

Assuring Access to Nutritional Treatment for Inborn Errors of Metabolism:
Michigan's Diet for Life Work Group
Process and Experience

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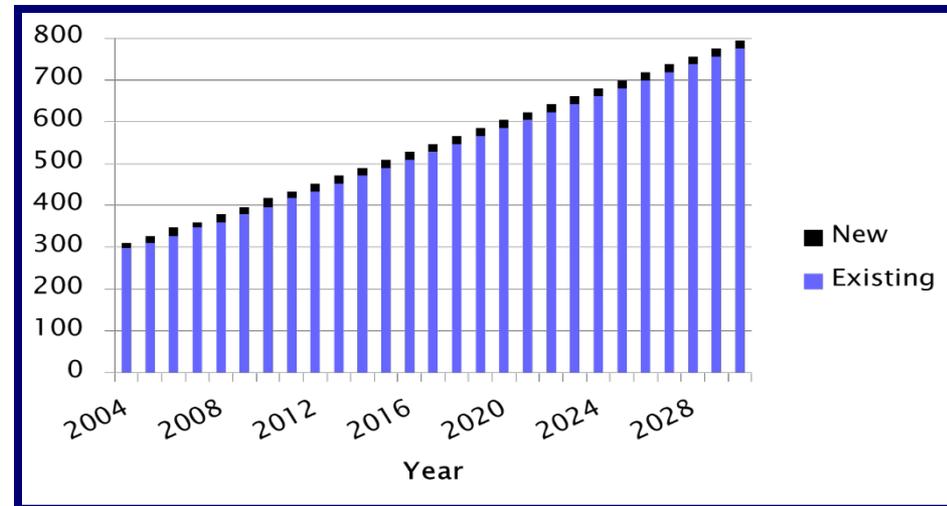
Background

- Michigan mandated newborn screening for PKU in 1965 and over the years, additional inborn errors of metabolism (IEM) requiring some form of nutritional treatment have been added to the screening panel.
- Diet for Life recommendations for treatment have evolved over time and may include:
 - Medical food or formula
 - Low protein modified food
 - Supplemental amino acids, amino acid mixtures or vitamins
- Unlike many states, Michigan has no mandate for insurance coverage.
- Historically, due to difficulties with procurement process and insurance reimbursement, NBS fee revenue was used as a funding source to provide coverage for medical formula through a centralized metabolic clinic.
 - Children's Special Health Care Services Program and WIC also provided funding that is no longer available as in the past

Increasing Costs

NBS spending began to exceed revenue in FY 2012

- Contributing factors include:
 - Increasing number of disorders requiring diet treatment
 - Diet for Life recommendation regardless of age or gender
 - Increasing patient volume, projected to double by 2030
 - Increased laboratory and medical management costs
 - Decreasing birth rate
- Medical formula costs
 - 1987: \$141,000
 - 2013: \$825,000



Projected Number of Michigan Patients
Requiring Diet for Life Treatment, Michigan, 2004-2030

Work Group Formation

- ▶ Internal discussions failed to yield long-lasting solutions until a program partner suggested convening a multi-disciplinary work group
- ▶ Letter mailed to all known adult patients and parents of children with metabolic conditions in September 2013, inviting participation in a “Diet for Life” work group
- ▶ Other invited stakeholders included:
 - Public health programs
 - Medicaid policy, managed care and medical consultant staff
 - Clinical experts
- ▶ Region 4 Midwest Genetics Collaborative staff provided assistance in coordinating and planning; neutral facilitation

Work Group Goals

1. Identify and understand existing clinical best practice guidelines for lifelong dietary treatment of individuals with IEM detected through newborn screening
2. Describe facilitators and barriers to dietary compliance in order to assure the best possible outcomes for individuals with IEM
3. Recommend feasible solutions that enable patients of all ages to receive appropriate metabolic formulas in light of Newborn Screening Program budgetary constraints
4. Suggest long term strategies for assisting families in obtaining insurance coverage and reimbursement for metabolic foods

“Let’s make sure these Michigan children have coverage for their life essential medical formula and dietary products so that they thrive to become productive, healthy Michigan adults.”

