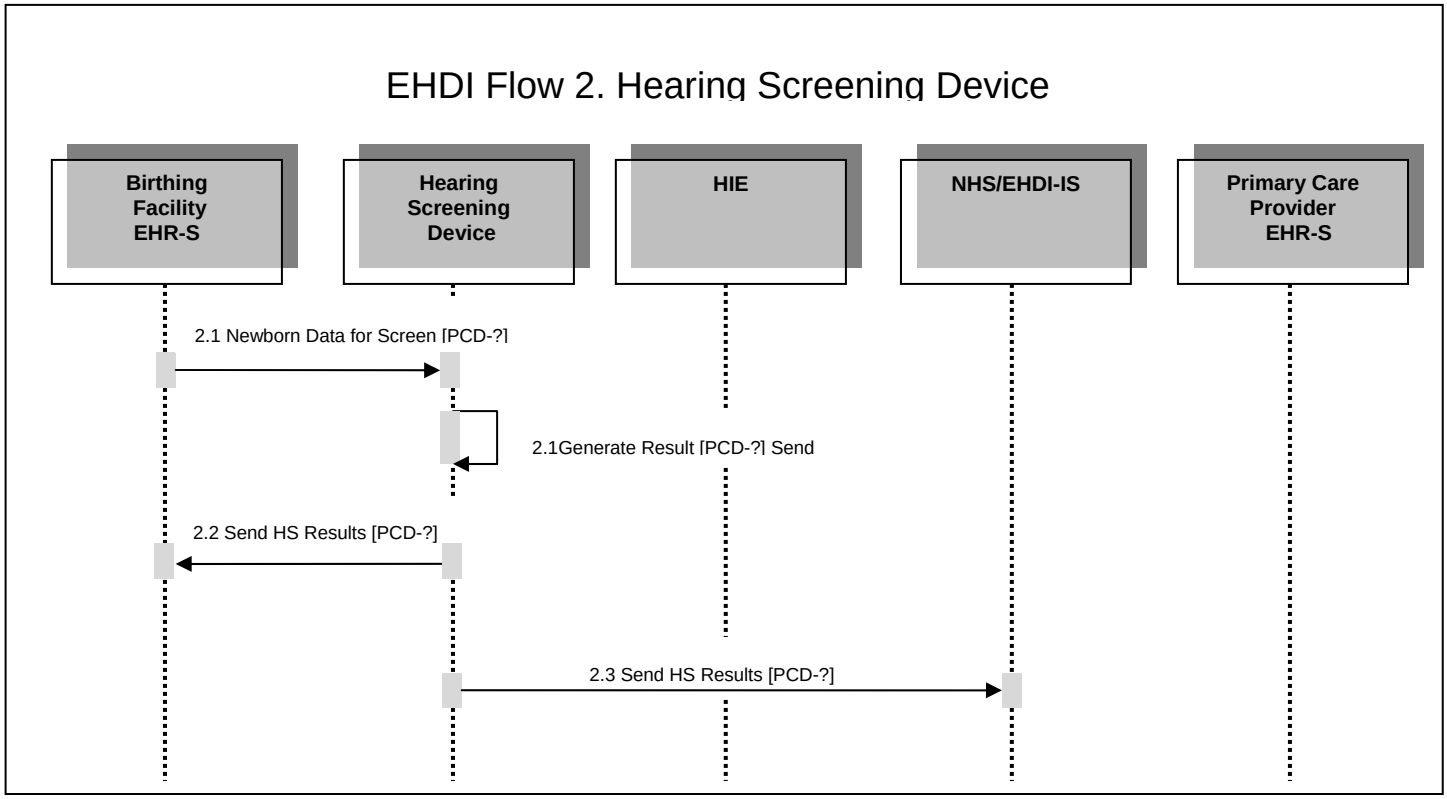

Figure 4-2: UML Workflow Diagram for NHS/EHDI: Hearing Screening Device

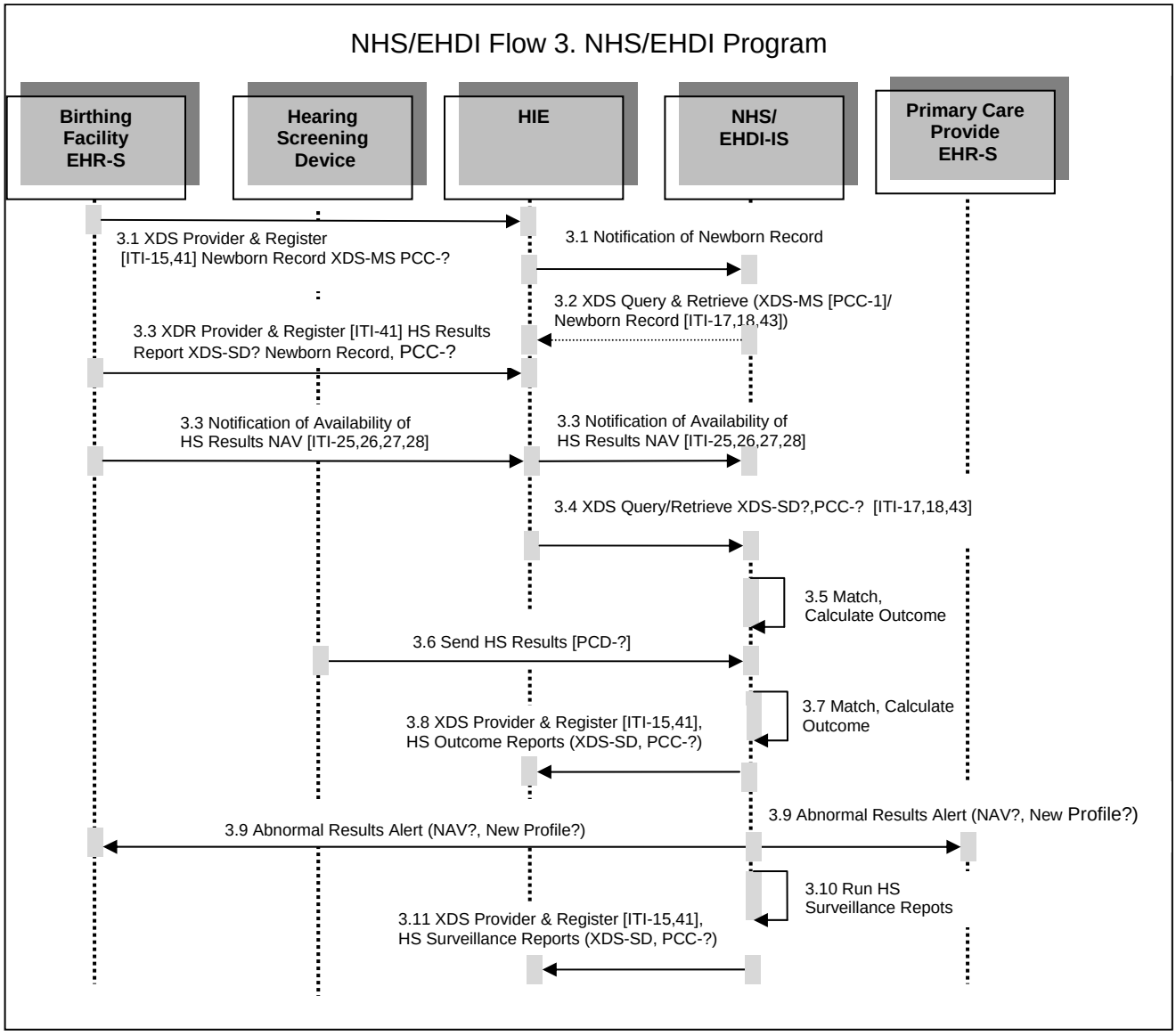

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Figure 4-3: UML Workflow Diagram for NHS/EHDI: NHS/EHDI Program

