Improving the Efficiency of Newborn Screening from Collection to Test Results

Research In Progress Webinar
Wednesday, July 19, 2017 12:00-1:00pm ET/ 11:00am-12:00pm CT
Agenda

Welcome: CB Mamaril, PhD, Research 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, Associate Professor and Division Director, General Pediatrics & Adolescent Medicine, U. of Iowa Carver College of Medicine  beth-tarini@uiowa.edu

Commentary: Julia Costich, JD, PhD, Professor, Health Management and Policy, University of Kentucky College of Public Health

Questions and Discussion
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
beth-tarini@uiowa.edu
Improving the Efficiency of Newborn Screening from Collection to Test Results

Beth A. Tarini, MD, MS
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General Pediatrics & Adolescent Medicine
University of Iowa Carver College of Medicine

S4A Research in Progress Webinar
Wednesday, July 19, 2017
Overview

• Project background & objectives
• Results
• Next steps
Newborn Screening (NBS)

• Complex process
  – NBS requires coordinated and timely collaboration between multiple stakeholders
    • Within and between clinical medicine and public health

• Different ways to organize and deliver NBS
  – Each state program designs its own process
  – Different designs can be equally effective
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.

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.

Hearing screening and heart screening take only a few minutes. Ask for your baby’s results when the tests are done.
Newborn Screening
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Collection, Transport, and Processing

**Collection**
- Timing
- Agent of Collection
- Staffing and availability

**Transport**
- Timing
- Frequency

**Processing**
- Staffing
- Timing

Births

Specimen Collection

Specimen Pick-up

Specimen Delivery

Lab Processing

Test Results

Hospital

Hospital or NBS Program

NBS Program
Collection, Transport, and Processing

Goal: 5-7 days

**Collection**
- Timing
- Agent of Collection
- Staffing and availability

**Transport**
- Timing
- Frequency

**Processing**
- Staffing
- Timing

*Hospital*

*Hospital or NBS Program*

*NBS Program*
Hospital Process: Preliminary Model

from Patient Arrival at Hospital to NBS test results returned

Stop 1: Mother arrives at Hospital
Stop 2: Birth
Stop 3: NBS Ordered
Stop 4: NBS Collected
Stop 5: NBS Processed (Dried, Logged, Etc.)
Stop 6: Courier Pick-up
Project Rationale

By taking a broader perspective of the process and performing a systematic analysis, we can identify leverage points where we can potentially intervene and improve process efficiency.
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.
Simulation Modeling

• What is it?
  – Statistical 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 linked to significant change in timeliness (i.e., leverage points)
  – Can be tailored to state’s specific process (i.e., state specific procedures and data)
Early Challenges and Barriers to the Project

- NBS Process complexity
- Variability in organization and implementation
  - At program and hospital level
- Availability of necessary NBS program and hospital data
- What is the health outcome gain of <5 days?
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 the 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 a state’s specific process (i.e., state specific procedures and data)
Model Development

- 94,770 NBS specimens
- 83 Michigan birthing hospitals
- April 2014 to March 2015
- Newborns from neonatal intensive care unit (NICU) or a special care unit were not included
- Hospital ID; time and date of birth, collection, and receipt of lab arrival; mileage from hospital to lab; and pickup schedules by hospital
Characteristics

Day of Birth

- Patients, %
- Sun, Mon, Tues, Wed, Thu, Fri, Sat
- Day of Birth

Hour of Birth

- Patients, %
- 12a, 4a, 8a, 12p, 4p, 8p
- Hour of Birth

Day of Collection

- Patients, %
- Sun, Mon, Tues, Wed, Thu, Fri, Sat

Hour of Collection

- Patients, %
- 12a, 4a, 8a, 12p, 4p, 8p
Characteristics

- Over 99% of specimens are collected within 36 hours of birth
- Most NBS specimens in Michigan are transported by state-funded couriers (UPS, Quest) from the hospital and arrive at the state lab on the following day
Regression*: Collection to lab arrival (hours)

<table>
<thead>
<tr>
<th>Model Term</th>
<th>Estimate</th>
<th>Std. Error</th>
<th>Statistic</th>
<th>Sig.</th>
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<tr>
<td>Intercept</td>
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<td>1.2</td>
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<td>&lt;0.001</td>
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<td>Hospital Volume</td>
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<td>0.4</td>
<td>0.690</td>
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<td>-47.8</td>
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<td>Saturday Collection</td>
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<td>Early Morning Collection</td>
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<td>Afternoon Collection</td>
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<td>0.1</td>
<td>6.6</td>
<td>&lt;0.001</td>
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<tr>
<td>Evening Collection</td>
<td>0\textsuperscript{b}</td>
<td>.</td>
<td>.</td>
<td>.</td>
</tr>
<tr>
<td>Mileage to Laboratory</td>
<td>0.035</td>
<td>0.005</td>
<td>6.6</td>
<td>&lt;0.001</td>
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<td>Residual Variance</td>
<td>225.2</td>
<td>1.0</td>
<td>217.6</td>
<td>&lt;0.001</td>
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<tr>
<td>Between-Hospital Variance</td>
<td>25.8</td>
<td>4.2</td>
<td>6.2</td>
<td>&lt;0.001</td>
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</table>

\textsuperscript{a}Linear mixed effects regression model; \textsuperscript{b}Term is redundant.
Simulation: Birth to Lab Arrival

Could collection timing be important to NBS timeliness through its relation to lab hours and courier schedules?

