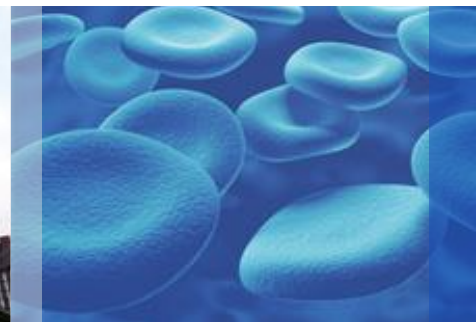
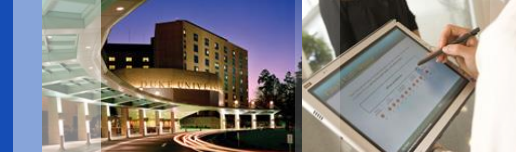


Cost Analysis Workgroup: Update

Alex R. Kemper, MD, MPH, MS

May 10, 2016





COST ANALYSIS WORKGROUP (CAWG)

Members (by Stakeholder Group)

CRW

Alex Kemper, MD (CHAIR)
Duke University/DCRI

K.K. Lam, PhD
Duke University

Jeffrey P. Brosco MD PhD
University of Miami, CMS South Region - FL Title V

Lisa A. Prosser, Ph.D.
Univ of Michigan Medical School, School of PH

Scott Grosse, PhD
Centers for Disease Control and Prevention

CONSUMERS

Annamarie Saarinen, M.S.
Newborn Foundation

NBS/STATE PUBLIC HEALTH

Mei W. Baker, MD, FACMG
Newborn Screening Laboratory/Univ of Wisconsin

Marci Sontag, PhD
NewSTEPS/ 360, CO School of Public Health

John D. Thompson, PhD
Office of Newborn Screening/WA State DOH

Sylvia Mann, M.S., C.G.C.
HI DOH, Western St Gen Services Collaborative

HRSA

Joan A. Scott, M.S., C.G.C.
Genetic Services Branch, MCHB

Debi Sarkar, M.P.H.
Genetic Services Branch, MCHB



Charge

- To consider methods to assess the “cost of newborn screening expansion” as required by the newly reauthorized legislation
- Deliverable: Report with recommendation to the ACHDNC on how to incorporate cost assessment into the decision-making process



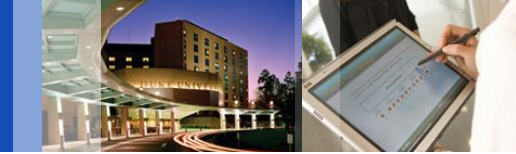
Cost Assessment (*Original*) Plan – Recap

- **Objective:** Budget Impact on States
- **Cost Data Sources**
 - *States, other programs/research if needed*
 - *Vendors*
- **Cost Data Targets**
 - *Primary (critical, costs incurred by state to expand NBS)*
 - Screening, laboratory costs, through STFU
 - Two year horizon (Yrs 1 and 2), annualized, costs per infant, total annually/100,000 newborns
 - *Secondary (per availability of info, time, & resources)*
 - Treatment, long-term follow up care and monitoring
- **Pretest the draft approach to help refine it**



Single most consistent Theme = *Costs of NBS Vary Greatly across Many Dimensions*

- State size, Birth rate, locale
- Existing laboratory facilities and personnel
- Structure of NBS costs and funding, lab facilities, collaborators, contractors, and the state PH department
- Cost arrangements within and across states, requirements and responsibilities of NBS program
- Purchases vs. Leasing/rental agreements
- Context at time of purchase/vendor negotiations
 - *And so on, and so on.....*



Cost Assessment Pretest - Aims

- To assess feasibility and effectiveness of proposed cost assessment methods
 - *Target conditions: MPS I and Pompe NBS*
 - LSD single- or multiplex
 - Currently use MSMS or DMF (FDA approval pending)
- NOT estimating costs for every variation
- As best as possible, gather informed estimates and ranges that can be useful for all states
 - *Describe the assumptions and complexities*
 - *inform the ACHDNC in understanding NBS expansion costs*
 - *inform other states that are considering expansion*



Key Questions for Pretest

- **How to gather state cost estimates with least burden**
- **How to ‘standardize’ highly variable state costs into a single point estimate and range that can reflect NBS expansion costs**
 - *No standard approach to estimating*
 - *Confidential/protected vendor pricing, estimates &*
 - *Estimates specific to states*
 - *Cost components and categories vary*

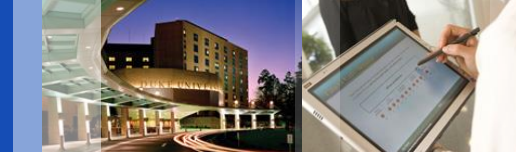


Pretesting the Draft Approach

- Information Gathering – States
- Contacted and received info from MO, IL

States Screening for Conditions Recommended for RUSP						
Condition	Date of AC Vote	MO	NY	IL	WI	KY
POMPE	5/13	Y	Y	Y	After state review (Pilot)	Y
MPS I	2/15	Y	(Selective)	Y	---	Y

Note: as reported in NewSTEPS, updated Apr 2016



State Public Health Lab Costs

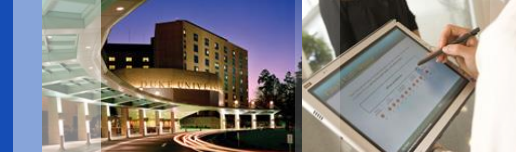
PRIMARY COST CATEGORIES – *Originally Proposed*

Laboratory

- Equipment and maintenance
- Supplies (disposables, reagents)
- Installation
- Space and utilities
- Staffing
- Laboratory information systems