Figure 4-4: UML Workflow Diagram for NHS/EHDI: Primary Care Provider

425

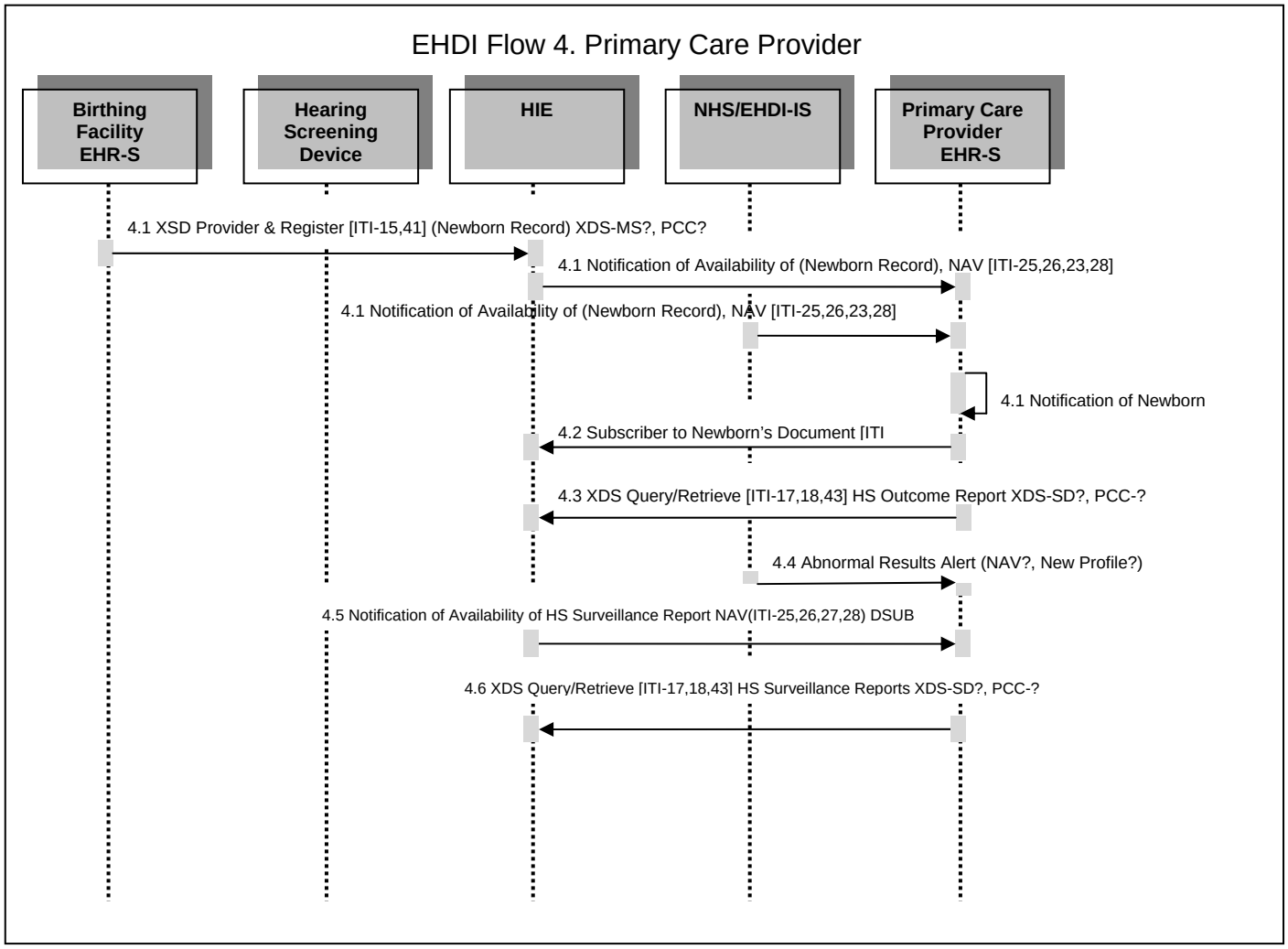

Figure 4-4: UML Workflow Diagram for NHS/EHDI: Primary Care Provider

Data Categories

The following data categories were identified for the NBS Use Case (Table 4):

1) *NBS Reminder*: Clinical Decision Support Data, Task Lists
2) *Consents:*
    1. Consent or Consent Refusal for NBS and
    2. Consent or Consent Refusal for NBS Information Sharing
3) *Lab Order:* NBS Specimen Card (Label) Data
4) *Lab Order=Lab Result*:
    1. Order Completion Notification Data
    2. NBS Result Report Data
    3. Alerts & Task Lists, if Abnormal Results
5) *NBS Surveillance*:
    1. NBS Surveillance Report Notification Data
    2. NBS Surveillance Reports Data

The following data categories were identified for the NHS Use Case (Table 5):

1) *NBS Reminder*: Clinical Decision Support Data, Task Lists
2) *Consents*:
    1. Consent or Consent Refusal for NHS and
    2. Consent or Consent Refusal for NHS Information Sharing
3) *Birth Record:* Notification Data
4) *HS Data*
5) *NHS Device*:
    1. Device Data
    2. Newborn ID Data
6) *NHS Results*:
    1. NHS Result Report Notification Data
    2. NHS Result Report Data
    3. NHS Outcome Report Notification Data
    4. NHS Outcome Report Data
    5. Alerts & Task Lists, if Abnormal Results
7) *Newborn Records*: Notification Data
8) *NHS Education*: HS Health Education Documents
9) *NHS Surveillance*:
    1. NHS Surveillance Report Notification Data
    2. NHS Surveillance Reports Data