- Mother of a daughter with homocystinuria

Work Group Process

Approximately 50 people, including ~20 family members and individuals with inborn errors of metabolism, participated in one or more meetings:

- **Meeting #1 (October 2013)**
 - Explanation of budget situation
 - Background on inborn errors of metabolism and diet for life recommendation
 - Diets for individuals with metabolic disorders
 - Family perspectives
- **Meeting #2: Focus on Adults/Focus on Children (2 meetings, November 2013)**
 - Family member presentations
 - Review of definitions
 - Review of funding sources and other state models
 - Brainstorming for possible solutions; identify facilitators and barriers
- **Meeting #3 (January 2014)**
 - Family member presentations
 - Proposed model for Michigan
 - Next steps
 - Feedback from family participants

Fact Finding

- Agreement on common definitions for nutritional treatment modalities
 - Medical food
 - Low protein modified special food
 - Medically necessary single amino acids, amino acid mixtures & vitamins
- Understanding of problems and barriers
 - Food vs. drug classification
 - Billing codes/reimbursement mechanisms
 - DME suppliers
 - Need for individual choice to maximize dietary compliance
- Other state models
- Clarification of role/limitations of public programs
 - NBS
 - CSHCS
 - Medicaid
 - WIC

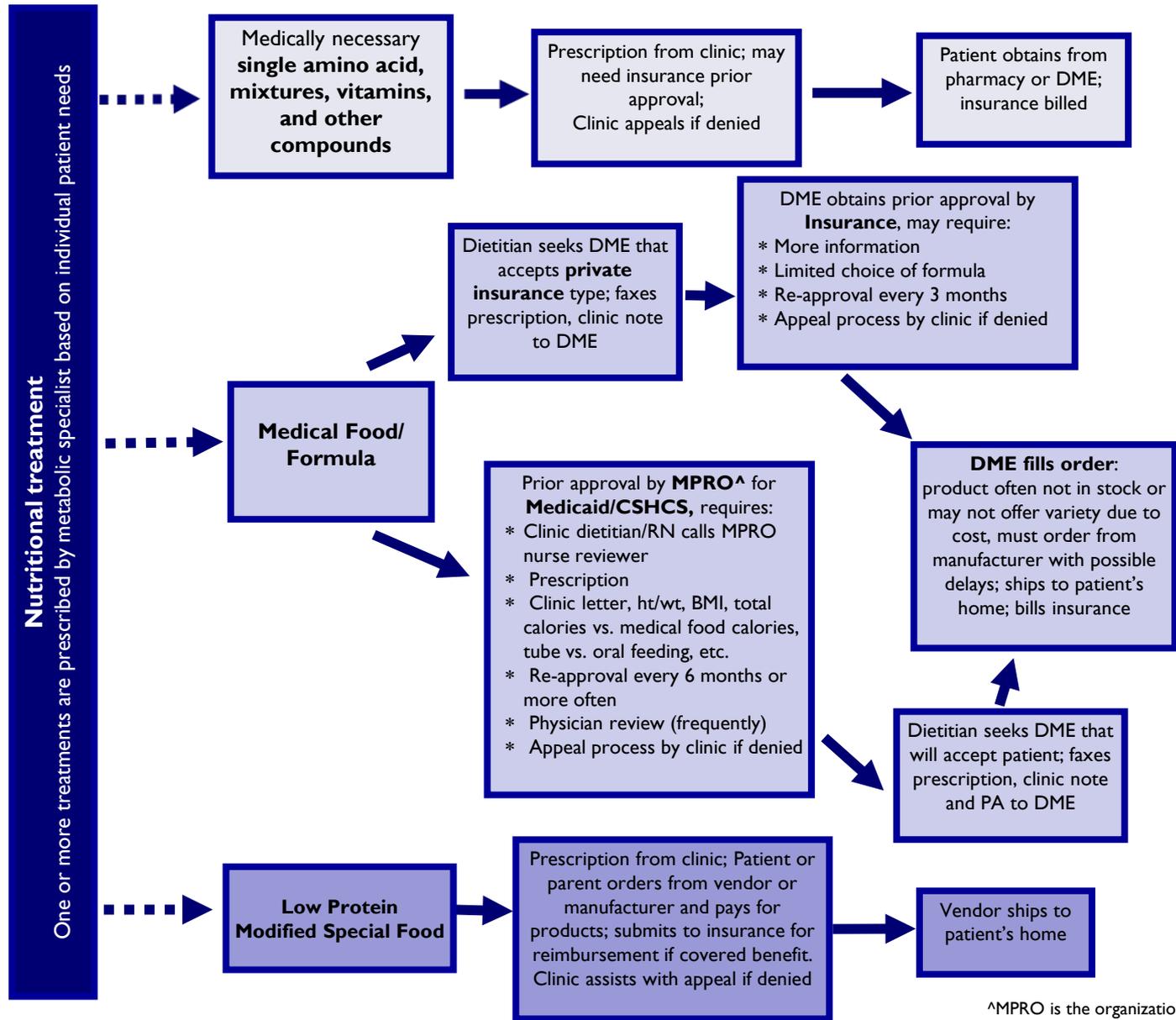
medical food

- ◆ Main alternative to natural protein
- ◆ Infant formula: substitute milk formula based on the composition of regular milk but lacking the toxic ingredients
