Systems for Action
National Coordinating Center
Systems and Services Research to Build a Culture of Health

Bridging Public Health and Health Care

Improving the Efficiency of Newborn Screening from Collection to Test Results

Research In Progress Webinar

Thursday, June 23, 2016 *12:00-1:00pm ET/ 11:00am -12:00pm CT*

Funded by the Robert Wood Johnson Foundation

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Agenda

Welcome: **Rick Ingram, DrPH,** RWJF *Systems for Action* National Coordinating Center, and Assistant Professor, University of Kentucky College of Public Health

Improving the Efficiency of Newborn Screening from Collection to Test Results

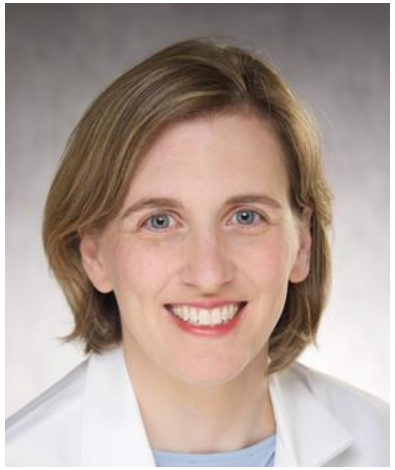
Presenter: **Beth Tarini, MD, MS**, Fred G. Smith Chair in Academic Pediatrics, Associate Professor of General Pediatrics and Adolescent Medicine, U. of Iowa College of Medicine *beth-tarini@uiowa.edu*

Commentary: **Aaron Goldenberg, PhD,** Associate Director, Center for Genetic Research Ethics and Law, Case Western Reserve University School of Medicine *aaron.goldenberg@case.edu* and

Carol Johnson, RN, PCCN, Iowa Newborn Screening Follow Up Coordinator, U. of Iowa Children's Hospital *carol-johnson@uihealthcare.org*

Questions and Discussion

Presenter



Beth Tarini, MD, MS

Fred G. Smith Chair in Academic Pediatrics

Associate Professor and Division Director, General Pediatrics and Adolescent Medicine

University of Iowa Carver College of Medicine

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RWJF Public Health Services and Systems Research

Improving the Efficiency of Newborn Screening from Collection to Test Results

June 23, 2016

Beth A. Tarini, MD, MS
University of Iowa
Department of Pediatrics

Goals Today

- Review Project Background & Objectives
- Discuss Preliminary Results
- Present Next Steps

Project Background & Objectives

Newborn Screening (NBS)

- **What is the goal?**
  - Identify children with inherited disorders shortly after birth and initiate treatment promptly to prevent irreversible damage or death
- **How is it implemented?**
  - It is a complex system
  - Involves multistep process coordinated by each state's public health department
  - Requires coordinated and timely collaboration between clinical and public health entities

Newborn Screening

How does it work?

Baby is born!

12-48 hours after birth

3 tests are done to check your baby's health:

- Hearing screening
- Heart screening
- Blood spot screening

Blood spot screening takes a few days. Your baby's dried blood spots are sent to the Minnesota Department of Health lab for testing.

Hearing screening and **heart screening** take only a few minutes. Ask for your baby's results when the tests are done.

At the lab, blood spots are cut into smaller circles for each of the tests. Your baby is **tested for more than 50 health problems.**

Negative Results: If everything looks ok, the results are sent to your baby's doctor. Ask for your baby's results at the first newborn visit!

Positive Results: If there might be a problem, the lab will call your baby's doctor. Screening can only tell us if a baby might have a health problem. We won't know for sure until the doctor does more tests. Your baby's doctor will talk to you about what needs to happen next.

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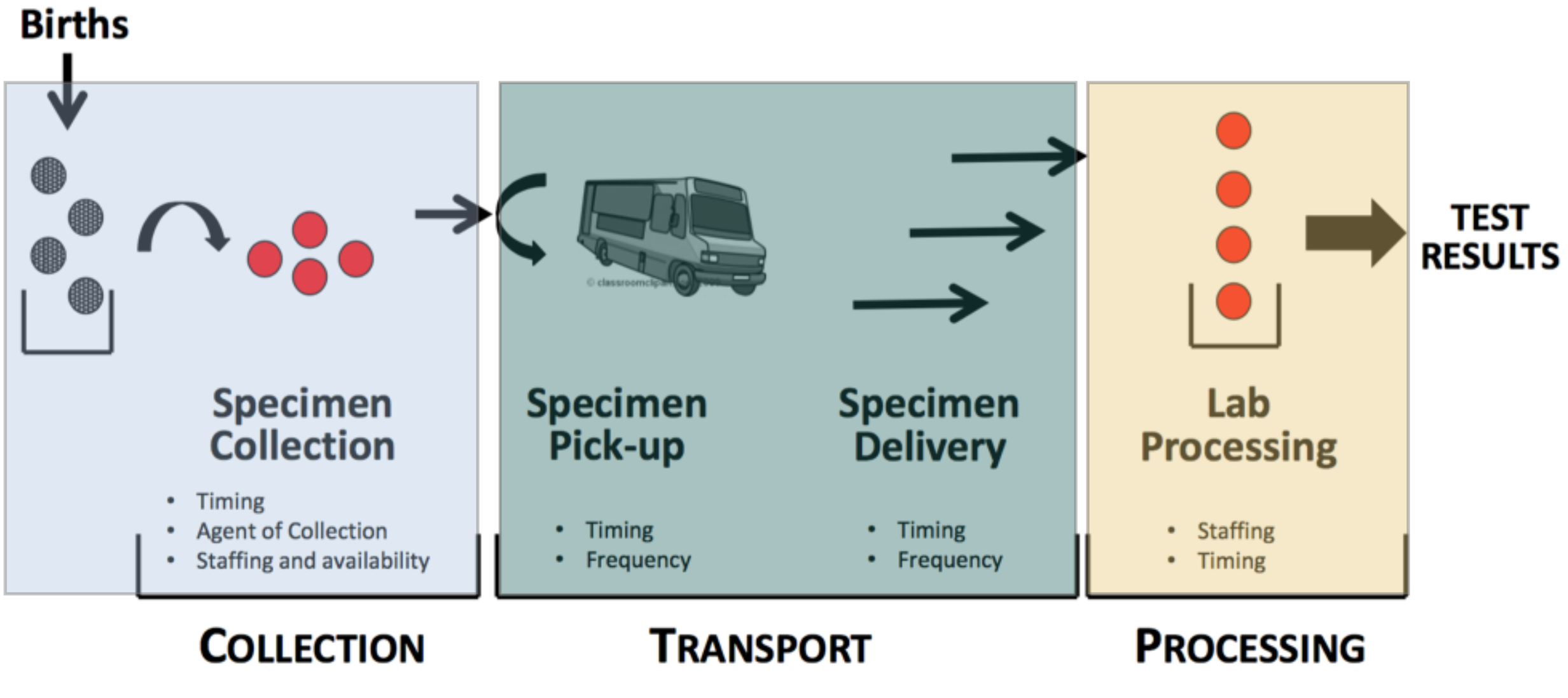
Collection, Transport, Processing



