

DIET FOR LIFE WORK GROUP

Rationale, Objectives and Process

October 15, 2013

- ### Overview of day
- ▶ Develop common understanding of very complex issues
 - Why we are here
 - Nature of disorders
 - Best practices in treatment
 - ▶ Establish common definition for treatment modalities for use by work group
 - ▶ Describe work group objectives, timeline and next steps

History

48 YEARS...

- ▶ Newborn screening for PKU mandated in 1965
- ▶ 1987 amended to have tests performed by the department

SENATE BILL No. 162 of 1987
 Sec. 5431. (1) Beginning July 1, 1987, a health professional in charge of the care of a newborn infant, or if none, the health professional in charge of the birth of an infant shall administer or cause to be administered to the infant a test for **phenylketonuria, galactosemia, hypothyroidism, maple syrup urine disease, biotinidase deficiency, sickle cell anemia, and other treatable but otherwise handicapping conditions** as designated by the department and report the results of a positive test to the infant's parents, guardian, or person in loco parentis. **The test shall be performed by the department.**
 (2) If the department performs a test required under subsection (1), the **department may charge a fee for the test** of not more than \$18.00.

452 Individuals with Metabolic Disorders Requiring Formula Detected by Michigan NBS, 1965–2012

Disorder	Added	Detected	Detection Rate
2MBG	2005	6	1:158,320
3MCC	2005	12	1:79,160
ARG	2005	1	1:949,922
ASA	2004	4	1:269,374
MMA	2005	14	1:67,852
CIT	2004	11	1:97,954
GA	2005	10	1:94,992
HCU	2004	4	1:269,374
IBG	2005	8	1:118,740
IVA	2005	2	1:474,961
LCHAD	2005	2	1:474,961
PA	2005	4	1:237,481
TFP	2005	0	-
TYR	2005	0	-
VLCAD	2005	14	1:67,852
PKU (diet treated)	1965	346	1:19,259
MSUD	1987	14	1:244,956

- ### Department funding for metabolic formula through clinics
- ▶ 1979–1983: federal grants and CSHCS
 - ▶ 1983: CSHCS and WIC
 - ▶ 1987: WIC, CSHCS and NBS
 - ▶ 1994: cost of “self-pay” children on formula was more than NBS fee so CSHCS contribution increased
 - ▶ 2009: CSHCS, NBS

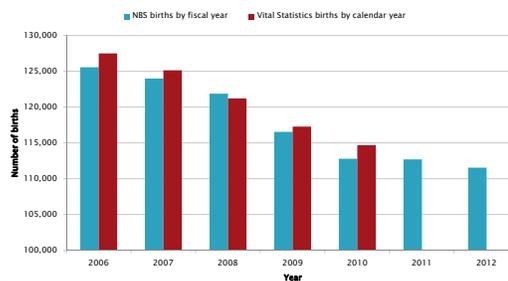
- ### NBS Fee Structure
- ▶ All state NBS laboratory and program costs supported by a fee for NBS card
 - ▶ Increases based on addition of new tests and Detroit Consumer Price Index
 - ▶ Historically fees were sufficient to cover costs with operating carry forward
 - ▶ 2012: spending exceeded revenue

Factors contributing to budget deficit

- ▶ Declining Michigan birth rate
- ▶ Increased costs for state and medical management centers personnel
- ▶ Increased costs for laboratory assays and equipment
- ▶ Increased need for metabolic formula
 - Diet for life
 - More disorders

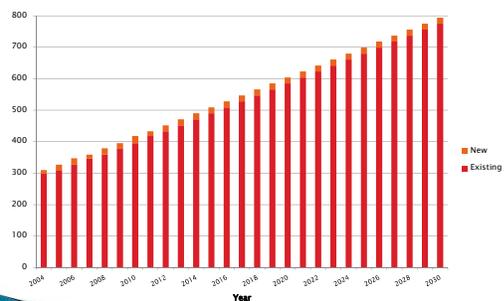
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Declining Birth Rate



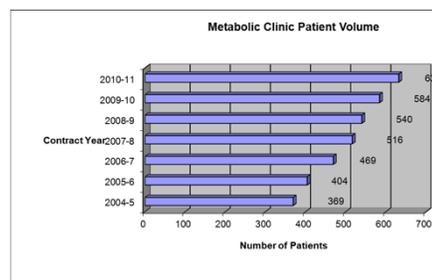
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Projected Number of Patients Requiring Diet for Life Treatment, Michigan, 2004–2030



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Example of Increased Patient Volume: CHM Metabolic Clinic Patients



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Adapted Table 4: Average annual wholesale costs for medical foods with protein in 2010 for select newborn screened disorders. Camp et al. / Molecular Genetics and Metabolism (2012)

Age (yrs)	Protein	PKU	MSD	GA 1	Tyr-1	Average
<1	10g	\$1,248	\$1,766	\$1,970	\$1,963	\$1,817
1-3	13g	\$1,806	\$2,551	\$2,845	\$2,836	\$2,520
4-8	19g	\$2,643	\$3,728	\$3,054	\$3,730	\$3,456
9-13	34g	\$4,829	\$6,185	\$6,488	\$7,111	\$6,249
Males 14-18	52g	\$7,386	\$9,459	\$9,922	\$10,876	\$9,551
Females 14+	46g	\$6,534	\$8,368	\$8,777	\$9,621	\$8,530
Males 19+	60g	\$8,522	\$10,915	\$11,449	\$12,549	\$11,021
Pregnant females	60g	\$8,522	\$10,915	\$11,449	\$12,549	\$11,021

