State Policy and Finance Framework for Newborn Screening Programs: Case Studies of Select States

*Presentation by:*
Kay Johnson, MPH, EdM

President, Johnson Group Consulting

Research Assistant Professor, Department of Pediatrics, Dartmouth Hitchcock Medical Center
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  – Michele Puryear, Chief, Genetics Services Branch, DCSHCN/MCHB/HRSA
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Policy History of Newborn Screening

- US newborn screening did not start as a legislated or public health activity.
  - During the 1970s, when physicians were slow to adopt screening, parents and organizations advocated for policy change.
  - As a result of this advocacy, legislatures mandated screening in most states.

- Similar advocacy and policy development is going on today.
States’ Authority & Challenge

“Only public health agencies – with their authority... – could implement systems that would mandate screening for all infants, ensure the quality and availability of testing, and provide follow-up on a population basis.”  N.A. Holtzman

• State public health agencies face the challenge of financing newborn screening systems, with:
  – additional tests and equipment,
  – staff skilled in new technology, and
  – more effective follow-up with families.
State Public Health Policy for NBS

State Policy Framework from National Task Force

• Focus on system, not just a test.
• Set policies for adequate funding.
• Involve professionals and consumers.
• Adopt mandates & privacy protections.
• Establish new criteria for adding tests.
• Set program guidelines (quality, etc.).
Framework for Financing
What needs to be financed?

Goals from National Task Force:

Adequate financing for:

1. Screening, short-term follow up, and diagnosis;
2. Comprehensive care and treatment for all individuals with conditions identified by newborn screening; and
3. Quality assurance and evaluation.
Financing Newborn Screening

Principles from National Task Force:

• Core funding for NBS programs:
  – Fees sufficient to finance testing, short-term follow-up, and diagnosis
  – Use other public health dollars as necessary

• Coordinate and blend funds for treatment
Financing for Treatment

Opportunities noted by National Task Force:

• States can coordinate public resources.
  – Medicaid, and SCHIP
  – Title V Maternal and Child Health Block Grant (MCHBG).

• In Medicaid/SCHIP managed care contracts:
  – require coverage of services related to NBS, and
  – require that MCOs ensure access to specialty providers, as necessary.

• For the health insurance plans they regulate, states can mandate coverage of services.
Federal/State Policies related to Financing for NBS

Federal policies

• HIPAA on genetics
• HIPAA on newborn coverage
• ADA rights
• IDEA entitlements
• Medicaid/EPSDT child health coverage

State policies

• NBS mandates & program structure
• NBS financing
• Insurance benefit mandates
• SCHIP benefits
• Children with special health needs program
Distribution of Funds, by Source, 2001

Source: GAO-03-449. State Newborn Screening Programs.
Financing Newborn Screening

Finance myth 1

NBS programs fully funded by fees.

In reality

- 5 states and DC not collecting fees.
- Fees typically cover only test/lab costs.
- Fees may not support expansion of new technology and equipment.
- Economic pressures may limit fee increases.
Financing Newborn Screening

Finance myth 2

Tax dollars fund newborn screening.

In reality

– 45 states use fees, not public dollars, as core funding for tests.

– For residual funding, mainly Title V – MCH and Medicaid to finance follow-up and treatment.
Financing Newborn Screening

Finance myth 3

NBS paid for by third-party reimbursement.

In reality

– Fees not always covered by insurance or Medicaid.
– Even when they pay the fees, Medicaid reimbursements are typically below cost.
What did we learn in this study?
Study questions:

• How did states address recent challenges?
  – State budget shortfalls
  – Consumer demand for more tests
  – Rapid technology change
  – Pressure to privatize

• What policies and finance strategies were used to expand and sustain NBS?
State Selection Criteria - MIX

• Geographic distribution
• Variation in number/type of tests
• Recent expansion or innovation
• Public vs. private labs
• Fee vs. blended funding
• Various approaches to follow-up
• One regional lab model
Study States: Primary Focus of Case Study

- California - Pilot MS/MS program
- Maryland - Integrated programming
- Minnesota – Public-private partnership
- Mississippi – Rapid expansion to 40 tests
- New York – Adding CF and others
- Oklahoma – Expansion with blended funds
- Oregon – Regional support
<table>
<thead>
<tr>
<th>State</th>
<th>PKU</th>
<th>CH</th>
<th>GAL</th>
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<th>HCY</th>
<th>BIO</th>
<th>SCD</th>
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✓ test for condition required by the state
★ test mandated/authorized but not yet implemented
Source: NNSGRC, NCHRAM, March of Dimes
# Overview of Screening: MS/MS

