Engaging Diverse Communities to Inform NBS and Biobanking Policies

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### ACKNOWLEDGEMENTS

#### CONSIDER PROJECT

**UCSF**

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#### PROJECT TEAM

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AHRQ R21 HS023547 (CONSIDER)
A nexus of issues facing the CDPH

California Biobank Program (samples dating back to 1980s)

• Privacy vs. Access; Ownership
• Public concerns leading to sample destruction in other states

Newborn Screening Program and Biobank Program

• The Role of Genomic Sequencing in Newborn Screening
• Requirement of consent for research with dried blood spots

Need for community engagement
Purpose

CONSIDER PROJECT

To generate informed, deliberative, community-based recommendations to inform critical and time urgent policy decisions.
Why engage communities?

• Complex, technical, and value-laden decisions
• Shifting paradigms
  – Technology driven decision-making
• Need to identify commonalities/disagreements
• Policy decision-making (as opposed to individual)
• **Create trustworthy and transparent structures**
Why Deliberative Community Engagement?

• Move past the limits of individual informed consent/choice as the sole strategy for implementation
• Debate/discuss tradeoffs
• Set meaningful “defaults” in the policy arena
• Consider impact of “false positive” results
• Address broad public concerns such as privacy vs. research benefit
Deliberative Community Engagement Method
Kristin L. Carman, Coretta Mallery, Maureen Maurer, Grace Wang, Steve Garfinkel, et al.; Effectiveness of public deliberation methods for gathering input on issues in healthcare: Results from a randomized trial. Social Science & Medicine, Volume 133, 2015, 11 - 20
Participants (Deliberants)

• 33 Participants selected to represent the diversity of the California population

• Simultaneous interpretation allowed the participation of mono-lingual Spanish speakers
Provide Information and Answer Questions

• Received “briefing book” ahead of event

• Organized around five major issues
  1) Permission for research moving forward
  2) Ensure that permission does not affect NBS
  3) Use of existing samples
  4) Planning for the future of NBS programs (NGS)
  5) Community involvement in NBS and Biobank Governance
Developing a Screening Method for SCID

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Large and Small Group Discussion

• Over four full days (two weekends)

• Professional facilitation
Recommendations
Not Forced Consensus

• Arrive at recommendations with broad support
• Highlight areas of persistent disagreement
Recommendations

Issue 2: How to ask for permission without damaging the public health goals of NBS

• 2A. The NBS program should remain mandatory.
• 2B. Clearly separate the activities of i) the NBS Program and, ii) asking permission for the biobank program.
Recommendations

**Issue 3: Appropriate use of existing biobank samples**

3A. Samples that were collected without permission prior to the new 2015 law should:

- Not be destroyed.
- Not require contact and permission.
- Be the subject of public education to raise awareness.
Nearly universal agreement on many topics

Clearly separate the process of collecting blood for newborn screening from asking permission for the biobank program

Yes

Abstain

No
And...

It is appropriate for existing biobank samples to be used for external research to benefit health and wellness.
But some issues were significantly divided

The CDPH should have a policy allowing return of results for biobanking research
When it came to whole genome screening of newborns

Expanded screening using whole genome sequencing should be a matter of parental choice (with your pediatrician) and not be part of state-mandated newborn screening.
Public funding should be provided for expanded screening using whole genome sequencing that is not mandatory and is a matter of parental choice.
Balancing Consent and Governance

Consent model

Governance

Entrustment model

* Copyright 2015 Based on Steven Joffe
On Community Governance

**Issue 5. Community Input/Guidance for NBS and Biobank Program**

- Strong recommendation for community representation and governance of the California Biobank Program
- Divided on the role of the community in governance of NBS program
Summary

NBS represents a large public program with little public awareness.

In the context of ethical uncertainty, growing public concern, and pressure for expansion, the need for authentic, community input and governance of NBS programs has reached a critical point.

Joined together, the information generated by this project will aid the development of robust policy recommendations for sequencing in the CA NBS program and provide a model for community governance and input in other NBS programs.
Aim 1a: Conduct in-person Deliberative Community Engagement (DCE)

Aim 1b: Conduct Online Engagement and Polling (n=1000)

Generate Recommendations

Aim 2: Evaluation of DCE
- Pre/Post Survey
- Quality Assessment (Independent Evaluator)
- Transcript analysis

Aim 3: Disseminate recommendations to CDPH and assess policy impact
- Key informant interviews with CDPH policy-makers