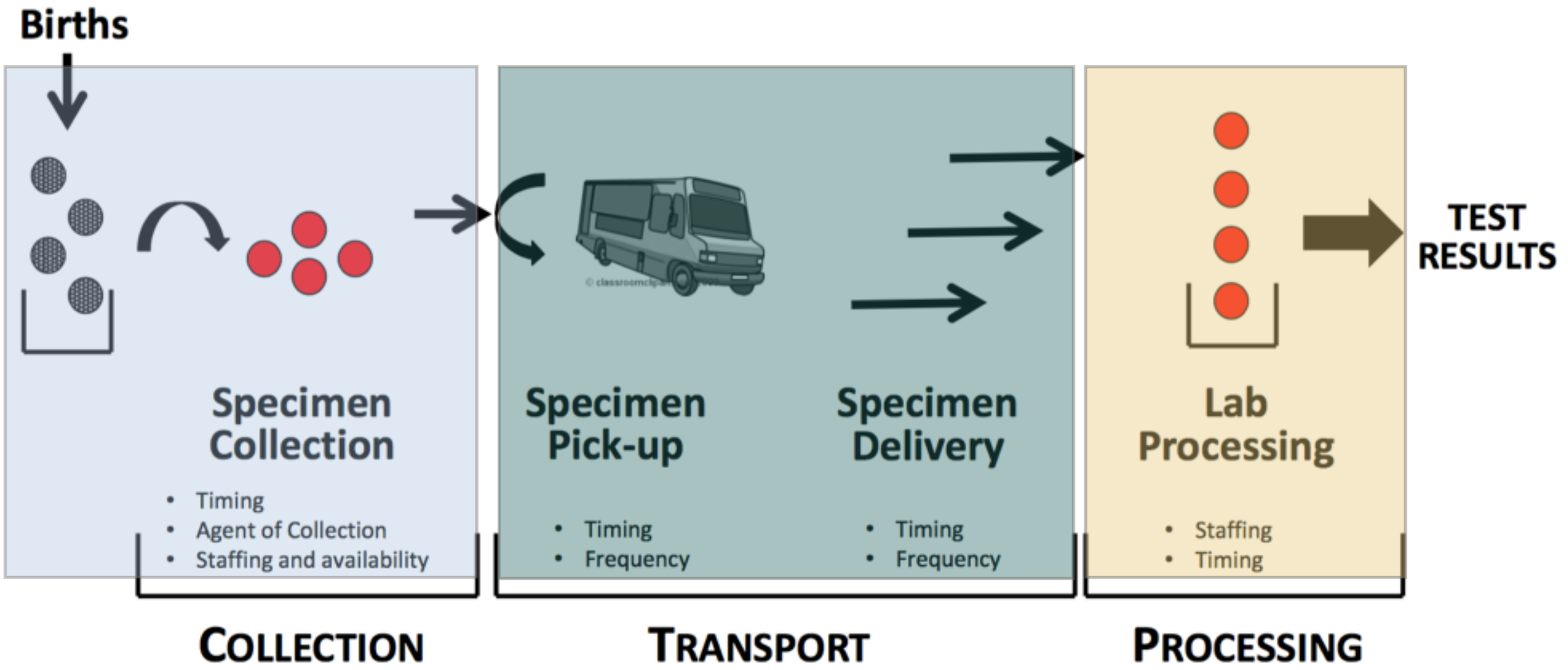
Hospital

Hospital or NBS Program

NBS Program

Collection, Transport, Processing

5-7 days

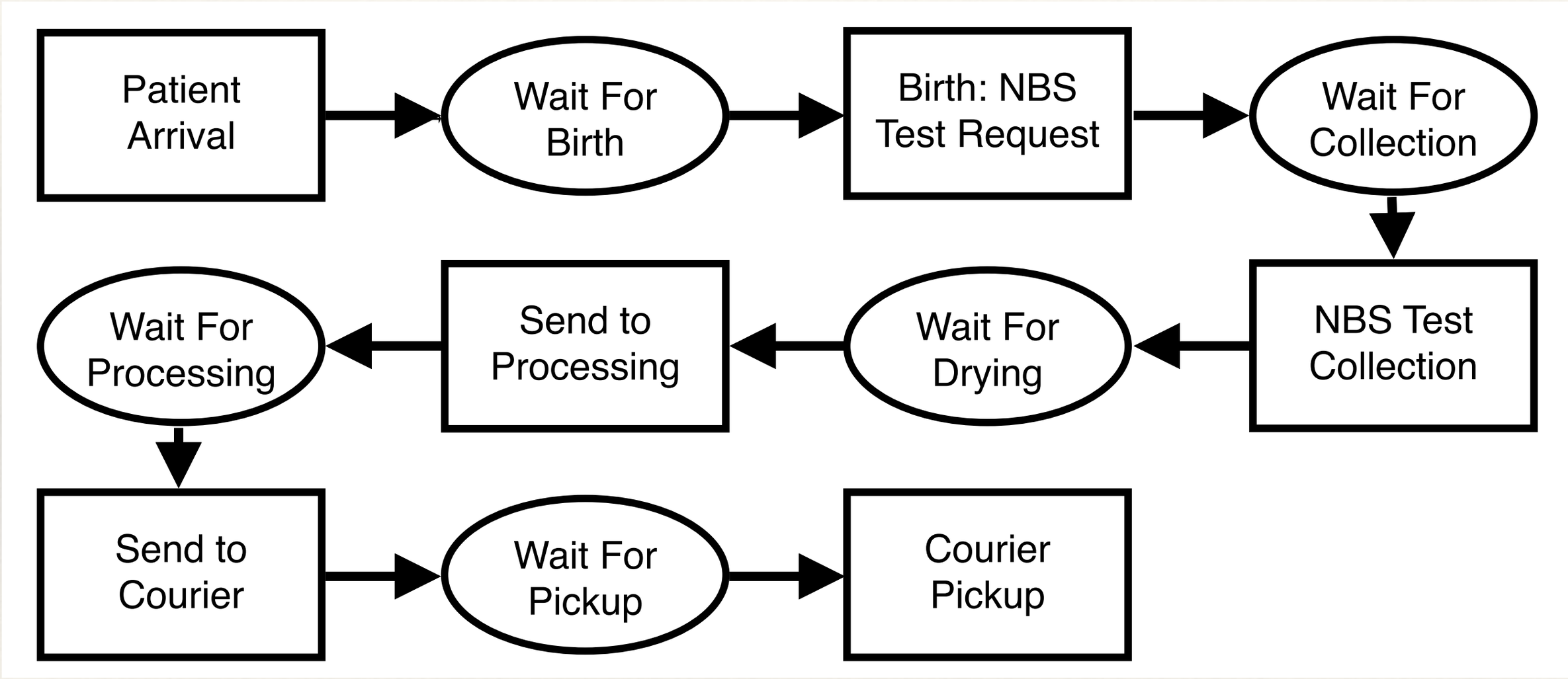


Hospital

Hospital or NBS Program

NBS Program

Hospital Process: Preliminary Model



Timeliness of the Process

- Recommendation is positive results communicated to provider 5 days after birth, negative results 7 days
- Lack of timeliness has led to permanent disability for affected children
- **How to improve timeliness?**
  - Optimize process design and implementation

Stakeholders

- **Hospitals**
  - Nurses
  - Laboratory staff
- **State Newborn Screening Programs**
  - Directors
  - Laboratory personnel
  - Follow-up personnel
- **Professional Organizations and Policymakers**
  - American Hospital Association
  - Regional Genetics Collaboratives
  - Advisory Committee on Heritable Disorders in Newborns and Children

Project Aims

- **Aim 1:** To identify strategies that will decrease the time from NBS specimen collection to return of test results.
- **Aim 2:** To determine incremental tradeoffs between time, cost, and lives saved for decreasing the time from NBS specimen collection to availability of test results.
- **Aim 3:** To rapidly disseminate the findings in order to speed translation of evidence into public health practice.

Preliminary Results

Early Challenges and Barriers to the Project

- **Clinical/public health interaction**
  - Facilitating communication and collaboration between states and hospitals
- **Complexity of process and variability in implementation**
  - Within hospitals: Number and identity of stakeholders involved in the process at a given hospital
