Developing a Quality Framework for Initial and Ongoing Evaluation of Birth Data Extracted from Electronic Health Records (EHRs) for Vital Statistics

Final Report

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1. Executive Summary

This report presents results and recommendations following a project to analyze the quality of birth certificate information abstracted from electronic health records (EHR) at two healthcare facilities, the University of Utah Healthcare (UUHC) in Salt Lake City and Sibley Memorial Hospital (SMH) in the District of Columbia (DC), using the Birth and Fetal Death Reporting Enhanced (BFDR-E) profile from Integrating the Healthcare Enterprise (IHE). BFDR-E defines a standard Labor and Delivery Summary (LDS) document conforming to the Health Level Seven International (HL7) Clinical Document Architecture (CDA). Automatically extracted EHR information was compared to birth certificate data from the electronic birth registration system (EBRS) that was submitted to vital statistics agencies in Utah and DC for randomly selected samples of 60 births at each facility. In addition, two independent expert reviewers in each jurisdiction examined maternal and child EHR records, adjudicated differences, and developed a reference standard to be used for comparison. In the absence of a "gold standard", a reference standard provides a benchmark for truth against which sources of information may be compared.

An automated process for reporting birth certificate information promises great gains in efficiency, quality, and timeliness by eliminating or reducing manual processes required for record abstraction and data entry. It was found that a) the clinical information to support birth certificate reporting is available in the EHR for most of the items examined, and b) the BFDR-E will support automated (or at least semi-automated) birth certificate reporting following refinement of the standard BFDR-E specification and implementation procedures.

It is important to understand that an EHR such as Epic is a complex information system designed to support information storage and retrieval for clinical care. The organization of information within an EHR system varies by vendor, implementation choices, and actual clinical use. This means that an event such as induction of labor may be stored in different locations within the EHR across different facilities, even facilities that share the same vendor. The BFDR-E specifies where to search for structured information stored in specific locations within the medical record. In this analysis, when an item was consistently missing on an LDS extract, further investigation was conducted to determine if the information was not recorded in the EHR, or if it was recorded in a location the BFDR-E did not specify to look. In almost all instances, we found the latter to be true, leading to several recommendations where the specification should be revised to allow for greater flexibility in retrieving information across diverse vendors and facilities. This process of using pilot results to inform standards specifications is critical for developing standards that support real-world practices.

This report contains findings related to a) birth certificate data collection processes, both manual and automated, and b) the design of a quality framework for initial and ongoing evaluation of birth data extracted from electronic health records (EHRs) for vital statistics.

Key findings regarding data collection:

1. The clinical information needed to support automated birth certificate reporting is available in the EHR for most of the items examined, particularly for items documented during the clinical encounter concerning labor and delivery and the newborn's care and outcomes. The automated process will require refinement and testing before implementing automated extraction in a production environment.
2. Prenatal information in the EHR can be automatically abstracted when prenatal care is provided within the health system and information is stored within the EHR. When external prenatal records are scanned into the EHR or not available, then the automated process is not successful in capturing prenatal information. Unfortunately, in both Utah and DC, prenatal records were often scanned into the EHR because care was provided outside the health system, making the data available for visual inspection but not for automated extraction. Therefore, before implementing automated extraction of prenatal information in a production environment, it will be important to assess information and work flow to capture prenatal information, and refine and test the extraction procedures. Scanned prenatal records cannot be used to automatically populate the profile, but processes can be implemented to improve efficiencies and automate capture of available prenatal information.
3. Labor and Delivery information in the EHR is mostly structured and amenable to automated abstraction. The quality of the abstracted data was similar across facilities in Utah and DC. Differences between data in the EHR and the automated extraction were primarily due to a mismatch between actual documentation practices and BFDR-E specification expectations.
4. Performance of the extract for capturing newborn-related data varied by item, with obstetric estimate of gestational age and neonatal intensive care Unit (NICU) admission showing strong agreement between the different sources of data, while items concerning assisted ventilation were not abstracted from the EHR primarily due to a mismatch between actual documentation practices and BFDR-E specification expectations.
5. Investigation about the differences in values for selected items revealed mismatches between the intent of an item on the birth certificate and the manner in which data collection has been operationalized. For example, clarification is needed about the definition of labor, and how to document if no labor occurred, to answer the question about administration of antibiotics during labor.

Key findings regarding quality monitoring procedures:

1. The use of an external reference standard based on information abstracted by health department personnel was problematic. Health department personnel may either not be given

adequate access to the EHR or may be unfamiliar with the EHR. We found the compiled reference standard did not represent truth.

2. The role of hospital birth clerks and health department birth certificate quality reviewers will need to be refined when birth registration information is reported using the BFDR-E standard.

Recommendations:

1. Enhance the BFDR-E standard to address the documentation practices observed and expected to be common in any EHR (e.g., allow the BFDR-E to extract 'method of delivery' as an observation, not solely as a procedure).
2. Clarify items on the birth certificate to reduce ambiguity and improve accuracy when abstracted manually or by automated systems. Provide definitions and logic to communicate the intent of items, particularly when single questions represent more complex concepts (e.g., antibiotics during labor is only relevant for mothers who labor).
3. Revise the quality framework evaluation paradigm, no longer using external 'expert' reviewers to establish a referent. Compare data obtained from the LDS extract with previously-reported EBRS data, adjudicating differences to establish a reference standard. Divide evaluation into two phases that may require different metrics and personnel: a) 'onboarding' quality analysis (test and refine interfaces to ensure data is captured based on unique documentation requirements used in the EHR), and b) 'maintenance' quality assurance (monitor for changes in expected values, based on historical facility and jurisdiction-specific trends).
4. After ensuring the BFDR-E profile can successfully be implemented to include required data and the LDS extract can be viewed using an XSL stylesheet, the analysis can be expanded incrementally to include additional birth certificate variables, larger samples of births, and additional facilities and jurisdictions. To perform the analysis on a larger scale, software that automatically extracts information from the Labor and Delivery Summary (LDS) needs to be refined. Additionally, Statistical Analysis Software (SAS) routines used in this analysis to extract information from the standard Interjurisdictional Exchange (IJE) format may be refined and shared to support other sites to implement the quality evaluation framework.

