

# Saving Lives: Newborn Screening Program Successes in Improving Timeliness

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# Outline

- NewSTEPs and NewSTEPs 360
- Clarification of reported timeliness data
- Aggregate timeliness progress made since the NewSTEPs Timeliness Report to the Government Accountability Office (GAO)
- Implemented changes by newborn screening programs that have resulted in timeliness improvements
- Important timeliness take-aways from efforts thus far
- Saving a baby in a timely New York minute
- Conclusion

# NewSTEPS & NewSTEPS 360

Promoting a Collaborative Paradigm to Improve Timeliness  
in Newborn Screening

# What is NewSTEPs?

- Newborn Screening Technical assistance and Evaluation Program (HRSA Grant # U22MC24078)
- Provides data services, technical assistance, and training to newborn screening programs and assists states with **quality improvement initiatives**
- Collaboration between:
  - Association of Public Health Laboratories (APHL)
  - Colorado School of Public Health (ColoradoSPH)

# What is the NewSTEPs Data Repository?

- Database that collects newborn screening:
  - State Profile data
  - Quality Indicator data
  - Public Health Surveillance Case data
- NBS programs required to have a fully ratified Memorandum of Understanding (MOU) to enter data into the repository
- Entering data into the NewSTEPs Repository is **completely voluntary** once the MOU is signed

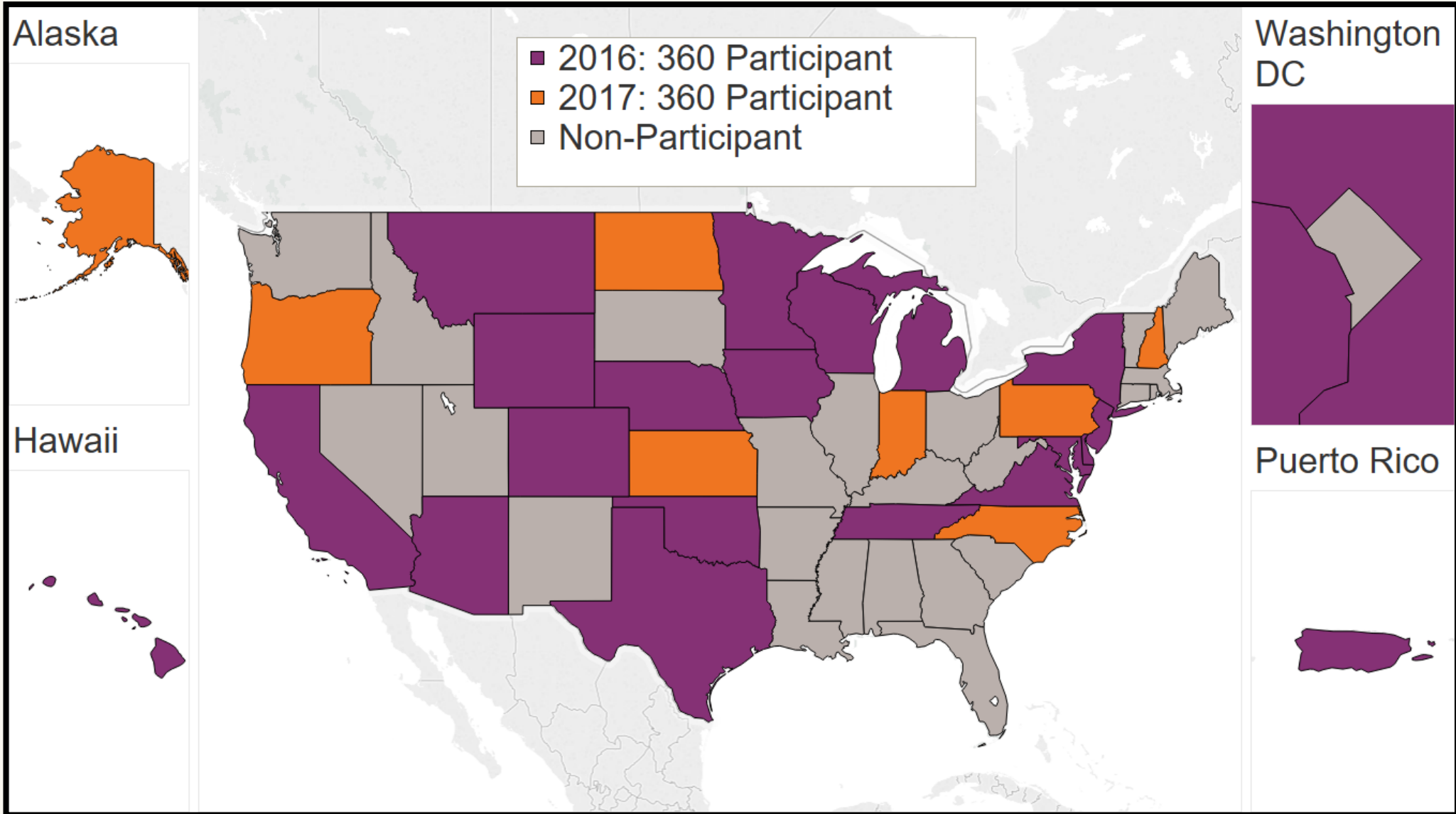
# What is NewSTEPS 360?

- Quality improvement initiative to improve timeliness in NBS (September 2015 – August 2018) (Grant # UG8MC28554)
- Collaboration between:
  - Colorado School of Public Health (ColoradoSPH)
  - Association of Public Health Laboratories (APHL)
- 28 states funded and actively working on improving timeliness
- CoIN (Collaborative Improvement & Innovation Network)

# NewSTEPS 360 is an initiative governed by the NewSTEPS Steering Committee

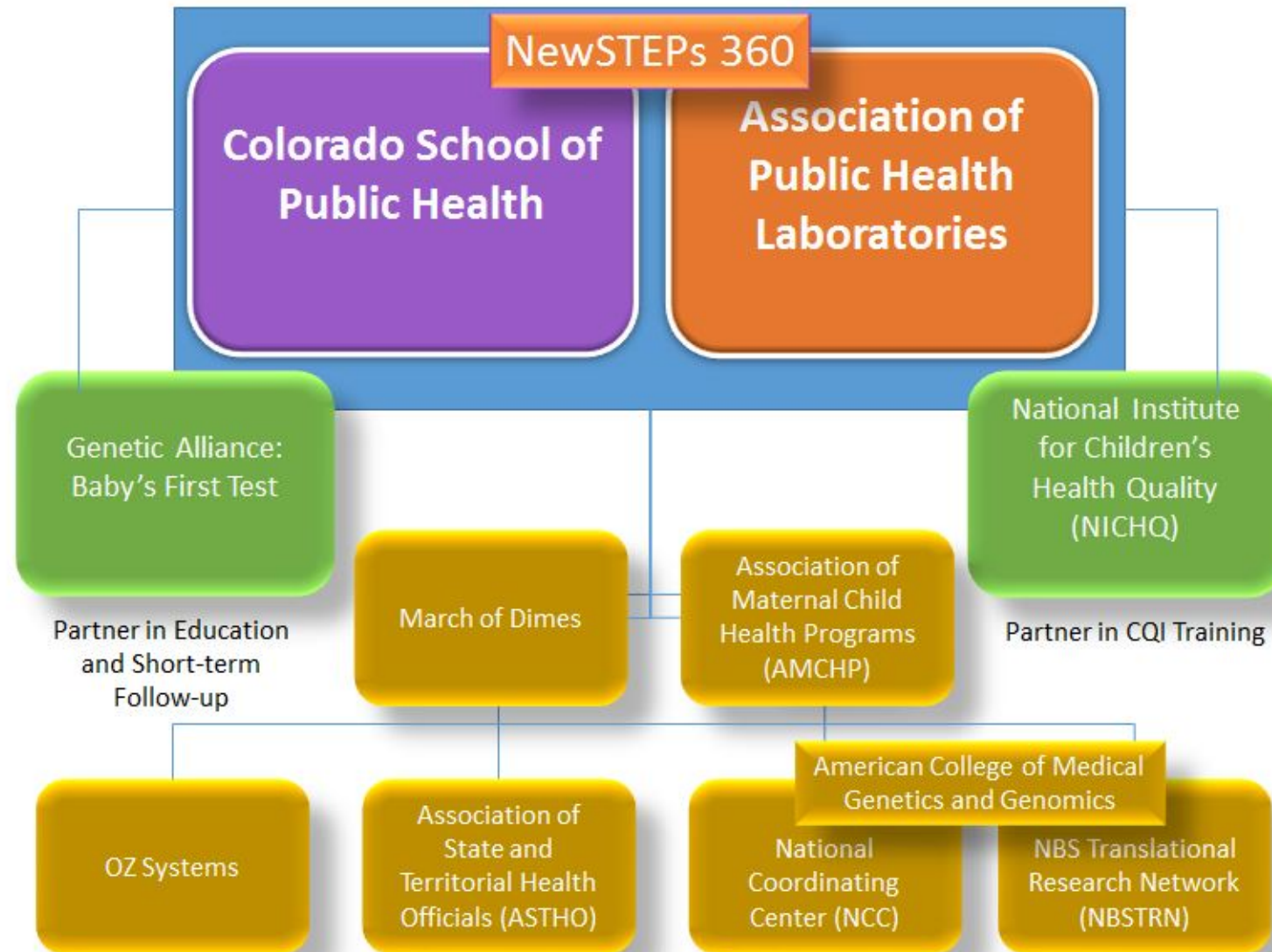


# NewSTEPs 360 Participants

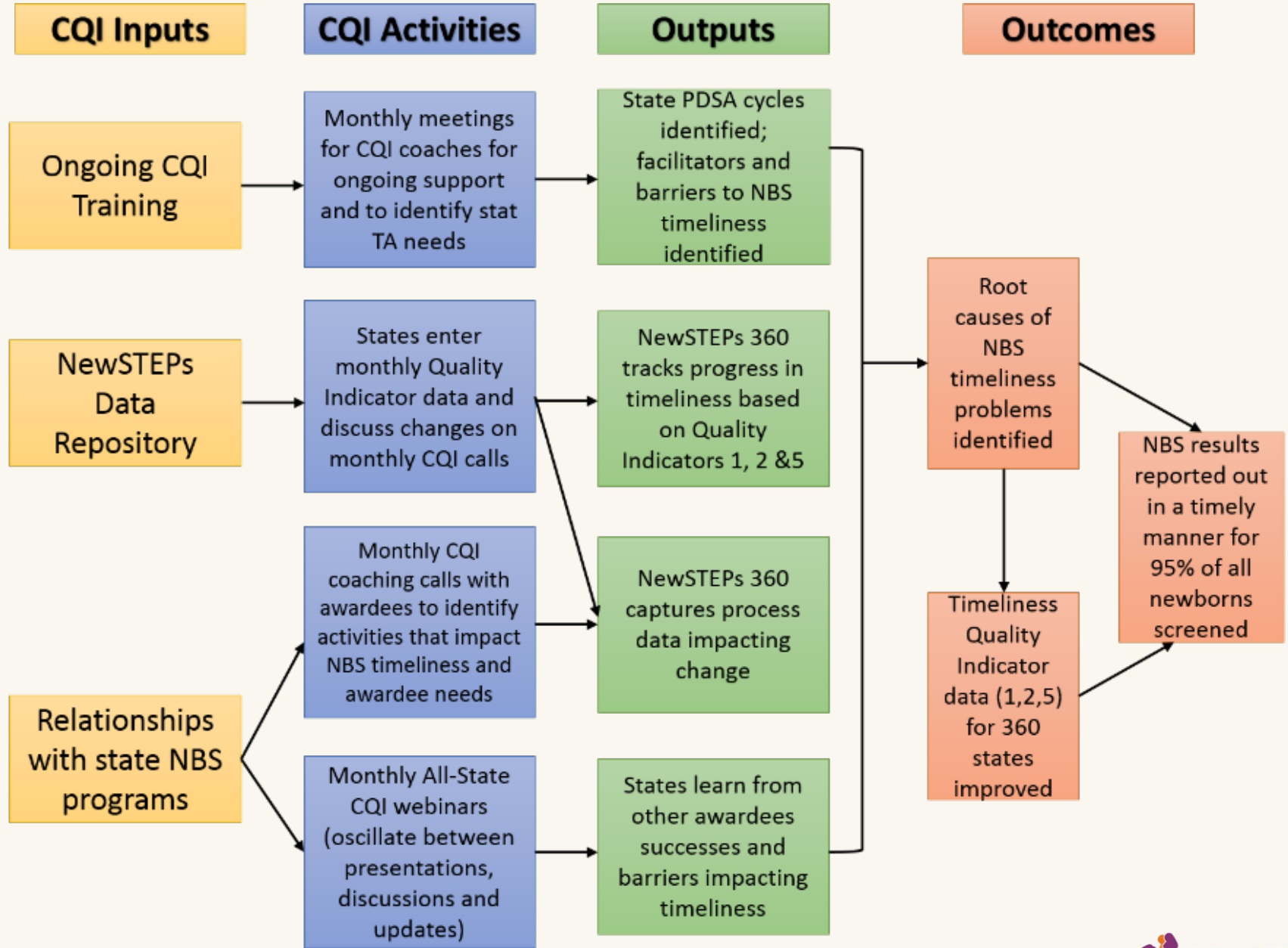




# NewSTEPS 360 Partners



# NewSTEPS 360 Activities



# NewSTEPS 360 Focus Areas

- Education
- Courier
- Operating Hours
- Laboratory Processes
- Short-term Follow-up
- Health Information Technology (HIT)