Simulated:

- Patterns of birth (including uncertainty)
- Birth to collection (including uncertainty) with tests ordered after 24 hours of birth
- Collection to pickup, allowing at least 4 hours of drying
- A fixed transit time of 10 hours †
- Processing starts immediately during laboratory hours ‡
- Varied laboratory hours and varied pickup schedules

† In Michigan, a typical pickup time is 6P and specimens arrive around 3-4A. Hospitals with their own courier have shorter transit times.
‡ Michigan lab hours: Mon–Fri 7A–5P, Sat 6:30A–4P
Simulation: Birth to Lab Arrival

Histograms showing the distribution of birth-to-arrival times for different time slots and days of the week:

- **6P Sun-Fri**
- **6P Mon-Sat**
- **12A Mon-Sat**
- **12A Sun-Fri**
Simulation: Birth to Lab Arrival

<table>
<thead>
<tr>
<th>Rank</th>
<th>Pickup times</th>
<th>Mean (h)</th>
<th>SD (h)</th>
<th>T&gt;48 h (%)</th>
<th>T&gt;60 h (%)</th>
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<tbody>
<tr>
<td>#1</td>
<td>12A Mon-Sat</td>
<td>55.2</td>
<td>11.4</td>
<td>68.0</td>
<td>30.2</td>
</tr>
<tr>
<td>#2</td>
<td>9P Sun-Fri</td>
<td>55.4</td>
<td>11.6</td>
<td>65.7</td>
<td>32.0</td>
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<td>#3</td>
<td>12A Wed-Mon</td>
<td>57.2</td>
<td>12.4</td>
<td>71.4</td>
<td>38.6</td>
</tr>
<tr>
<td>#4</td>
<td>12A Tue-Sun</td>
<td>57.6</td>
<td>12.7</td>
<td>71.7</td>
<td>39.4</td>
</tr>
<tr>
<td>#5</td>
<td>9P Tue-Sun</td>
<td>58.0</td>
<td>13.2</td>
<td>69.5</td>
<td>40.6</td>
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<tr>
<td>#18</td>
<td>6P Sun-Fri</td>
<td>59.1</td>
<td>11.8</td>
<td>78.2</td>
<td>44.6</td>
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<tr>
<td>Minimum</td>
<td></td>
<td>55.2</td>
<td>11.2</td>
<td>65.7</td>
<td>30.2</td>
</tr>
</tbody>
</table>

- \( T \) is simulated time between birth and receipt of lab arrival
- 35 pickup schedules (six days at 12A, 6A, 12P, 6P, or 9P)
- Schedules are ranked on metrics
- Laboratory hours fixed (Mon–Fri 7A–5P, Sat 6:30A–4P).
Simulation: Birth to Lab Arrival

<table>
<thead>
<tr>
<th>Laboratory hours</th>
<th>Mean (h)</th>
<th>SD (h)</th>
<th>T&gt;48 h (%)</th>
<th>T&gt;60 h (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>7A-5P Mon-Fri, 6:30A-4P Sat</td>
<td>55.4</td>
<td>11.5</td>
<td>66.0</td>
<td>32.1</td>
</tr>
<tr>
<td>7A-5P Mon-Fri, 6:30A-4P Sat-Sun</td>
<td>51.7</td>
<td>7.7</td>
<td>59.0</td>
<td>19.2</td>
</tr>
<tr>
<td>7A-5P Mon-Fri</td>
<td>63.0</td>
<td>19.6</td>
<td>72.3</td>
<td>44.9</td>
</tr>
<tr>
<td>7A-5P Tue-Sat, 6:30A-4P Sun</td>
<td>54.6</td>
<td>11.4</td>
<td>63.0</td>
<td>28.9</td>
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<tr>
<td>7A-5P Mon-Fri, 6:30A-4P Sun</td>
<td>55.5</td>
<td>11.8</td>
<td>65.6</td>
<td>31.7</td>
</tr>
<tr>
<td>5A-3P Mon-Fri, 5A-2:30P Sat</td>
<td>55.9</td>
<td>11.7</td>
<td>69.5</td>
<td>33.5</td>
</tr>
<tr>
<td>9A-7P Mon-Fri, 9A-6:30P Sat</td>
<td>55.3</td>
<td>11.5</td>
<td>67.2</td>
<td>30.7</td>
</tr>
</tbody>
</table>

