

Using the National Library of Medicine's HL7 Result Message to Calculate Newborn Screening Lab Quality Indicators

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Collection of Quality Indicators Will Be a Major Activity at NewSTEPs

- ▶ The Newborn Screening Technical assistance and Evaluation Program (NewSTEPs) developed a set of proposed quality indicators (QIs) to measure newborn screening (NBS) system performance
- ▶ Over time, and after multiple reviews, the QIs have expanded beyond primarily assessing NBS dried blood spot tests to more broadly cover newborn screening programs as a whole, including point of care tests
- ▶ Ideally, calculating these QIs should not require significant additional effort by laboratory or program staff so we explored using the data in standard HL7 NBS lab result messages as a starting point for automatically computing proposed QI results
- ▶ The extension of QIs to point of care testing for CCHD and EHDI also reminds us that HL7 result messages can be used for point of care as well as laboratory testing



Understanding the Different Electronic Data Sources that can populate the QI

- ▶ Many of the QIs require data from more than one data source
- ▶ Relevant data systems include:
 - **Laboratory Information Systems (LIS)**
 - Manage the performance of tests in the lab and generate paper, web, or electronic message reports
 - **Remote data entry or Lab order messages**
 - Allow hospitals to send demographics to the lab electronically rather than hand-written on the filter paper card
 - **Lab result messages**
 - Send results to hospital or other electronic health record (EHR) systems
 - **Vital Records and Electronic Birth Certificates**
 - Counts number of births and neonatal deaths
 - **Short term follow-up system (STFU)**
 - Track infants with an out-of-range result until confirmatory testing is complete
 - **Long term follow-up system (LTFU)**
 - Monitor cases over the long-run, starting at the time of diagnosis confirmation
 - **Newborn Hearing Systems (EHDI) and CCHD Systems**
 - Combine the LIS and STFU functions for point of care testing, can include both EHDI and CCHD



Using Terminology Standards

- ▶ Several standard terminology systems have been federally designated for the electronic health record (EHR) Incentive Program
- ▶ Lab tests should be coded using Logical Observation Identifiers Names and Codes (LOINC®)
- ▶ NLM has created a standard HL7 message template for NBS results that includes these standard codes
- ▶ HL7 lab result messages carry NBS results and related data from laboratory information system (LIS) to EHRs
- ▶ As labs adopt the federally-designated terminology standards, data collected will become increasingly interoperable
- ▶ The differences between the individual systems that each source is using will become less important facilitating health information exchange.
- ▶ Codes can move results into EHR and codes can also help extract data from EHR for follow-up or case confirmation



Methods

- ▶ We reviewed the proposed NewSTEPs quality indicators, many of which will be calculated independently for DBS, CCHD or EHDI, or for different analytes or disorders
- ▶ We then examined sample HL7 newborn screening messages and the HL7 NBS lab result message implementation guide to see whether they contain the data needed to generate or help compile the proposed quality measures
- ▶ We also examined the potential role of LOINC codes to uniformly identify analytes, result interpretation, and data about the newborn or sample that will be required for quality indicators



Summary of Results

- ▶ Some data for most of the quality indicators was included in the lab result messages
- ▶ Some indicators are specific to point of care testing
- ▶ Some indicators could be computed solely based on the data in the message
- ▶ The denominator for additional measures and the numerator for some measures could also be calculated based on the messages
- ▶ Linkage to Vital Records is the key to identifying the percentage of births screened
- ▶ Linkage to Short Term Follow-Up systems is needed to identify the disposition of out of range results
- ▶ A few indicators are based on data not found in electronic lab result messages such as confirmed cases
- ▶ Calculating some of the details on timing of specimen receipt and processing may require enhancing the message content



Invalid Specimens and Missing Information

- ▶ QI-1 Percent of invalid dried blood spot specimens due to improper collection and/or transport
 - Applies only to dried blood spot and not point of care
 - Part of the HL7 message
- ▶ QI-2 Percent of dried blood spot specimens missing essential information
 - Essential information is defined by each state based on what they need to run, report, and interpret tests
 - LOINC codes in messages capture the data from the filter paper card



QI-3 Percent of eligible infants not receiving valid newborn screening test

- ▶ Stratified by dried blood spot or point of care test(s) [DBS/CCHD/EHDI]
- ▶ QI-3a Percent of total infants without a satisfactory newborn screening test
 - ▶ Requires combining several reasons a satisfactory test was not done
 - ▶ Requires matching lab reports with master list of infants (vital records)
- ▶ QI-3b Percent of deceased infants who were eligible for screening without a valid newborn screening test
 - ▶ A subset of QI-3a that requires linkage to a master list of newborns and neonatal deaths
- ▶ QI-3c Percent of infants without a valid newborn screening test due to parental refusal
 - ▶ Parental refusal has a LOINC code and orders need to be sent to the lab to document why a test was not done
- ▶ QI-3d Percent of infants without a valid newborn screening test due to error [in sample collection]
 - Refers to errors in sample collection which are identified by CLSI based LOINC answer codes
- ▶ QI-3e Percent of infants without a valid screening test due to a missing second screen, in second screen states
 - Only in second screen states (screen not completed or not able to be matched to other valid screen)