# NewSTEPs vs. NewSTEPs 360 Quality Indicator Timeliness Data

- 8 quality indicators and their subparts
  - NewSTEPs Data Repository collects annual data
  - NewSTEPs 360 collects monthly data to track NBS program progress in improving timeliness
- Quality Indicator 5 measures timeliness processes
  - 5d) Time from birth to reporting results
    - Presumptive positives for time critical disorders
    - Presumptive positives for non-time critical disorders
    - All results (presumptive positives and normal)
  - 5a) Time from birth to specimen collection
  - 5b) Time from specimen collection to specimen receipt at the testing laboratory
  - 5c) Time from specimen receipt to reporting results
    - Presumptive positives for time critical disorders
    - Presumptive positives for non-time critical disorders
    - All results (presumptive positives and normal)
- Entered as the number of specimens that fall into specific time interval categories
- Reported as the percentage of total specimens

# How many NBS programs submitted data?

| Data Type                  | Total Possible | # with Signed MOU         | # Submitted     |
|----------------------------|----------------|---------------------------|-----------------|
| NewSTEPs Timeliness Report | 53             | 20 (38%)<br>(August 2016) | <b>38</b> (72%) |
| NewSTEPs 360               | 28             | 25 (89%)                  | <b>22</b> (79%) |

- Non-MOU states submitted data via excel spreadsheet for 2016 report
- Final data submitted are not consistent across measures
- November 2017: 42/53 (79%) states have a signed MOU
  - NewSTEPs 360: 26/28 (93%)

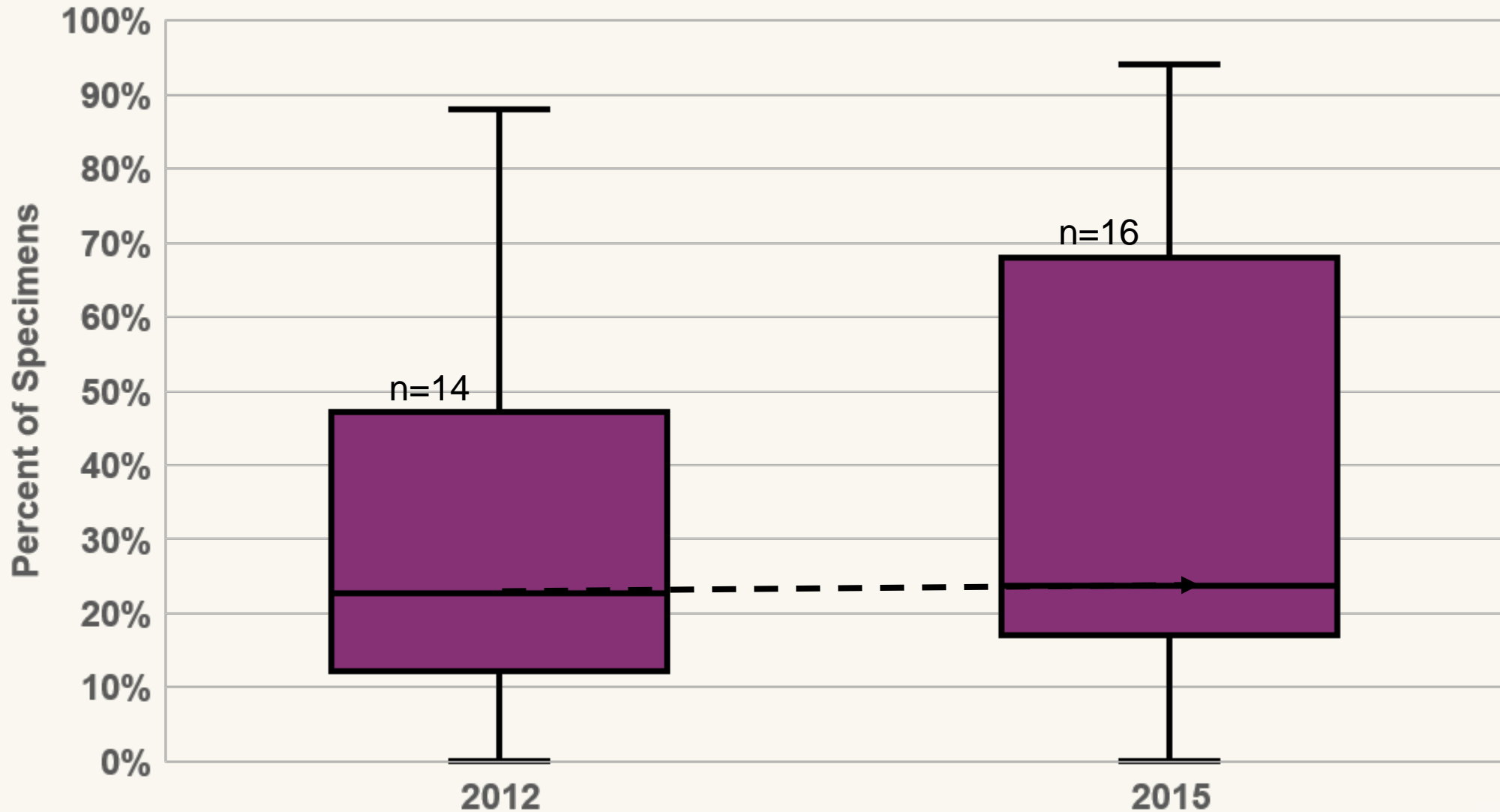
# Timeliness Progress

Aggregate level progress in achieving the ACHDNC recommended timeliness goals

# Timeliness Recommendation 1: Reporting Presumptive Positive Results for Time Critical Disorders

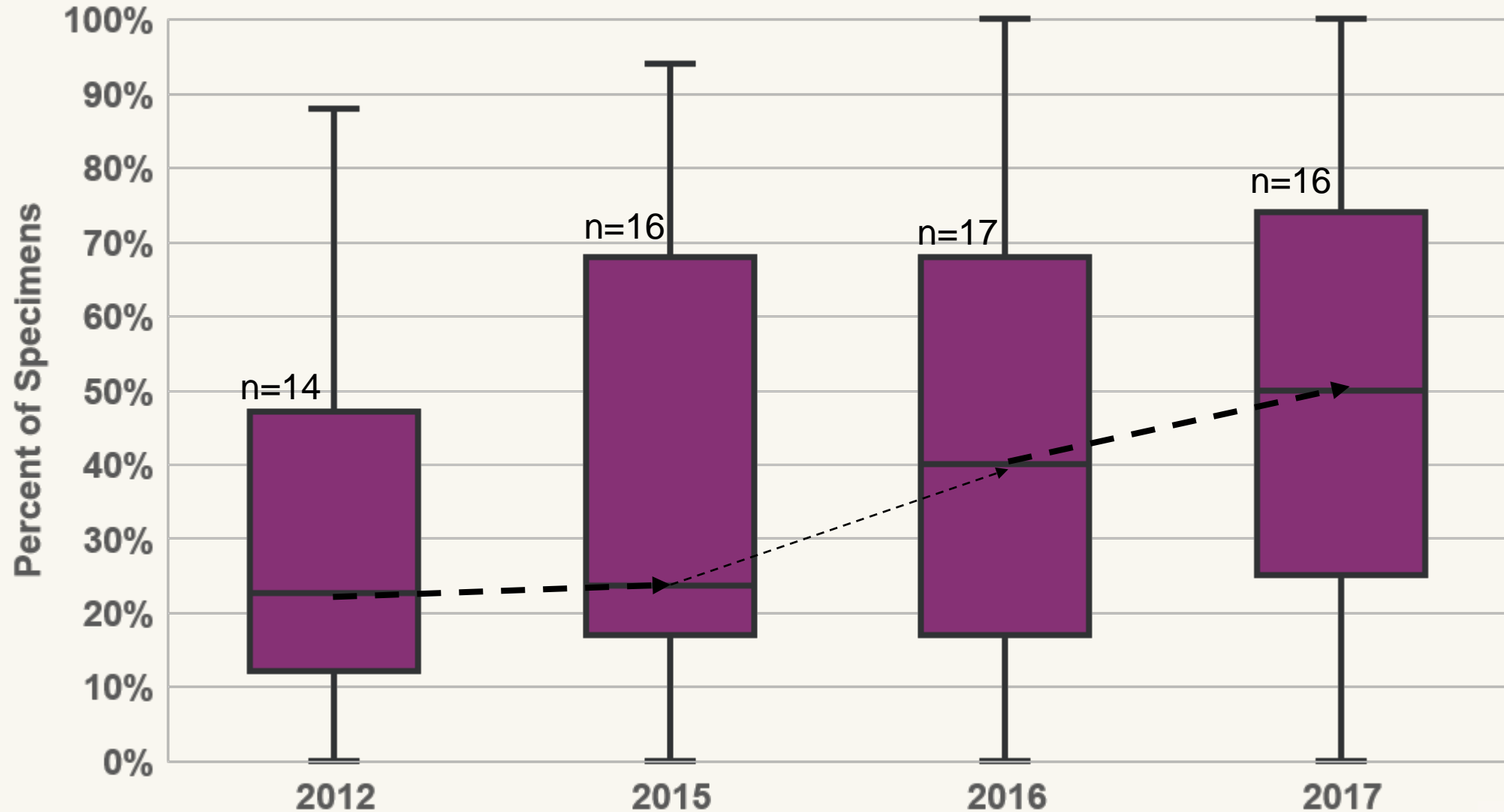
| Entity   | Result Type   | Time Elapsed from Birth | Goal                     |
|----------|---------------|-------------------------|--------------------------|
| ACHDNC   | Time Critical | $\leq 5$ Days           | 95% of initial specimens |
| NewSTEPS | Time Critical | $\leq 5$ Days           | 95% of Specimens         |

# NewSTEPS Report: Median percent of specimens with a presumptive positive result for time critical disorders reported within 5 days of birth increased from 23% in 2012 to 24% in 2015

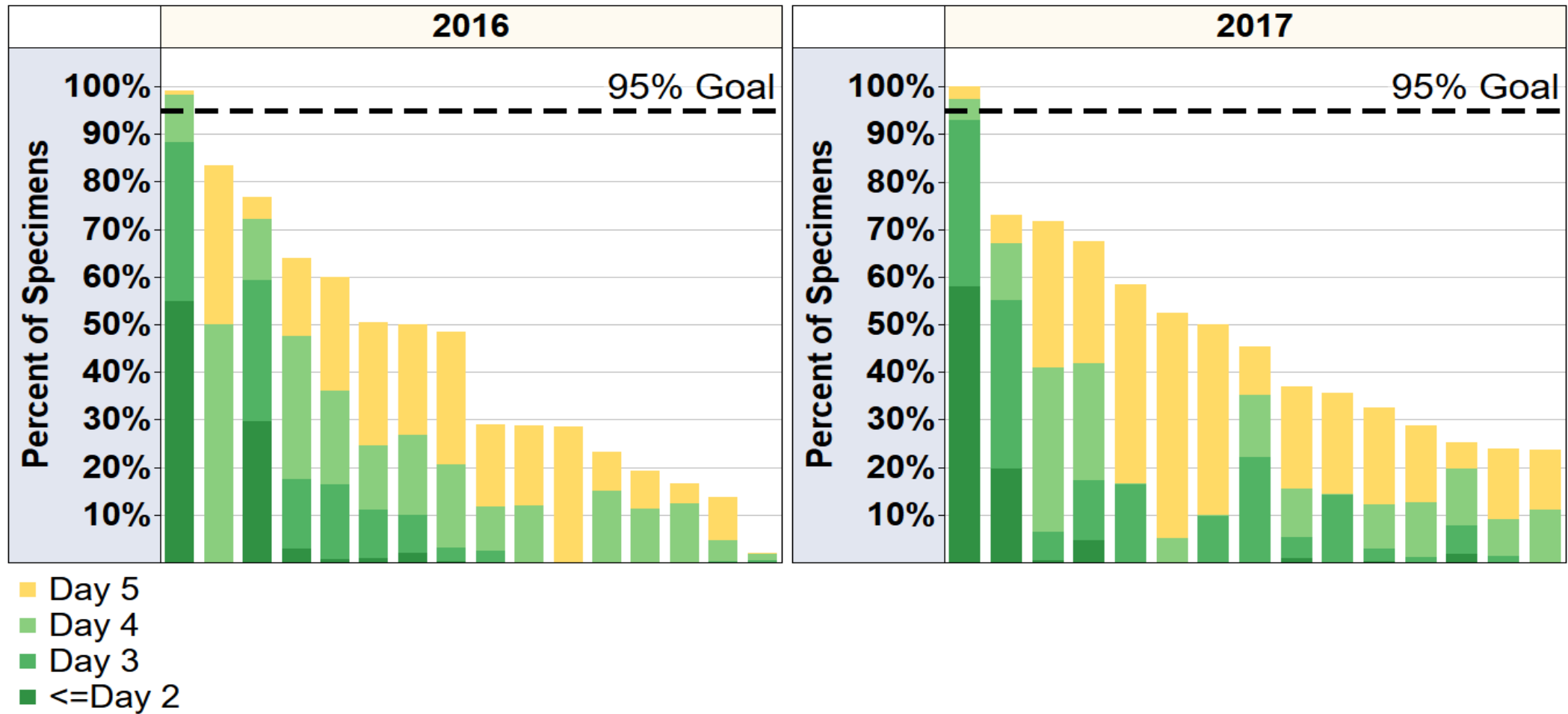




# NewSTEPS 360: Median percent of specimens with a presumptive positive result for time critical disorders within 5 days of birth improved to 40% in 2016 and 50% in 2017