2. Background and Objectives

As healthcare facilities increasingly adopt EHR technology, there is a growing interest in automating the capture and reporting of medical and health information for birth certificates and fetal death reports. To this end, the National Center for Health Statistics (NCHS) has organized teams from state jurisdictions and vendors of both EHR and vital records systems to develop and test standards for both the content and transmission of birth and fetal death information. These standards have been tested and demonstrated at the Integrating the Healthcare Enterprise (IHE) annual Connectathon but have never been operationally tested.

As the standards mature and jurisdictions prepare to implement automated reporting of birth certificate and fetal death information, it is important to understand the quality and limitations of information stored in an EHR and used for birth certificate and fetal death reporting purposes. Additionally, it is important to develop ongoing processes and metrics to measure and manage this information.

The specific objectives of this project were to:

1. Assess agreement between information stored in an EHR, extracted in a Health Level Seven International (HL7) Clinical Document Architecture (CDA) for a retrospective sample of births and for selected maternal and child data elements reported on birth certificates.

2. Using information in the EHR as a reference standard, assess accuracy of data extracted in a CDA-based LDS extract compared to that reported on birth certificates for selected maternal and child data elements.

3. Develop an understanding of the strengths and limitations of automated birth certificate reporting and strategies to ensure birth certificate data quality.

3. Methods

Study sites

Vital statistics agencies at UDOH and the District of Columbia Department of Health (DCDOH) collaborated with University of Utah Healthcare (UUHC) and Sibley Memorial Hospital (SMH), respectively, to analyze content contained in EHRs and reported on birth certificates. UUHC and SMH were chosen by UDOH and DCDOH because both use Epic inpatient health records and have implemented Epic's Stork specialty module for obstetrics. Epic is the only EHR vendor that has worked to develop, test, and validate the ability to extract and report birth certificate items using the Birth and Fetal Death Reporting Enhanced (BFDR-E) standard.

Human subjects research exemptions were obtained from both UUHC and SMH in November, 2015. In Utah, a simple random sample of 60 birth certificates was drawn from Utah's electronic birth registration system (EBRS) for all births at UUHSC that occurred in November 2015, to residents of Utah, and that were not subsequently marked deceased. In DC, a similar sample of 60 records was drawn for births occurring at SMH in the same time frame.

Data for the selected analysis variables for each of the sample records were exported from each jurisdiction's EBRS in a standard interjurisdictional exchange (IJE) format for specific birth certificate variables.

The Epic Stork module at each study site was used to generate standard Labor and Delivery Summary (LDS) documents (i.e., an 'LDS extract') for each of the sample births. The implemented version of Stork at each facility supported the generation of LDS extracts containing all required birth certificate items. Stork-derived values for each of the selected variables under study were also documented in Research Electronic Data Capture (RedCap), a browser-based open source solution for capturing clinical and translational research, using the following procedure.

Data elements reviewed

Only select birth certificate data elements were compared in this study. The data elements included were chosen by staff from the NCHS, Utah Department of Health (UDOH), and the District of Columbia (DC) Department of Health because of their historical completeness and/or potential impact on policy. Table 1 lists the selected birth certificate data elements that were analyzed for this project.

Table 1. Description of data fields included in the analysis and representation of the expected values on the US Standard Certificate of Live Birth

Observation/Concept	Datatype in Target Vital Record System	Expected Value
Medical Risk Factors and Prenatal Care History		
Date of Last Normal Menses (M-D-Y)	Date	
Date of first prenatal care (M-D-Y)	Date	
Number of Prenatal Visits	Numeric	
Gestational diabetes (diagnosis in this pregnancy)	Boolean	Yes (Checked item) No (Checked ‘‘None of the above’’)
Delivery Information		
Induction of Labor	Boolean	Yes (Checked item) No (Checked ‘‘None of the above’’)
Augmentation of Labor	Boolean	Yes (Checked item) No (Checked ‘‘None of the above’’)
Antibiotics received by mother during labor	Boolean	Yes (Checked item) No (Checked ‘‘None of the above’’)
Method of Delivery—Fetal Presentation at Birth	Enumerated	Cephalic Breech Other Unknown
Method of Delivery—Route and Method of Delivery	Enumerated	Vaginal, Spontaneous Vaginal, Forceps Vaginal, Vacuum Cesarean Unknown
If cesarean, was a trial of labor attempted?	Boolean	Yes (Checked item) No (Checked ‘‘None of the above’’)
Newborn Information		
Obstetric estimate of gestation (in weeks)	Numeric	# in weeks, rounded down
Assisted Ventilation Required Immediately Following Delivery	Boolean	Yes (Checked item) No (Checked ‘‘None of the above’’)
Assisted ventilation required for more than 6 hours	Boolean	Yes (Checked item) No (Checked ‘‘None of the above’’)
Abnormal Conditions of the Newborn--Admission to NICU	Boolean	Yes (Checked item) No (Checked ‘‘None of the above’’)
NICU Admission ≤ 24 hours (Utah only)	Boolean	Yes (Checked item) No (Checked ‘‘None of the above’’)

The data elements in Table 1 are divided into three groups based on their original source of information. Prenatal group data elements include characteristics or objective facts that are established during prenatal care and are documented in the mother's prenatal care record, beginning months prior to delivery. The prenatal care record is separate from the hospital's inpatient EHR. The prenatal record may or may not be available when the mother is admitted to the hospital for labor. Labor and Delivery data elements are documented in the mother's inpatient EHR when the child is being delivered. Newborn data elements are documented in the newborn baby's inpatient EHR.

Data abstraction processes

Process used by Epic to create a Labor and Delivery Summary (i.e., LDS extract)

The Epic interface team implemented the interface that is based on Integrating the Healthcare Enterprise (IHE) Standards and Interoperability (S & I) framework. The Epic experts performed the data pull and provided the files in a CDA-based xml format for the study team to manually review. To document the information included in the extracted files, the study team viewed the rendered files using a CDA stylesheet and manually inspected the xml and used 'control-f' for key words to look for concepts in the records. As described in Table 2, the following steps were taken to manually abstract information about each item. Note that this process can introduce errors that may be avoided when the files can be automatically processed. Figure 1 shows an example of information currently presented in a rendered Labor and Delivery Summary (LDS) extract.