Staff Development & Services

- Training, education
- Outreach and referral for confirmatory testing & STFU



PRIMARY COSTS for NBS Cost Assessment

– *Refined (v1.1)*

State PH Lab Cost Categories	Description
EQUIPMENT	Direct purchase or lease/RRA
CONSUMABLES	supplies, reagents
OTHER LAB EXPENSES	not already included; maintenance, repairs, installation, LIMS
LABOR – LAB & FU	FTES, by position, salary + fringe
CONFIRMATORY TESTING REFERRALS	Contracts with genetic referral center(s)
OVERHEAD/(INDIRECT COSTS	space, building, utilities



NBS Cost Estimates to Add 1 Condition

Newborns screened annually: _____ = X

Platform (*MSMS, DMF, POC, other*) _____

NBS LABORATORY - DIRECT COSTS

EQUIPMENT

Reagent Rental Agreement (RRA)

Direct equipment purchase:

Service agreement (annual cost)

CONSUMABLES

Disposable supplies (pipettes, etc.)

Reagents

OTHER LAB EXPENSES

LABOR - TOTAL FTES (x)

Lab Personnel

FTEs

SAL

FB (36.4%)

Follow-Up

CONFIRMATORY TESTING REFERRALS

Contract costs with genetic referral center(s)

OVERHEAD /INDIRECT COSTS

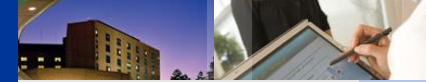
TOTAL Annual Cost for State

Total Annual Cost for 1 of multi-plex

Est Cost per infant for 1 of -plex

???

Current NBS Cost Template



				STATE A	STATE B
Newborns screened annually:				100,000	180,000
Platform (MSMS, DMF, POC, other)				DMF	MSMS w/ UPLC
NBS LABORATORY - DIRECT COSTS					
EQUIPMENT					
Reagent Rental Agreement (RRA)	[A: 4-plex; B: 6-plex]			\$ 400,000	\$ 1,300,000
Direct equipment purchase:					
Service agreement (annual cost)					
CONSUMABLES				\$ -	\$ 200,000
Disposable supplies (pipettes, etc.)					
Reagents					
OTHER LAB EXPENSES				\$ -	\$ 30,000
LABOR - TOTAL FTES (x)				\$ -	\$ 461,000
<u>Lab Personnel</u>	<u>FTEs</u>	<u>SAL</u>	<u>FB (36.4%)</u>	\$ 124,000	
Supervisor	0.75				
Lab Tech	0.75				
<u>Follow-Up</u>				\$ 36,000	???
PH Nurse	0.25				
SR PH Nurse	0.25				
CONFIRMATORY TESTING REFERRALS				\$ 250,000	???
Contract costs with genetic referral center(s)					
OVERHEAD /INDIRECT COSTS				\$??? -	\$ 250,000
TOTAL Annual Cost for State				\$ 810,000	\$ 2,241,000
Total Annual Cost for 1 of multi-plex				\$ 202,500	\$ 373,500

Preliminary Pretest Results



Newborns screened annually:
Platform (*MSMS, DMF, POC, other*)

STATE A

STATE B

100,000
DMF

180,000
MSMS w/ UPLC

NBS LABORATORY - DIRECT COSTS

EQUIPMENT

\$ 400,000

Reagent Rental Agreement (RRA) [A: 4-plex; B: 6-plex]

\$ 1,300,000

CONSUMABLES

\$ -

\$ 200,000

Disposable supplies (pipettes, etc.)

Reagents

OTHER LAB EXPENSES

\$ -

\$ 30,000

LABOR - TOTAL FTES (x)

\$ -

\$ 461,000

Lab Personnel

FTEs

SAL

FB (36.4%)

\$ 124,000

Supervisor

0.75

Lab Tech

0.75

Follow-Up

\$ 36,000

???

PH Nurse

0.25

SR PH Nurse

0.25

CONFIRMATORY TESTING REFERRALS

\$ 250,000

???

Contract costs with genetic referral center(s)

OVERHEAD /INDIRECT COSTS

\$??? -

\$ 250,000

TOTAL Annual Cost for State

\$ 810,000

\$ 2,241,000

Total Annual Cost for 1 of multi-plex

\$ 202,500

\$ 373,500

Est Cost per infant for 1 condition (of Xplex)

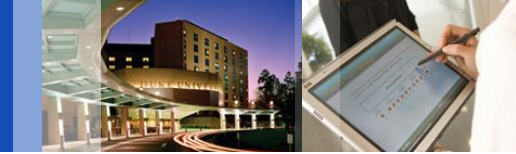
\$ 2.03

\$ 2.08

Est total annual cost to screen 100,00 infants

\$ 202,500

\$ 208,000



Next Steps

- Finish Pretest
 - *Follow up with states for pretest, direct purchase if possible*
 - *Interview, contact vendors*
 - *Synthesize information, add cost detail and assumptions*
- Use pretest experience to revise cost assessment, gather input from CAWG, CRW, other stakeholders
- Identify secondary cost issues to consider (treatment, LT care)
- Present CAWG/Cost Assessment final report and recommendations to AC in Aug 2016
- Incorporate cost assessment into Condition Review procedures and timeline



Bigger Questions Looming...

- What are the minimum requirements for a pilot study to adequately inform screening implementation and costs?
- What are the minimum cost estimate inputs needed for a cost assessment? From how many states?
- What is the likely timing of pilot and cost info, and how will that the overall nomination and review process?
- How useful will the cost estimates be (with limited time and resources)?
 - *For states?*
 - *For the Advisory Committee?*
- How will the Advisory Committee use the cost estimates in decision-making?



Thank You!

Questions?