To identify common data elements for NBS we conducted data mapping of US NBS Specimen Cards from participating states (Texas, Iowa, Alaska, Maryland) as well as NBS Cards from

France, Germany and Austria. We also mapped Oregon NBS Specimen Cards because specimens from Alaska are analyzed by the Oregon State Department's Public Health Laboratory. US cards for mapping were provided by participating States Programs. European cards were provided by the IHE Lab Committee members.

We further mapped the NBS dataset to the NHS dataset using NHS data provide by the US Centers for Disease Control and Prevention (CDC) EHDI Data Committee. Attachment 1 contains the Newborn Screening Data Concepts Mapping Table of 134 newborn screening data field sets by participating state and country. The table also shows variability in data formats (free text, structured, check box, etc.) across the forms.

For the NBS analytes list we propose to use the National Library of Medicine LOINC Codes.

3 Existing IHE Profiles Supporting Newborn Screening

IHE Domain	IHE Profile	• Use Case • Information Flows	• Comments
ITI	PIX/PDQ	NBS 1.3, 1.11, 2.8, 2.11, 2.12, 3.1, 3.2, 3.5, 3.6, 3.11, 4.1, 4.3, 4.6 EHDI 1.3, 1.8, 1.9, 1.11, 1.12, 1.14, 1.15, 3.1, 3.4, 3.5, 3.6, 3.8, 3.12, 4.1, 4.3, 4.6	XDS-related and merging steps
ITI	BPPC	NBS 1.3, EHDI 1.3	
ITI	XDS	NBS 1.3, 1.11, 2.8, 2.11, 2.12, 3.1, 3.2, 3.5, 3.6, 3.11, 4.1, 4.3, 4.6 EHDI 1.3, 1.8, 1.9, 1.11, 1.12, 1.14, 1.15, 3.1, 3.4, 3.5, 3.12, 4.1, 4.3, 4.6	
ITI	RFD	NBS:1.4, 1.7	Pre-populate from Newborn Record or Labor & Delivery Record
ITI	SVS	NBS 1.1, 1.4 EHDI 1.1	Further analysis needed
ITI	XDS-SD	NBS1.14, 3.9, 3.11, 4.6, EHDI 1.8, 1.9, 1.11, 1.12, 1.14, 1.15, 2.3, 3.3, 3.5, 3.12, 4.6	Use as interim for screening results and patient-level biosurveillance reports
ITI	DRR	EHDI 1.4, 2.1	Not specific to these information flows, but in atypical management, may service referral information flow
ITI	NAV	NBS 3.1, 3.4, 3.9, 1.2, 1.13, 2.9, 2.10, 3.4, 4.4, 4.5 EHDI 1.14, 1.15, 1.10, 1.11, 1.14, 2.9, 2.10, 3.1, 3.4, 3.10, 4.1, 4.5	DSUB to be reviewed as possible alternative to these
ITI	XDR	NBS 2.11, 2.12 EHDI 1.8, 3.3	Possible alternate for additional XDS-based flows
LAB	XD*Lab	NBS 2.8, 2.11, 2.12, 3.3, 3.6	
LAB	Lab-?	NBS 1.2, 1.7, 1.10, 2.2, 2.4, 2.5, 2.6	Further analysis needed
PCD-?		EHDI 1.2, 1.4, 1.5, 1.7, 1.8, 2.1, 2.2, 2.3	Further analysis needed
PCC	Care Management	NBS 1.1, EHDI 1.1	Further analysis needed
PCC	XDS-MS	NBS 3.1, 3.2, 4.1, 4.3 EHDI 3.1, 3.2, 4.1, .4.2	Possible interim for newborn record