  - Within state NBS Programs: Availability of individual and hospital-level data

Project Aims

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Primary Project Product: Simulation Model

- **What is it?**
  - Method for identifying steps in a state's NBS process that can be modified to improve timeliness
- **What are implications?**
  - Systematic and efficient method for assessing timeliness of a state's NBS process
  - Can identify steps in process that are linked to significant change in timeliness
  - Can be tailored to state's specific process (i.e., state specific procedures and data)

Simulation Model: Timeline

- Development: April 2016
- Testing: May 2016 through October 2016
- Available for Dissemination and Additional Testing: October 2016 through January 2017

Model Development: Data Source 1

- Michigan Department of Health Program Data
- Secondary data on 94,770 NBS samples from non-NICU infants across 83 birthing hospitals collected from April 2014 to March 2015
- Includes: encrypted identification number of the hospital, time and date of birth, time and date of NBS sample collection, NBS sample transit time from birth to state lab, mileage from hospital to lab, and pickup schedules by hospital

Preliminary Results: Data Source 2

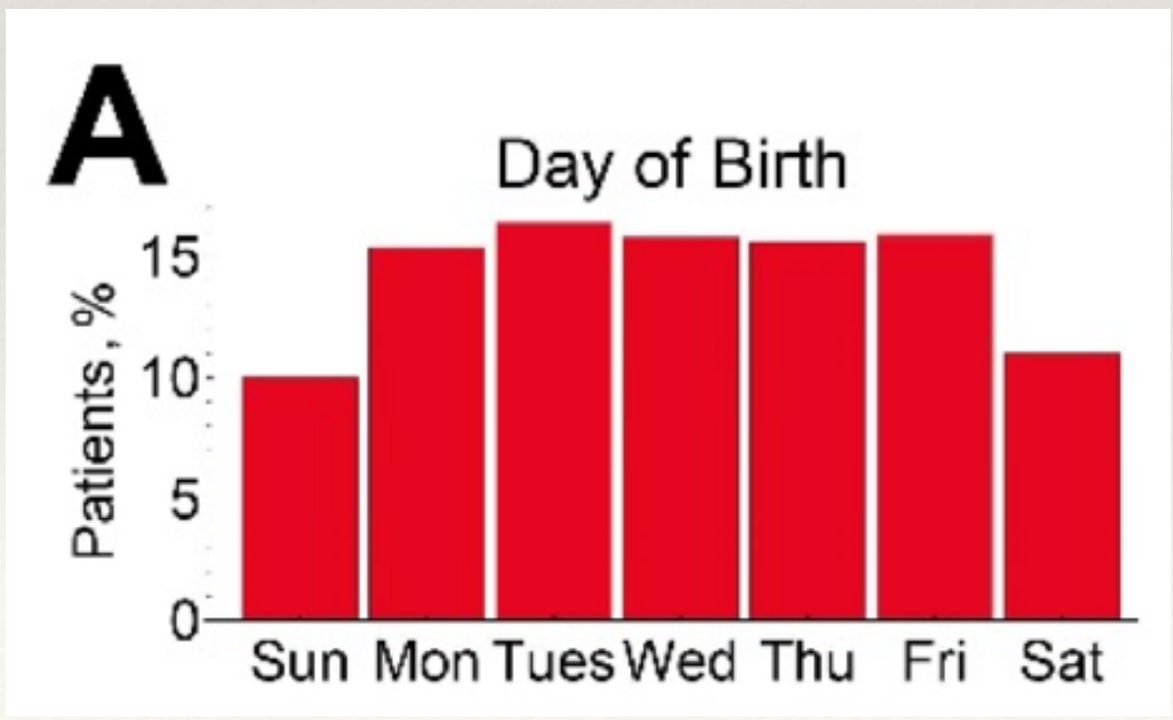
- University of Michigan (U-M) Hospital System Data Warehouse
- Data on information on 4653 NBS samples from non-NICU births at UM over 1 year period
- Includes: time and date of birth, time and date when NBS was ordered, time and date of collection, time and date of test return, and type of delivery