Table 2. Methods for abstracting birth certificate concepts from the CDA-based LDS extract

Concept	Method for Abstraction	Comment
Date of Last Normal Menses (M-D-Y)	Date in table	
Date of first prenatal care (M-D-Y)	Date in table	
Number of Prenatal Visits	# in table	
Gestational diabetes (diagnosis in this pregnancy)	Review the problem list displayed in table. Queried xml file for: "gdm", "diabetes".	
Induction of Labor	Queried xml file for: "induct"	The Chief complaint included "labor induction" but this does not necessarily mean the mother was actually induced.
Augmentation of Labor	Queried xml file for: "augment"	
Antibiotics received by mother during labor	Reviewed the Medication list for any antibiotics	No time provided to be able to determine if it were given

		during labor. But also, timing of labor Is not included in the file.
Fetal Presentation at Birth	Reported as “Vertex” in Stork, a subset of “Cephalic”	
Route and Method of Delivery	Queried xml file for: “vbac”, “cesarean”	
If cesarean, was a trial of labor attempted?	Queried xml file for: “trial”	
Obstetric estimate of gestation (in weeks)	# in table	
Assisted Ventilation Required Immediately Following Delivery	Queried xml file for: “venti”, Cpap”	
Assisted ventilation required for more than 6 hours	Queried xml file for: “venti”, Cpap”	
NICU Admission > 24 hours (Utah only)	Queried xml file for: NICU	
NICU Admission ≤ 24 hours (Utah only)	Queried xml file for: NICU	

Pregnancy History

Event	Value
Date of Last Menses	02/07/2015
First Prenatal Care Visit Date	07/14/2015
Last Prenatal Care Visit Date	11/13/2015
Number of Prenatal Care Visits	10
Number of Previous C Sections	0
Obstetric Estimate of Gestation	39 weeks

Figure 1. Example of a section of a rendered Labor and Delivery Summary (LDS) extract

Process for obtaining data from the electronic birth registration system (i.e., EBRS record)

Birth certificate information for each sample record in Utah and DC was exported from its jurisdiction’s EBRS in a standard inter-jurisdictional exchange (IJE) format. The IJE format is a national standard used by state vital records agencies and NCHS to share records. SAS was used to parse the IJE records, extract information for the select birth variables being analyzed. This information was uploaded into RedCap.

Process for creating the referent file using vital records experts (i.e., Referent record)

In each jurisdiction, two public health experts in birth registration independently reviewed each of the 60 records included in the study. The goal was to establish the true value for each item being analyzed. Reviewers entered information for each record directly into RedCap. Differences in the independent assessments were adjudicated between the two reviewers to form a single, uniform reference standard to serve as the reference for comparison. While the reference standard values were to be derived from these independent assessments of each medical record, however, reviewers at both sites did not have access to the entire medical record. For example, at UUHC, the reviewers did not have access to the EHR, but rather only had access to clinical notes printed by the UUHC Health Information Management Office for the relevant patients during the time frames involved. This caused a number of missing values in the Reference Standard for which values were recorded on the birth certificate.

Data analysis

After downloading all information from RedCap, SAS was used for analysis. EBRS and LDS values for dichotomous variables were compared to the reference standard and classified by truth status. Pearson's Correlation Coefficient was calculated for numeric variables, including dates. Results for categorical variables are displayed in contingency tables. Statistical tests for independence are not reported due to the small sample sizes.

Review process

In Utah, findings were discussed with birth clerks and Health Information Management staff to understand workflow and other reasons for differences.

Then, we reviewed the findings with the larger study team including members from Epic, UUHC, DCDOH, NCHS. This group pooled their different perspectives to discuss our findings and identify reasons and changes required both to the BDRF-E specification and NCHS guidance to clarify the intent of the questions being asked.

4. Results

4.1 Overall Results

Tables 3a and 3b show a simple comparison of counts for categorical variables for both Utah and DC births, assuming that the referent records represent truth.

Table 3a. Results for categorical variables, including true positives (TP), false positives (FP), and false negatives (FN), Utah Births

	Reference Standard	LDS extract (n=60)						Birth Certificate (n=60)					
	n(Yes)	TP		FN		FP		TP		FN		FP	
		n	%	n	%	n	%	n	%	n	%	n	%
Induction of Labor	21 (35%)	8	3.3%	13	21.7%	0		16	26.7%	5	8.3%	0	
Gestational Diabetes	5 (8.3%)	2	3.3%	3	5.0%	0		5	8.3%	0		0	
Augmentation of Labor	11 (18.3%)	0		11	18.3%	0		8	13.3%	3	5.0%	1	1.7%
Antibiotics	34 (56.7%)	15	25.0%	19	31.7%	0		27	45.0%	7	11.7%	4	6.7%
NICU	8 (13.3%)	7	11.7%	1	1.7%	0		6	10.0%	2	3.3%	5	8.3%
Assisted Ventilation	7 (11.7%)	0		7	11.7%	0		2	3.3%	5	8.3%	0	
Assisted Vent(> 6 hours)	4 (6.7%)	0		4	6.7%	0		3	5.0%	1		2	3.3%

Table 3b. **Results for categorical variables, including true positives (TP), false positives (FP), and false negatives (FN)**, DC **Births**

	Reference Standard (n=Yes)		**LDS extract(n=60)**						**Birth Certificate (n=60)**					
			TP		FN		FP		TP		FN		FP	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Induction of Labor	14	23%	1	3.30%	13		0	0.0%	11	18.3%	3	5.0%	1	1.7%
Gestational Diabetes	4	7%	3	3.30%	1		0	0.0%	3	5.0%	1	1.7%	0	
Augmentation of Labor	14	23%	0		14		0	0.0%	11	18.3%	3	5.0%	1	1.7%
Antibiotics	36	60%	26	43.3%	10	16.7%	22	36.7%	25	41.7%	11	18.3%	2	3.3%
NICU	10	17%	7	11.7%	3	5.0%	1	1.7%	5	8.3%	5	8.3%	0	
Assisted Ventilation	1	2%	0		1		0	0.0%	0		1	1.7%	0	
Assisted Vent(> 6 hours)	0		0		0		0		0		0		0	

Overall, the EBRS system showed greater agreement with the Reference Standard than the LDS extract for most variables. Some items, such as number of prenatal visits, showed high rates of incorrect values for both EBRS and LDS extracts compared to the Reference Standard. In such cases, it is questionable as to whether the reference standard is most accurate. Referent values were derived from independent assessments of each medical record. However, reviewers at both sites did not have access to the entire medical record. This caused many missing values in the Referent records for which values were recorded on the birth certificate.