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Live birth outcomes for women born 1965–1992 with PKU, Michigan

- ▶ Women with PKU need to be on diet prior to becoming pregnant to prevent *in utero* exposure
- ▶ More than 1 in 5 births to Michigan mothers with PKU had microcephaly (22%)

Source: Kleyn, et al. Phenylketonuria in Michigan. Michigan Newborn Screening Follow-Up Brief. Vol. 2, Nov. 2010

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Change in Need

1987

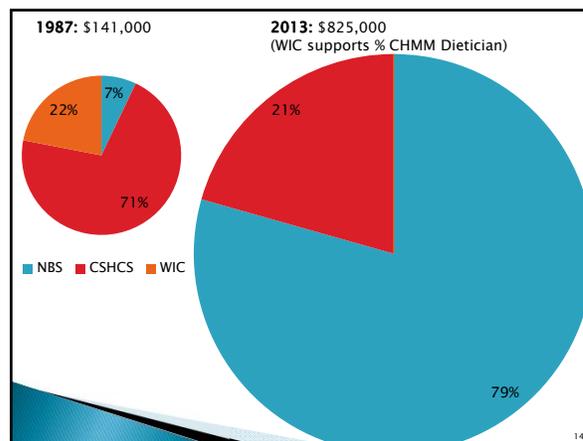
- ▶ 3 metabolic disorders
- ▶ Treatment: early life

2013

- ▶ At least 16 disorders
- ▶ Treatment: Diet for life

- More people
- More years
- Increasing demands

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Adapted Table 5. Costs of selected foods modified to be low in protein and their regular counterparts.
Camp et al. / Molecular Genetics and Metabolism 2012.

Regular food option	Cost/100g	Low-protein version	Cost/100g
Spaghetti	\$0.37	Aproten low protein pasta	\$2.20
Flour	\$0.17	Wel-plan baking mix	\$1.29
Bisquick	\$0.31	Taste connections low protein baking mix	\$0.58
Crackers	\$0.64	Loprofin crackers	\$1.94
Tortillas	\$0.40	Low-pro tortillas	\$2.04
Peanut butter	\$0.70	Low-pro peanut spread	\$1.94

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Michigan today....

- ▶ Increasing need for treatment
- ▶ Funding model in structural deficit
- ▶ No state mandated coverage for dietary treatment for inborn errors of metabolism
- ▶ Funding model has to be adjusted
- ▶ Department committed to ensuring access to treatment

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Work thus far

- ▶ Forecasted need
- ▶ Identified some problems and barriers
 - Access importance to maintaining treatment
 - Lack of information on existing insurance policies
 - Availability of DME suppliers
 - Additional food costs to families
- ▶ Explored potential and partial solutions among NBS, Medicaid, CSHCS, WIC programs
- ▶ Gathered information from other states

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Work Group Objectives

- ▶ To identify and understand existing clinical best practice guidelines for lifelong dietary treatment of individuals with inborn errors of metabolism detected through newborn screening
- ▶ To describe facilitators and barriers to dietary compliance in order to assure the best possible outcomes
- ▶ To recommend feasible solutions that enable patients of all ages to receive appropriate metabolic formulas in light of Newborn Screening Program budgetary constraints
- ▶ To suggest long term strategies for assisting families in obtaining insurance coverage and reimbursement for metabolic foods

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Process

- ▶ Bring families, key programs and other stakeholders together for discussion and brainstorming
- ▶ Neutral facilitators
- ▶ Research, information gathering, fact checking between meetings
- ▶ Work Group recommendations transmitted to deputy directors of MDCH Public Health and Medical Services Administrations
 - Recommendations may be beyond MDCH control

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Timeline

- ▶ Meeting #1 (today)
 - Objectives 1 & 2: common understanding of issues; current guidelines; barriers/facilitators; complexity
- ▶ Meeting #2
 - Objective 3: possible solutions for diet for life coverage
 - A: For children
 - B: For adults
- ▶ Meeting #3
 - Objective 3: consensus recommendations on formula
 - Objective 4: long term strategies for coverage of foods
- ▶ Additional meetings- if needed

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Possible Meeting Dates

(Doodle Poll to follow)

Meeting #2

Date	Children	Adults
Mon 11/18	9 am - 12 pm	1 - 4 pm *
Fri 11/22	9 am - 12 pm	1 - 4 pm
Tues 11/26	9 am - 12 pm	1 - 4 pm
Mon 12/2	1 - 4 pm	9 am - 12 pm
Tues 12/3	9 am - 12 pm	1 - 4 pm*

Meeting #3

Date	Time
Thurs 12/19	9 am - 12 pm
Thurs 12/19	1 - 4 pm
Multiple Jan dates	

* MI State Library Auditorium 21