Improving Quality Indicators Associated with Specimen Collection and Transport

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NBSGTS
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Looking Back: Making the Past a Part of Your Present

www.newlywedsurvival.com
RESULTS

Q1. Percent of Unsatisfactory Specimens Due to Improper Collection

• Table shows number of births reported to the State's electronic birth certificates (EBC) system for the 1st quarter of 2011, the number of 1st quarter specimens received by the laboratory, the number of unsatisfactory 1st quarter specimens, the number of "valid" 1st quarter specimens (i.e. specific defects unreported), and percent of births screened.
• First specimen includes initial specimens, repeat specimens with the same specific defects in the laboratory information system (LIS), and out of some births. In addition, maternal patent data is not matched between the EBC and LIS. Therefore, this is the best available approximation of the QI measure.

Q2. Percent of Specimens Lacking Essential Information

• Results include all initial and repeat specimens that were received missing essential demographic data or collection information (even if the data was ultimately provided).
• Table includes date of notification of medical provider data in the current system.
• The "broad" category includes newborns in the "narrow" category and newborns for whom there is no way to currently differentiate.
• The difference between the time to confirmation and the time to clearance would also be of interest.

Q3. Frequency of a Condition Detected at Birth: 1st Screen vs. 2nd Screen

• Table shows the number of defects and frequency of detection at first screen for all confirmed cases.

Q4. Rate of Loss to Follow-up

• Table shows the number of newborns referred for evaluation with a confirmed posterior and the number of newborns referred for evaluation.
• The "broad" category includes newborns in the "narrow" category and newborns for whom contact was made with the family or physician but have no final disposition (confirmed or cleared).

Q5. Percent of Parent Refusals

• Table shows number of births reported to the State's electronic birth certificates (EBC) system for the 1st quarter of 2011, the number of 1st quarter specimens received by the laboratory, the number of unsatisfactory 1st quarter specimens, the number of "valid" 1st quarter specimens (i.e. specific defects unreported), and percent of births screened.
• First specimen includes initial specimens, repeat specimens with the same specific defects in the laboratory information system (LIS), and out of some births. In addition, maternal patient data is not matched between the EBC and LIS. Therefore, this is the best available approximation of the QI measure.

CONCLUSIONS

• The difference between the time to notification and the time to clearance would also be of interest.
• Delay in reporting due to medical provider data in the current system.
• The "broad" category includes newborns in the "narrow" category and newborns for whom there is no way to currently differentiate.
• The difference between the time to confirmation and the time to clearance would also be of interest.

Q7. Average cont. (cont.)

• The definition of a confirmed CH case is debated and may change over time.

METHODS

• Data from the Program's information system and the National Newborn Screening Database, which covers all the births who were screened in the participating states and that have ongoing newborn screening programs.
• All of the QIs selected by the APHL for inclusion in the National Newborn Screening Data Repository.
• The difference between the time to notification and the time to clearance would also be of interest.

CONCLUSIONS

• Time of medical intervention is not recorded in hours, therefore, all data in Chart E, which covers the first half of 2011, is presented in days. In addition, date of written report is used as a proxy for time of release.
• Treatment well in advance of report date was due to symptoms noted on birth or as a result of a critical result called prior to the written report.
• Delay in treatment was most often related to hematological results or NICU babies already under close observation with multiple ongoing treatments.
• Data shown in Chart F is from the first half of 2011 and includes both cleared and confirmed cases as well as infants and repeat specimens.
• Time to diagnosis varies significantly by disorder and stratification of results would be beneficial for the QI measure.

Q7: Average cont. (cont.)

• Time of medical intervention is not recorded in hours, therefore, all data in Chart E, which covers the first half of 2011, is presented in days. In addition, date of written report is used as a proxy for time of release.

Q8: Positive Predictive Value for Out of Range Results

• For newborns born in 2010, 138,788 first specimens were tested with 4,006 out of range results and 832 positive results.
• Stray results by disorder will give a better idea of assay performance and workload for future studies.
• It is currently possible to stratify by conditions such as NICU or TPN.