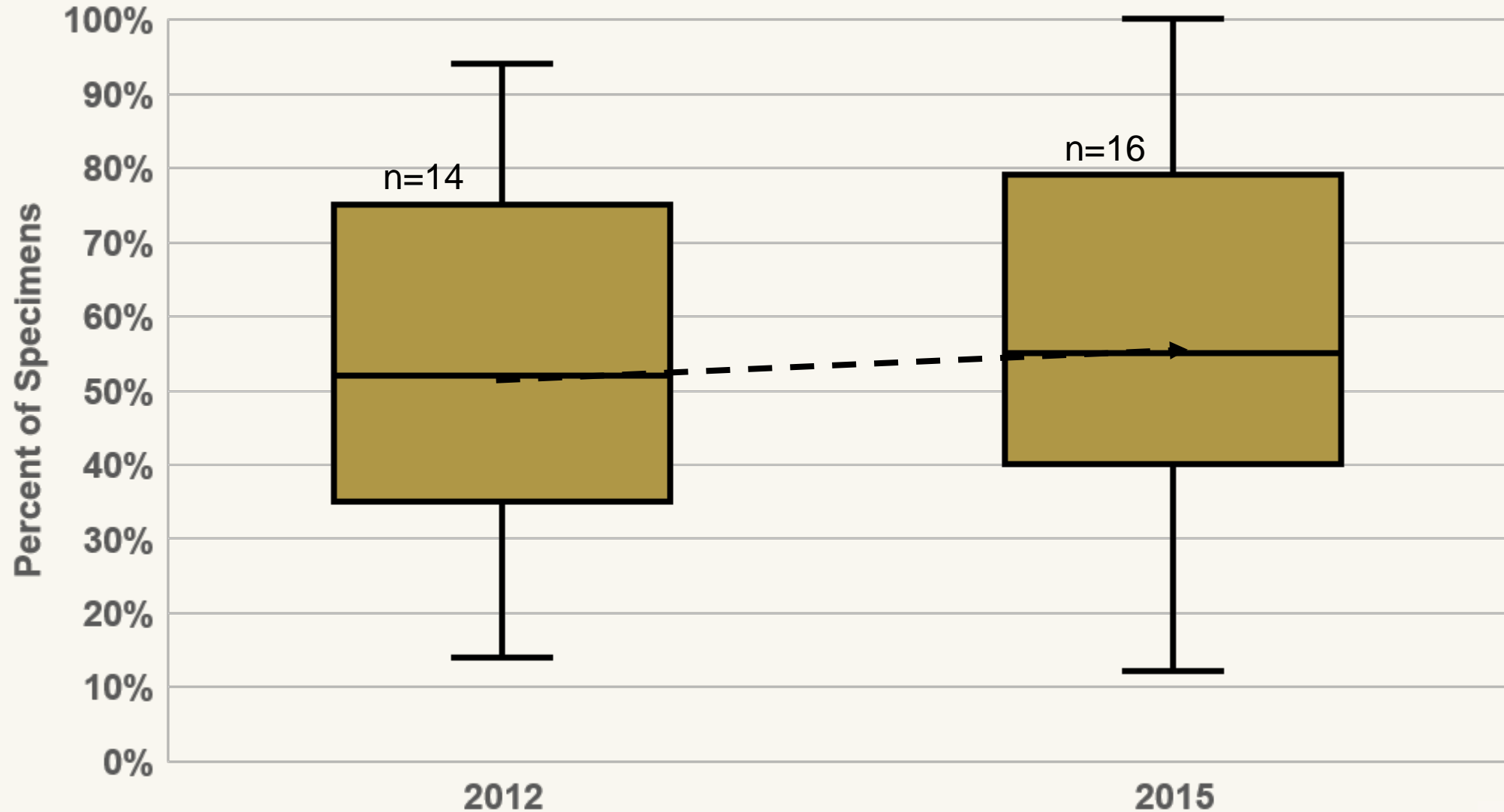
# NewSTEPS 360: 1 (6%) NBS program in 2016 and 1 (6%) in 2017 achieved reporting 95% of specimens with a presumptive positive result for time critical disorders within 5 days of birth



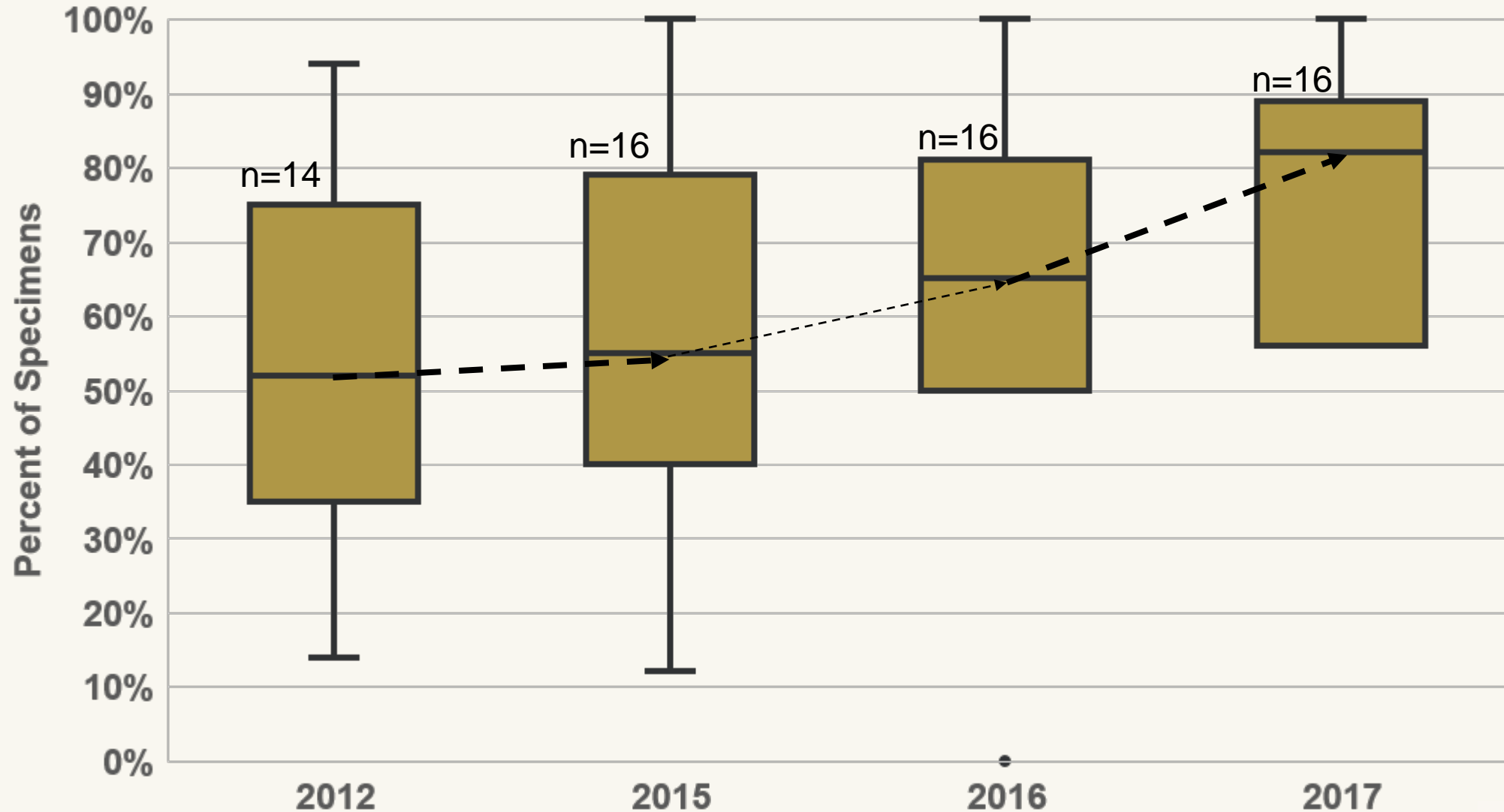
# Timeliness Recommendation 2: Reporting Presumptive Positive Results for Non-Time Critical Disorders

| Entity   | Result Type       | Time Elapsed from Birth | Goal                     |
|----------|-------------------|-------------------------|--------------------------|
| ACHDNC   | Non-Time Critical | $\leq 7$ Days           | 95% of initial specimens |
| NewSTEPs | Non-Time Critical | $\leq 7$ Days           | 95% of Specimens         |

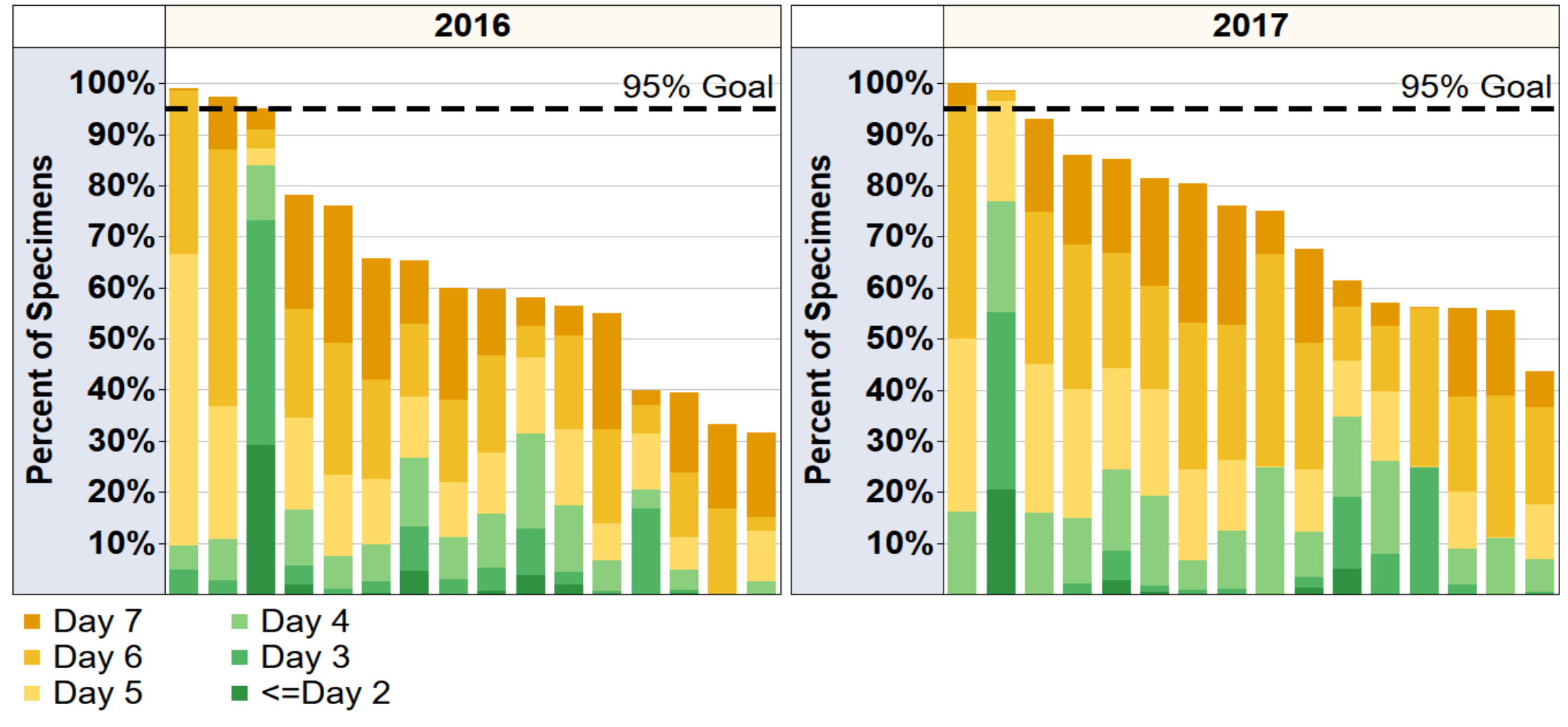
# NewSTEPS Report: Median percent of specimens with a presumptive positive result for non-time critical disorders reported within 7 days of birth increased from 52% in 2012 to 55% in 2015



# NewSTEPS 360: Median percent of specimens with a presumptive positive result for non-time critical disorders reported within 7 days of birth improved to 65% in 2016 and 82% in 2017