- ◆ Alternative protein products: solid and powder forms of critical nutrients, amino acids and protein free beverages that are more acceptable to older children, adolescents and adults

low protein modified special food

- ◆ Energy source important for a balanced diet; used in conjunction with medical foods to prevent metabolic decompensation
- ◆ Low protein substitute products designed to be as similar as possible to the “normal” counterparts but with minimal protein (eg baking mixes, pasta, sauces, etc)
- ◆ Important dietary component to increase patient acceptance and compliance
- ◆ Does not include foods naturally low in protein

Nutritional Treatment: Access & Billing Process



^MPRO is the organization contracted to provide prior authorizations for Medicaid & CSHCS

Work Group Results

Members suggested more than 40 strategies which were grouped into 7 overarching themes that represent the key components of Michigan's approach to assuring lifelong access to nutritional treatments.

- ✓ A Coordinated Metabolic Treatment Program
- ✓ Family Education and Advocacy
- ✓ Maximum Use of Third Party Insurance Benefits for Medical Foods and Other Nutritional Treatments
- ✓ Increased Access to Low Protein Modified Foods
- ✓ A Safety Net for People with No Available Coverage
- ✓ Coordination with State and Federal Supplemental Food Programs
- ✓ Possible Legislation, if needed

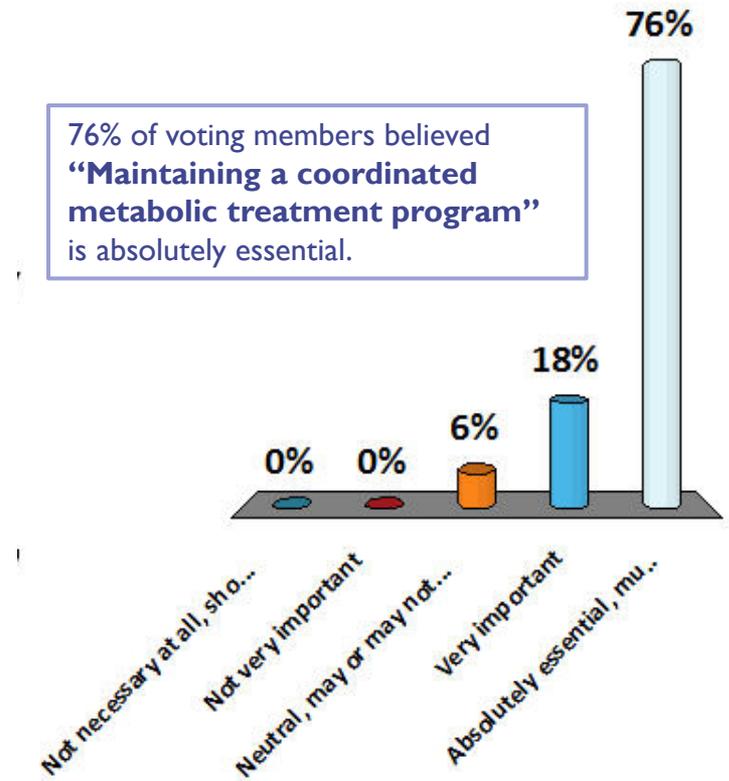
Prioritization Process

All work group members were asked to rank the importance of suggested strategies for each component on a worksheet.