Q9: Rate of Out of Range Results

• For newborns born in 2010, a total of 4 cases out of 277 confirmed cases were not detected.
• The total number of confirmed cases was not detected by NICU specimens.

Q10: Rate of Missed Cases

• For newborns born in 2010, a total of 4 cases out of 277 confirmed cases were not detected by NICU specimens.

Methods

• All of the QIs selected by the APHL for inclusion in the National Newborn Screening Data Repository.
• The difference between the time to notification and the time to clearance would also be of interest.
• The definition of a confirmed CH case is debated and may change over time.
Pilot Study of Quality Indicators for the Next Generation of Data Collection into a National Newborn Screening Data Repository

RESULTS

Q1: Percent of Unreliable Samples Due to Inadequate Collection

Q2: Percent of Samples Lacking Essential Information

Q3: Frequency of a Condition Diagnosed at Birth: 1st Trimester, 7th Trimester

Q4: Rate of Correct Follow-up

Q5: Rate of Incorrect Follow-up

Q6: Rate of False Positive

Q7: Rate of False Negative

Q8: Rate of False Positive Follow-up

Q9: Rate of False Negative Follow-up

Q10: Rate of Discordant Results

Q11: Rate of Missing Data

Q12: Rate of Out of Range

Q13: Rate of Out of Range Follow-up

Q14: Rate of Correct Follow-up

Q15: Rate of Incorrect Follow-up

Q16: Rate of False Positive

Q17: Rate of False Negative

Q18: Rate of False Positive Follow-up

Q19: Rate of False Negative Follow-up

Q20: Rate of Discordant Results

Q21: Rate of Missing Data

Q22: Rate of Out of Range

Q23: Rate of Out of Range Follow-up

Q24: Rate of Correct Follow-up

Q25: Rate of Incorrect Follow-up

Q26: Rate of False Positive

Q27: Rate of False Negative

Q28: Rate of False Positive Follow-up

Q29: Rate of False Negative Follow-up

Q30: Rate of Discordant Results

Q31: Rate of Missing Data

Q32: Rate of Out of Range

Q33: Rate of Out of Range Follow-up

Q34: Rate of Correct Follow-up

Q35: Rate of Incorrect Follow-up

Q36: Rate of False Positive

Q37: Rate of False Negative

Q38: Rate of False Positive Follow-up

Q39: Rate of False Negative Follow-up

Q40: Rate of Discordant Results

Q41: Rate of Missing Data

Q42: Rate of Out of Range

Q43: Rate of Out of Range Follow-up

Q44: Rate of Correct Follow-up

Q45: Rate of Incorrect Follow-up

Q46: Rate of False Positive

Q47: Rate of False Negative

Q48: Rate of False Positive Follow-up

Q49: Rate of False Negative Follow-up

Q50: Rate of Discordant Results

Q51: Rate of Missing Data

Q52: Rate of Out of Range

Q53: Rate of Out of Range Follow-up

Q54: Rate of Correct Follow-up

Q55: Rate of Incorrect Follow-up

Q56: Rate of False Positive

Q57: Rate of False Negative

Q58: Rate of False Positive Follow-up

Q59: Rate of False Negative Follow-up

Q60: Rate of Discordant Results

Q61: Rate of Missing Data

Q62: Rate of Out of Range

Q63: Rate of Out of Range Follow-up

Q64: Rate of Correct Follow-up

Q65: Rate of Incorrect Follow-up

Q66: Rate of False Positive

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Q70: Rate of Discordant Results

Q71: Rate of Missing Data

Q72: Rate of Out of Range

Q73: Rate of Out of Range Follow-up

Q74: Rate of Correct Follow-up

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Q76: Rate of False Positive

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Q78: Rate of False Positive Follow-up

