

# Banking Newborn Dried Blood Spots for Public Health



Developing a  
Strategic Plan to  
Assess the  
Feasibility, Utility,  
and Practical  
Implementation of  
Establishing a  
National/Multi-state  
Bank of Leftover  
Newborn DBS

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Koger Rhodes Building, Room 4029 AB  
Atlanta, GA



**CDC**

# Newborn Screening Task Force Recommendations-2000

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- AAP / HRSA / CDC/ HHS – call for U.S. agenda
  - Develop policies for unlinked/unlinked residual samples in research/surveillance
  - Organize collaborative efforts to develop minimum standards for storage of residual samples at the state level
  - Consider creating national or multi-state population-based specimen resource for research

# Residual Dried Blood Spot Guidelines-CORN 1996

- Frozen ( $-20^{\circ}\text{C}$ ) or if DNA, refrigerated ( $4^{\circ}\text{C}$ )
- Sealed in bags of low gas permeability containing desiccant and humidity indicator
- Catalogued (identifiable) storage
- Control samples for QA
- All studies require IRB approval
- Released samples should be unlinked; any release of identifiable information requires informed consent

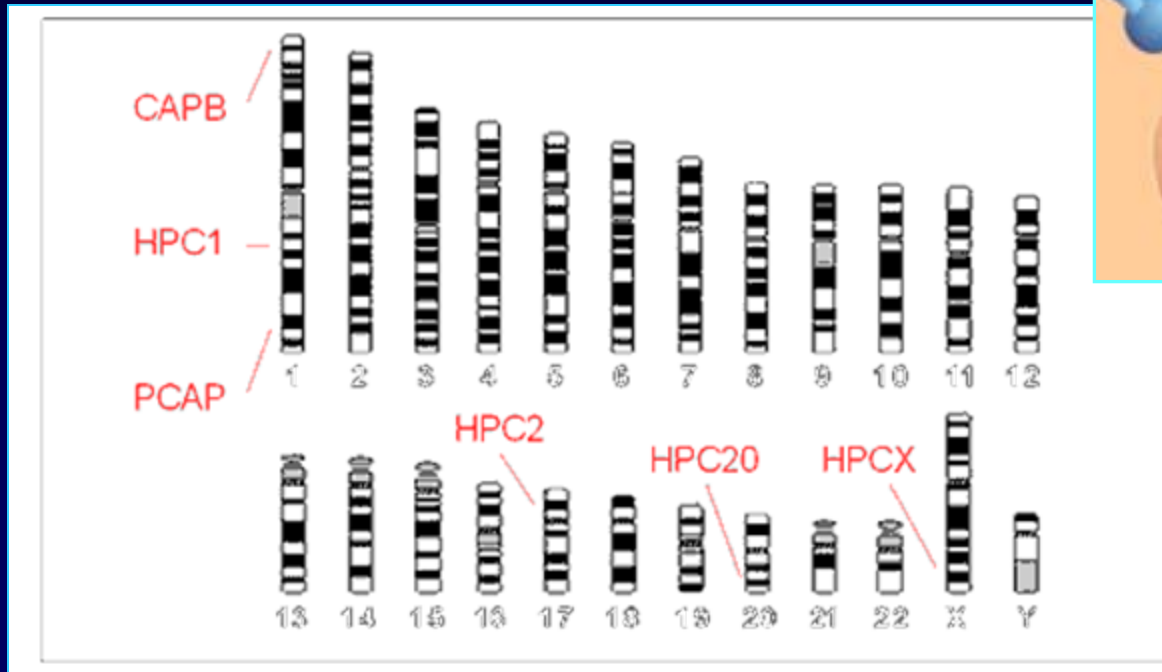
# Potential Value of Banks of Leftover Newborn Dried Blood Spots



- Unique, population-based, representative data
- Prevalence of gene variants of public health importance
- Markers of environmental exposures, infectious disease, etc
- Linkage to outcome data sources or follow-up to assess outcomes
  - Association of gene variants and other potential markers with risk of disease, disability, death
- Collaboration with states



# Directions in Genomics



# Top 10 Public Health Challenges for 21<sup>st</sup> Century

(Koplan and Fleming JAMA 2000)

- Health Care System
- Health Disparities
- Child Development
- Healthspan
- Physical Activity
- Environment
- Emerging Infections
- Mental Health
- Violence

Genetic  
Breakthroughs/  
Technologies



# National Report on Genomics and Health

## Need for population-based data

- Population-based data on gene variants
  - Prevalence of gene variants
  - Association with risk of disease, death
  - Gene-environment and gene-gene interactions
- Genetic test evaluation (validity, utility)
- Development of Public health interventions, e.g., newborn screening
- Currently, minimal population-based data on gene variants to guide genetic screening or interventions