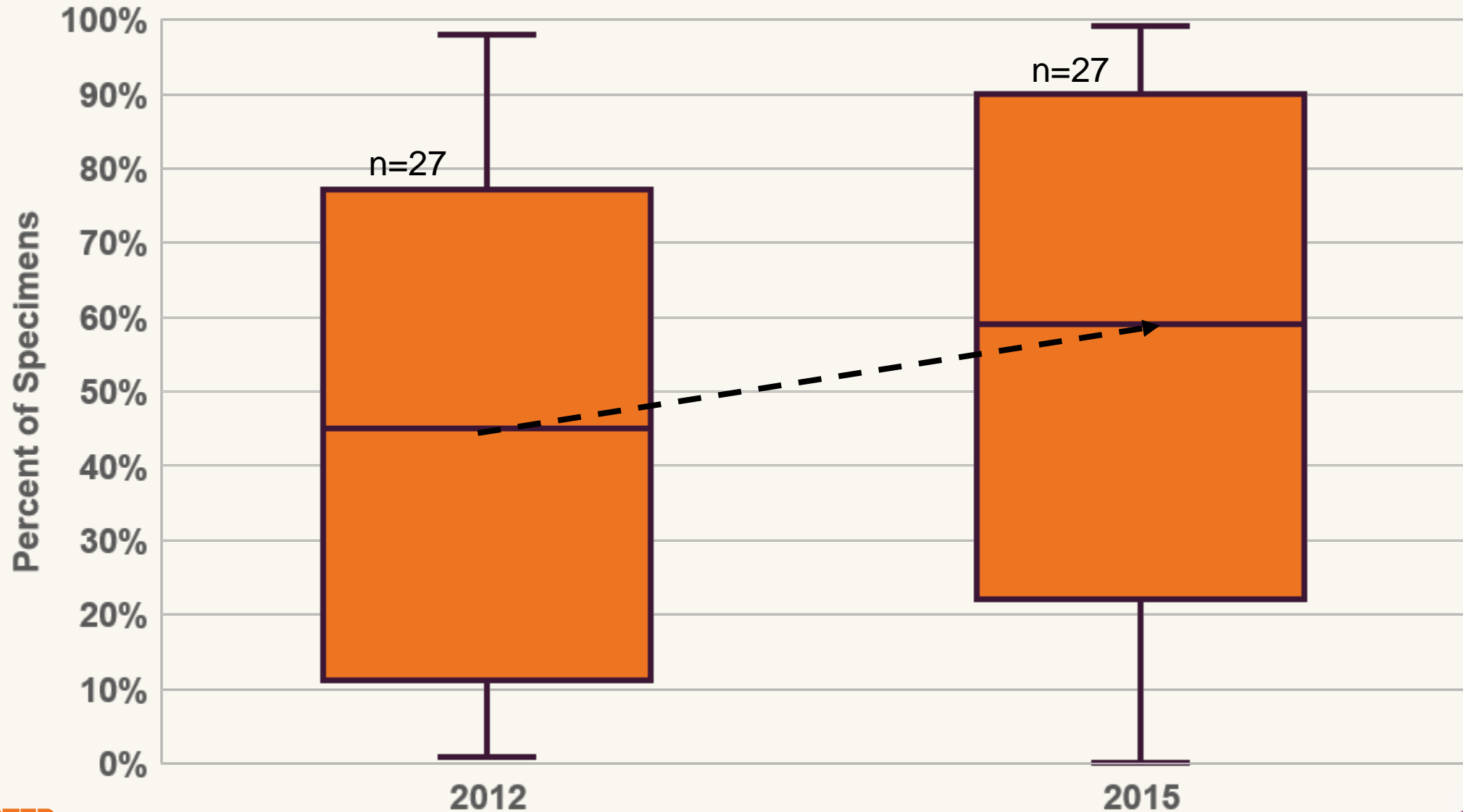
# NewSTEPS 360: 3 (19%) NBS program in 2016 and 2 (13%) in 2017 achieved reporting 95% of specimens with a presumptive positive result for non-time critical disorders within 7 days of birth



# Timeliness Recommendation 3: Reporting All Results from All Tests

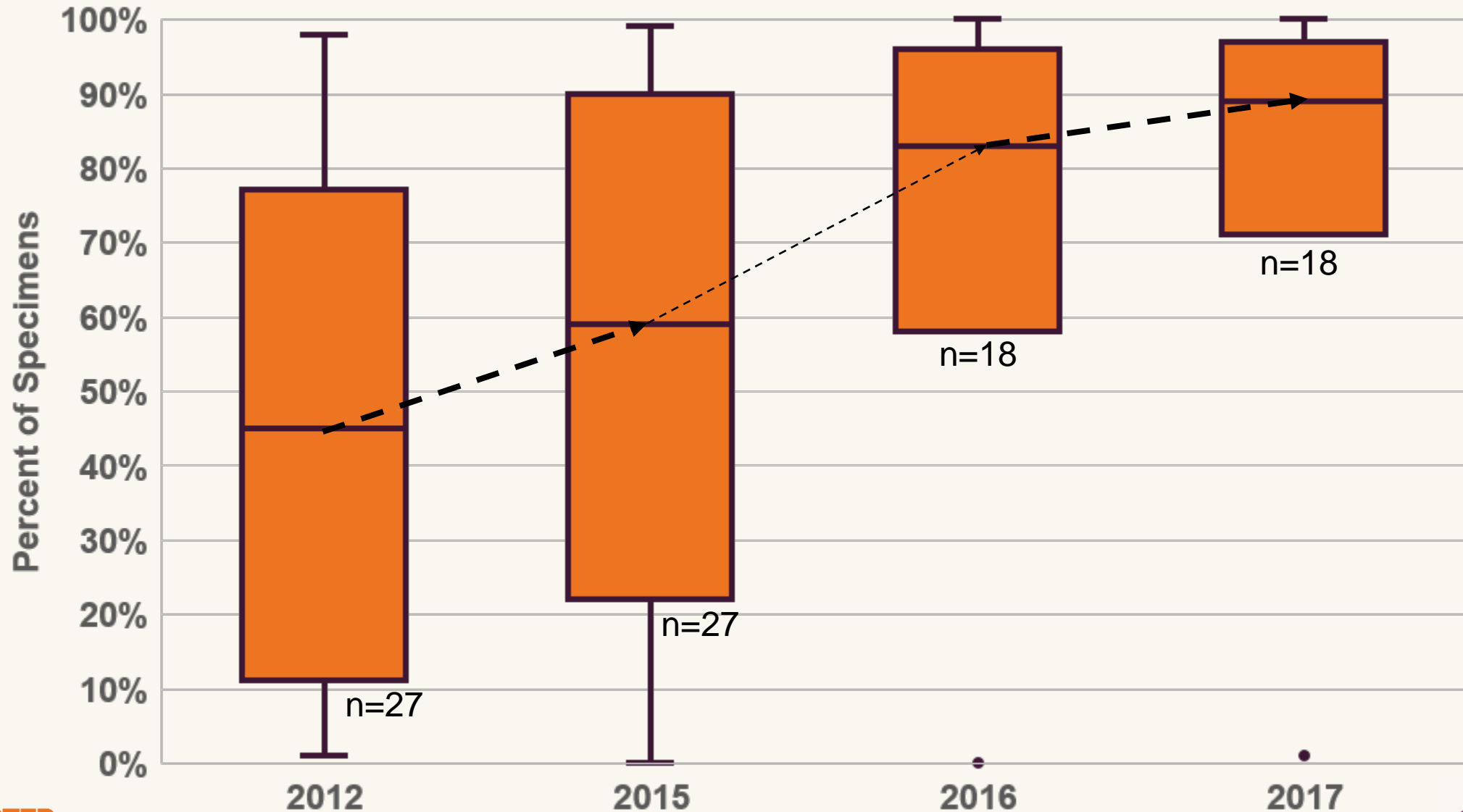
| Entity   | Result Type | Time Elapsed from Birth | Goal                     |
|----------|-------------|-------------------------|--------------------------|
| ACHDNC   | All         | $\leq 7$ Days           | 95% of initial specimens |
| NewSTEPs | All         | $\leq 7$ Days           | 95% of initial specimens |

# NewSTEPS Report: Median percent of specimens for all results reported within 7 days of birth increased from 45% in 2012 to 59% in 2015

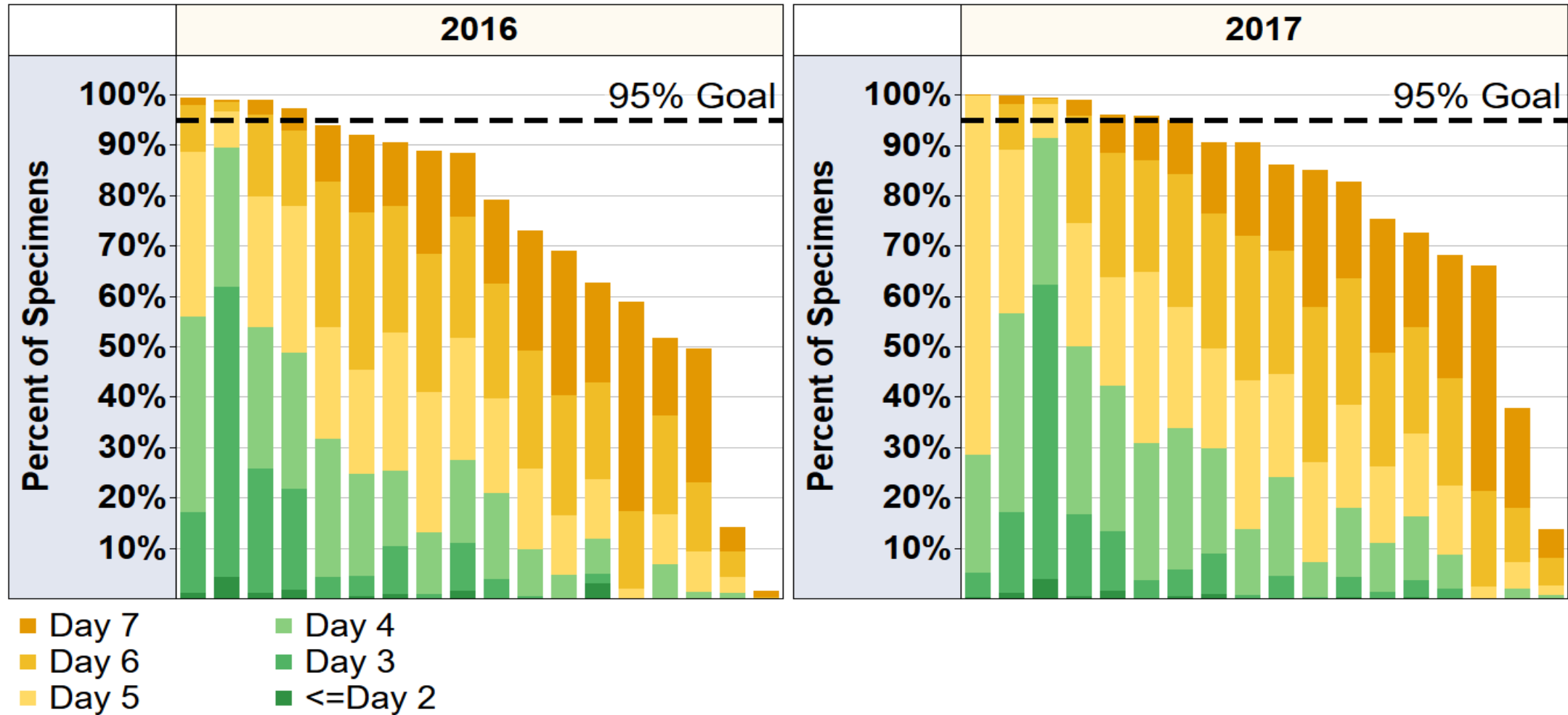




# NewSTEPS 360: Median percent of specimens for all results reported within 7 days of birth improved to 83% in 2016 and 89% in 2017



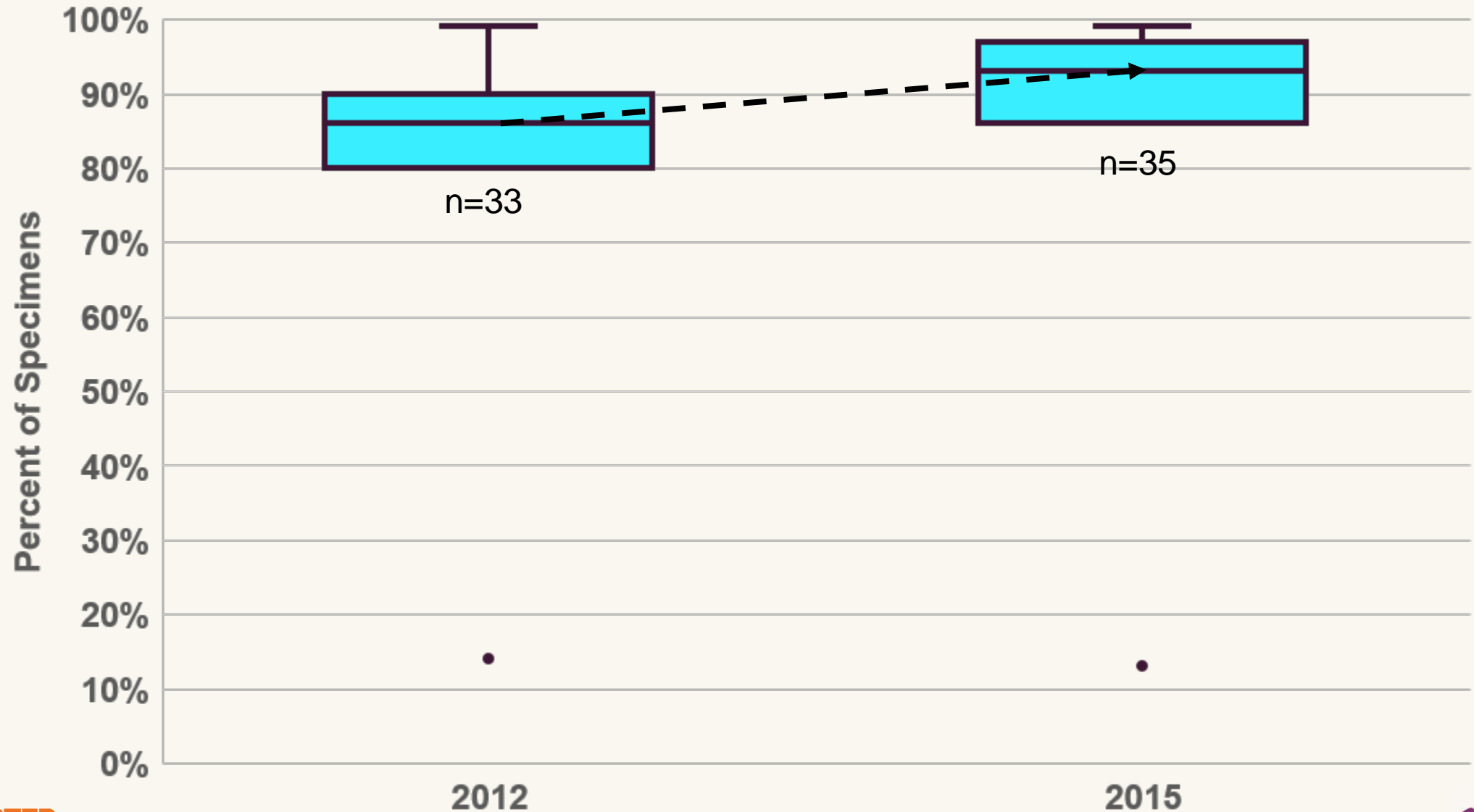
# NewSTEPS 360: 4 (22%) NBS program in 2016 and 7 (39%) in 2017 achieved reporting 95% of specimens for all normal and presumptive positive results within 7 days of birth