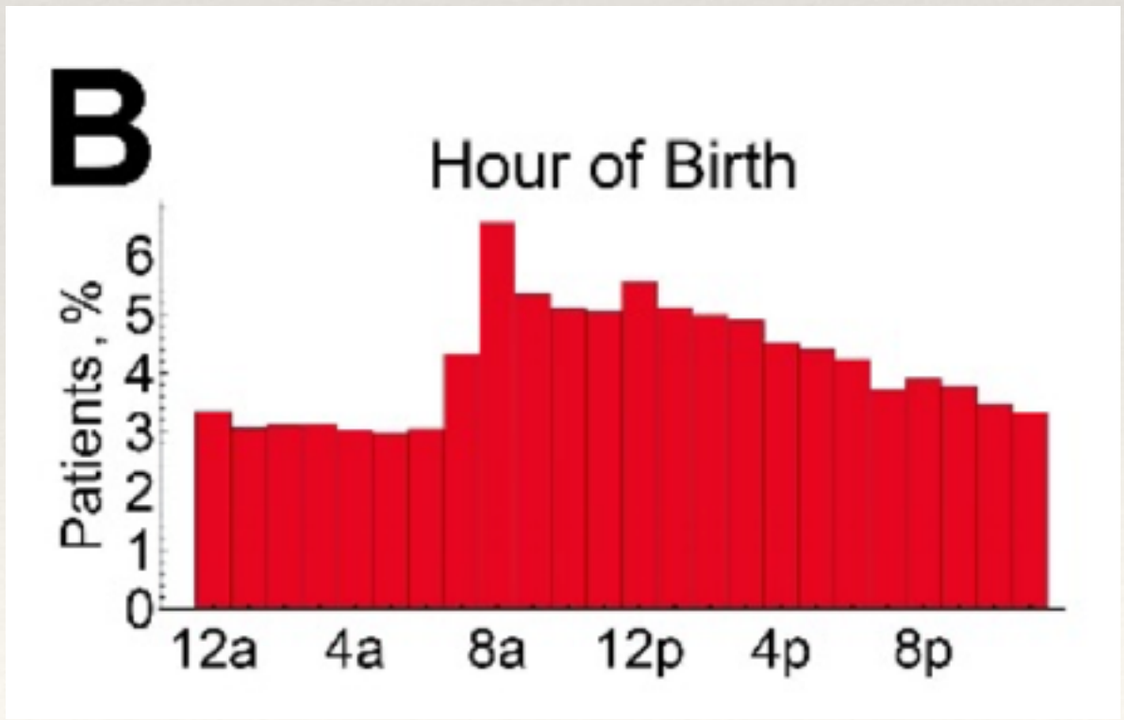
Preliminary Results: Methods

- Linear mixed effects regression models to estimate effect of hospital and newborn features on the time between steps in the NBS process.
- Discrete-event simulation was conducted to determine whether NBS timeliness can be improved by modifying hospital schedules for picking up NBS samples

Preliminary Results

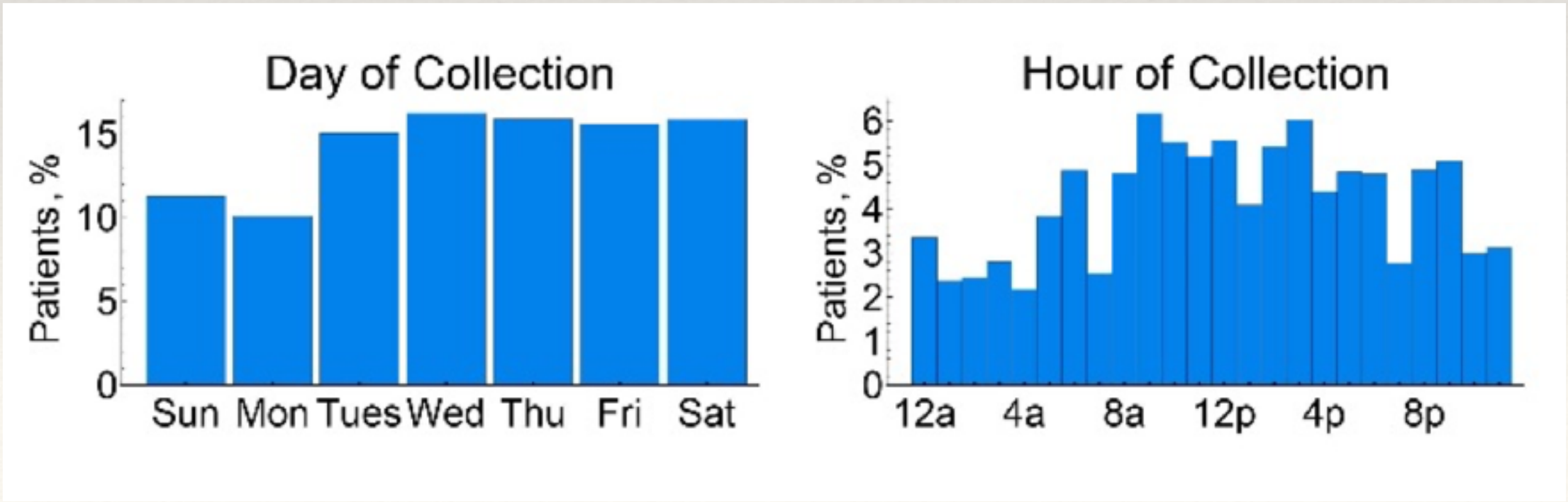
- Births follow a general pattern
  - More common on weekdays than weekends and in the morning
  - Rates peak around 8A, and then decline throughout the day; consistently low throughout the early morning