<table>
<thead>
<tr>
<th>State</th>
<th>MS/MS</th>
<th>Fatty acids</th>
<th>Organic acids</th>
<th>Amino/urea</th>
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<tbody>
<tr>
<td>CA</td>
<td>pilot completed</td>
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<td></td>
<td></td>
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<td>MD</td>
<td>✓</td>
<td>9</td>
<td>11</td>
<td>4</td>
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<td>10</td>
<td>12</td>
<td>5</td>
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<td>10</td>
<td>12</td>
<td>8</td>
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<td></td>
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<tr>
<td>OK</td>
<td>✭</td>
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</tr>
<tr>
<td>OR</td>
<td>✓</td>
<td>9</td>
<td>13</td>
<td>3</td>
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* test mandated/authorized but not yet implemented

Source: NNSGRC, NCHRAM, March of Dimes
## Change in Fees, 1997-2004

<table>
<thead>
<tr>
<th>State</th>
<th>Fees 1997</th>
<th>Fees 2004</th>
<th>% increase</th>
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<tbody>
<tr>
<td>CA</td>
<td>$ 42.00</td>
<td>$ 60.00</td>
<td>43%</td>
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<td>MD</td>
<td>$ 15.00</td>
<td>$ 42.00</td>
<td>180%</td>
</tr>
<tr>
<td>MN</td>
<td>$ 13.00</td>
<td>$ 61.00</td>
<td>369%</td>
</tr>
<tr>
<td>MS</td>
<td>$ 20.00</td>
<td>$ 70.00</td>
<td>250%</td>
</tr>
<tr>
<td>NY</td>
<td>$ -</td>
<td>No fee</td>
<td></td>
</tr>
<tr>
<td>OK</td>
<td>$ 10.50</td>
<td>$ 75.59*</td>
<td>620%</td>
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<tr>
<td>OR</td>
<td>$ 28.00</td>
<td>$ 54.00</td>
<td>93%</td>
</tr>
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</table>

* Fee increase approved, scheduled to take effect on January 1, 2005.

Source: NNSGRC, NCHRAM, March of Dimes
## Sources of core funding for:
Screening, Short-term follow up and Diagnosis

<table>
<thead>
<tr>
<th>State</th>
<th>Fees 2004-2005</th>
<th>Fee</th>
<th>State</th>
<th>MCHBG</th>
<th>Medicaid</th>
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<tr>
<td>CA</td>
<td>$ 60.00</td>
<td>✔</td>
<td></td>
<td>Not routinely</td>
<td></td>
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<tr>
<td>MD</td>
<td>$ 42.00</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td></td>
</tr>
<tr>
<td>MN</td>
<td>$ 61.00</td>
<td>✔</td>
<td></td>
<td>Not routinely</td>
<td></td>
</tr>
<tr>
<td>MS</td>
<td>$ 70.00</td>
<td>✔</td>
<td></td>
<td>Not routinely</td>
<td>✔</td>
</tr>
<tr>
<td>NY</td>
<td></td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td></td>
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<tr>
<td>OK</td>
<td>$ 75.59</td>
<td>✔</td>
<td>✔</td>
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<td>✔</td>
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<tr>
<td>OR</td>
<td>$ 54.00</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
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</table>
# Medicaid Financing for Births

<table>
<thead>
<tr>
<th>State</th>
<th>Number of Births (2002)</th>
<th>% Births financed by Medicaid</th>
<th>Income eligibility limit as % Poverty (FPL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CA</td>
<td>529,357</td>
<td>42%</td>
<td>300% FPL</td>
</tr>
<tr>
<td>MD</td>
<td>73,323</td>
<td>29%</td>
<td>250% FPL</td>
</tr>
<tr>
<td>MN</td>
<td>68,025</td>
<td>31%</td>
<td>275% FPL</td>
</tr>
<tr>
<td>MS</td>
<td>41,518</td>
<td>54%</td>
<td>185% FPL</td>
</tr>
<tr>
<td>NY</td>
<td>251,415</td>
<td>41%</td>
<td>200% FPL</td>
</tr>
<tr>
<td>OK</td>
<td>50,387</td>
<td>46%</td>
<td>185% FPL</td>
</tr>
<tr>
<td>OR</td>
<td>45,192</td>
<td>32%</td>
<td>170% FPL</td>
</tr>
<tr>
<td>U.S.</td>
<td>Study states = 26% of total US births</td>
<td>36%</td>
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</tr>
</tbody>
</table>

California

- Finance approach
  - Fees pay for program up to diagnosis
  - $1 per test form + $59 per baby screened
  - Hospitals may charge (keep) $6 for collecting blood

- Challenges in adding tests
  - Huge undertaking for 500,000 births
  - Success with pilot project on MS/MS
  - Unable to increase test panel or add MS/MS due to state budget pressures