4 In-Process IHE Profiles Supporting Newborn Screening

IHE Domain	IHE Profile	Use Case Information Flows	Comments
ITI	MPQ	• NBS 3.10, EHDI 3.11	• e.g. (how many birth events are there)
ITI	DSUB	• NBS 3.2, 3.3, 3.5, 4.2, 4.3, 4.5 • EHDI 3.2, 3.5, 3.7, 3.12, 4.2	• Public health may subscribe to Newborn records, medical summaries for birth events, and blood spot test results(?) • subscribe to protocol/guideline • subscribe to patient records
ITI	SOA WP	• TBD	• Concepts may apply to numerous steps
LAB	External Orders	• NBS 2.1	• Further analysis pending
LAB	Others?	•	• Further analysis pending
QRPH	RPE	• NBS 1.1, EHDI 1.1	• Further analysis needed
QRPH	Performance Quality Report	• NBS 3.10, EHDI 3.11	• Further analysis needed; • e.g. How many birth events happened per day within a jurisdiction/catchment area = denominator • ADT submission counts • Newborn event – see new • e.g. Exclusion possibility
PCC	Labor and Delivery	• NBS 3.1, 3.2, 4.1, 4.3 • EHDI 3.1, 3.2, 4.1, 4.2	• For pre-population of Lab Order form; Surveillance (e.g. Notification of birth)
PCD	Others?	•	• Further analysis pending

5 New IHE Profile Work to Support Newborn Screening

IHE Domain	IHE Profile	Use Case Information Flows	Comments
ITI	• Communicate Aggregate (non-patient-specific) surveillance Reports	• NBS 3.11 • EHDI 3.12	Use Patient-specific report with XDS-SD
ITI/PCC	• Abnormal Results Alert	• NBS 1.12, 2.7, 3.9, 4.4 • EHDI 1.10, 4.4, 3.10	Further analysis needed – can this be satisfied with NAV and published results?
PCC	• Newborn Record	• NBS 3.1, 3.2, 4.1, 4.3 • EHDI 3.1, 3.2, 4.2, 4.3	Interim Options – use L&D record or XDS-MS; needs to be published at the time of birth – may need to populate eventCodeList to be able to perform counts or document type counts; may want to include events such as stillborns – look at guidelines for key concepts
PCC	• Hearing Screening Results	• EHDI 1.8, 1.9, 1.11, 1.12, 2.3, 3.3, 3.4, 3.5	May be PCD profile
PCD	• Send Results • Generate HS Results • NBS Screening Data/Request	• EHDI 2.1, 2.2, 2.3 •	hearing screening results capture; Further analysis needed
LAB	• Notification of Lab Order Receipt to Public Health	• NBS 1.7, 1.10, 2.3, 3.3	Is this covered by existing profiles?
QRPH	• Surveillance Report	• NBS 3.11, 4.6 • EHDI 3.12, 4.6	Use XDS-SD with patient-level reporting in the interim
QRPH	• NBS Pre-population	• NBS 1.4	•

6 Summary

The NBS and NHS domains are the first ones in the life course (timeline) of a healthy newborn that involves information exchanges between clinical care and public health. This White Paper will help specify how the EHR on a newborn created at the birthing facility will interoperate with NBS and NHS information systems to lay the foundation for coordinated care between two sectors and to enable population-based surveillance.

Appendix A – Glossary

Attachment 1.

Newborn Screening Data Concepts Mapping

Data Category	Data Group / Data Sub-Group	Data Field Set	Hearing Screening Dataset	US New Born Screening Specimen Cards					European New Born Screening Specimen Cards		
				Maryland	Iowa	Oregon	Texas	Alaska	France	Austria	Germany
FORM		Form Name		Text	Text		Text				
		Form ID		Barcode	Barcode	Barcode	Barcode	Barcode		Barcode	Number
CARE SETTING	**Hospital of Birth**	Hospital Name		Free Text		Free Text		Free Text	Free Text		
		Hospital Code	BRTHFACID			Free Text		Free Text	Free Text		
		Department Name		Free Text : FT/NICU	Check						
		Address							Free Text		
		Phone Number							Free Text		
		Number of Birth in this Location							Free Text (number)		
		Physician Name			Free Text			Free Text : Last Name, Initial(s)			
		Physician ID						Free Text			
		Physician Address						Free Text			
		Physician Phone Number			Area Code: | | | Number: | | | | | | |						
		Submitter's Name		Free Text			Free Text				
		Submitter's Code		Free Text		Free Text					
		Submitting Facility's Name			Free Text					Free Text	Free Text
		Facility Number			| | | |						
		Submitter's Address		Free Text	Free Text : Street, City, State, Zip Code	Free Text	Address, City, Zip Code				
		Submitter's Phone		Free Text	Area Code: | | | Number: | | | | | | |						| | | | | | | | | |
		Submitter's Stamp									Stamp