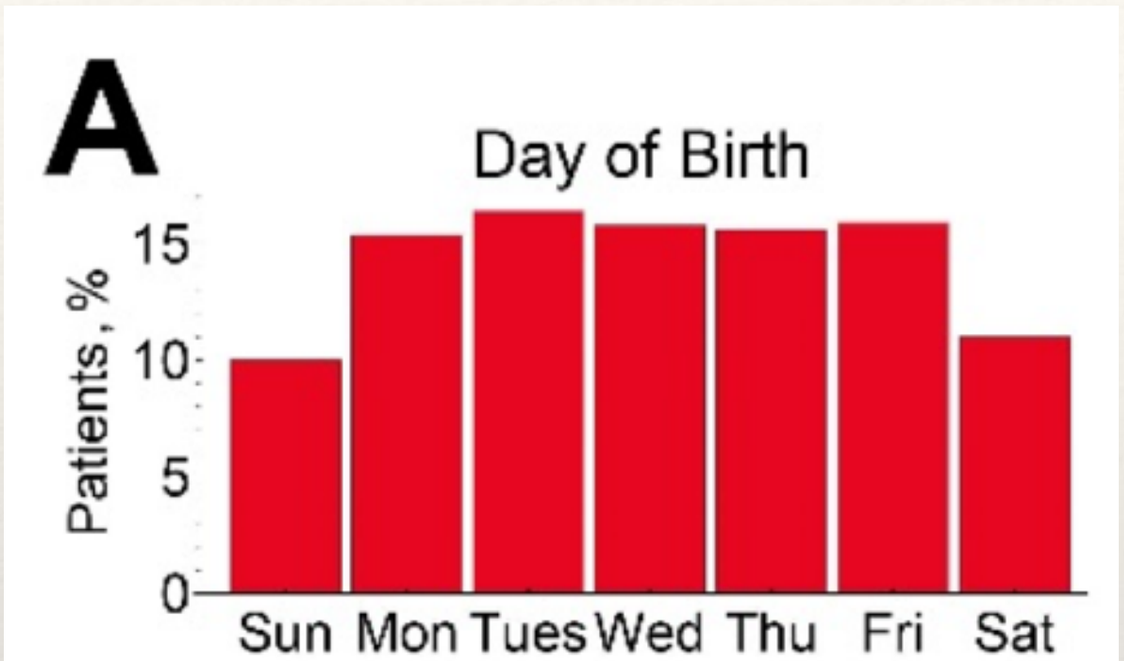


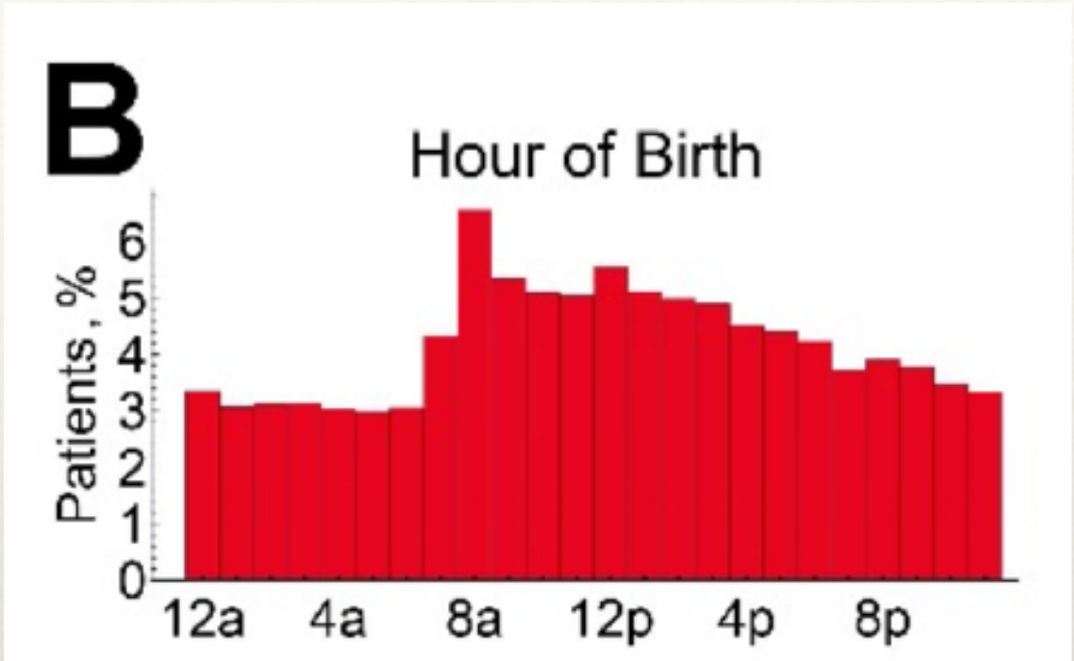
Preliminary Results

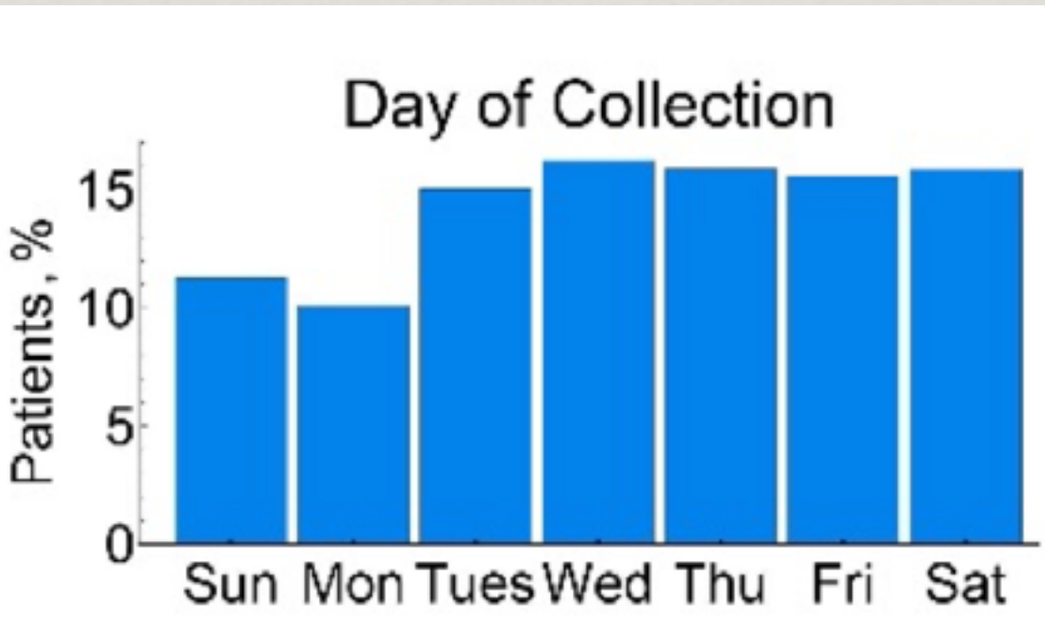
- Specimen collection
  - Day of collection follows the same trend as the day of birth, except delayed by one day
  - Hour of collection is less similar in pattern to the hour of birth;
    - Slightly higher rates of collection during morning hours