4.2 Prenatal Items

Prenatal items on the birth certificate include items documented during a mother's prenatal care. These values are typically documented in an ambulatory medical record, either paper or electronic, as opposed to a hospital inpatient EHR. While a growing majority of ambulatory medical records used in obstetrics practices are electronic, there are still issues with interoperability. Ambulatory prenatal care records are often not available when a mother is admitted to a hospital for delivery. If they are available, they often arrive at the hospital as paper documents that are scanned into the inpatient EHR.

Further complicating the quality of prenatal variables in the EHR is the fact that self-reported values may often be obtained from the mother when the prenatal care record is not available although this is not consistent with best practices for birth reporting. In both Utah and DC, self-reported items are collected from mothers and used as a last resort, when no other objective source for this information is available.

Table 4. Correlation of prenatal items compared to Reference Standard by source and jurisdiction

	Utah		DC	
	LDS extract (n=60)	**EBRS (n=60)**	**LDS extract (n=60)**	**EBRS (n=60)**
Number of prenatal visits	0.744*	0.682*	0.175	0.441*
Date first prenatal Care	0.676*	0.813*	0.226	0.605*
Date of Last Normal Menses	0.870*	0.963*	0.944*	0.58*

*p<.001

The results at each jurisdiction showed that, in general, the LDS extract showed less correlation to the reference standard than did the EBRS. In many cases, the EBRS showed much weaker correlation to the Reference Standard than would be expected. Since there are ongoing efforts to ensure the quality of EBRS-submitted information, this poor correlation led us to question the value of the Reference Standard.

In the EBRS group, the number of prenatal visits may represent a self-reported number provided by the mother.

The LDS extract routinely reported 0 prenatal visits when the prenatal record is missing and the true number is unknown. Providing a 0 value in this field confounds the use of correlation statistics to measure agreement. Specific NCHS guidance for this item states that if there is no prenatal care, a '0' should be entered and the checkbox for no prenatal care should be checked. After discussion with

NCHS it was decided that the number of prenatal visits should not be pre-populated with a 0 when prenatal information is not found, prompting further review by a birth information specialist or other reviewer.

Findings for each of the individual prenatal data elements are presented below.

Date of Last Normal Menses

Among the 60 Utah records, the date of last menstrual period (LMP) was reported in 59/60 EBRS records, 54/60 LDS extract records, and only 49/60 of the referent records. Among the 49 Utah records with data from all three sources, there was complete agreement among 37/49 (75%) of the records. The remaining 25% of the records disagreed for a variety of reasons that sometimes involved errors in more than one of the sources. Here are three examples of errors identified:

- Example 1. The referent source was using a prenatal care record from an earlier (miscarried) pregnancy than the current one. This caused the LMP to be 3 months earlier than the correct LMP.
- Example 2. The birth clerks and the UDOH team likely made typographical errors that occurred when keying in abstracted information, resulting in errors in both the EBRS and the referent records.
- Example 3. Information was taken from the mother's worksheet or an outside record rather than the information in the EHR.

Among the 60 DC records, the date of LMP was reported in all 60 EBRS records, 57/60 referent records, and only 23/60 LDS extract records. Among the 23 DC records with data from all three records, there was nearly complete agreement ($\pm$ 1 day) in 18/23 (78%). Reviewers in DC noted that in 55/60 births, the prenatal record was scanned into the hospital chart, explaining the high number of missing values in the LDS extract records.

Date of First Prenatal Care and Number of Prenatal Visits

These two items are documented in a similar manner so they will be reported together.

Identifying the encounters that should be classified as a 'prenatal care visit' is problematic. The following scenarios were identified in Utah records that account for the variation in findings reported from the different sources:

1. Records about prenatal care provided outside the UUHC system are located in the Media tab. The Birth clerks can manually review the records and identify a first prenatal visit and determine which visits to include, but these records are not available to the "Prenatal Vitals" section of the Episode report that is typically used to count prenatal visits and they are not considered by the Labor and Delivery Summary for automatically determining the first and total number of prenatal visits. Finally, the outside records were not available to the UDOH team who only reviewed UUHC records.

2. Prenatal visits are defined differently for the different abstraction methods:
    a. The birth clerks generally rely on the "Prenatal vitals" tab which appears to only include "OB visits" and "Admission type" visits for the Obstetric Emergency Room (OB ER), inpatient, and delivery room. The Birth Clerks have been instructed to exclude visits in this list, however, that do not include both a blood pressure and a weight. This fact requires the Birth Clerk to manually review and scroll the list and exclude visits without these features.
    b. The Birth Clerks and the UDOH team creating the referent data sometimes included other types of visits, such as "urgent care", or "Office Visits" that were determined to be pre-OB or OB planning visits when the pregnancy was confirmed. These visits were not labeled as "OB Visits", but they were visits to an outpatient clinic and the pregnancy was noted in the clinic notes.
    c. The LDS extract appears to only count visits labelled "OB Visit".
3. While the Epic EHR record now has a summary report that includes a count of prenatal visits, the birth clerks continue to manually count the visits, which is difficult when you have to scroll and keep track of the count and the dates. This is done because of the inconsistencies identified in the way the visits are counted. The new report needs to be evaluated.
4. No written guidance from the Health Department was identified for classifying OB visits in Utah.