Q79: Rate of False Negative Follow-up

Q80: Rate of Discordant Results

Q81: Rate of Missing Data

Q82: Rate of Out of Range

Q83: Rate of Out of Range Follow-up

Q84: Rate of Correct Follow-up

Q85: Rate of Incorrect Follow-up

Q86: Rate of False Positive

Q87: Rate of False Negative

Q88: Rate of False Positive Follow-up

Q89: Rate of False Negative Follow-up

Q90: Rate of Discordant Results

Q91: Rate of Missing Data

Q92: Rate of Out of Range

Q93: Rate of Out of Range Follow-up

Q94: Rate of Correct Follow-up

Q95: Rate of Incorrect Follow-up

Q96: Rate of False Positive

Q97: Rate of False Negative

Q98: Rate of False Positive Follow-up

Q99: Rate of False Negative Follow-up

Q100: Rate of Discordant Results

Q101: Rate of Missing Data

Q102: Rate of Out of Range

Q103: Rate of Out of Range Follow-up

Q104: Rate of Correct Follow-up

Q105: Rate of Incorrect Follow-up

Q106: Rate of False Positive

Q107: Rate of False Negative

Q108: Rate of False Positive Follow-up

Q109: Rate of False Negative Follow-up

Q110: Rate of Discordant Results

Q111: Rate of Missing Data

Q112: Rate of Out of Range

Q113: Rate of Out of Range Follow-up

Q114: Rate of Correct Follow-up

Q115: Rate of Incorrect Follow-up

Q116: Rate of False Positive

Q117: Rate of False Negative

Q118: Rate of False Positive Follow-up

Q119: Rate of False Negative Follow-up

Q120: Rate of Discordant Results

Q121: Rate of Missing Data

Q122: Rate of Out of Range

Q123: Rate of Out of Range Follow-up

Q124: Rate of Correct Follow-up

Q125: Rate of Incorrect Follow-up

Q126: Rate of False Positive

Q127: Rate of False Negative

Q128: Rate of False Positive Follow-up

Q129: Rate of False Negative Follow-up

Q130: Rate of Discordant Results

Q131: Rate of Missing Data

Q132: Rate of Out of Range

Q133: Rate of Out of Range Follow-up

Q134: Rate of Correct Follow-up

Q135: Rate of Incorrect Follow-up

Q136: Rate of False Positive

Q137: Rate of False Negative

Q138: Rate of False Positive Follow-up

Q139: Rate of False Negative Follow-up

Q140: Rate of Discordant Results

Q141: Rate of Missing Data

Q142: Rate of Out of Range

Q143: Rate of Out of Range Follow-up

Q144: Rate of Correct Follow-up

Q145: Rate of Incorrect Follow-up

Q146: Rate of False Positive

Q147: Rate of False Negative

Q148: Rate of False Positive Follow-up

Q149: Rate of False Negative Follow-up

Q150: Rate of Discordant Results
Pilot Study of Quality Indicators for the Next Generation of Data Collection into a National Newborn Screening Data Repository

1. Percent of unsatisfactory specimens due to improper collection
2. Percent of cards with all essential information
3. Frequency of condition detected at birth: First screen vs. Second screen
4. Rate of loss to follow-up: unsatisfactory & out-of-range
5. Percent of parental refusals
6. Percent of eligible infants receiving valid newborn screening test
7. Average time:
   a) From birth to specimen collection
   b) From specimen collection to receipt by lab
   c) From specimen receipt to reporting out results
   d) From release of out-of-range results to notification of medical provider
   e) From release of out-of-range results to medical intervention
   f) From birth to diagnosis
8. Positive predictive value (PPV) of out-of-range screening results
9. Rate of out-of-range results, any referral to evaluation
10. Rate of missed cases (false negatives)
Welcome to the NewSTEPs Data Repository

The repository is now ready for data entry for basic state profiles, cases and quality indicators. We anticipate updates to occur on a quarterly basis, or sooner if needed. Please continue to check this page for announcements of new features. FAQs for the NewSTEPs Data Repository can be found linked here. To consult the General User Guide please click here. The State Administrators User Guide can be found here.

What is Available Now?