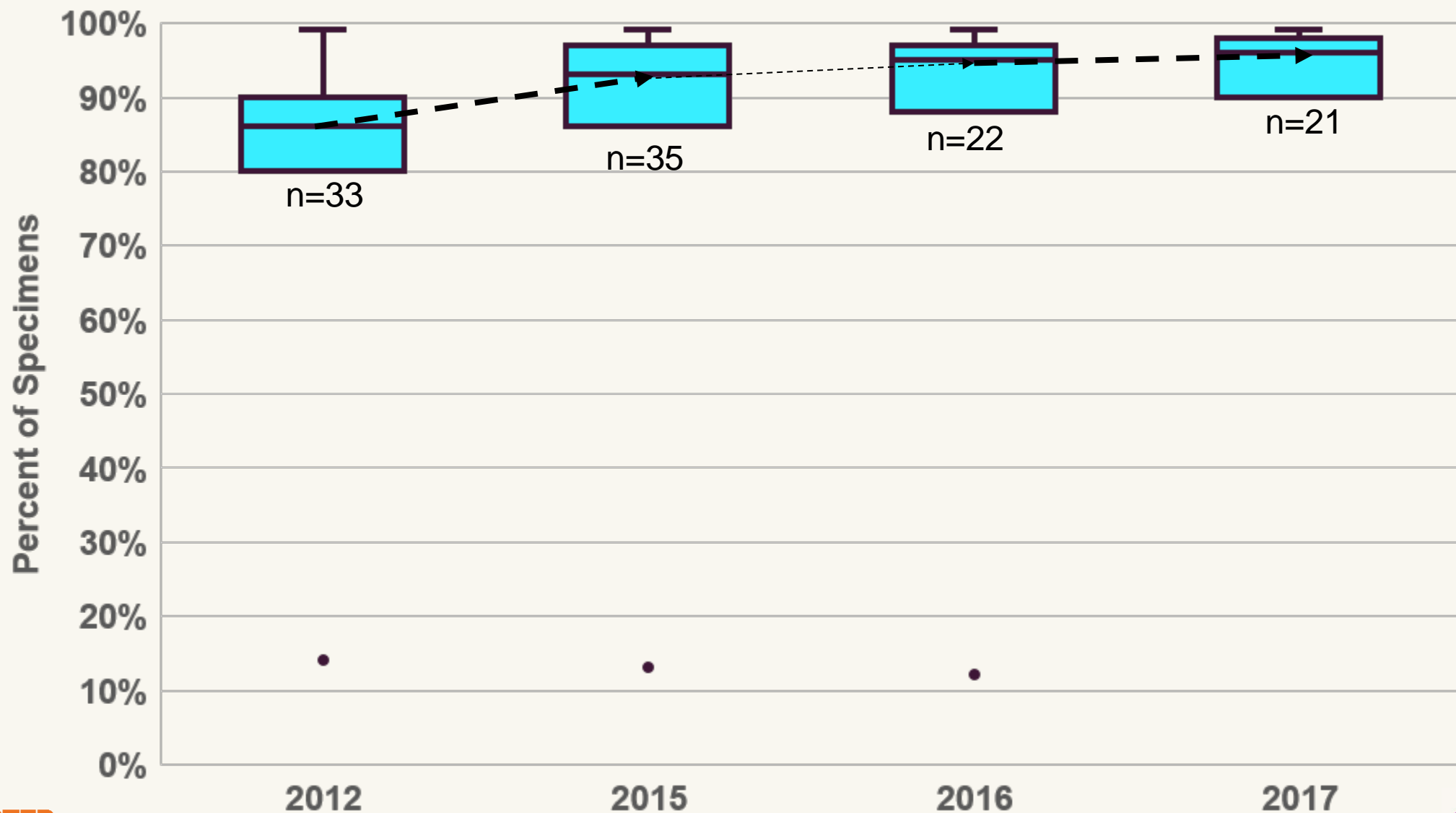
# Timeliness Recommendation 4: Specimen Collection

| Entity   | Process             | Time Elapsed from Birth | Goal                     |
|----------|---------------------|-------------------------|--------------------------|
| ACHDNC   | Specimen Collection | $\leq 48$ Hours         | 95% initial specimens    |
| NewSTEPs | Specimen Collection | $\leq 48$ Hours         | 95% of initial specimens |

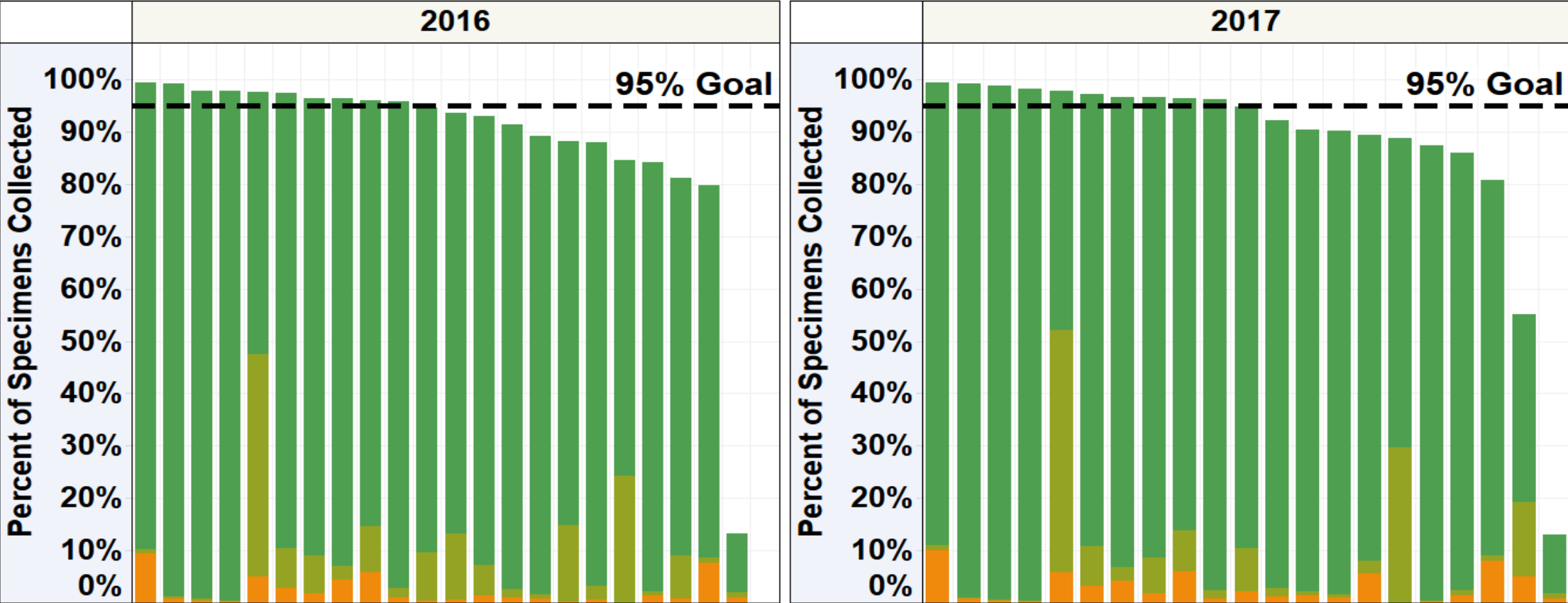
# NewSTEPS Report: Median percent of specimens collected within 48 hours of birth increased from 86% in 2012 to 93% in 2015



# NewSTEPS 360: Median percent of specimens collected within 48 hours of birth increased from 95% in 2016 to 96% in 2017



# NewSTEPS 360: 11 (50%) NBS programs in 2016 and 11 (52%) in 2017 achieved collecting 95% of first specimens within 48 hours of birth