• For each laboratory schedule, assumed courier picked up specimens 10 hours prior to when the laboratory opens each day.
Simulation Results

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

- Time from collection to receipt of lab arrival is an important bottleneck in the NBS process.
- Pickup schedules and lab hours may be adjusted to improve NBS timeliness, by accounting for:
  - Patterns of births (more on weekdays, in the morning)
  - When laboratory is open
- Simulation can estimate *a priori* impact on timeliness:
  - E.g., switching pickup schedules from 6P Sun-Fri to 9P Sun-Fri is estimated to have 12.6% fewer specimens received by the state laboratory 60 hours after birth.
- Considerations: cost of changing courier or lab schedules, contacting primary care provider, lab processing.
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
Dissemination

• **Articles**
  – Cochran AL, Tarini BA, Kleyn M, Zayas-Cabán G. Timeliness of the Newborn Screening Process in Michigan Birthing Hospitals. (Unpublished, revised and resubmitting to *Maternal and Child Health Journal*)

• **Presentations, Proceedings, and Testimony**
  – “What Predicts NBS Specimen Timeliness in a State-based Cohort of Birthing Hospital?”
    Annual Public Health Newborn Screening and Genetic Testing Symposium
    March 3, 2016; St. Louis, MO
  – Presentation at the University of Iowa, Frontiers in Research
    August 22, 2016
  – Presentation to the Secretary of HHS Advisory Committee on Heritable Diseases in Newborns and Children
    August 26, 2016; Washington, DC
  – Invited presentation at the Heartland Genetics Collaborative
    October 13, 2016; Little Rock, AR
  – “Improving the Efficiency of Newborn Screening from Collection to Test Results”
    PHSSR Research in Progress Webinar, National Coordinating Center for Public Health Services and Systems Research, June 23, 2016
NBS Lab Survey

Background

- Survey several NBS laboratories regarding their current activities, constraints and costs for executing NBS collection processes.

- Identify potential strategies for decreasing the time from collection of specimens to return of results.
NBS Lab Survey

Methods

• Semi-structured phone interviews with state NBS laboratory personnel between November and December 2016.

• Participant Recruitment
  – A targeted sample of 16 state NBS program sites was identified for study recruitment. Sites were selected based on geographic location, NBS testing volume, and laboratory organization.
  – The Association of Public Health Laboratories (APHL) e-mailed an invitation to laboratory directors and key personnel to participate in the study.

• Semi-structured Interviews
  – Phone interviews were conducted by a staff member from APHL and lasted between 45-60 minutes.

• Data collection
  – Interviews with the labs queried the following domains:
    • Specimen receiving to laboratory including delivery mode, timing and specimen preparation
    • Lab testing and processing procedures
    • Notification of results to hospitals and physicians
    • Laboratory program staffing
    • Quality measures and data sharing
NBS Lab Survey

Analysis

• 13 NBS sites consented to an interview
• Qualitative content analysis was conducted to explore laboratory practices, processes, and procedures
  – A coding schema was created *a priori*
  – The final coding schema included 22 codes among 6 topic areas
• Describe how the processes and procedures are both similar and different across lab sites.
• Summarize potential gaps and best practices that may have a significant impact on timeliness and are within the purview of state laboratories.
NBS Lab Survey

Results

• **What processes/procedures are similar across lab sites?**
  – Sample preparation (accessioning, quality control, punching, plating, etc.)
  – Daily “cut-off” for sample receipt
  – Reporting procedures – interest in identifying / informing stakeholders about timeliness issues

• **What processes/procedures differ across lab sites?**
  – Transportation/Tracking Procedures
  – Delivery timing
  – Processing (prioritization – assay duration vs. time-sensitiveness of disorder)
  – Lab hours and staffing
  – Technology

• **Where are potential gaps that may have a significant impact on timeliness?**
  – Lab responsibility – What parts of the process does the lab have control over? What parts of the process should labs track?
  – Common definitions – quality metrics need to be defined consistently and need to be meaningful

• **What seem to be best practices that facilitate timeliness?**
  – Looking at the process as a whole, and tracking each step
  – Ensuring processes are integrated – smart data systems
  – Hospital education
Michigan Hospital Survey

Background

• Survey several Michigan hospitals regarding their current activities, constraints and costs for executing NBS collection processes.

• Identify potential strategies for decreasing the time from collection of specimens to return of results.
Michigan Hospital Survey

Methods

• Semi-structured phone interviews with Michigan hospital personnel between January and May 2017.