Among the Utah records, prenatal visit variables were missing for 17-20% of records in the Referent and LDS extract records. When the number of prenatal visits is unknown in Epic, the system reports 0 prenatal visits, rather than a missing or unknown value. Values submitted on the EBRS were rarely missing, however, as hospital birth a clerk are often able to derive this information from other available sources including available paper records and self-reports from mothers.

Among DC records, the number of prenatal visits is often reported as 0 in the LDS extract when the actual number is missing or not available. This accounts for the very low correlation between the LDS extract and the referent records.

Gestational Diabetes

For the five Utah records that included gestational diabetes, there was complete agreement between the EBRS and the referent records. Two of the LDS extracts were in agreement, for which both included gestational diabetes in the problem list. Three LDS extracts did not agree with the EBRS or referent records for the following reasons:

- Mismatched file #1: The info was not correctly abstracted by the study team. The LDS extract actually did include 'gestational diabetes'.
- Mismatched file #2: The EHR Problem list stated: Maternal diabetes mellitus in third trimester.
- Mismatched file #3: Diabetes was not actually in the problem list, although text in a note included "Glucose intolerance (impaired glucose tolerance)" and the patient was on metformin.

The study team determined that further investigation by clinical experts would be necessary to confirm the status of gestational diabetes for these patients.

In the DC group, there were four referent records that indicated gestational diabetes, of which LDS extracted files correctly identified three. The EBRS also correctly identified three out of four records with gestational diabetes. The one record missed by the LDS extract was not the same record missed in EBRS reporting.

Recommendations for prenatal items:

- NCHS should review and revise the BFDR-E specification for counting the number of prenatal visits based upon release of updated NCHS guidelines.
- Create a flag if a patient has outside prenatal visits, defined as visits that are not documented in the hospital's EHR, so manual processes can be used to review these records, but automated processes can be used for the remaining patients for whom prenatal care records are within the EHR. A question about 'outside prenatal visits' could be asked on the mother's worksheet, and additional data could be gathered if she says yes. There is no need to ask about the number of prenatal visits on the worksheet if all care is internal to the health system used for the birth.
- Automate the logic and verify the outcomes. The birth clerks should expect that if an outside prenatal visit flag is not affirmative, then the system should be able to consistently count visits that meet acceptable logic.
- The LDS extract should report missing or unknown prenatal visits as null, not 0.
- Facilities in which the practice is to scan prenatal records will have to either key certain information into the EHR including references to the primary source of the information, or continue to have the birth clerk key that information into the birth certificate form.

4.3 Labor and Delivery Items

Induction of Labor

The occurrence of induction of labor was identified in none of the LDS extracts from Utah and was identified correctly in only one record from DC. A summary of results for Induction of labor are presented in Tables 5 and 6.

Table 5. Induction of Labor: EBRS and Stork compared to Reference Standard Utah Birth Certificates (n=60)

		LDS extract		EBRS		Total
		Y	N	Y	N	
Reference Standard	Y	0	13	16	5	21
	N	0	39	0	39	39
Total		0	52	16	44	

Table 6. Induction of Labor: EBRS and Stork compared to Reference Standard DC Birth Certificates (n=60)

		LDS Extract		EBRS		Total
		Y	N	Y	N	
Reference Standard	Y	1	13	11	3	14
	N	0	46	1	45	46
Total		0	59	12	48	

Among the 60 Utah records, LDS extracts identified several births where induction was documented on the problem list, or as an admitting diagnosis, but no records included documentation of induction as a procedure. Inductions were documented in the EHR as observations in a field labelled 'induction type', but this field in not included in the LDS extract.

Among the 60 Utah records, the EBRS and the referent standard were in agreement 55/60 (92%) of the time. The remaining 5 records all were reported as Induction = Yes and EBRS = No. The EBRS was underreported while the reference standard over-reported. They were in disagreement for the following reasons:

- 3/5 were situations where induction occurred, but the EBRS system said No. The birth clerks appear to have missed following information in the Delivery notes. All included “Labor type: Scheduled induction of Labor” and “Induction type: Elective”.
- 1/5 was a situation where induction did not occur, but the referent source says it did. The Delivery record reports “Labor type: Spontaneous” but the referent source reports Induction=Yes.
- 1/5 was a bit unclear, but the Delivery note states: “Labor type: scheduled induction of labor”

Among the DC records, only one of 14 induction events was correctly identified by the LDS extract. There is no additional information available on differences between data from the referent and EBRS records.

After discussion with an Epic engineer and facility staff at both UUHC and SMH, it was determined that the BFDR-E specification is expecting induction of labor to be documented as a procedure but it is actually being documented in Epic as an observation. Thus, there is a mismatch between the BFDR-E specification and how the item is documented in practice. To resolve this issue, the BFDR-E specification should be revised to include observations as well as procedures.

Recommendations:

- Revise BFDR-E specification for induction of labor to include observations as well as procedures

Augmentation of Labor

Despite 12 occurrences of Augmentation of Labor in the Utah Referent records and 14 occurrences in the DC Referent records, the LDS extracts did not identify any augmentation events in either group. A summary of results for Augmentation of Labor are presented in Tables 7 and 8.

Table 7. Augmentation of Labor: EBRS and Stork compared to Reference Standard Utah Birth Certificates (n=60)

		LDS Extract		EBRS		Total
		Y	N	Y	N	
Reference Standard	Y	0	12	7	4	12
	N	0	48	1	48	49
Total		0	60	8	52	

Table 8. Augmentation of Labor: EBRS and Stork compared to Reference Standard DC Birth Certificates (n=60)

		LDS Extract		EBRS		Total
		Y	N	Y	N	
Reference Standard	Y	0	14	11	3	14
	N	0	46	1	45	46
Total		0	60	12	48	

The Epic LDS extract does not include a field for "Augmentation" so this information is missing from all the Epic LDS extracts. Therefore, there was no need to evaluate differences between the LDS extract and the other two sources.

Among the 60 Utah records, the EBRS and the referent standard were in agreement 56/60 (93%) of the time. The remaining 4 Utah records were in disagreement. Three records had referent = YES, while EBRS = NO, and one record had referent = NO, and EBRS = YES. In all the records, no structured documentation was found to indicate that augmentation occurred.

