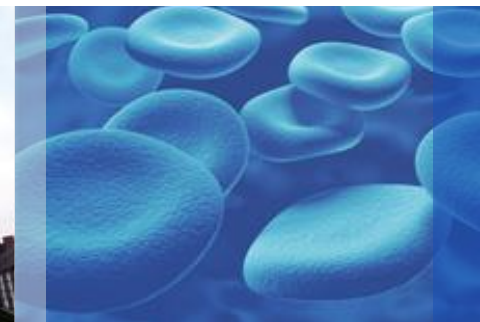


Cost Assessment Methods Update

Alex R. Kemper, MD, MPH, MS

August 26, 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



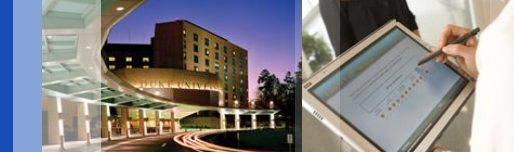
Charge

- To consider methods to assess the “cost of newborn screening expansion” as required by the newly reauthorized legislation



Cost Assessment Pretest – Aims (Recap)

- To assess feasibility of cost assessment methods
 - *Target conditions: MPS I and Pompe disease*
 - Multiple platforms and can be multiplexed with other screening tests
- NOT estimating costs for each possible screening strategy
- Gather informed estimates and ranges that can be useful for all states and the ACHDNC, minimizing burden on respondents



PRIMARY COSTS for NBS Cost Assessment

State Public Health Lab Cost Categories	Description	
EQUIPMENT	Direct purchase or lease	Reagent Rental Agreement (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) – Only in some states	
OVERHEAD (INDIRECT COSTS)	Space/building, utilities	



NBS Cost Data Collection Template

Specimens annually: _____ = X

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

NBS LABORATORY - DIRECT COSTS

EQUIPMENT

Option: Reagent Rental Agreement (RRA)

Option: Direct equipment purchase

Expected Life

Service agreement if not included

CONSUMABLES

Disposable supplies (pipettes, etc.)

Reagents

OTHER LAB EXPENSES

LABOR - TOTAL FTES (x)

Lab Personnel

FTEs

SAL

FB

Follow-Up

CONFIRMATORY TESTING REFERRALS

Contract costs with genetic referral center(s)

OVERHEAD /INDIRECT COSTS

Preliminary Pretest Results



NBS LABORATORY - DIRECT COSTS

Specimens tested annually:

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

	STATE A	STATE B
	100,000	180,000
	DMF	MSMS w/ UPLC
Reagent Rental Agreement (RRA)	\$ 400,000	\$ 1,300,000
<i>Number of conditions tested using platform</i>	4	6
CONSUMABLES	\$ N/A	\$ 200,000
OTHER LAB EXPENSES	\$ -	\$ 30,000
LABOR	\$ -	\$ 461,000
<u>Lab Personnel</u> <u>FTEs</u> <u>SAL</u> <u>FB (36.4%)</u>	\$ 167,560	
OVERHEAD /INDIRECT COSTS	\$ Not reported	\$ 250,000
Total Laboratory	\$ 560,000	\$ 2,241,000
Cost/Specimen and Cost/Specimen/Condition	\$5.60, \$1.40	\$12.45, \$2.08

Cost Pretest -- Added States



NBS LABORATORY - DIRECT COSTS

Specimens tested annually:

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

Reagent Rental Agreement (RRA)

Equipment purchase – annual cost (assume 8 years)

Number of conditions tested using platform

CONSUMABLES

OTHER LAB EXPENSES

LABOR

Lab Personnel

FTEs

SAL

FB (36.4%)

Supervisor

0.75

Lab Tech

0.75

OVERHEAD /INDIRECT COSTS

Total Laboratory

Cost/Specimen and Cost/Specimen/Condition

	STATE C	STATE D
	80,000	98,000
	MSMS w/ UPLC	MSMS w/ UPLC
	\$ 286,517	\$ 1,800,000
		\$ 360,000
	1	5
	\$ N/A	\$ 780,000
	\$ -	\$ 150,000
	\$ -	\$ 269,596
	\$ 124,000	
	\$ 177,868	\$ 23,454
	\$ 631,885	\$ 1,433,050
	\$7.90, \$7.90	\$14.63, \$2.44



Pre-test results: Post-analytic costs

- All states incur some sort of follow-up cost
 - *One state reported follow-up costs and costs of confirmatory testing*
- Most state NBS programs do not pay confirmatory testing. However, Medicaid often covers for this testing



Apples to Apples...

...but how many different varieties of apples are there?

- **2,500 varieties** of apples grown in the U.S.
- **7,500 varieties** of apples grown throughout the world.
- 100 varieties of apples grown commercially in the U.S.
- Apples are a great source of the fiber pectin.

-- *U.S. Apple Association and the U.S. Nat'l Agric Statistics Service*





Apples to Apples...

...but how many different varieties of applies are there?

Apple Computer Design Evolution with Base Prices





Assumptions, Cost Drivers, Context

- State annual birth cohort (range ~6,000 - ~500,000)
- Variations in number of specimens per baby (e.g., Texas does two per baby)
- State budget vs. NBS cost structure – who pays for what?
- Timing is Everything
 - **Start-up Year**
 - Purchases vs. Leasing/rental agreements
 - Funding source – fed-funded pilot vs. state-funded start-up
 - Post start-up period ⇒ Screening efficiencies
 - **State Political Context, Advocacy and Appropriations**
- And all the other sources of variation
 - *different screening algorithms, in-house vs. outsource contractor labs, proximity to specialized services, the condition itself*



Additional Challenges in Assessing Costs

- Limited time for collecting data
- NBS programs do not have cost data available for us in the way we need it (but that is not their job)
- Estimates will mostly represent early adopters
- Costs will be higher for states with lower testing volumes
- State NBS laboratories face privacy issues that limit what they can share with us



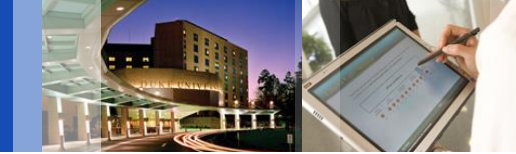
Anticipating Challenges

- If no U.S. state has started screening or planning to screen
 - *Vendors and researchers may be sources but may not be representative of state public health NBS program*
- Changes in vendor pricing, FDA-approvals, new screening technology that are ongoing



What Might the Cost Assessment Provide?

- If there is at least 1 state that has started planning for or screening for the condition, and is willing to provide cost information
 - *Overall estimate of NBS start-up screening laboratory costs and other estimates based on the unique characteristics of the state NBS program*



Cost Assessment Plan

- **Objective:** Budget Impact on State NBS program
- **Cost Data Sources**
 - *Primary: States*
 - *Secondary: other programs/research, vendors if needed*
- **Cost Estimates**
 - *Cost per specimen to add the condition under consideration*
- **Caveat:** The approach reflects traditional dried-blood spot screening in a centralized lab, not point-of-care newborn screening



Cost Assessment Plan

- **Narrative Description**

- *Requirements for screening*
- *Assumptions for cost assessment*
- *Descriptions of sources and methods of cost estimates*



Next Steps

- Finalize approach
- Submit draft report and methods recommendations to AC (Oct 2016)
- Incorporate cost assessment into Condition Review procedures and timeline



Thank You!

Questions?