• Participant Recruitment
  – Hospital sites were identified for study recruitment through an NBS outreach event.
  – Research team e-mailed an invitation to hospital coordinators and key personnel to participate in the study.

• Semi-structured Interviews
  – Phone interviews were conducted by a research team member and lasted between 45-60 minutes.

• Data collection
  – Interviews with the hospitals queried the following domains:
    • Activities and related policies for collection and transport of NBS specimens
    • Time to complete activities
    • Process constraints
  – Participating sites were also asked to identify what aspects of the newborn screening process they felt were most important to improving NBS timeliness.
Michigan Hospital Survey

Analysis

• 7 hospital sites consented to an interview
• Hospitals were of varying size, and located in urban and rural settings
• Interviewees varied from nurse managers to hospital quality assurance coordinators, lab staff and phlebotomists, and individual interviews included anywhere from one to 7 stakeholders
• Qualitative content analysis to explore hospital practices, processes, and procedures is in progress
Michigan Hospital Survey

Results

• **What processes/procedures are similar across hospital sites?**
• **What processes/procedures differ across hospital sites?**
• **Where are potential gaps that may have a significant impact on timeliness?**
• **What seem to be best practices that facilitate timeliness?**
Post-Grant Projects

• Potential opportunities for future funding to convert our model into a web-based tool that would allow for broader accessibility and use by NBS programs

  – A web-based tool would convert our model from a static assessment of process links (it’s the next level by allowing state NBS programs to “test” potential process changes before they are implemented

  – Seeking HRSA funding to move forward
Acknowledgements

Research Team

Principal Investigator
Beth Tarini, MD, MS

Co-Investigators
Amy Cohn, PhD
Lisa Prosser, PhD
Gabriel Zayas-Caban, PhD

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Anne Atkins, MPH
Acknowledgements

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 Coordinator
- Carol Johnson — Newborn Screening Follow-up Coordinator, Iowa NBS
- Mary Kleyn, MS — NBS Epidemiologist, Michigan NBS
- Neil MacVicar — Michigan Health and Hospital Association
- Jelili Ojodu, MPH — NewSteps Director
- Susan Tanksley, Phd — Lab Operations Director, Texas NBS
- Lois Turbett, MS, RN — NBS Nurse Consultant, Michigan NBS
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  – Public Health Services and Systems Research Robert Wood Johnson Foundation
  – Institutional Awardee: University of Michigan
Commentary

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Professor, Health Management and Policy
Associate Director, Kentucky Injury Prevention
and Research Center
University of Kentucky College of Public Health

Questions and Discussion
Webinar Archives

http://systemsforaction.org/research-progress-webinars

## Upcoming Webinars

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Timezone</th>
<th>Title</th>
<th>Speakers</th>
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<tbody>
<tr>
<td>Thursday, July 27</td>
<td>12pm ET/ 10am PT</td>
<td></td>
<td><strong>Clinical-Community Partnerships &amp; 2-1-1 Technology to Improve Early Childhood Development</strong></td>
<td>Bergen Nelson, MD, MSHS, UCLA and Virginia Commonwealth University School of Medicine</td>
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<tr>
<td>Thursday, August 10</td>
<td>12pm ET/ 10am MT</td>
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<td><strong>Hospital Investment and Interaction in Public Health Systems</strong></td>
<td>Danielle Varda, PhD and Adam Atherly, PhD, University of Colorado</td>
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<tr>
<td>Wednesday, August 23</td>
<td>12pm ET/ 9am PT</td>
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<td><strong>Comprehensive Population Health Systems &amp; Hospital Uncompensated Care Costs</strong></td>
<td>C. B. Mamaril, PhD, University of Kentucky College of Public Health</td>
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Thank you for participating in today’s webinar!

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For more information about the webinars, contact:
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111 Washington Avenue #201, Lexington, KY 40536
**Acknowledgements**

*Systems for Action* is a National Program Office of the Robert Wood Johnson Foundation and a collaborative effort of the Center for Public Health Systems and Services Research in the College of Public Health, and the Center for Poverty Research in the Gatton College of Business and Economics, administered by the University of Kentucky, Lexington, Ky.
Beth Tarini, MD, MS, is the Fred G. Smith Chair of Academic Pediatrics and the Division Director of General Pediatrics 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.

Julia Costich, JD, PhD, is a professor in the Dept. of Health Services Management, and also serves as associate director of the Kentucky Injury Prevention and Research Center. Her current research focuses on legal and policy issues in public health and health care, health reform, and electronic health information exchange. She previously served as department chair, director of the Master of Health Administration program, and director of the Kentucky Injury Prevention and Research Center. Before joining the UK public health faculty in 1998, she administered academic medical programs, practiced health care law, and served as a policy specialist and administrator for state health care programs.