Among the 60 DC records, results were very similar to Utah with 56/60 EBRS (93%) records in perfect agreement with the reference standard.

Subsequent discussions with Epic and facility staff revealed that augmentation of labor, similar to induction, is being documented as an observation as opposed to a procedure. Resolution for this item, as with induction, is to revise the BFDR-E specification.

Recommendations:

- Revise BFDR-E specification for induction of labor to include observations as well as procedures.

Antibiotics Received by Mother during Labor

In the Utah group, Epic undercounted the number of mothers given antibiotics during delivery (Table 9). The DC group's Epic extract correlated strongly with what was reported on the EBRS (Table 10). When manually reviewing the Epic extract, it was difficult to determine if an antibiotic was listed, whether it was administered during delivery, during prenatal care, or after delivery. To complicate this determination, when the LDS is rendered with an XSL stylesheet it does not display date of birth, timing of labor, or the date and time of administration of antibiotics.

Table 9. Antibiotics Received by Mother: EBRS and Stork compared to Reference Standard Utah Birth Certificates (n=60)

		LDS Extract		EBRS		Total
		Y	N	Y	N	
Reference Standard	Y	15	19	27	7	34
	N	1	25	4	22	26
Total		16	44	31	29	

Table 10. Antibiotics Received by Mother: EBRS and Stork compared to Reference Standard DC Birth Certificates (n=60)

		LDS Extract		EBRS		Total
		Y	N	Y	N	
Reference Standard	Y	26	10	25	11	36
	N	2	22	2	22	24
Total		28	32	27	33	

Among the 60 Utah records, the three sources agreed for 37/60 (62%) of the time. Therefore, there were 23 mismatched records. We identified that antibiotics administered during delivery were problematic to identify. In particular, we found that:

- Among the 21 patients who had a cesarean delivery, 16 (76%) had mismatched information about antibiotics. In most cases, the EBRS correctly said YES and the Epic LDS extract said NO, but there were also cases where the referent said YES, and the EBRS said NO.
- It appears that medications associated with documentation in the operative notes and shown in the Anesthesia med list are not always included in the Epic LDS extract. Specific examples can be shared.
- The current LDS extract does not include the time of administration of medications in order to determine whether they were administered during labor.

Among the 60 DC records, 42/60 (70%) were in perfect agreement between all three sources. Specific reasons for differences in the DC group were not determined.

Results for this item on all three sources were clouded by confusion regarding the specific objective of this question. In particular, there was confusion between the concepts of labor and delivery. During a call with the study team, it became clear that this question is being misinterpreted. In Utah, the reviewers are including antibiotics administered during a cesarean section, unaware that this question is only supposed to be affirmative if labor occurs.

Recommendations:

- NCHS should review the BFDR-E specification and clarify the derivation rules for this item, specifically including the start and end times of labor in the logic for this item.
- Display Date of Birth and Time of Birth and onset of labor on the rendered version of the LDS for those births in which labor occurs.

Method of Delivery

The LDS extract performed poorly in identifying the method of delivery because the BDRF-E specification expects the delivery method to be documented as a procedure. A summary of results for Method of Delivery are presented in Tables 11 and 12.

Table 11. Method of Delivery: EBRS and LDS extract compared to Referent records, Utah (n=60)

Reference Group	LDS Extract					EBRS					Total
	Spontaneous	Forceps	Vacuum	Cesarean	Unk	Spontaneous	Forceps	Vacuum	Cesarean	Unk	
Spontaneous	0	0	0	0	36	36	0	0	0	0	36
Forceps	0	0	0	0	0	0	0	0	0	0	0
Vacuum	0	0	0	0	2	0	0	2	0	0	2
Cesarean	0	0	0	3	19	0	1	0	21	0	22
Unk	0	0	0	0	0	0	0	0	0	0	0
Total	0	0	0	3	57	36	1	2	21	0	

Table 12. Method of Delivery: EBRS and LDS extract compared to Referent records, DC (n=60)

Reference Group	LDS Extract					EBRS					Total
	Spontaneous	Forceps	Vacuum	Cesarean	Unk	Spontaneous	Forceps	Vacuum	Cesarean	Unk	
Spontaneous	1	0	0	0	27	28	0	0	0	0	28
Forceps	0	0	0	0	1	0	1	0	0	0	1
Vacuum	0	0	0	0	1	0	0	1	0	0	1
Cesarean	0	0	0	23	7	0		0	30	0	30
Unknown	0	0	0	0	0	0	0	0	0	0	0
Total	1	0	0	23	36	28	1	1	30	0	

Among the 60 Utah records, none of the 36 spontaneous or 2 vacuum-assisted deliveries documented in the referent records were correctly identified in the LDS extracts. In addition, only 3 of the 22 cesarean deliveries were identifiable from information from the LDS extract. Agreement was much higher between the EBRS and referent records (58/60 (97%)). One of the records in disagreement was classified as a vaginal, vacuum-assisted delivery but was in fact a cesarean delivery with the use of a vacuum. It is an unusual situation.

Among the 60 DC records, only 1 of 28 spontaneous deliveries was correctly identified in the LDS extract; however, 23 of 30 Cesarean deliveries were correctly identified.

Subsequent analysis revealed a discrepancy between the specification and documentation practices at both UUHC and SMH. Specifically, method of delivery is documented as a discrete observation rather than a procedure.

Recommendations:

- Revise the BFDR-E specification to pull from discrete observations as well as procedures.

Fetal Presentation

Table 13. Fetal Presentation: EBRS and LDS extract compared to Referent records, Utah (n=60)

Reference Group	LDS Extract				EBRS		TOTAL
	Cephalic	Breech	Other	Unknown	Vertex	Breech	
Cephalic	56	0	0	3	59	0	59
Breech	0	1	0	0	0	1	1
Other	0	0	0	0	0	0	0
Unknown	0	0	0	0	0	0	0
Total	56	1	0	3	59	1	60

Table 14. Fetal Presentation: EBRS and LDS extract compared to Referent records, DC (n=60)

Reference Group	LDS Extract				EBRS		TOTAL
	Cephalic	Breech	Other	Unknown	Cephalic	Breech	
Cephalic	48	0	2	2	51	1	52
Breech	4	1	3	0	3	5	8
Other	0	0	0	0	0	0	0
Unknown	0	0	0	0	0	0	0
Total	52	1	5	2	54	6	60

Among the 60 Utah records, there was complete agreement between the EBRS and the referent records. In contrast, three of the 60 LDS extract records did not contain information about fetal presentation.