		NBS ID No. NPI No. Medical Record Number		 Free Text	Infant's Chart Number | | | | | | |	Free Text	Free Text Free Text Free Text				
	Primary Care	Primary Care Clinic Name Address Phone Number Code Physician Type Physician Name Fax Number Phone Number				Free Text Free Text Free Text Free Text	 Free Text : Street Address, Apt. No., City, Zip Code, State Free Text : Last, First - - - -		Free Text Free Text Free Text		
PATIENT											
	Patient	Patient ID	PTID					Free Text			| | |
	Demographics	Date of Birth Time of Birth Place of Birth Age Patient Name Sex/Gender Race Ethnicity	PTDOB PTBRTHSTATE, PTBRTHZIP PTFNAME, PTMNAME, PTLNAME, PTSUFNAME PTSEX	MM | DD | YYYY HH | MM Last, First Check:M/F/A Check:W/B/A/N A/H/O	MM|DD|YY HH | MM Free Text : Infant's Last Name, Infant's First Name Check: M/F	(_ _/_ _/_ _) (:) am/pm Free Text Baby's Last Name|Baby's First Name Check: M, F Check: W/B/AI|AN/U|O/ A|PI Check: Hispanic No, Yes	MM|DD|YY HH|MM Free Text : Newborn's Last Name, First Name Check: Male, Female Check: W, AA, H, A, AI, O	mm/dd/yy HH/MM Free Text : Baby's Last Name, First Name Circle: M, F Check: W/B/AI|AN/U| O/A|PI Check: Hispanic No, Yes	Free Text Free Text : Last name, 1st name Check Box: M/F	Free Text Free Text : LastName (family name), FirstName Check Box: Female/Male	| | | | | | | | | | : LastName (family name), FirstName Check Box: male/female

Anthropometry	Weight		Free Text	| | |	Free Text	Free Text	Free Text			
Health Insurance	Insured's Name									Free Text
	Mother's Insurance									Free Text
	Mothers Medicaid No.					Free Text				
	Medicaid Eligible					1=Yes, 2=No				
	Mother's ID of Insured Person									Free Text
	Mother's Insurance Number									Free Text
	Mother's Insurance Status									Free Text
	Mother's SHI-accredited Physician (panel Doctor)									Free Text
	Mother's Insurance Card Valid Through									Free Text
	Date									Free Text
	Direct Payer (privately financed)									Free Text
Family	Name	MATFNAME, MATMNAME, MATLNAME, MATSUFNAME	Free Text : Last Name, First Name	Free Text : Mothers Last Name, Mothers First Name	Free Text : Last Name, First Name	Free Text : Mothers Last Name, Mothers First Name	Free Text : Mothers Last Name, First Name	Free Text	Free Text : first/last name	Free Text : first/last name
Demographics	Mother's Maiden Name					Free Text				
Mother	Mother's SSN	MATID	Free Text			- -				
	Mother's Residence	MATRESSTATE, MATRESCITY, MATRESSTRT, MATRESAPT, MATMAILZIP								
	Address	MATMAILSTATE, MATMAILCITY, MATMAILSTRT, MATMAILAPT, MATMAILZIP	Free Text , City, State , Zipcode	Zip Code: | | | | | |	Free Text : Number & Street, City/Village, State, Zip Code	Free Text : Street Address, Apt No., City, Zip Code, State	Free Text , City, State , Zipcode	Free Text	Free Text : Street, Postal Code, City	Free Text : Street, Postal Code, City
	Phone		Free Text	Area Code: | | | Number:	Free Text	- -		Free Text	Free Text	| | | | | | | | | |

					| | | | | | | |					
		Age Date of Birth Place of Birth Race Ethnicity Education Signature (Consent) Relationship	 MATDOB MATBRTHPL MATRACE MATETHNIC MATEDU MATMARRIED	Free Text	 MM|DD|YY	 Free Text	 MM|DD|YY	Free Text	 Check Box: Yes/No + Free Text : Signature	 Free Text	 Free Text
	Father	Name Date of Birth Place of Birth Race Ethnicity Address Signature (Consent) Education	PATFNAME, PATMNAME, PATLNAME, PATSUFNAME PATDOB PATBRTHPL PATRACE PATETHNIC PATMAILSTATE, PATMAILCITY, PATMAILSTRT, PATMAILAPT, PATMAILZIP PATEDU				Free Text : Last Name		 Check Box: Yes/No + Free Text : Signature		
	Patient Medical History: Birth History	Place of Birth Birth Weight APGAR	 BRTHWTGRM APGAR5, APGAR10	Check: Hospital birth, Home Birth, Other		 Free Text		 Free Text	 Free Text	 | | | |	 | | | |