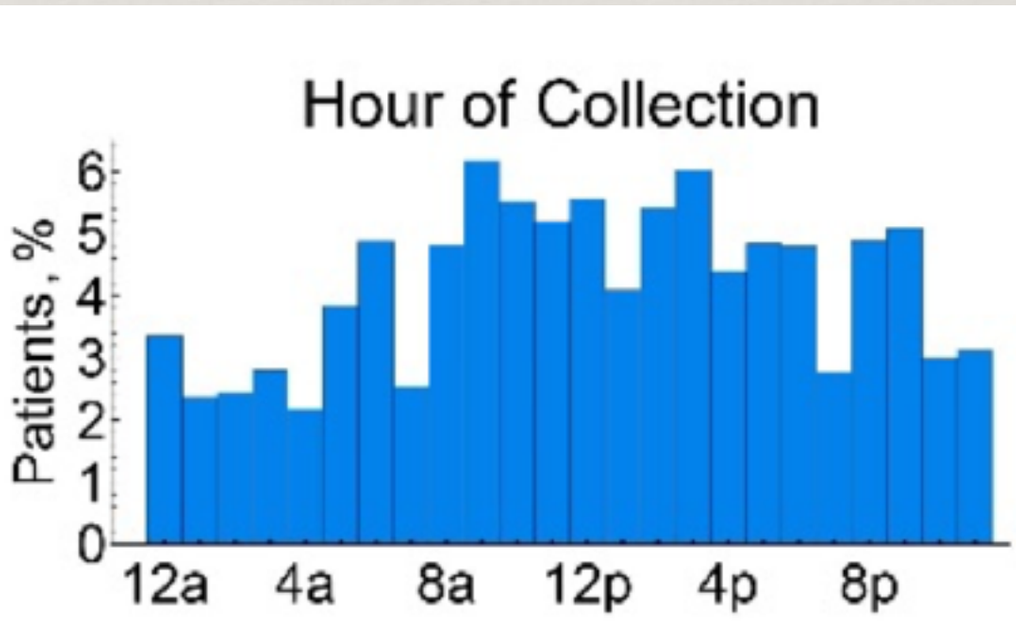


Preliminary Results



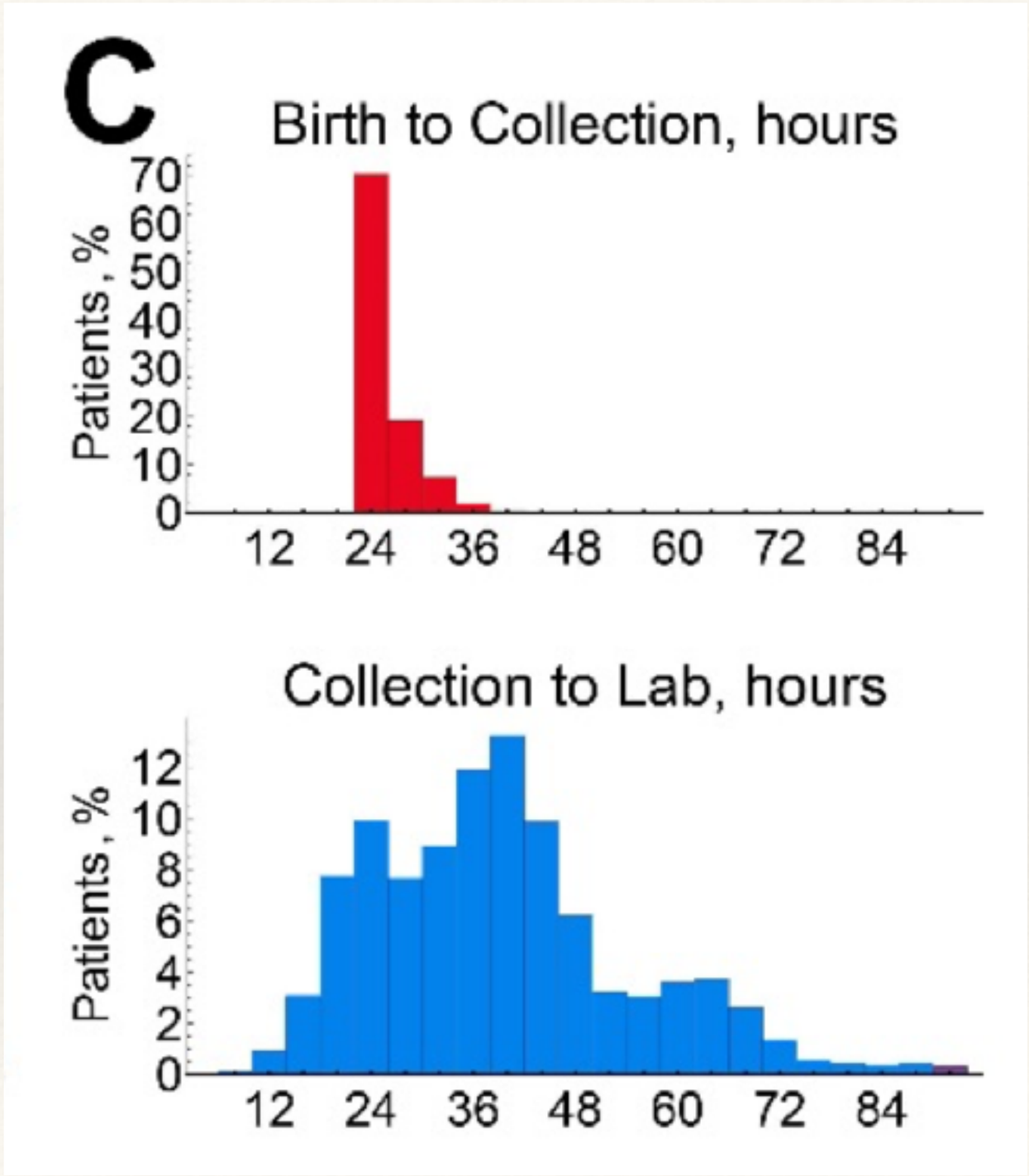






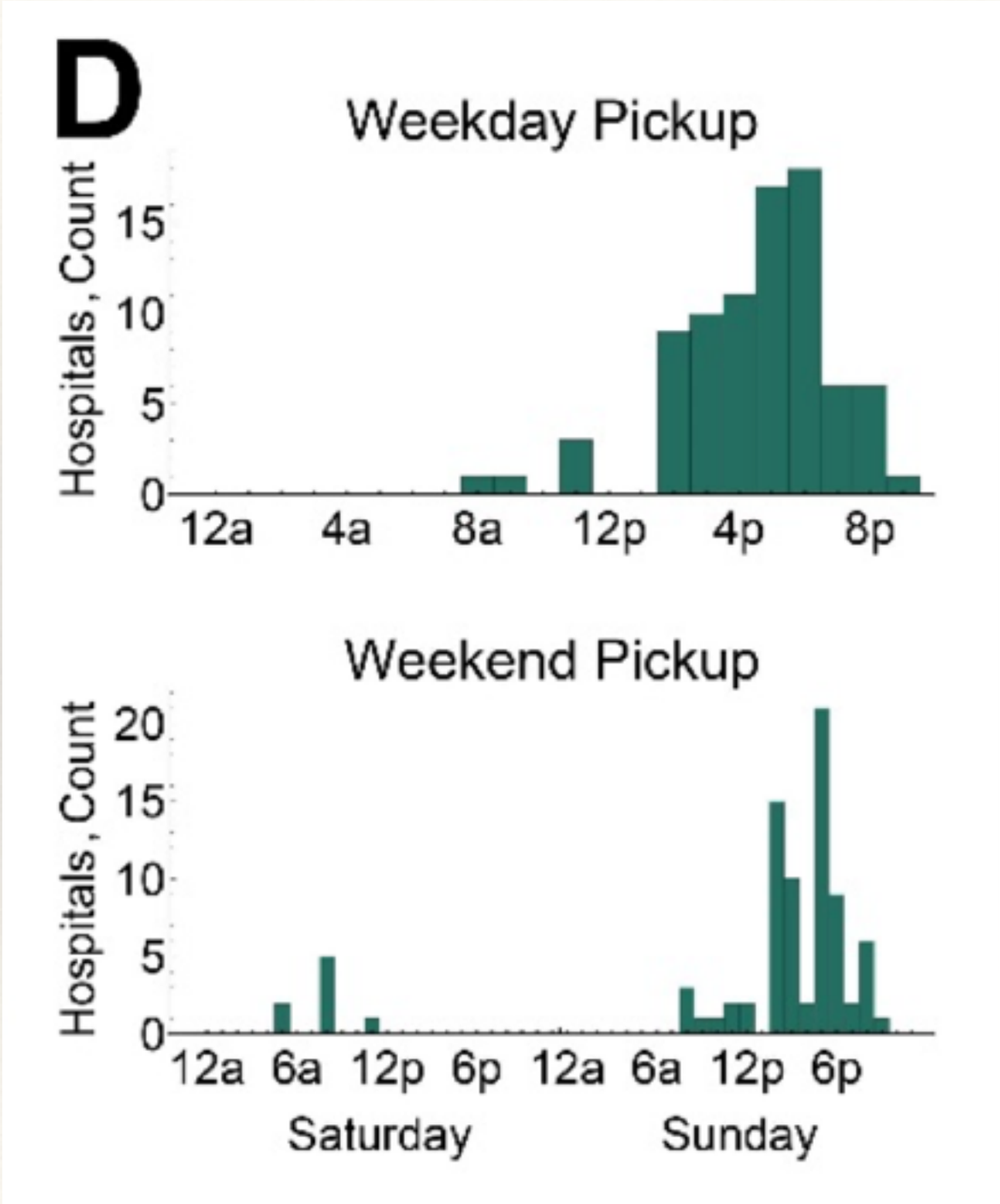
Preliminary Results

- Compared to birth-to-collection time, collection-to-lab arrival time has wider distribution
  - Three peaks, each separated by about a day
- Collection to lab represents an important bottleneck in the NBS process



Preliminary Results

- The majority of hospitals use schedules for picking up NBS samples from the hospital around 6P Monday through Friday and Sunday
- A small number of hospitals have pickup times that occur before noon and/or on Saturday



Preliminary Results: Time from Birth to Collection across Hospitals

- Across hospitals, birth-to-collection time best explained by time of birth ($P < 0.001$)
- Morning and afternoon births have earlier collection times by about 20 minutes
  - Possible explanations: staffing schedules, parents sleeping, medical care schedule
- Day of birth also contributes significantly to the collection time ($P=0.004$)
  - Thursday and Friday births having longer collection times by about 5-10 minutes
- Significant variation between hospitals
  - Accounts for about 18% of the total variance in collection.
  - Not explained by the volume of births in the hospital ($P=0.78$)

Preliminary Results: Time from Collection to Lab Arrival across All Hospitals

- Across all hospitals, **day of collection** was the most significant factor in explaining the collection-to-lab arrival time (P<0.001)
  - Saturday collection leads to an average of 9–12 hours longer times from collection to lab arrival than collection from Sunday through Thursday
  - Friday collection leads to even longer times, about 2.7 hours longer on average than those for collection on Saturday.
- Collection-to-lab arrival time was also explained by **collection time of day** (P<0.001)
