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Goal of Newborn Screening

- Improve health outcomes in the screening population of newborns
- Six parts
  - Testing
  - Follow-Up
  - Diagnosis
  - Intervention and/or management
  - Evaluation
  - Education

Maximum benefit to the child
The Need for Equitable Therapeutic Access

Children identified with inborn errors of metabolism through newborn screening may be unable to gain the full benefits associated with early detection due to:

Lack of universal, guaranteed *access to* and *coverage* of medically recommended foods, formulas and dietary supplements.
This is Not a New Issue :-(

- Surveys have been done
- Meetings held
- Papers published
- Medical Foods Equity Act attempted
- Position statements

And yet... we’re still talking about this topic!
MN Medical Foods Initiative: Purpose

Develop a long term strategy to assist families to obtain medical foods, formulas and dietary supplements as recommended or prescribed by their medical specialty providers for the management of rare inborn errors of metabolism.
Initial Steps

October 2014: Work Group formed to examine:

• Commonalities and differences in programs, services, coverage within and between states

• Evidentiary basis
Goal

Develop a feasible and sustainable solution that enables patients with IBEMs of all ages to receive appropriate medical foods, formulas, vitamins, and supplements.
Initiative Strategies

• Identify current barriers to therapeutic access
• Utilize best/evidence-based practice guidelines for lifelong management
• Collaborate with public health colleagues to improve understanding of program/service/coverage successes and challenges
• Collaborate with other agencies involved in the coverage of medical interventions (DHS, Commerce, etc.)
• Explore and propose solutions to achieve equitable therapeutic access
2015 Medical Foods Survey

Purpose:

• Improve understanding of current programs, services and requirements related to medical foods/formula and dietary supplement access and coverage, and

• Incorporate knowledge to explore sustainable options to assist MN families living with IBEM in obtaining the recommended/prescribed medical foods/formulas and dietary supplements to optimize long term health outcomes
2015 Medical Foods Survey

Key survey content:

• State provided or guaranteed medical foods and/or formula coverage (by each condition on the RUSP)
• Statute information relating to coverage (including vitamins/supplements)
• Program eligibility, types, advice, obstacles
2015 Medical Foods Survey

Survey process:

• Sent to all states
  – Used known Newborn Screening Program contacts and/or Baby’s First Test contacts
  – Some states forwarded on to WIC, CYSHN, etc.

• 45 of 51 respondents completed the survey/responded: (response rate = 88%)
Timespan of Coverage

![Chart showing age ranges covered](chart.png)
Timespan of Coverage

Medical Food: Age Ranges Covered

<table>
<thead>
<tr>
<th>Age Range</th>
<th>Number of States</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Age Limit</td>
<td></td>
</tr>
<tr>
<td>0-100</td>
<td></td>
</tr>
<tr>
<td>Through Childbearing Age</td>
<td></td>
</tr>
<tr>
<td>0-18; Women of Childbearing Age</td>
<td></td>
</tr>
<tr>
<td>Males 0-21; Females 0-44</td>
<td></td>
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<tr>
<td>0-16</td>
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<td>0-19</td>
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<tr>
<td>0-18 [no answer]</td>
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<td>N/A</td>
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Age Ranges Covered
Funding Sources

Medical Formula and Food: Funding Sources

Number of States

- Birth Certificate Fee
- Medicaid
- Medicare
- Newborn Screening Fee
- State Children’s Health Insurance Program
- Title V Block Grant
- WIC Program
- Other: Private Insurance
- Other: State Allocation
- Other: Children’s Special Health Care...
- Other: Earned Revenue
- Other: State Money
- Other: Federal Funds & Grants
- Other: California Children’s Services Fund

MDH
Minnesota Department of Health

UNIVERSITY OF MINNESOTA
Department of Pediatrics
1915–2015
### Funding Allocated
(Cover Med Foods/Formula for ALL Disorders)

<table>
<thead>
<tr>
<th>STATE</th>
<th>AMOUNT</th>
<th>APPROX BIRTHS PER YEAR</th>
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</thead>
<tbody>
<tr>
<td>A</td>
<td>$2000 to $3000 per clinic</td>
<td>36,000</td>
</tr>
<tr>
<td>B</td>
<td>$15,000</td>
<td>11,000</td>
</tr>
<tr>
<td>C</td>
<td>65,000 in NBS (Title V funds vary)</td>
<td>102,000</td>
</tr>
<tr>
<td>D</td>
<td>$160,000 + insurance/family pmts</td>
<td>39,000</td>
</tr>
<tr>
<td>E</td>
<td>$200,000</td>
<td>56,000</td>
</tr>
<tr>
<td>F</td>
<td>300,000</td>
<td>21,000</td>
</tr>
<tr>
<td>G</td>
<td>$550,000 formula/$68-75000 foods</td>
<td>26,000</td>
</tr>
</tbody>
</table>
# Funding Allocated