# Objectives of the Meeting

- Outline potential uses of banks for public health
- Assess storage, laboratory, and database technology issues
- Propose multi-state models for the future: methods, formats, access, unlinked, linked
- Review feasibility issues-challenges + barriers
- Update status of storage and use policies of leftover specimens for all 50 states
- Design collaborative, strategic plan for future implementation



# Objectives (continued)

- Gain insight from individual state experiences in developing policies and using state-based spot banks for public health applications
- Explore possibilities of using this resource in broader application for public health
- Explore options within states, between states, and systems



# Uses of Stored Newborn Dried Blood Spot Specimens



- Newborn screening issues
- New technology assessment
- Laboratory quality control
- Public health epidemiologic research
- Others





# Current Examples of Spot Bank Uses Public Health Epidemiologic Research



- Anonymous State Based Banks
  - Prevalence of Gene variants
- Anonymous multi-state
  - HIV seroprevalence in childbearing women
- Linked State Based Banks
  - Gene-environment interaction in etiology of birth defects
- Linked, Prospective Follow-up
  - Increased risk for Type 1 Diabetes





# Uses of Spot Bank

## Future Possibilities and Issues

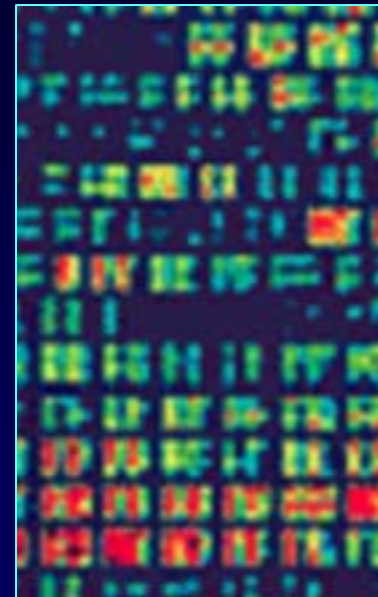


- What are the highest priority uses?
- How should research priorities be set?
- What are new, emerging technologies?
- How should access, collaboration be determined?



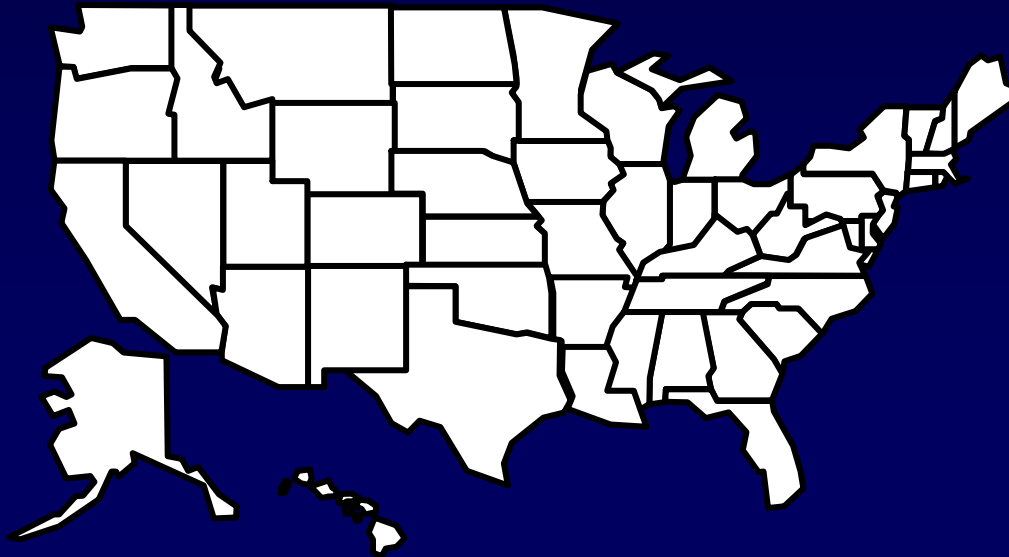
# Technology Issues

- Storage Facilities and Conditions
- Cataloguing and Retrieval
- Minimum data elements
- Data Linkage
- New Lab technologies
- Quality control
- Resources
- Envisioning use: stability of analytes



# Models of Multi-State Banks

- Virtual, multi-site, state-based
- Physical clip to central bank
- Unlinked and Linked



# Challenges

- Resources
- Data sharing issues
- Confidentiality, security, privacy issues
- Ethical, legal, social issues
- IRB
- Informed consent issues
- Maintain primary functions of NBS programs
- HIPPA



# Outcomes of Meeting Strategic Plan for Practical Implementation

- Pilot Studies
- Publish strategic plan
- Update storage + use policies
- Address gaps + feasibility issues
- Input into Nov UCLA meeting
- Larger stakeholders meeting



# Facing the Challenge