  - Samples collected in the early morning arrive about 3.1–3.4 hours earlier to the lab over those collected in the evening
  - Samples collected in the afternoon arrive about 0.9 hours later to the lab than those in the evening
- Hospital volume was not significant (P=0.69)

Preliminary Results:
Time from Collection to Lab Arrival across All Hospitals

Why?

- Majority of hospitals do not pick up samples on Saturday
- Majority of hospitals pick up samples in the evening
  - may explain why samples collected in the morning and afternoon arrive to NBS lab earlier than samples collected in evening or early morning

Preliminary Results:
Time from Collection to Lab Arrival across All Hospitals

- Collection-to-lab arrival time also explained by the number of miles from the hospital to the laboratory ($P<0.001$)
- Every mile adds about 2 minutes to the time
- YET…after controlling for variables that include hospital volume and mileage to the laboratory, still significant variation in collection-to-lab arrival time between hospitals
  - about 10% of the total variance in collection time; $P<0.001$

Simulation Results

- Confirms data from these regression analysis
- Simple changes to hospital pickup schedules can reduce time from birth to NBS specimen pickup

Simulation Results

- **Potential intervention - Reduce gaps between specimen pickups**
  - Shifting the typical Sunday 6P pickup to a Saturday 6A pickup greatly reduces the number of samples with long birth-to-pickup times (>60 hours)
  - A 6A Saturday pickup reduces the largest gap between consecutive pickup times
    - 6A Saturday pickup occurs exactly 36 hours after the latest pickup and 36 hours before the next pickup
    - In comparison, a 6P Sunday pickup occurs 48 hours after the latest pickup and 24 hours before the next pickup