The DC results were more mixed, particularly when presentation was not cephalic. The LDS extract identified 4/8 breech births as cephalic, 3/8 as other, and correctly identified only one breech birth. The EBRS in DC showed agreement with referent records in 5/8 breech births.

Subsequent discussion with Epic and facility staff determined that there may be an issue with system settings at UUHSC and SMH that affect mapping to breech/vertex presentation.

Recommendations:

- Review system settings at UUHSC and SMH that affect mapping to breech/vertex presentations.

4.4 Newborn Items

Obstetric Estimate of Gestational Age

Table 15. Obstetric Estimate of Gestational Age: Correlation between LDS extract, Referent, and EBRS records, Utah

	LDS extract	Reference	Birth Cert.
Epic extract		99.9% (<.0001)	1 (<.0001)
Reference	99.9% (<.0001)		99.9% (<.0001)
Birth Cert	1 (<.0001)	99.9% (<.0001)	

Table 16. Obstetric Estimate of Gestational Age: Correlation between Epic, Referent, and EBRS records, DC

	LDS extract	Reference	Birth Cert.
Epic extract		1 (<.0001)	1 (<.0001)
Reference	1 (<.0001)		1 (<.0001)
Birth Cert	1 (<.0001)	1 (<.0001)	

Among the 60 Utah records, there was perfect agreement across all three sources for 59/60 records. The one Utah record that disagreed was a situation whereby the referent source reported the gestational age at the time the mother was admitted that was on day 6 of week 36. This is rounded down to 36 weeks. The baby was born the next day however, so the actual estimate of gestational age was 37 which was reported correctly in the EBRS and the LDS extract.

There was perfect agreement (60/60) across all three sources for DC records.

This suggests that this item is likely to be consistently documented in both facilities and correctly extracted by the interface to create the LDS extract.

Recommendations:

- No changes recommended

Newborn Admitted to NICU

Table 17. Newborn Admitted to NICU: EBRS and LDS extract compared to Reference Standard Utah Birth Certificates (n=60)

		LDS extract		EBRS		Total
		Y	N	Y	N	
Reference Standard	Y	7	1	6	2	8
	N	4	48	5	47	52
Total		11	49	11	49	

Table 18. Newborn Admitted to NICU: EBRS and LDS extract compared to Reference Standard DC Birth Certificates (n=60)

		LDS extract		EBRS		Total
		Y	N	Y	N	
Reference Standard	Y	7	3	5	5	10
	N	1	49	0	55	55
Total		8	52	5	60	

Analysis of differences between the three sources:

- In Utah, 53/60 records were in perfect agreement between the 3 sources. The 7 that disagreed included a variety of issues with no single predominant problem:
    - One scenario involved the mother's record stating the baby was admitted to the NICU, but the baby's admission note stated that the baby was admitted to the Intermediate care nursery (ICN) which is not an ICU. This record was classified as NICU in the EBRS and the Epic LDS extract.
    - One scenario involved a baby cared for immediately by the NICU team then passed back to the peds team minutes later. This record was classified as NICU in the EBRS but not in the LDS extract.
    - The other records were a mix of abstracting errors in the referent source (n=3) and the EBRS (n=1)
- The birth clerks identified an issue concerning the classification of NICU care that may impact data reported prior to January 2016. Prior to Jan 2016, the birth clerks had been classifying the Intermediate Care Nursery (ICN) as a setting where a newborn received NICU care.
- **Relevant only to Utah:** The birth clerks in Utah said that is it very difficult to discern the duration of the NICU stay. They used dates and times in the clinical notes to get clues about the duration

of the NICU stay. They used to be able to use the bed status information to see the timing of transfers, but are no longer able to view this information.

- *Recommendation (relevant only to Utah):* Investigate ways to present information systematically so the birth clerks can see the duration of the NICU stay.

Review of results from both UUHC and SMH revealed that the results from Epic are likely better than the results from birth clerks or the Reference Standard, because the extract is counting only actual NICU admissions while there was some question among human reviewers as to what counts as a NICU admission.

Recommendations:

- Revise the BFDR-E specification to include amount of time in NICU for jurisdictions such as Utah that want to capture this information.

Assisted Ventilation Following Delivery

The LDS extracts did not identify any occurrences of assisted ventilation in either the Utah or DC records. It is not clear if this is a facility documentation issue or a problem with the LDS extract identifying occurrences of assisted ventilation.

Table 19. Assisted Ventilation Following Delivery: EBRS and Stork compared to Reference Standard Utah Birth Certificates (n=60)

		LDS extract		EBRS		Total
		Y	N	Y	N	
Reference Standard	Y	0	7	2	5	7
	N	0	53	0	53	53
Total		0	60	2	58	

Table 20. Assisted Ventilation Following Delivery: EBRS and Stork compared to Reference Standard DC Birth Certificates (n=60)

		LDS extract		EBRS		Total
		Y	N	Y	N	
Reference Standard	Y	0	1	0	1	1
	N	0	59	0	59	59
Total		0	60	0	60	

Analysis of differences between the three sources:

- Since information is not included in the LDS extract in either Utah or DC, consideration should be limited to agreement between the EBRS and the referent sources. 56/60 (93%) records were in agreement.
- The 4 records not in agreement are a mix of issues:
  - 1 record is unclear – states Mec (meconium?) intubated, but not sure if this should be classified as YES.
  - 2 records were misclassified in EBRS. The EBRS says NO, when it should be YES.
  - 1 record was misclassified in the referent. The referent says YES, when it should be NO.

Among DC records, 1/60 indicated assisted ventilation following delivery in the reference standard. This event was not identified by Epic. It is unknown if the reference standard was correct for this event.