Each state has the ability to review and revise basic state profile data, enter cases and quality indicator data through one designated state contact.

Quality Indicators

The 8 Quality Indicators that will be used to provide longitudinal comparisons within a program as well as comparisons to aggregate data across programs can be found linked here: Quality Indicators. Worksheets demonstrating data that will be requested to populate the Quality Indicators can be found linked here.

Reports

Sample Reports depicting fictional data summaries demonstrating the range of responses in quality indicators throughout newborn screening systems in the country while protecting the confidentiality of each state newborn screening program can be found linked here: Sample Reports

Current Activities

State Profile data can be entered prior to the ratification of the MOU. NewSTEPs has convened a series of webinars detailing the Memorandums of Understanding (MOUs) that will be entered into between APHL and newborn screening programs. NewSTEPs has contacted state representatives to help facilitate signatures. We request that all Quality Indicator and Infant level data entry be held until the MOUs are fully ratified.
Pilot Study of Quality Indicators for the Next Generation of Data Collection into a National Newborn Screening Data Repository

1. Percent of unsatisfactory specimens due to improper collection
2. Percent of cards with all essential information
3. Frequency of condition detected at birth: First screen vs. Second screen
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8. Positive predictive value (PPV) of out-of-range screening results
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Specimen Collection and Submission

- N.J.A.C. 8:18-1.4(a)
  - Responsibilities of the chief executive officer
    - 9. Assure that specimens are taken before the infant is 48 hours old. If an infant is transferred or discharged from a facility prior to 48 hours of life, a specimen shall be collected prior to discharge unless there are medical reasons to prevent specimen collection.
Specimen Collection and Submission

- N.J.A.C. 8:18-1.4(a)
  - Responsibilities of the chief executive officer
    - 16. Assure that all specimens are forwarded to the testing laboratory within 24 hours of collection by next day delivery, or in the event service is unavailable with respect to Sundays and Federally designated holidays, then as soon thereafter as is practicable, using an account number the Department shall establish with an overnight package delivery service, which number the Department shall make available upon request
UPS CampusShip

- Printing a shipping label
- Scheduling pickups
- Selecting Saturday delivery
- Tracking Packages
Time from Birth to Collection

2011

By 48 hours = 91.8%
Median = 35.9h
Days from Collection to Receipt

Cumulative %

- >7 d
- 7 d
- 6 d
- 5 d
- 4 d
- 3 d
- 2 d
- 1 d
- Same day

By 3 days = 86%
## Transmittal >3 days

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Variety of Issues

Collection
- Did not know
- Errors in reporting
- Medical issues
- Transferred

Transportation
- Saturday deliveries/Saturday pickups
- Batching specimens
- Timing of collection
- Incorrect use of UPS CampusShip system
- UPS delivery problem
Batching
Let Us Help You!

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Blood Collection on Filter Paper for Newborn Screening Programs; Approved Standard—Fifth Edition

This document addresses the issues associated with specimen collection, the filter paper collection device, and the application of blood to filter paper, and provides uniform techniques for collecting the best possible specimen for use in newborn screening programs.

A standard for global application developed through the Clinical and Laboratory Standards Institute consensus process.
Time from Birth to Collection

By 48 hours = 91.8%
Median = 35.9h

By 48 hours = 94.6%
Median = 36.0h

2011
2014
Days from Collection to Receipt

- By 3 days = 86%
- By 3 days = 92%
The NJ NBS Laboratory is open Monday through Saturday and Holidays

- On Saturdays and Holiday, the most time sensitive procedures are performed with reduced staff.
- Critical abnormal results are also reported on Saturdays and Holidays.

The NJ NBS Laboratory works during all recent winter (and non-winter) states of emergency to ensure continuity of this critical testing service.

Hospitals who do not follow these requirements are referred to HFE&L for investigation

- In December 2013, a hospital was cited and fined for violations of the NJ NBS regulation

The NJ NBS Laboratory is continuing education efforts and developing a new shipping system in collaboration with UPS.