Simulation Results

- **Potential intervention - More frequent specimen pickup**
  - Adjust specimen pickup to account for the specific patterns of births
  - Compared to a 6–day schedule, a 7–day schedule can reduce the number of samples with long birth-to-pickup times (>60 hours)
  - Twice daily, 7–day schedule can also reduce samples with birth-to-pickup >48 hours

Limitations of Current Analyses

- Current model output focuses on Michigan NBS Program
- Pickup times may be limited by current availability of transport companies - both types and pickup times
- Do not consider cost of process changes

Future Steps

Future Steps

- Collect data on costs
- Refine model with additional data from surveys of other hospitals and state NBS programs
  - Survey of Michigan birthing hospitals
  - Survey of State NBS Programs
    - fielded by New Steps

Additional Anticipated Products

- Presentations
- Reports
- Peer-reviewed manuscripts

Dissemination - completed

- NBS programs
  - 2016 Newborn Screening & Genetic Testing Symposium
- Manuscript for model simulation: submission in progress

Dissemination - future presentations

- **Public health practitioners**
  - Regional collaborative meetings - Fall 2016
  - State NBS Meetings - Fall 2016
  - APHL Webinar for NBS programs - Late Fall 2016
- **NBS Policymakers**
  - Advisory Committee on Heritable Disorders of Newborns and Children - August 2016
- **Public health policymakers**
  - 2016 PHSSR & 2017 Academy Health Conference

Acknowledgements

Research Team

- **Principle Investigator**
  - Beth Tarini, MD, MS
- **Co-Investigators**
  - Amy Cohn, PhD
  - Lisa Prosser, PhD
  - Gabriel Zayas-Caban, PhD*
- **Consultants**
  - David Bundy, MD, MPH
  - Amy Cochran, PhD*
  - Marci Sontag, PhD
- **Project Managers**
  - Dalton Simancek, BA
  - Norma-Jean Simon, MPH

* Designed and conducted regression and simulation models

Funding

- Grant #72453
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- Institutional Awardee: University of Michigan

Advisory Committee

- Janice Bach, MS — Manager, Genomics and Genetic Disorders Section, Michigan Department of Health
- Stanton Berberich, Phd — Program Manager, Iowa NBS
- Amy Gaviglio, MS — Minnesota NBS Follow-up
- Mary Kleyn, MPH —NBS Epidemiologist, Michigan NBS
- Neil MacVicar — Michigan Hospital Association
- Jelili Ojodu, MPH — NewSteps
- Susan Tanksley, Phd — Lab Operations Director, Texas NBS
- Lois Turbett, MS, RN — NBS Nurse Consultant, Michigan NBS

Project Information & Updates

go to: http://www.publichealthsystems.org/improving-efficiency-newborn-screening-collection-test-results

Commentary

Aaron Goldenberg, PhD, MA, MPH
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Questions and Discussion

Webinar Archives & Upcoming Events

go to: http://www.publichealthsystems.org/phssr-research-progress-webinars

Upcoming Webinars

July 6, 2016 (12-1p ET/ 9-10a PT)

DEVELOPING PUBLIC HEALTH POLICY RESEARCH FRAMEWORKS WITH CONCEPT MAPPING

Marjorie MacDonald, RN, MSc, PhD, Applied Public Health Chair and Bernadette M. Pauly, RN, PhD, Associate Director, Research and Scholarship, School of Nursing, University of Victoria, British Columbia

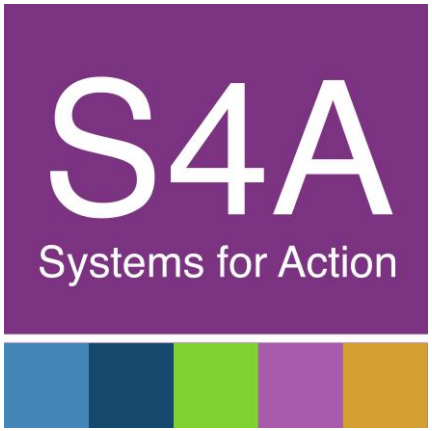
July 13, 2016 (12-1p ET/ 9-10a PT)

LOCAL PUBLIC HEALTH AND PRIMARY CARE COLLABORATION: A PRACTICE-BASED APPROACH

Elizabeth Gyllstrom, PhD, MPH, Research Scientist, Minnesota Department of Health and

Rebekah Pratt, PhD, Assistant Professor, Family Medicine and Community Health, University of Minnesota School of Medicine

Thank you for participating in today's webinar!



For more information about the webinars, contact:

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Speaker Bios

- **Beth Tarini, MD, MS**, is the Fred G. Smith Chair of Academic Pediatrics and the Division Director of General Pediatrics and Adolescent Medicine at the University of Iowa. Her research focuses on optimizing the use of genetic testing technology in pediatrics. She is particularly interested in the organization and delivery of health care services through population-based screening programs such as newborn screening. Dr. Tarini received her medical degree from the Albert Einstein College of Medicine and completed her pediatric residency training at the University of Washington. She is a graduate of the Robert Wood Johnson Clinical Scholars Program at the University of Washington, where she received a Master of Science in Health Services. *beth-tarini@uiowa.edu*

- **Aaron Goldenberg, PhD, MA, MPH** is an Associate Professor in the Department of Bioethics at Case Western Reserve University (CWRU), and is the Associate Director of the Center for Genetic Research Ethics and Law. Dr. Goldenberg received his PhD in Bioethics from Case Western Reserve and was formerly the Center Manager for the University of Michigan's Center for Genomics and Public Health. He also has an MA in Bioethics from Case Western Reserve and an MPH in Health Education and Public Health Genetics from the University of Michigan. Dr. Goldenberg's work focuses on the ethical and social issues surrounding advances in public health genomics, biobanking, health disparities, and the intersection between bioethics and public health ethics. His recent research focuses on the use of biobanked pediatric samples for genetic research, the use of stored tissues from recently deceased individuals for gene-tissue expression studies (GTEX), and public attitudes towards the use of genetic research to address health disparities. *aaron.goldenberg@case.edu*

- **Carol Johnson, RN, PCCN,** has been the Follow Up Coordinator for the Iowa Newborn Screening Program since 2011 and has been involved with the newborn screening program in an administrative capacity since 2005. She is the co-chair of the APHL/NewSTEPS Short Term Follow Up Workgroup and a member of the APHL/NewSTEPs 360/Cystic Fibrosis Foundation's special interest group to improve timeliness in cystic fibrosis newborn screening. *carol-johnson@uihealthcare.org*