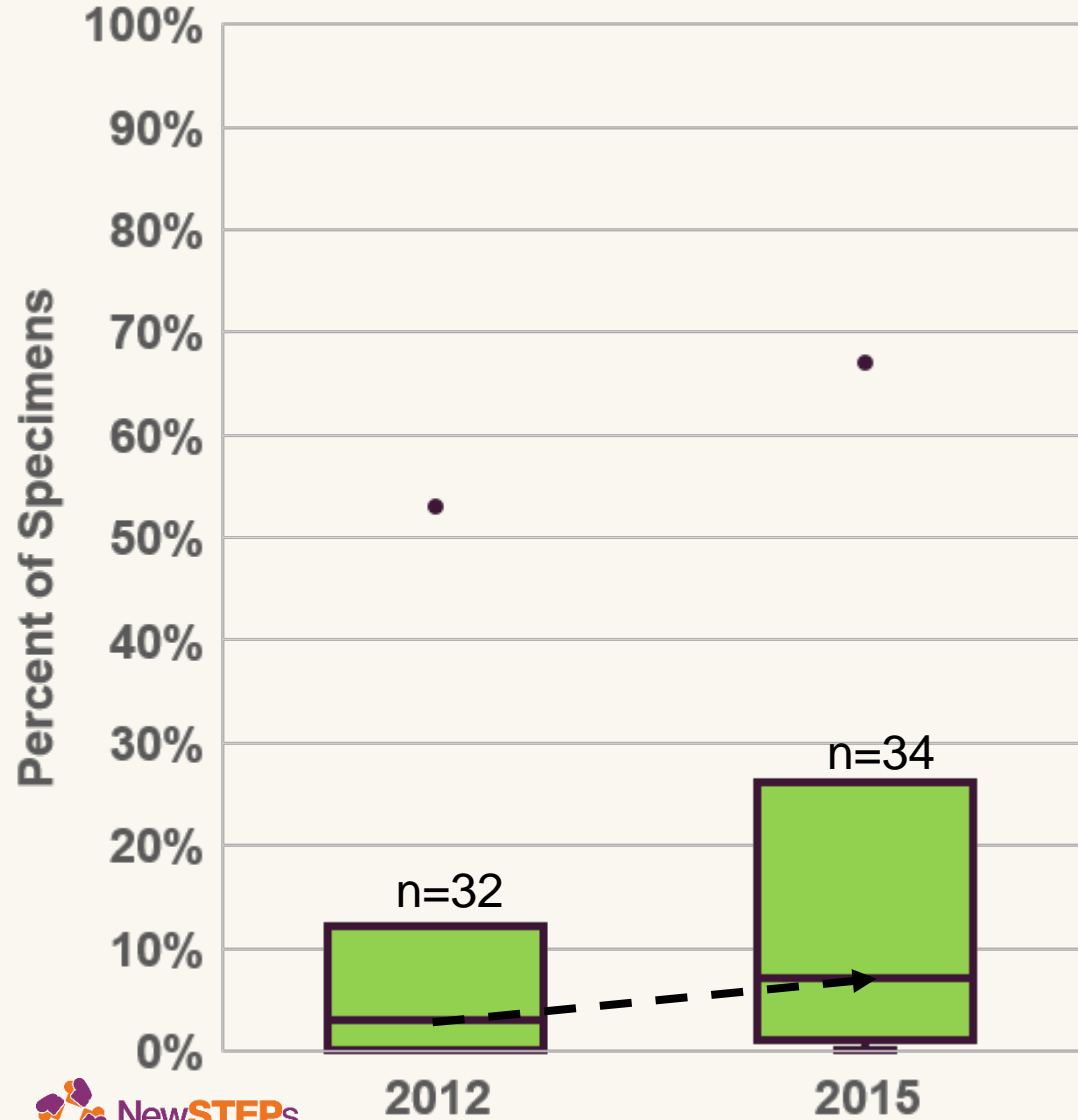


- >24 to 48 Hours
- 12 to 24 Hours
- <12 Hours

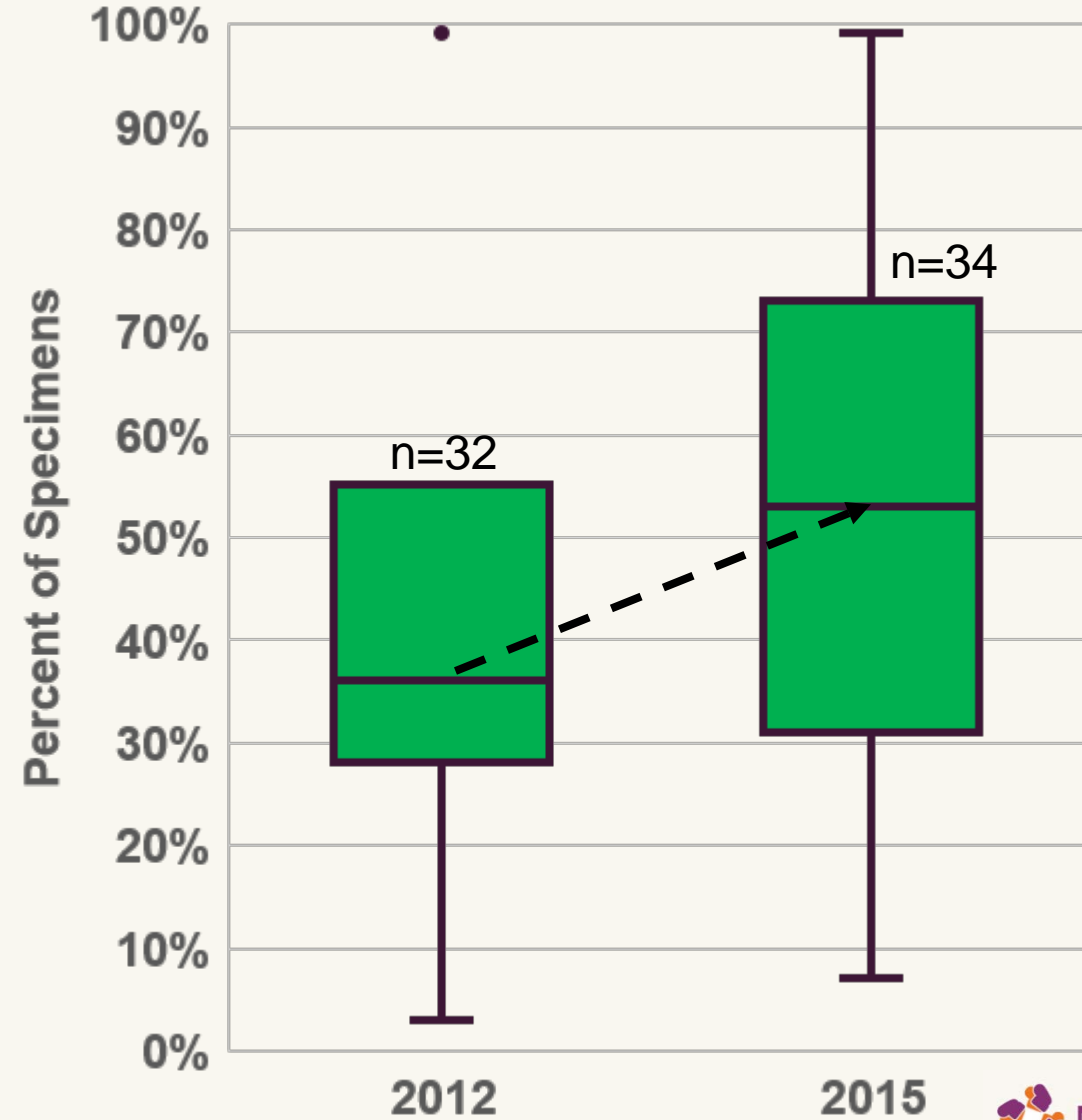
# Timeliness Recommendation 5: Specimen Receipt at the Laboratory

| Entity       | Process          | Time Elapsed from <b>Specimen Collection</b> | Goal                     |
|--------------|------------------|--|--------------------------|
| ACHDNC       | Specimen Receipt | Ideally $\leq 24$ Hours                      | 95% of initial specimens |
| NewSTEPs     | Specimen Receipt | Ideally $\leq 24$ Hours                      | 95% of initial specimens |
| NewSTEPs 360 | Specimen Receipt | Realistically $\leq 2$ Days                  | 95% of initial specimens |

**NewSTEPs Report: Median percent of specimens received within 24 hours of collection increased from 3% in 2012 to 7% in 2015**

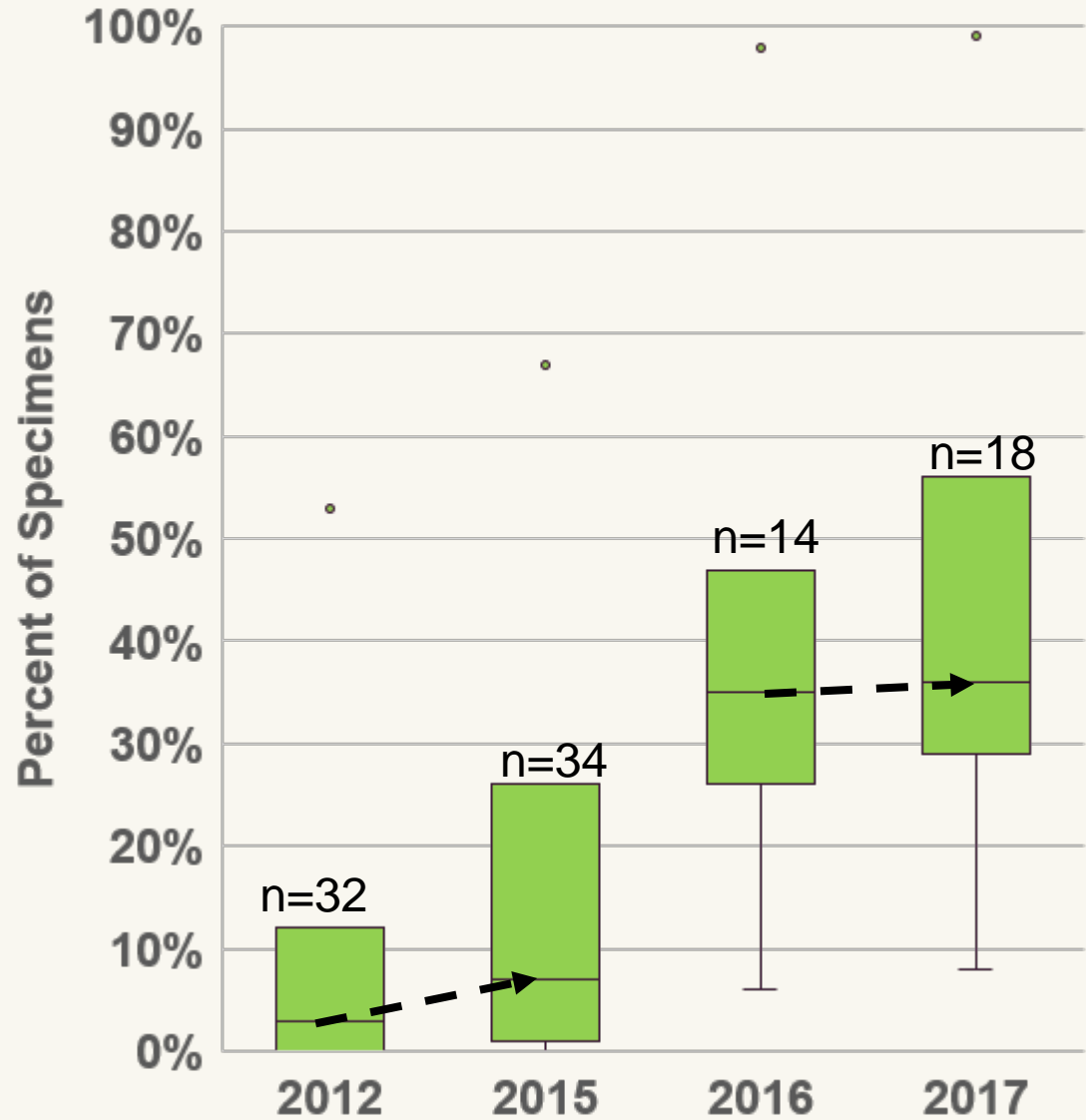


**NewSTEPs Report: Median percent of specimens received within 48 hours of collection increased from 36% in 2012 to 53% in 2015**

