Data Driven Strategies for Quality Improvement

Kim Hart, MS, CGC
Utah Newborn Screening

• 50,000 births
• 2 screen state
  • 1st NBS collected at 24-48 hours of life
  • 2nd NBS 7-16 days of life
• $115 kit fee
• No additional funds or subsidies
• Fee includes diagnostic testing
• Hired informaticist
• Active engagement of clinical specialists
Analytics + engagement of clinical specialists = improved outcomes
Cystic Fibrosis Screening

- Started 2009
- IRT/IRT/DNA
- 97.5% cutoff
- CFTR DNA outsourced
Median age at diagnosis, by state

CF Patients Born 2013-2016
Diagnosed after DOB
Median Age at Diagnosis, dx made one day or later after birth
So, we could just get rid of the second screen?
Two screens are beneficial

<table>
<thead>
<tr>
<th></th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abnormal 1\textsuperscript{st} IRT (n)</td>
<td>967</td>
<td>1002</td>
<td>1044</td>
<td>1014</td>
</tr>
<tr>
<td>Abnormal 2\textsuperscript{nd} IRT (n)</td>
<td>84</td>
<td>86</td>
<td>81</td>
<td>116</td>
</tr>
<tr>
<td>Abnormal DNA (n)</td>
<td>21</td>
<td>27</td>
<td>23</td>
<td>26</td>
</tr>
</tbody>
</table>

- Reduced number reflexed to DNA; \textbf{>$100,000 savings per year or $2/kit}
- Reduced number of sweat chloride tests in comparison with an IRT/DNA algorithm
- Avoids resource saturation
- Reduced stress for patients/families
Identify and prioritize bottlenecks: CF DNA Testing

Outsourced
- Average age of infant at CF DNA result – 35 days

In-house testing - 2017
- Average age of infant at CF DNA result – 23 days

Is there a significant clinical impact?
Benefits of earlier diagnosis: NBS improvement effect?

Weight-for-Length Percentile
2016 & 2017

<table>
<thead>
<tr>
<th>Percentile</th>
<th>2016 Weight-for-Length (Median)</th>
<th>2017 Weight-for-Length (Median)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-1 mo</td>
<td>38.3</td>
<td>44.3</td>
</tr>
<tr>
<td>2-3 mo</td>
<td>35.8</td>
<td>50.5</td>
</tr>
<tr>
<td>4-5 mo</td>
<td>45.9</td>
<td>59.9</td>
</tr>
<tr>
<td>6-7 mo</td>
<td>42.6</td>
<td>46.8</td>
</tr>
</tbody>
</table>
Cutoff effects on process

- Retrospective comparisons
- Population analysis of IRT distributions for 1\textsuperscript{st} and 2\textsuperscript{nd} screens
## Effect of cut-off changes on sample size

<table>
<thead>
<tr>
<th>Card Type</th>
<th>Cut-Off (ng/mL)</th>
<th>Samples above 97.5% (2016)</th>
<th>Increase (+ n)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>97.5%</td>
<td>1213</td>
<td></td>
</tr>
<tr>
<td>FIRST</td>
<td>51 (2-SD)</td>
<td>1769</td>
<td>556</td>
</tr>
<tr>
<td>SECOND</td>
<td>42 (3-SD)</td>
<td>13</td>
<td>5</td>
</tr>
</tbody>
</table>
Process Improvement: 2018 outcomes

• Average age of infant at CF DNA result - 21 days

• Average age of infant at CF diagnosis – 25 days
  (includes sweat chloride testing & genetic counseling)
The Annual Cystic Fibrosis Foundation's Quality Care Award:

Recognizing Outstanding QI Processes and Accomplishments, 2016 - 2017

U.S News & World Report has ranked Primary Children's as a top hospital in the nation for pulmonary care.
Congenital Hypothyroidism Screening

• Utah incidence: 1 in 2,300 births

• TSH primary screen
  routine on 1\textsuperscript{st} and 2\textsuperscript{nd} screens
Importance of the Second Screen

- 10 year data review
- TSH cutoff >40 µIU/mL (critical cut off >230 µIU/mL)
- 130 cases
- 20% identified on the 2nd Screen (1st screen normal)

CH cases identified only through second screen
Effect of cut-off changes on sample size

<table>
<thead>
<tr>
<th>Card Type</th>
<th>Cut-Off (µIU/mL)</th>
<th>Total Sample Size</th>
<th>Increase (+ n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>FIRST (n)</td>
<td>40</td>
<td>773</td>
<td></td>
</tr>
<tr>
<td>SECOND (n)</td>
<td>20</td>
<td>67</td>
<td>41</td>
</tr>
</tbody>
</table>
### Universal Issue: Timing of the Second Screen

<table>
<thead>
<tr>
<th>Condition</th>
<th>Goal</th>
<th>Delayed cases in 10yr period (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Congenital Hypothyroidism</td>
<td>21 days</td>
<td>10</td>
</tr>
<tr>
<td>Cystic Fibrosis</td>
<td>&lt; 4 weeks</td>
<td>39</td>
</tr>
</tbody>
</table>
Utah Age Distribution: 2\textsuperscript{nd} NBS
Utah Rule Change

• July 1, 2018 - 2\textsuperscript{nd} NBS collection required between 7-16 days of life
• Previously 7-28 days
## Delayed CF Diagnoses

<table>
<thead>
<tr>
<th></th>
<th>&lt;2017</th>
<th>2018</th>
<th>Since July 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>39</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Estimated annual average</td>
<td>5.4</td>
<td>2</td>
<td>0</td>
</tr>
</tbody>
</table>
Summary

• Engage clinical specialists in regular assessment of cut-off values and follow-up logic

• Benefits of 2\textsuperscript{nd} screen
  • Clinical
  • Prevent saturation of resources
  • Financial
  • Less stress/anxiety for patients and families

• Timely 2\textsuperscript{nd} screen important
Acknowledgments

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- David Jones PhD, Informaticist

Newborn Screen Program Consultants:

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- Mary Murray, MD (Endocrinology)
- Hassan Yaish, MD (Hematology)