- Public health management + private lab capacity
Maryland

• Finance approach
  – Fees cover lab costs
    • Increase to finance upgrade of lab equipment
  – MCHBG for short and long-term follow up

• Challenges as tests added
  – Pediatrix in competition with state lab
  – Effective parent informing/consent
  – Two screens (repeats)
  – Follow-up for many more families
  – State budget pressures
“hit the restart button”

- Financed a new approach with fee increase
- Focused on family as customer
- Expanded number of tests
- Created new public-private partnership
  - State lab (initial screening)
  - Mayo Clinic (MS/MS screen and specialist care)
  - University of Minnesota (coordination & specialist care)
- Structured linkages to medical home/primary care pediatricians
Mississippi

- Expansion to “comprehensive screening” (~40 tests)
- Finance approach
  - Did fiscal analysis, doubled fee $35 up to $70
  - Hospital charges vary, insurance & Medicaid pay through global payment for birth
- Political pressure to change
  - Parents and others through legislature
  - Recommendation of Genetics Advisory Committee
- Lab services
  - No state lab capacity (formerly used Tenn.)
  - Found desired services & price with Pediatrix
- More PH follow up staff in each health district
New York

• Finance approach
  – Not fee-based program
  – Public health dollars directly finance NBS

• Change and challenges
  – Advocacy by parents and other organizations (MOD, AAP) stimulated interest of Governor & legislature
  – State budget pressures ongoing
  – 3-year push to add cystic fibrosis testing in 2003
  – Large scale effort -250,000 births, 3,800 positive screens
  – Innovations to link primary and specialty physicians
Oklahoma

• Finance approach
  – Fee increase to do more tests
  – Medicaid and private insurance billing
  – Legislative commitment to financing
  – Small HRSA grants to plan for innovation

• Political pressures & opportunities
  – Genetics Advisory Committee strong role
  – Parents and others advocate to legislature
  – Medicaid agency and hospitals involved

• Authority to expand tests, implement 2005

• More public health staff for follow-up
Oregon

• Finance approach
  – Fee-based budget
    • Fees are collected at the time prepaid kits are ordered.
    • Reconsidering allocation for lab vs. follow up

• Change process
  – In 2001, legislature approved adding 20 disorders
    **No to cystic fibrosis:** Considered seeking legislative approval to increase fees and add CF test. Instead, created a task force to guide decision.

• Regional lab is a vendor
  – Regional lab for 5 states (AK, HI, ID, OR, and NV)
  – Testing for 100,000 newborns
What factors are enabling states to expand and sustain newborn screening programs?
Creating a Climate for Change

Federal system support through:

• Genetics planning grants
• Program integration grants
• National Newborn Screening & Genetics Resource Center (NNSGRC)
• Demonstration projects
• Regional collaboratives
• National Advisory Committee
• Laboratory quality control

Action & advocacy by:

• Parents
• March of Dimes
• State Genetics Advisory Committees
• Health professionals (AAP, AAFP, etc.)
• Condition-focused support groups
• Pediatrix
NBS – What is driving change?

• State perspective
  – National Task Force recommendations
  – Advocacy by parents and professionals
  – Arguments for equity across states
  – HRSA efforts to increase state capacity
  – Advances in science and technology
What did these states do?

• Focused on a system, not just testing
• Expanded the number of conditions/tests
• Invested in state-of-the-art testing
• Financed more follow up
• Engaged parents/advisory committees
• Negotiated quality and privacy issues
Three Factors affecting Future

• Adding MS/MS capacity in the lab is simple, compared to the fiscal, ethical, and system of care (follow-up) decisions.
• NBS follows in the wake of genetic science
• Introducing profit into newborn screening programs has changed everything.
  – What does it mean when private lab takes funding but not the public health role?
  • Like Medicaid managed care, requires oversight
Political Pressures & Finance

• The political pressure is against increasing health care costs.
• Legislators may say:
  – Nice idea but we cannot afford it.
  – Good idea, do it (with no new resources)
• Health insurance plans and Medicaid may come forward to say this will drive up costs.
• Fiscal constraints often drive policy instead of policy driving fiscal decisions.
Without a broad, inclusive panel of tests established by states:

“Parents may go from doctor to doctor seeking a diagnosis (for their child) and generating costs, without being prepared for the outcome. If you miss a child and miss the opportunity for intervention, the costs are much higher. Program managers have to look at all of the costs and make judgments that balance the interest of individual child and the public. We are not (just) spending taxpayers money.”
Goals for NBS Today?

• Every baby, regardless of where born, has access to newborn screening (NBS).

• Every child receives screening, diagnosis, and needed treatment.

• New consensus on criteria for adding tests to NBS programs achieved.

• NBS programs meet quality standards.