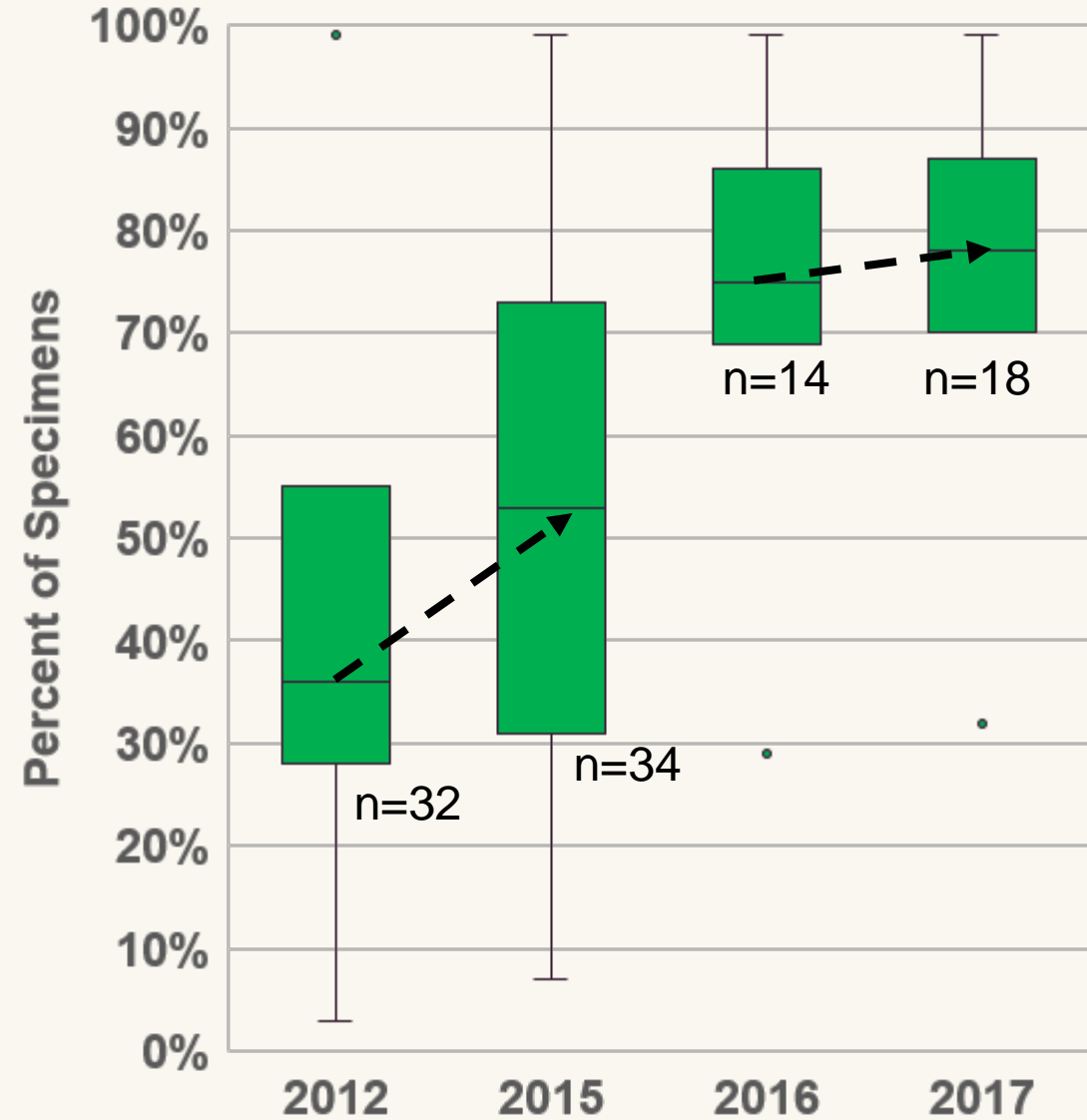




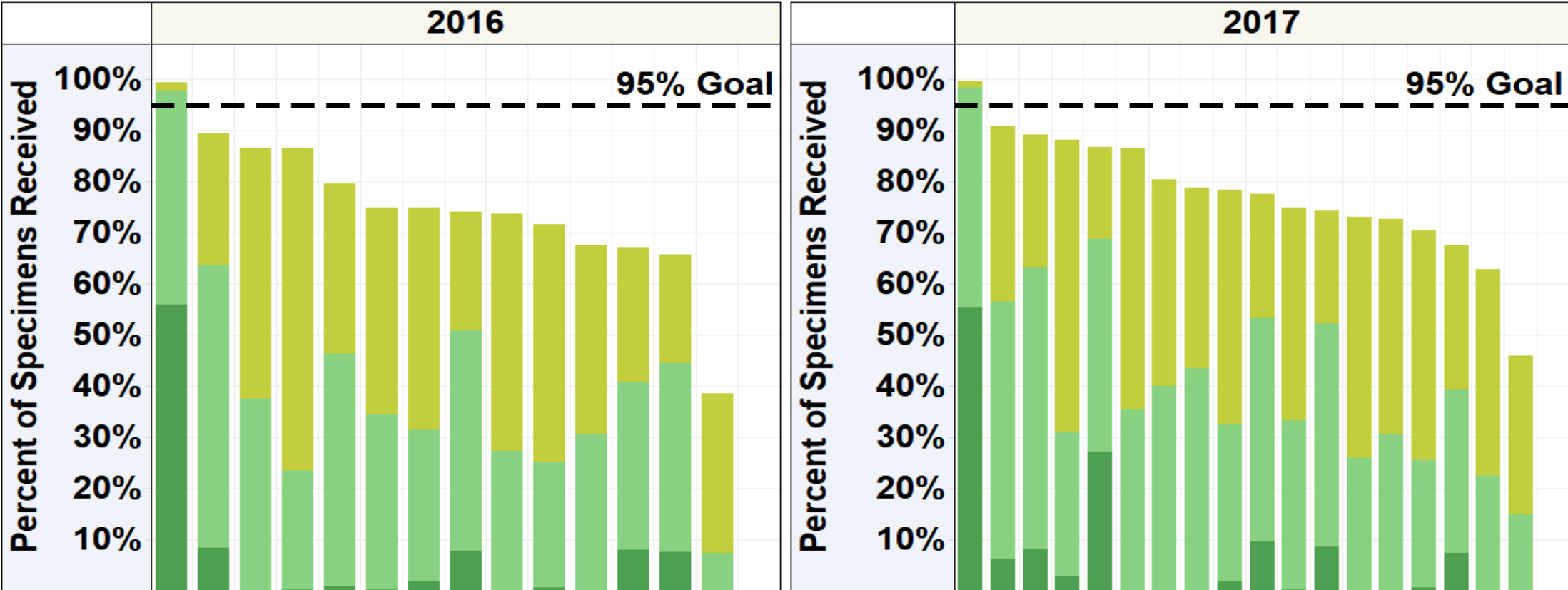
**NewSTEPS 360: Median percent of specimens received within 1 day of collection increased from 35% in 2016 to 36% in 2017**



**NewSTEPS 360: Median percent of specimens received within 2 days of collection increased from 75% in 2012 to 78% in 2015**



# NewSTEPs 360: 1 (7%) NBS program in 2016 and 1 (6%) in 2017 achieved receiving 95% of first specimens within 2 days of specimen collection

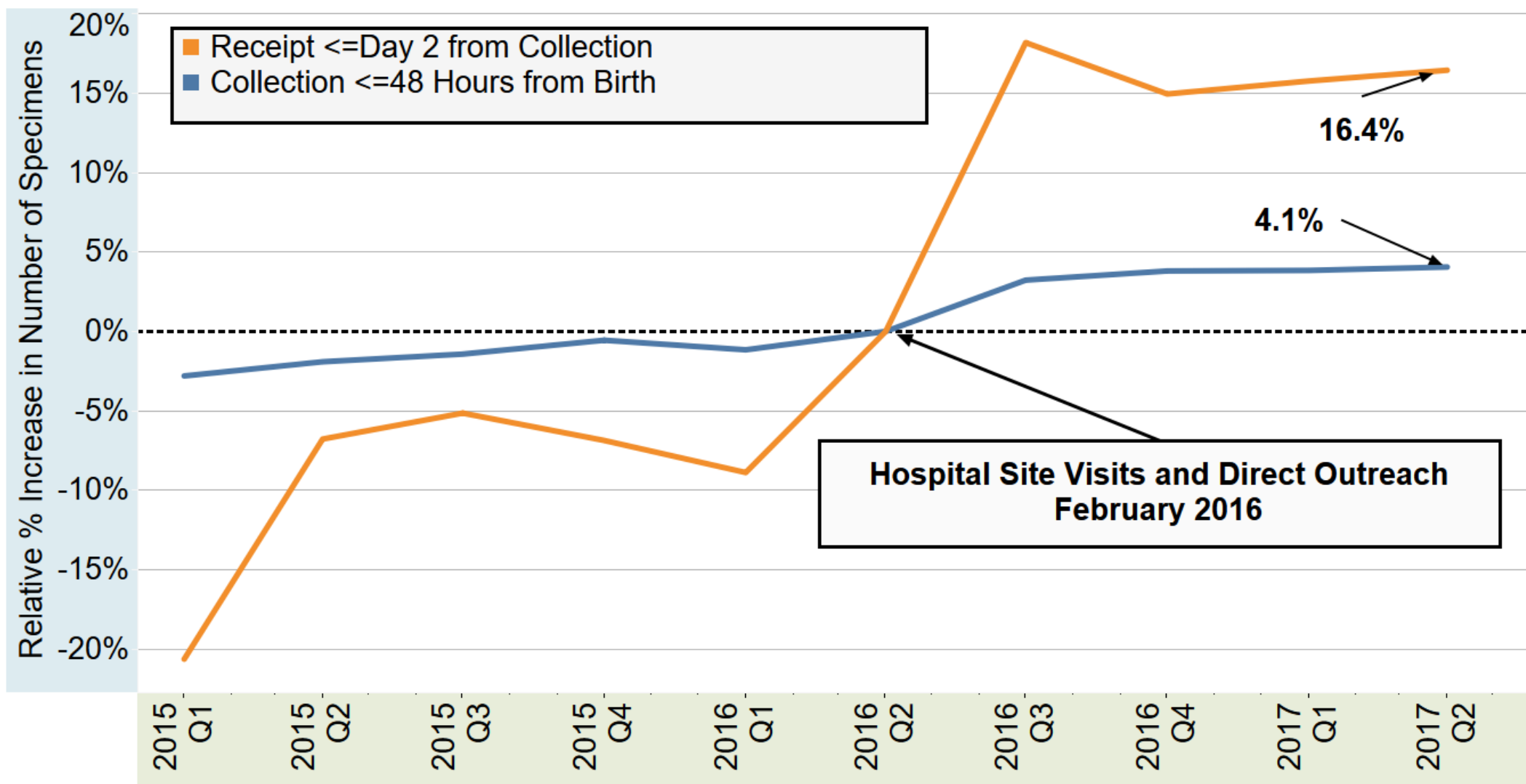


- Day 2
- Day 1 (Next Day)
- Day 0 (Same Day)

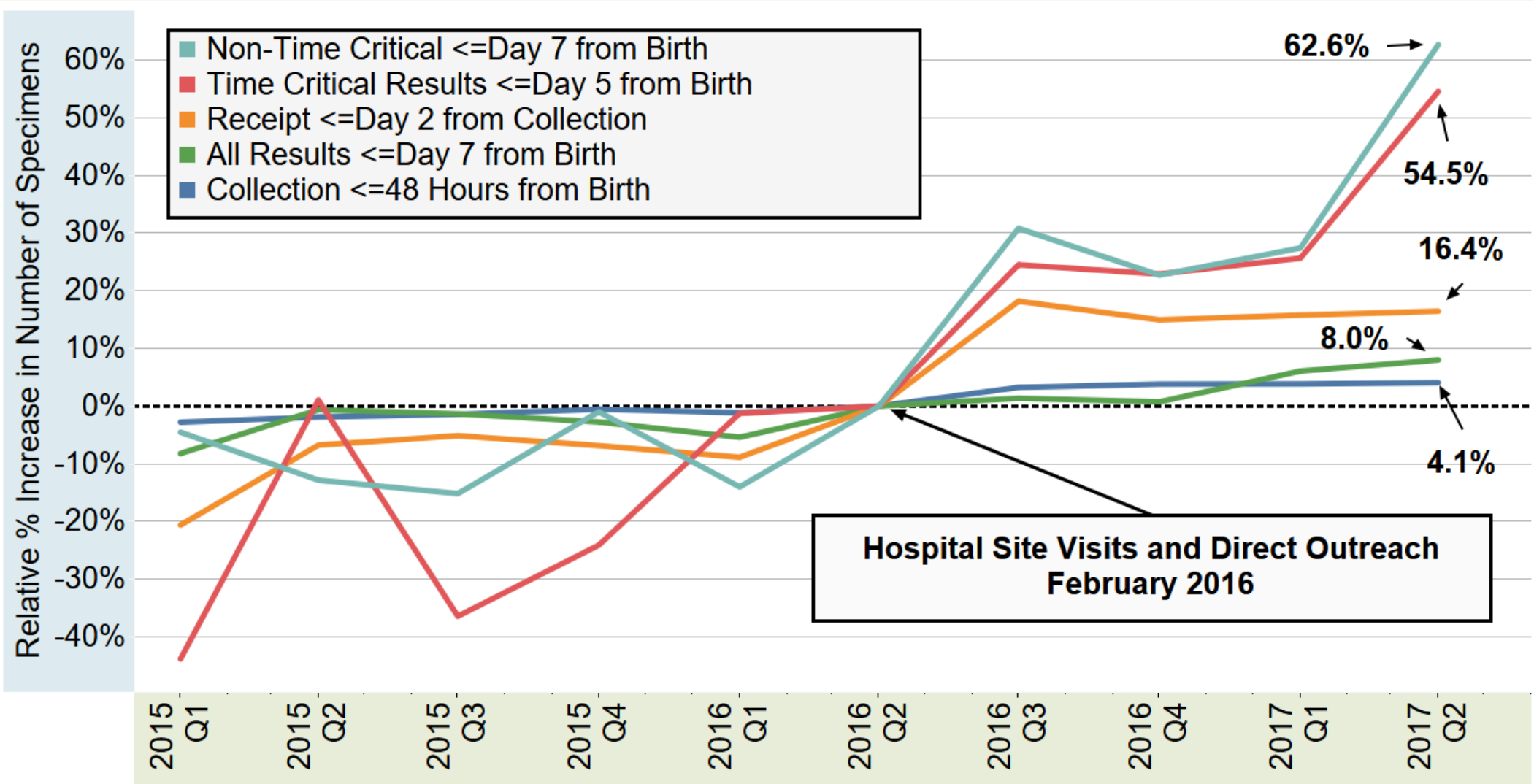
# Factors that Impact Timeliness

Examples of implemented changes by newborn screening programs that have resulted in timeliness improvements

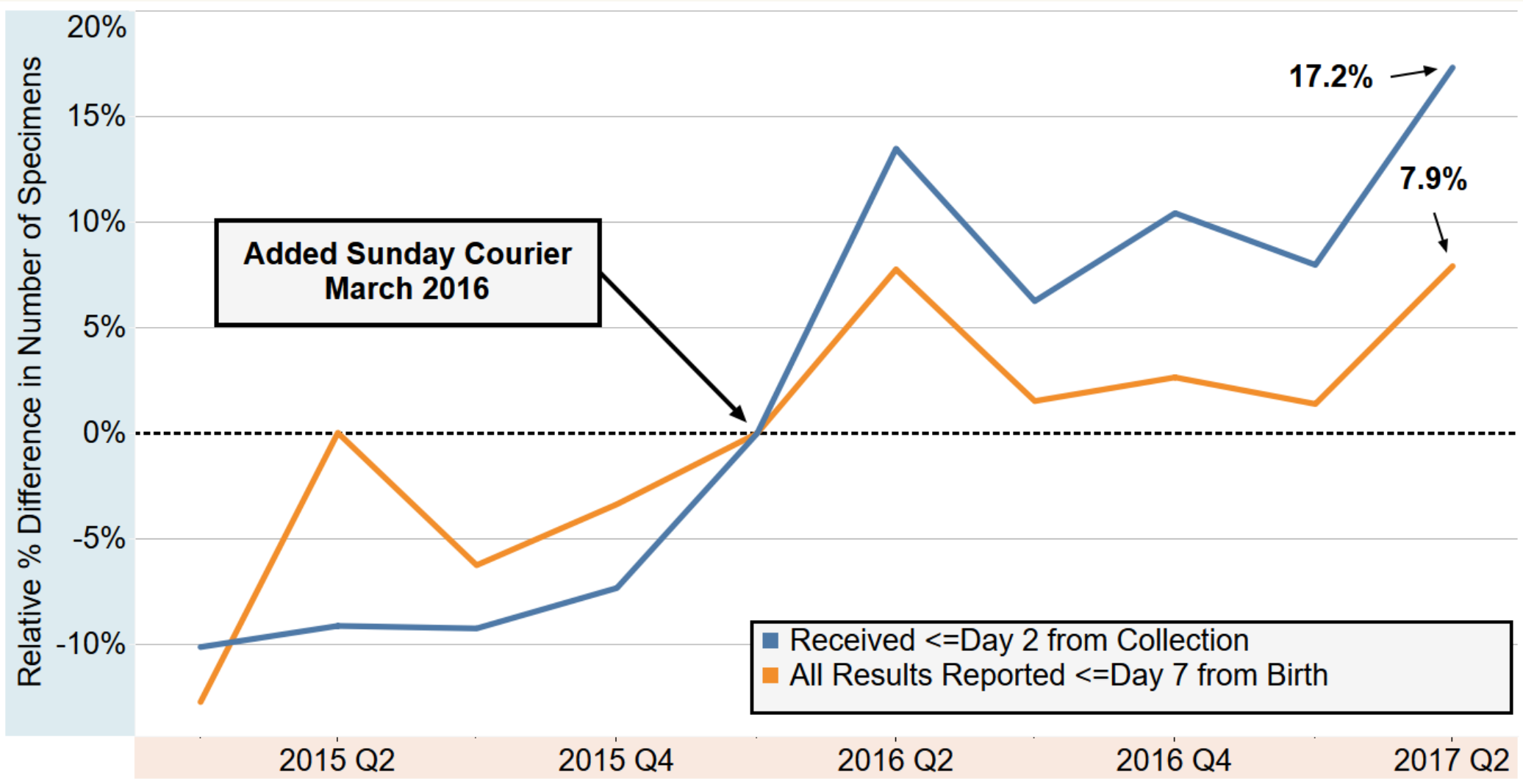
**Virginia:** A combination of educational efforts including hospital site visits, direct outreach via phone to nurse managers, and educational videos increased the percent of specimens collected within 48 hours of birth by 4% and the percent of specimens received within 2 days of collection by 16%



