

U.S. Government Accountability Office Report – Newborn Screening Timeliness



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Background

- **The Newborn Screening Saves Lives Reauthorization Act of 2014**
 - Timeliness is an explicit goal for HRSA-supported newborn screening programs.
 - The Act includes a provision for GAO to review newborn screening timeliness.
- **The GOA Report examines:**
 - What is known about the timeliness of NBS.
 - Barriers identified as contributing to delays and strategies used to address them.

Background

- **Resources GAO used to develop the report:**
 - **Time-frame goals from the Advisory Committee**
 - **August 2016 report from NewSTEPs (data from 38 states between 2012-2105)**
 - **Results of the 2014 survey done by the Advisory Committee**
 - **Interviews**
 - **Other relevant documents**

Recommendations from the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children

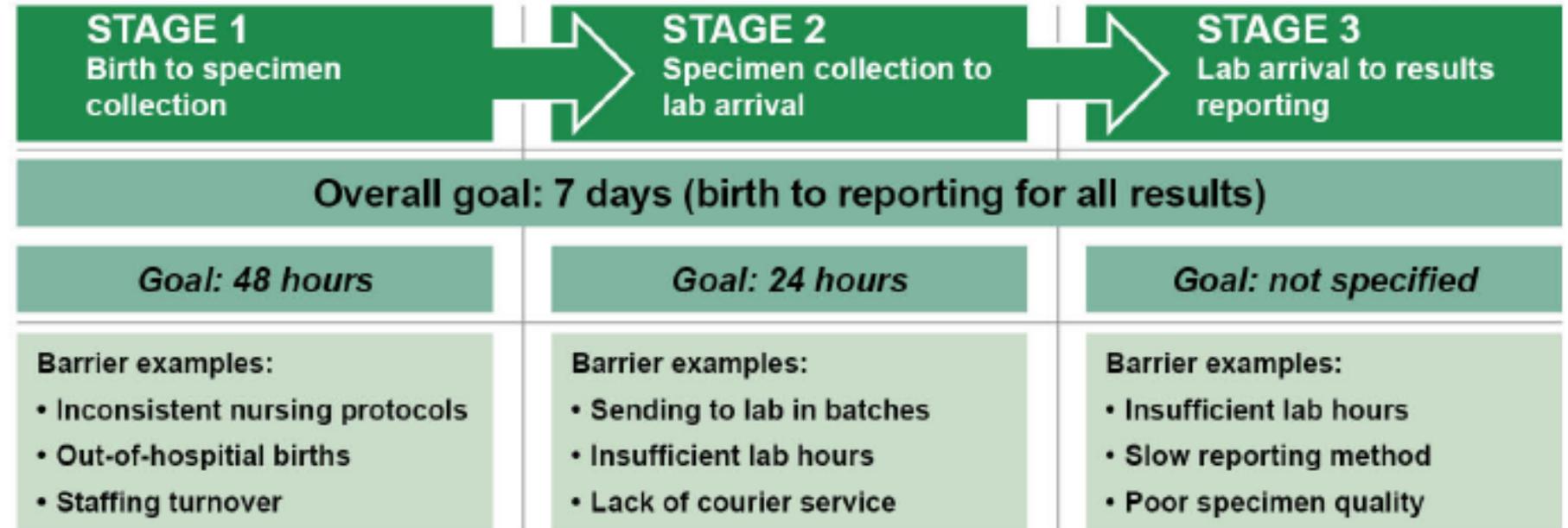
- **Sent to Secretary Burwell on April 16, 2015**
- **To achieve the goals of timely diagnosis and treatment of screened conditions and to avoid associated disability, morbidity and mortality, the following time frames should be achieved by NBS systems for the initial newborn screening specimen:**
 - 1. Presumptive positive results for time-critical conditions should be communicated immediately to the newborn's healthcare provider but no later than five days of life.**
 - 2. Presumptive positive results for all other conditions should be communicated to the newborn's healthcare provider as soon as possible but no later than seven days of life.**
 - 3. All NBS tests should be completed within seven days of life with results reported to the healthcare provider as soon as possible.**

Recommendations from the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children

- In order to achieve the goals:
 1. Initial NBS specimens should be collected in the appropriate time frame for the newborn's condition but no later than 48 hours after birth, and
 2. NBS specimens should be received at the laboratory as soon as possible; ideally within 24 hours of collection.
- Encouraged states to monitor progress and make results readily available

TIME-FRAME GOALS

Advisory Committee's Newborn Screening Time-Frame Goals and Barriers Identified by States



Sources: GAO analysis of information from the Advisory Committee on Heritable Disorders in Newborns and Children and selected states. | GAO-17-196

Report Highlights

- “Most states that reported 2015 timeliness data (the most recent data available) to NewSTEPs had not met the advisory committee’s 95% benchmark for newborn screening timeliness for all conditions within 7 days.
- “In 2015, states also had not met the advisory committee’s benchmark for timely reporting of presumptive positive results for time-critical conditions.”
- “However, timeliness for completing this screening process improved over time for the majority of states.”

Report Highlights

- **Improvements noted:**
 - 21 states demonstrated improvement from 2012 to 2015 (According to NewSTEPS)
 - 5 of 27 states met the 95% benchmark for reporting all newborn screening results for all conditions within 7 days, and 1 state was within 1 percentage point of the benchmark.
 - Median percentage of specimens screened within 7 days was higher in 2015 than in the previous 3 years.

Report Highlights

■ Barriers

- Lack of understanding why timely screening is important amongst those collecting/submitting specimens
- Limited courier availability to transport specimens
- Insufficient lab hours

Limitations

- “Missing data and variations in data collection limit a full understanding of timeliness trends...” (GAO-17-196)
- NewSTEPs data is from 38 states
- States only had < 9 months from when the recommendations were developed to implement change

Next Steps

- **NewSTEPs 360 will:**
 - **Standardize data definitions**
 - **Continue data collection**
 - **Work to improve data collection**
 - **Present an update to the Committee at the August 2017 Meeting**