Utah Newborn Screening: Towards Improved Timeliness, Accuracy and Operational Efficiency

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I have **no** conflict of interests and **no** personal gains from the outcomes of this work.
Newborn Screening in Utah

- 52,000 births
- 99% of total baby population screened
- Kit fee: $112
- 2-Screen State
- Frontier state with many rural/remote areas
- Utah NBS program operates based on kit fee alone
Total NBS Fee $112
$7 Hearing, CCHD; NBS $105

• NBS Testing including Logistics, Testing, Follow-up
• Outsourced MS/MS with ARUP,
• 2\textsuperscript{nd} tier testing (17-OHP (MS/MS), DNA testing),
• Diagnostic testing (except Congenital Hypothyroidism, SCID),
• CF sweat chloride testing & genetic counseling,
• Long-term Follow-up Services (Diet Monitoring),
• Metabolic formula program
Improvement Timeline


$103  
Financial deep dive
Accounting to the
$100 level

$ 24h data
entry
completion

2015  2016  2017  2018  2019

$ 112
FEDEx
program

7-day
operation

replaced 1
position

24h data
entry
completion

2016  2017  2018  2019

Follow-up Program
Integration

Health
Informaticist

Molecular
Supervisor

cut 2
positions

7-day
operation

SCID:
LDT/EnLite
TREC
validation/in
house

CFLuminex
Validation
CF testing
in-house

SMA

Illumina
validation
SMA,
Pompe,
MPS1, XALD

Automated
timeliness;
data
warehouse

$ non-lapsing fund
authority

Financial deep dive
Accounting to the
$100 level

Follow-up Program
Integration
Utah’s **Key Performance Indicators (KPIs)** in days

<table>
<thead>
<tr>
<th></th>
<th>TAT collection</th>
<th>TAT TESTING</th>
<th>TAT collection to Result</th>
<th>Age at NBS completion</th>
<th>Completion % by day 7 (of life)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2017</td>
<td>1.45</td>
<td>1.93</td>
<td>3.59</td>
<td>5.04</td>
<td><strong>94.2%</strong></td>
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Strategic Prioritization = Understanding Cost Benefit

Like a business: we need to understand revenue, costs of goods sold (expenses directly attributed to the tests), SG&A (Selling, General and Administrative expenses)

Key Performance Indicators (KPIs)

NBS is very much governed by market forces and competition

Hiding behind “We are Public Health” prevents process improvements
Strategic Prioritization = Understanding Cost Benefit

Improvement 1  Cost 1  Effect on Process/$/baby

Improvement 2  Cost 2  Effect on Process/$/baby

Improvement 3  Cost 3  Effect on Process/$/baby

Discuss, Rank, Implement, Remeasure
A customer centric system approach

Who is really the customer?
What exact value do we provide?
Who defines value?

Sample Collection & Logistics

Sample Receiving
Sample Testing

On-time Results & care/care coordination
Redefinition of our Services
“Time-to-diagnosis” = insufficient indicator
Eliminate Silo-Perspectives, adopt system view

Assess all steps and their respective utility in the overall process together with all parties involved (sample receiving, lab, follow-up, medical care teams, IT, finance)

Redesign Processes and IT infrastructure across silos
Operational Success Stories
FedEx Courier Service for Underperforming Hospitals

Transport time
\[ t = f(\text{distance, corporate status}); \ p < 0.005 \]

TAT: from 4.14 days to 2.9 days; costs $19,832
Special Delivery
FedEx offers the world-class solutions our important packages deserve.

The Utah Department of Health is pleased to announce that FedEx is now a carrier for samples shipped to our facility located in Taylorsville, UT, effective May 2014.

All newborn screening samples sent to the Utah Department of Health must now be shipped via FedEx Priority Overnight®. All shipping labels must be created using FedEx Ship Manager® at fedex.com with Shipping Administration.

A separate invitation has been sent via e-mail from the Utah Department of Health with a login user name and password.

Use this login to create a shipping label for FedEx Express® shipments. The shipping label will auto-populate the billing, recipient address and service for you. Simply print the shipping label on 8 1/2 x 11 white paper using a laser printer, insert the sample into FedEx Express packaging, seal the package, fold the label and insert it into the plastic sleeve, and ship.

This simple-to-use online shipping program allows you to quickly create a shipping label and track the status of the shipment. Refer to “Shipping Details” in this PDF for more information.

Thank you, Arizona!
February 2015: 7-days operations

Saturday
1. Specimen accessioning
2. Result reporting (Friday testing)
3. On-call Follow-up

Sunday:
1. Full day of testing (all tests)
2. On-call Follow-up
Sample Receiving Problems

Central Problem:
• **Unmatched demand and supply environments**

Solution:
• 2016 same day data entry mandate
• Part-time FTEs on high demand days
• Shift from Mo-Fri 8-5 to staggered 5-on/2-off
• 2017 same day processing AND testing of ALL specimens
Implementation of SCID Testing *in-house*  
*(from ARUP Laboratories)*

*Cost Reallocation Issue*
Significant TAT improvements
$0 net impact

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<tr>
<td>2016</td>
<td>1.46</td>
<td>2.46</td>
<td>4.18</td>
<td>5.64</td>
<td>86.1%</td>
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CF Performance Improvement Story
- Birth
- 1st Screen: 7 d
- 2nd Screen: 7 d
- DNA testing: 14-21 d
- Dx: 1-2 d
- Total Process Duration
- DX/TX
With in-house CF mutation analysis only

age at Dx (DNA and sweat chloride): 23.8 days
(from 30+days; n>100, 8/29/17)

Utah CF Center: same or next business day priority
How can we completely automate timeliness?
How can we achieve a complete chain-of-custody environment?

OZ Systems and STACS DNA Enter into Strategic Alliance to Provide Essential Solutions to Newborn Screening Programs

End-to-end systems for timely and accurate newborn screening address previous gaps that put infants at risk

ARLINGTON, TX AND OTTAWA, ON—APRIL 18, 2017—OZ Systems and STACS DNA have partnered to create end-to-end systems specifically designed to achieve timely and accurate newborn screening care. The partnership was inspired by the lack of robust newborn screening IT solutions in the market—a gap that has endangered newborn lives in the past. The collaboration will marry solutions for newborn blood spot screening from OZ Systems with sample tracking from STACS DNA.

Please visit David Jones poster: An Integrated, Interoperable IT Infrastructure P-131
Automated Timeliness/Real-time Decision Support

- Automated Timeliness
- Complete Chain-of-Custody Solution
- Automated Demographic Data Retrieval
- Operational Decision Support
- Statistics (Cut-Off Logic)

Hospital/Provider/Parents

Data Warehouse
LIMS-independent

OZ/NBS Screening
Suite/Specimen Gate

- Transparency
- Informational Dashboards
Thank you!