QI-4 Percent of loss to follow-up

- ▶ QI-4a: Percent of loss to follow-up following the receipt of an invalid specimen.
 - Requires linking report with unsatisfactory specimen quality to repeat with adequate quality
- ▶ QI-4b: Percent of loss to follow-up following an out-of-range test result.
 - QI-4b1: In samples requesting a repeat dried blood spot
 - QI-4b2: In infants requiring referral for evaluation
 - LOINC codes identify out of range results that request a repeat screen and code referral separately
- ▶ QI-4c: Percent of loss of follow-up for infants who do not receive follow-up testing after an out of range pulse oximetry screen
 - Usually done immediately in the hospital and will require documentation of consult and/or echocardiogram
- ▶ QI-4d: Percent of loss of follow-up for infants who do not receive follow-up test after an out of range newborn hearing screening result
 - Goal is 1 month for repeat screen and 3 months for diagnostic audiology
 - Usually done as an outpatient



QI-5 Time elapsed from:

- ▶ QI-5a: Birth to specimen collection/initial point of care testing
 - Recorded by the hospital for CCHD and EHDI, part of the specimen data entered by the lab or by the specimen collector
- ▶ QI-5b: Specimen collection to receipt by lab
 - Not relevant for point of care tests
 - Lab must add time received to the message
- ▶ QI-5c: Specimen receipt to reporting out results
 - All necessary time stamps are part of the standard HL7 lab report message
- ▶ QI-5d: Release of out-of-range results to notification of medical provider
 - The time for release of results is in the lab report but notification of providers is documented in STFU



QI-5 Time elapsed from: (con't)

- ▶ QI-5e: Release of out-of-range results to intervention by appropriate medical professional
 - Will require documentation in short term follow-up system
- ▶ QI-5f: Birth to follow-up testing
 - Will require linking initial screen to repeat screen or confirmatory testing
- ▶ QI-5g: Birth to confirmation of diagnosis
 - Short term follow-up or enrollment in long term follow-up
 - Requires case definition confirmatory data
- ▶ QI-5h: Birth to ruling out diagnosis
 - Short term follow-up
 - Requires case definition confirmatory data to document the rule out



QI-6 Percent of out-of-range results any referral to evaluation

- ▶ Stratified by analyte and analyte reporting can be standardized by using LOINC codes
 - The list of analytes to track has yet to be developed but the messaging standard provides a list to select from
 - The overall rate of any out of range results is in the message
- ▶ Stratified by point of care test [CCHD/EHDI]
 - HL7 messages can be used for point of care tests as well as laboratory tests and can provide reliable and complete data to short term follow-up systems
 - Direct communication from point of care test instruments to public health is feasible
- ▶ Limited to referral to a specialist (parents informed of a problem) and does not include second tier testing or a repeat screen



QI-7 Frequency of condition detected by newborn screening for each disorder

- ▶ QI-7a Overall frequency of condition detected by the newborn screen for each disorder
 - Usually requires reporting confirmatory testing to match case definition requirements
 - Would benefit from an electronic case report form
- ▶ QI-7b Frequency of condition detected by initial newborn screening for each disorder
 - Requires linking out of range screen to confirmatory testing to identify first screen
 - LOINC codes identify the purpose of the specimen
- ▶ QI-7c Frequency of condition detected by second (or other subsequent) newborn screen for each disorder
 - Requires linking out of range screen to confirmatory testing to identify first screen



QI-8 Percent of missed cases (false negatives), stratified by disorder

- ▶ An important challenge for newborn screening programs
- ▶ Requires data from sources other than the newborn screening program or point of care testing
- ▶ Would benefit from linking false negative missed cases to the results of the dried blood spot or point of care testing
- ▶ May be able to use data from birth defects surveillance systems



Positive Predictive Value (PPV) is No Longer One of the Quality Indicators

- ▶ The March 2013 revision of the Quality Indicators no longer includes Positive Predictive Value (PPV) as a quality indicator
- ▶ The intent is to encourage labs to use PPV internally, but not for comparisons between states
- ▶ PPV is very important clinically because it describes the percent of all positive screening tests that are true positives and have the disease
- ▶ PPV depends on many factors that vary from state to state
 - PPV depends on the population screened and the prevalence of the condition screened
 - PPV depends on the methods and strategy for screening



Conclusions

- ▶ Health information technology (HIT) will continue play an important role in NBS and using HIT to calculate quality indicators has the potential to improve the accuracy and timeliness of reporting
- ▶ In addition, HIT's potential to reduce the burden on laboratory staff, it provides an incentive for laboratories to adopt new technology for interoperability with electronic health records
- ▶ Labs and Hospitals should assure that those systems are properly designed and include the necessary information to automatically monitor program performance and report to national databases.
- ▶ The removal Positive Predictive Value (PPV) from the quality indicators will simplify the task of generating comparable measures in all states
- ▶ The inclusion of point of care testing in NewSTEPs highlights the importance of hospitals sending data to public health and HL7 messages can support this information exchange
- ▶ Attention to privacy and human subjects considerations are essential and in progress.



Vision of a Future World of NBS

- ▶ Newborn screening today is very different from what it was fifty years ago and we can expect more changes in the future
- ▶ States will continue to use a wide variety of organizational structures and data systems
- ▶ A simple set of national standard electronic records may come into more common use and provide a uniform pathway to reporting quality indicators
 - We have a national **Electronic Birth Certificate** and some states add DBS filter paper ID and hearing or CCHD results
 - We have a national standard **HL7 Lab Report** that could be produced for all lab as well as point of care testing results, even if its use today is limited
 - We could develop a uniform **Case Report Form** for confirmed and ruled out cases which could carry the data from short term follow-up including confirmatory testing results, links to initial screening, date and time of contacts and key events, and all other data required for case definition. It could start as a web form and move to electronic output from short term follow-up systems
 - **Birth Defects Surveillance** systems could help find false negative missed cases



For more information

- ▶ <http://www.newsteps.org>
- ▶ <http://newbornscreeningcodes.nlm.nih.gov>
 - HL7 tab for sample messages and codes
- ▶ Contact:
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