		Status at Birth/Init.Appearance					Check: 0. Normal, 1. Sick/Premature, 2. On antibiotics, 3. Transfused, 4. Both 1 & 2, 5. Both 1 & 3, 6. Both 2 & 3, 7. All 1-3				
		Premature Infant							Free Text	Check Box	Check Box
		Mature Infant									Check Box
		Neonatal Intensive Care	NICU, DAYSNICU								
		Current Status/Impression		Check: Well/Ill							
		Multiple Births	PLURALITY		Multiple Births: Check - Yes, No		Twin A or B	Check: Single Birth;			Check Box
		Birth Order		Check: Single, Twin A, Twin B, Triplet A, Triplet B, Triplet C, Other	Free Text	Check: Single Birth or Multi-Birth A B C D E F Circle One	Number: 1-9, Select	(1) Twin A, (2) Twin B, (3) Other			
	Maternal History	Number of visits	NUMPRENAVST								
		Gestational Age		Free Text	| | |					| | |	| |
		ECMO	ECMO								
		Exposure to ototoxic medications	OTOTOX								
		Hyperbilirubinemia	HYPERBILI								
		Craniofacial anomalies	ENTANOM								
		Neurodegenerative disorders	NEURODEGEN								
		Head trauma	HEADTRAUMA								
		Assisted ventilation	ASSISTVENT								
		Loop diuretics	LOOPDIURET								
		In utero infections	INUTEROINF								
		Syndromes associated with hearing loss	HLSYNDROM								

		Culture-positive postnatal infections Chemotherapy	POSTNATINF CHEMO								
	Current Medications	Drug, dose, frequency		Antibiotics: Check; Type: Free Text							Check Box: Mother, Child
	Family Medical History Conditions/Family Members	Sickle Cell Anemia Hearing Loss Other Family Stress	 FMHSTHL						Check: Yes		 Free Text Free Text
PATIENT VISIT	**Service Type**	Name: Chief Complaint	VISIT								
	Physical Exam	Feeding Date & Time of First Food Intake		Check: Breast, Lactose Formula, Lactose-free Formula, TPN + Free Text , NPO, Other	Check: Formula, Breast, NPO, Parenteral Nutrition, Other	Multiple Check: 0. Other + Free Text , 3. Soy Formula, 4. Breast, 5. NPO, 6. Lactose Formula, 7. Tube Feeding	Check: Breast, Bottle, TPN, Breast/Bottle	Check: 0. Other + Free Text , 4. Breast, 3. Soy Formula, 6. Lactose Formula			 | | | | & | |
	Diagnostic Tests	Laboratory Number Diagnosis Center Location Hearing Screen Method Hearing Test Results Results Serial Number	 OPVSTLCT METHODSCREEN LEFTEARSCRRSLT, RIGHTEARSCRRSLT, CHILDSCREENRSLT SCREENSTATUS				Free Text | - |				| |
	Specimen Information	Collection Location Name Collection Location Address Collection Location Phone							Free Text Free Text Free Text		

		Collection Location ID							Free Text		
		Specimen: Date, Hr	DATESCREEN, TIMESCREEN	MM | DD | YYYY, HH | MM	MM|DD|YY, HH|MM	(_ _/_ _/_ _), (:) am/pm	MM|DD|YY, HH|MM	MM|DD|YY, HH|MM		Free Text	| | | | & | |
		Sampling within 48 hours after birth								Check Box	
		Sampling later than 48 hours after birth								Check Box	
		Sampling within 36 hours after birth									Check Box
		Sampling later than 36 hours after birth									Check Box
		Specimen Number						| |	Bar Code		
		Collectors Initials		Free Text	| |	Free Text					
		Screener ID	SCREENERID								
		Screener Name	SCREENERNAME								
	Procedures	RBC Transfusion		Check	Check: Yes, No	Check: None		Check	Check Box: Yes/No		Check Box
		Transfusion Date		Free Text	MM|DD|YY	/ /		/ /			
		Hyperalimentation				Check		Check			Check Box
	Transfer	Time	TRANSFERRED								
		Place	TRANSFERTO								
OTHER	**Other**	Notes									Free Text