Strategies for Component #1: A Coordinated Metabolic Treatment Program		Rank importance of each strategy on scale of 1-5
A	Maintain a comprehensive metabolic disease treatment program supported by MDCH to assure qualified clinic personnel are available to provide appropriate diagnostic and follow-up services for all patients with inborn errors of metabolism	
B	Develop policies that strive to minimize disruption of current system for providing medical formula/food shipped directly to the patient's home based on metabolic dietitian and physician recommendations	
C	Establish a centralized Durable Medical Equipment Supplier (DME) as a single source supplier for medical foods	
D	Establish a centralized pharmacy as a single source supplier for medically necessary single amino acids, amino acid mixtures and vitamins	
Other		

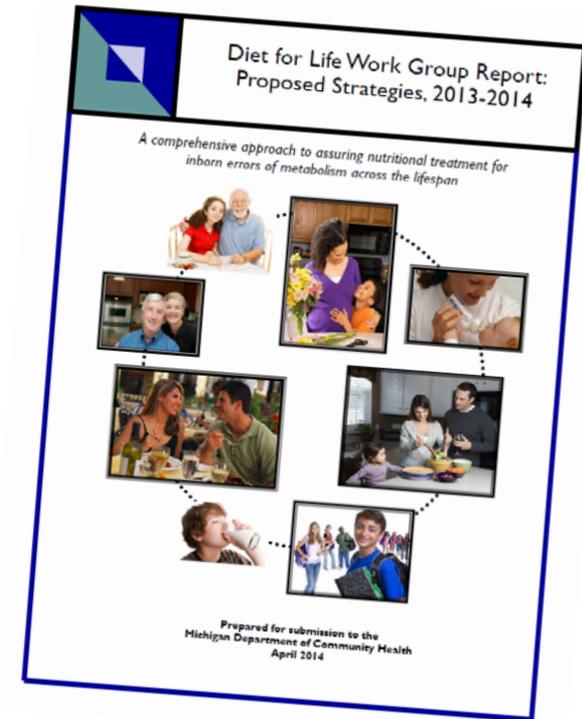
Prioritization Process

- At the final meeting, work group members voted on the importance of each of the 7 core components using audience response clickers
- Strategy work sheets tallied
- Members invited to submit any other ideas that may have been missed



Outcomes and Next Steps

- Prepared a Diet for Life summary report describing issues, why Michigan needs a change, the work group process and identified components/strategies
 - Sent to work group members for review and comment
 - Submitted to directors of the MDCH Public Health and Medical Services Administrations
- Developed webpage for work group materials and Diet for Life resources at www.michigan.gov/IEMtreatment
- Used findings as basis for continued dialogue with internal partners in working toward implementation of identified strategies
- Established communication with families and recognition of need for their continued involvement as any changes are implemented
 - Volunteers are currently being recruited for a new work group to test third party billing and collect data on insurance coverage and gaps



Conclusion

The Diet for Life Work Group process provided:

- A forum for bringing together family members, public health/Medicaid staff and clinical experts to explore the complexities of treating inborn errors of metabolism
- A greater understanding of the barriers faced by families and providers in maintaining dietary compliance and procuring products for nutritional treatment
- Awareness of fiscal constraints and need to identify sustainable funding sources
- Greater awareness of the importance of continued family involvement as strategies are pursued
- Increased visibility of issues at top levels of administration

“...my formula is my medicine. I need it... It is the single most important thing to me...”

- a teenager with PKU

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