Further analysis of specific records at UUHC revealed that assisted ventilation is documented as an observation in a template, not as a procedure.

Recommendations:

- Revise the BFDR-E specification to pull from discrete observations as well as procedures.

Assisted Ventilation > 6 Hours

Results for this item are similar to those for the assisted ventilation question above. No incidents are identified in either the Utah or DC groups.

Table 21. Assisted Ventilation Greater than 6 Hours: EBRS and Stork compared to Reference Standard, Utah Birth Certificates (n=60)

		LDS extract		EBRS		Total
		Y	N	Y	N	
Reference Standard	Y	0	4	3	1	4
	N	0	56	2	54	56
Total		0	60	5	55	

Table 22. Assisted Ventilation Greater than 6 Hours: EBRS and Stork compared to Reference Standard, DC Birth Certificates (n=60)

		LDS extract		EBRS		Total
		Y	N	Y	N	
Reference Standard	Y	0	0	0	0	0
	N	0	60	0	60	60
Total		0	60	0	60	

Analysis of differences between the three sources:

Results in Utah for the LDS extract were similar to the assisted ventilation item with none of 4 assisted ventilation records identified in the LDS extract. In the DC sample, neither the LDS extract nor EBRS identified any assisted ventilation for more than six hours.

5. Discussion and Recommendations

Overall, the results of this study demonstrated that the clinical content to report birth certificate information for the items examined is generally available within Epic, but in many cases was not pulled into the LDS extract because of a mismatch between documentation practices in the two Epic facilities compared to the BFDR-E specification.

The LDS extract performed well on some items and poorly on others because of the mismatch described above. Clearly, missing prenatal records, i.e. those that are not available at the birth facility during labor and delivery, or those that are scanned complicate the ability of the LDS extract or any automated process to correctly identify these values. As interoperability between ambulatory and inpatient records improves, these items may eventually be populated in the inpatient EHR and be available for automatic reporting. There is the potential for improvements in interoperability between prenatal care providers' systems and hospital EHRs through the use of health information exchanges. This process merits monitoring as pilot implementations advance in this area. Until those processes are in place, careful monitoring of prenatal care variables should continue until a hospital's EHR demonstrates interoperability with prenatal EHRs.

This analysis was limited in both the scope of variables from the birth record that were examined, and the number of records randomly chosen at each site. As such, we are not concerned about the statistical significance of the findings, but rather the patterns observed that inform how birth certificate quality may be monitored and improved when automated birth reporting from an EHR is implemented.

A further limitation of this analysis is the use of a Reference Standard formed by two independent health department expert reviewers at each site. Investigation into many problematic items in Utah revealed that the Reference Standard itself was often incorrect. This may have been due to the fact that health department reviewers in Utah were not provided access to entire medical records. In addition, health department reviewers are not as familiar with the often complex documentation practices in evolving electronic health record systems. Ongoing record audits by health department expert reviewers are a longstanding quality control practice for birth certificates, but their use in the EHR era should be examined.

Without the need to train hospital birth clerks on how to abstract and document complex clinical information, the role of health department birth certificate reviewers may shift to back end quality analysis and collaboration with providers and EHR analysts to ensure documentation templates and workflow support data needs for birth registration. To establish a reference standard for quality assessment, it may be more appropriate for hospital birth clerks to independently review records than having health department experts independently review records in an EHR system with which they are not familiar. Moreover, a larger, statistically significant sample that compares automatically extracted information to EBRS values and historical facility and jurisdiction-specific trends may disprove the need for a reference standard to ensure quality.

The results of this preliminary analysis indicate that automated reporting of birth certificate items using the BFDR-E profile is feasible. Further pilot implementations and analysis of the BFDR-E specification across multiple facilities, jurisdictions, and EHR vendors should be encouraged. These pilots will provide the feedback that is needed to ensure the standard is flexible and robust enough to meet diverse needs of real-world implementations.

Since the Epic interface has been licensed at SMH and UUHSC and the teams now have experience with performing this analysis, continuing analysis at these two facilities is recommended, expanding the scope of analysis to include all birth certificate items reported in the LDS. This ongoing analysis will not include a reference standard because of problems identified with that process, and because of the time commitment required to complete a reference standard. This will allow identification of items where the standard specification will need to be modified to reflect actual clinical documentation practices. Given that the process of revising and testing the standard specification is time consuming, we recommend this analysis occur in the near term.

To achieve this objective, a streamlined reporting for both EBRS and LDS documents should be developed. In addition, software to automatically parse EHR-provided LDS documents needs to be refined. An XML Stylesheet designed specifically to render the LDS document should be developed.

In addition, it is recommended that the number of hospitals and jurisdictions comparing LDS extracted data to information reported on EBRS be expanded.

This analysis demonstrated that the clinical information to support automated birth certificate reporting for these select items is largely available within the Epic EHR. We identified instances where the BFDR-E specification must be modified to reflect clinical documentation practices. On a much higher level, we identified a process that can be used to examine the quality of information automatically extracted from electronic health records.

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Appendix A

Acronym	Definition
BFDR-E	**Birth and Fetal Death Reporting-Enhanced** BFDR-E provides a means to capture and report births and fetal deaths for vital registration.
CDA	**Clinical Document Architecture** An XML-based HL7 standard for exchanging clinical information
DCDOH	**District of Columbia Department of Health**
EBRS	**Electronic birth registration system** A web-based system used by state vital records agencies to collect birth certificate information from hospitals
HL7	**Health Level Seven** A standards organization that develops and promotes standards for electronic exchange of health information
IHE	**Integrating the Healthcare Enterprise** An international non-profit organization working to promote interoperability between systems in healthcare and public health
LDS	**Labor and Delivery Summary** A standard CDA specification developed to contain all birth certificate elements
NCHS	**National Center for Health Statistics**
RFD	**Retrieve Form for Data capture** An IHE-approved profile for form-based information exchange between systems. BFDR-E is a type of RFD.
SMH	**Sibley Memorial Hospital**
UDOH	**Utah Department of Health**
UUHC	**University of Utah Healthcare**
XML	**eXtensible Markup Language**