(Cover Med Formula for ALL Disorders and Med Foods for SOME Disorders)

<table>
<thead>
<tr>
<th>STATE</th>
<th>AMOUNT</th>
<th>APPROX BIRTHS PER YEAR</th>
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</thead>
<tbody>
<tr>
<td>H</td>
<td>$100,000</td>
<td>39,000</td>
</tr>
<tr>
<td>I</td>
<td>$900,000</td>
<td>139,000</td>
</tr>
<tr>
<td>J</td>
<td>$1,000,000</td>
<td>113,500</td>
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</table>
Funding Allocated
(Cover Med Formula for ALL Disorders and Med Foods for NO Disorders)

<table>
<thead>
<tr>
<th>STATE</th>
<th>AMOUNT</th>
<th>APPROX BIRTHS PER YEAR</th>
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</thead>
<tbody>
<tr>
<td>K</td>
<td>$20,000</td>
<td>26,300</td>
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## Funding Allocated
(Cover Med Formula for SOME Disorders and Med Foods for SOME Disorders)

<table>
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<th>STATE</th>
<th>AMOUNT</th>
<th>APPROX BIRTHS PER YEAR</th>
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<tr>
<td>L</td>
<td>$65,804</td>
<td>10,600</td>
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<tr>
<td>M</td>
<td>$135,000</td>
<td>22,400</td>
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<tr>
<td>N</td>
<td>$167,200</td>
<td>86,600</td>
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<tr>
<td>O</td>
<td>$800,000</td>
<td>387,000</td>
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<tr>
<td>P</td>
<td>$1,750,000</td>
<td>67,000</td>
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## Funding Allocated

(Cover Med Formula for SOME Disorders and Med Foods for NO Disorders)

<table>
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<tr>
<th>STATE</th>
<th>AMOUNT</th>
<th>APPROX BIRTHS PER YEAR</th>
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</thead>
<tbody>
<tr>
<td>Q</td>
<td>$60,000</td>
<td>51,000</td>
</tr>
<tr>
<td>R</td>
<td>$66,000</td>
<td>53,000</td>
</tr>
<tr>
<td>S</td>
<td>$150,000 to $200,000</td>
<td>75,000</td>
</tr>
<tr>
<td>T</td>
<td>$841,000</td>
<td>215,500</td>
</tr>
<tr>
<td>U</td>
<td>$2,000,000</td>
<td>157,000</td>
</tr>
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</table>
Obstacles identified by respondents

- No formal application process/eligibility criteria
- Limited funds/Staffing/Budget/Procurement Process
- No insurance mandate
- Program runs in a deficit/Escalating costs
- Pharmacy Ordering Process
- Coverage of Medical Food by Medicaid/care in adults
- Contracts with food vendors
- List of needed medical foods/Lack of understanding of complex reimbursement structure
Proposal: *Nutritional and pharmacotherapy coverage, program participation and adherence for children with select IBEM enrolled in the IBEMC*

- Proposal designed and submitted, review pending

**Goals:** Utilize IBEMC data to determine

- Whether self-pay/lack of insurance correlates with higher rate of therapeutic non-adherence
- Whether those receiving WIC or Patient Assistance have a higher rate of therapeutic adherence
Adherence to treatments:

- Medical Foods: 82%
- Supplements/Pharmacotherapies: 96%
- Special Metabolic Formula: 96%

% of subjects who adhered to treatment
Medical Coverage at IBEMC Intake:

- 63% Private
- 25% Medicare/Medicaid
- 5% Other
- 3% Private & Medicare/Medicaid
- 2% Medicare/Medicaid & Other
- 1% Private and Other
- 1% None

* Medical coverage was unknown for 91 subjects.
Method of payment:

% of subjects who were self-pay for treatments (of those with known payment status):

- Medical Foods: 35%
- Supplements/Pharmacotherapies: 9%
- Special Metabolic Formula: 1%

0%
Advice

• Strong state law is important
• Work with insurance carriers to maximize coverage
  – Understand if insurance mandate would cover self employed, etc.
• Secure as much funding as you can
• Work with dieticians on best products/keep formulary broad
• Collaborate with Medicaid/WIC/CSHCN Program
• Have clear eligibility guidelines
Acknowledgements

• Individuals and families living with inborn errors of metabolism
• MN Medical Foods Initiative Team – especially
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  – Melinda Marsolek
• Medical Foods Survey respondents
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• Inborn Errors of Metabolism Collaborative
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