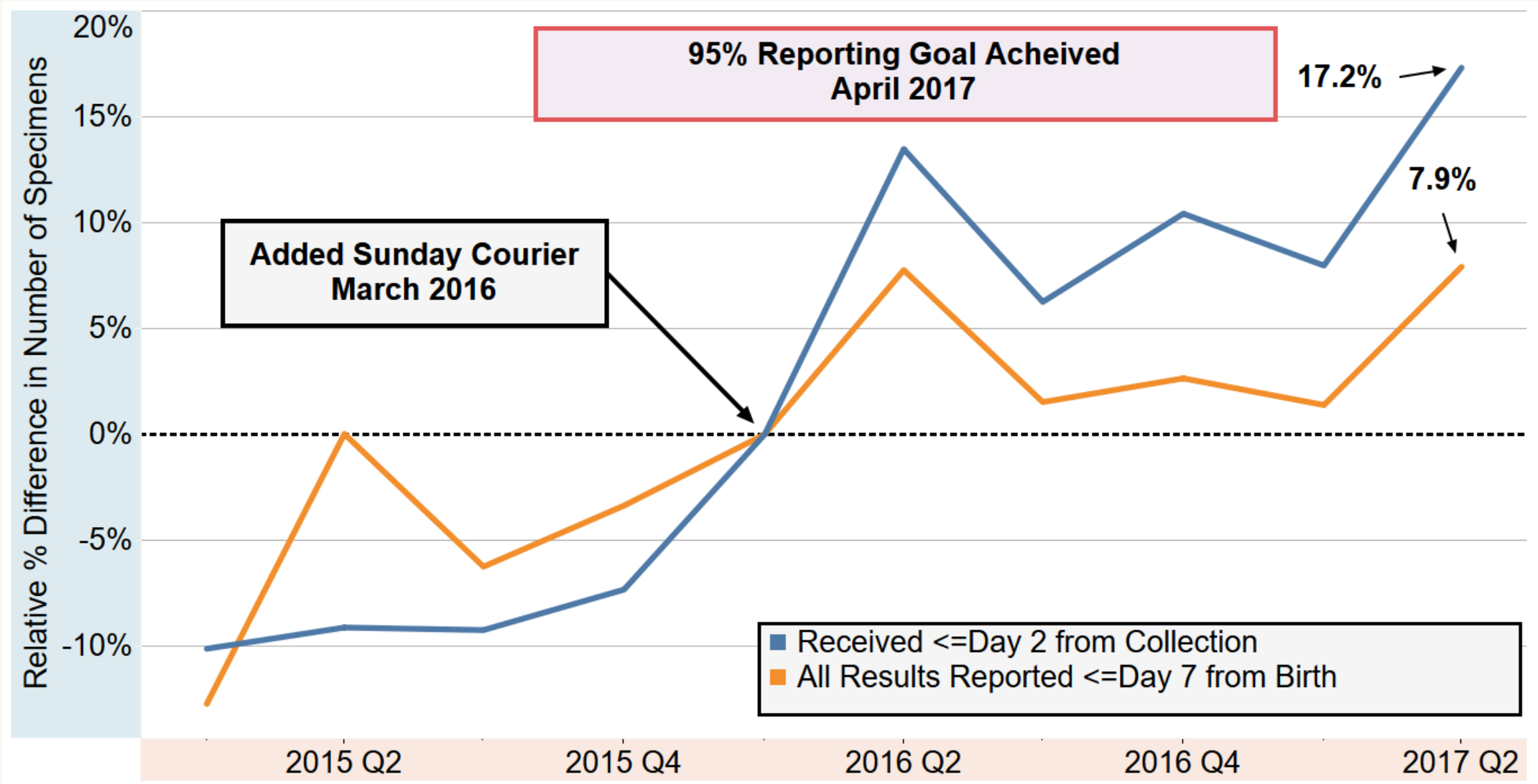
**Virginia:** A combination of educational efforts including hospital site visits, direct outreach via phone to nurse managers, and educational videos increased the percent of specimens with a non-time critical result reported within 7 days of birth by 63% and the percent of specimens with a time-critical result reported within 5 days of birth by 55%



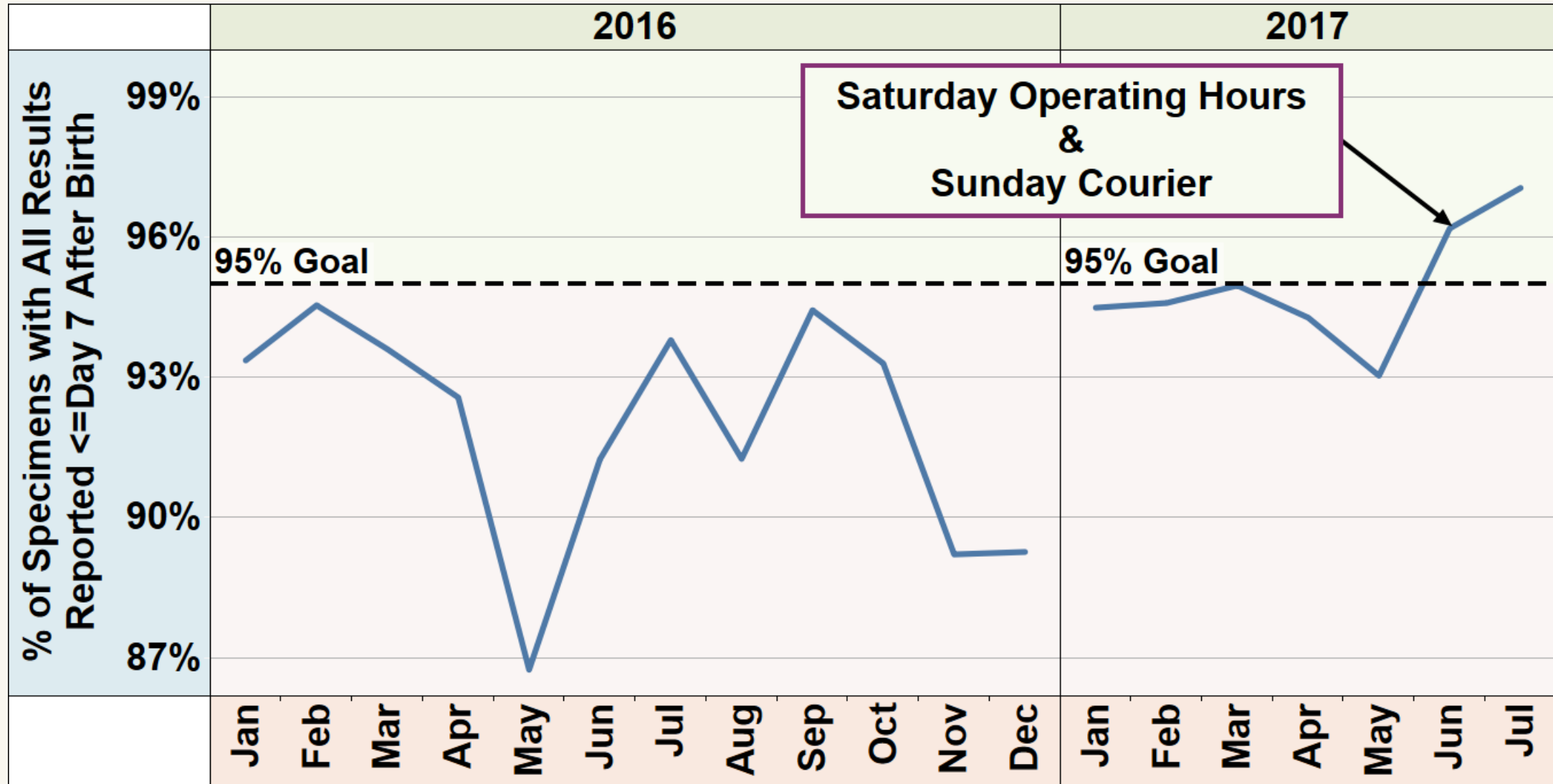
**Montana:** Adding a 6<sup>th</sup> day (Sunday) courier for larger facilities and overnight UPS shipping for facilities not on the courier route increased the percent of specimens received within 2 days of collection by 17% and increased the percent of specimens with all results reported within 7 days of birth by 8%



**Montana:** Adding a 6<sup>th</sup> day (Sunday) courier for larger facilities and overnight UPS shipping for facilities not on the courier route increased the percent of specimens received within 2 days of collection by 17% and increased the percent of specimens with all results reported within 7 days of birth by 8%

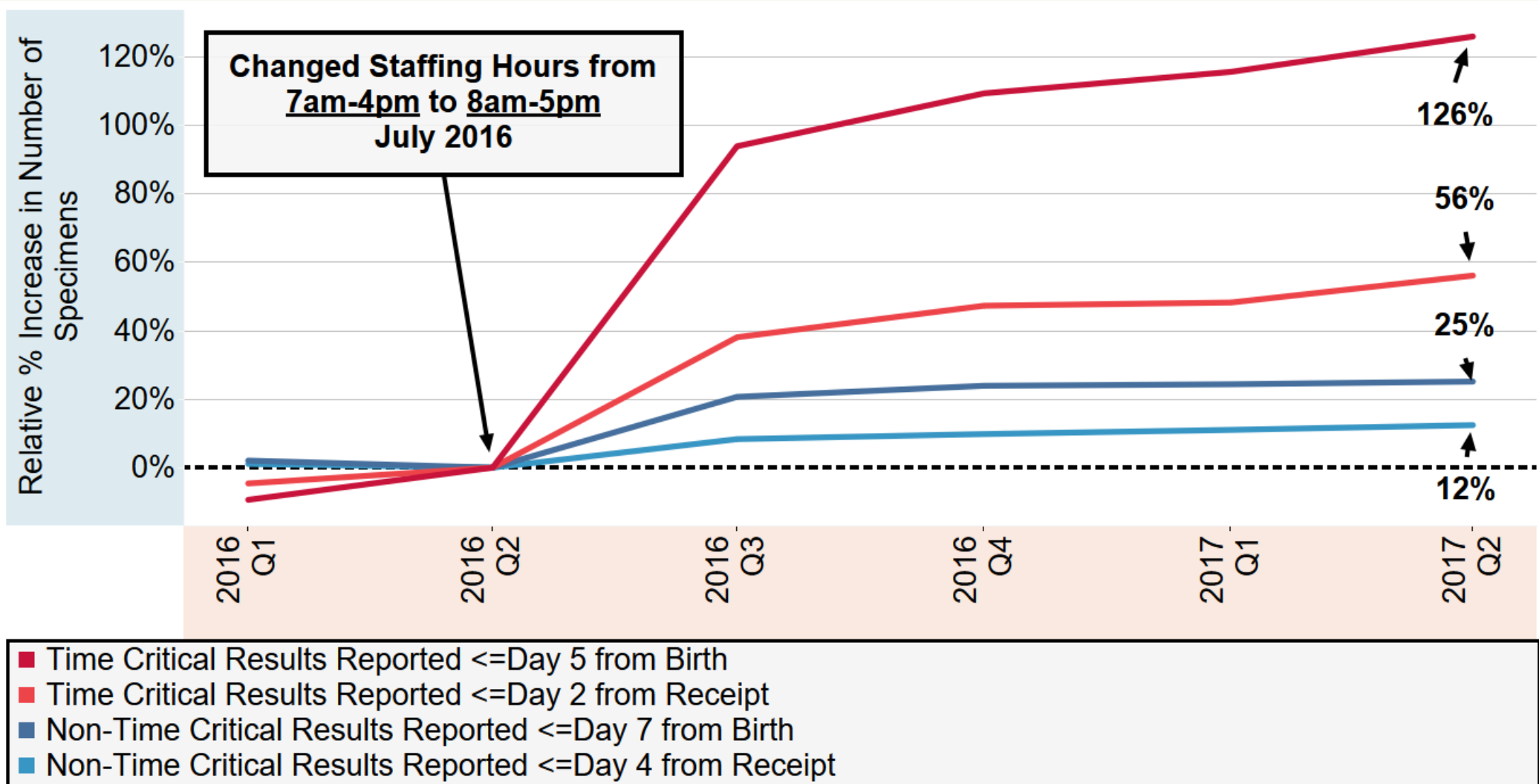


# Indiana: Adding Saturday laboratory operating hours and a Sunday courier in June 2017 led to all results being reported within 7 days of birth for >95% specimens





**Texas:** Shifting laboratory staff hours by one hour ensured daily specimens received at 2pm were accessioned and tested on the same day as delivery instead of the next day, and increased the percent of specimens with time critical results reported within 5 days of birth by 126% and the percent of specimens with a non-time critical result reported within 7 days of birth by 56%



# Alaska: Newborn Screening Quick Facts

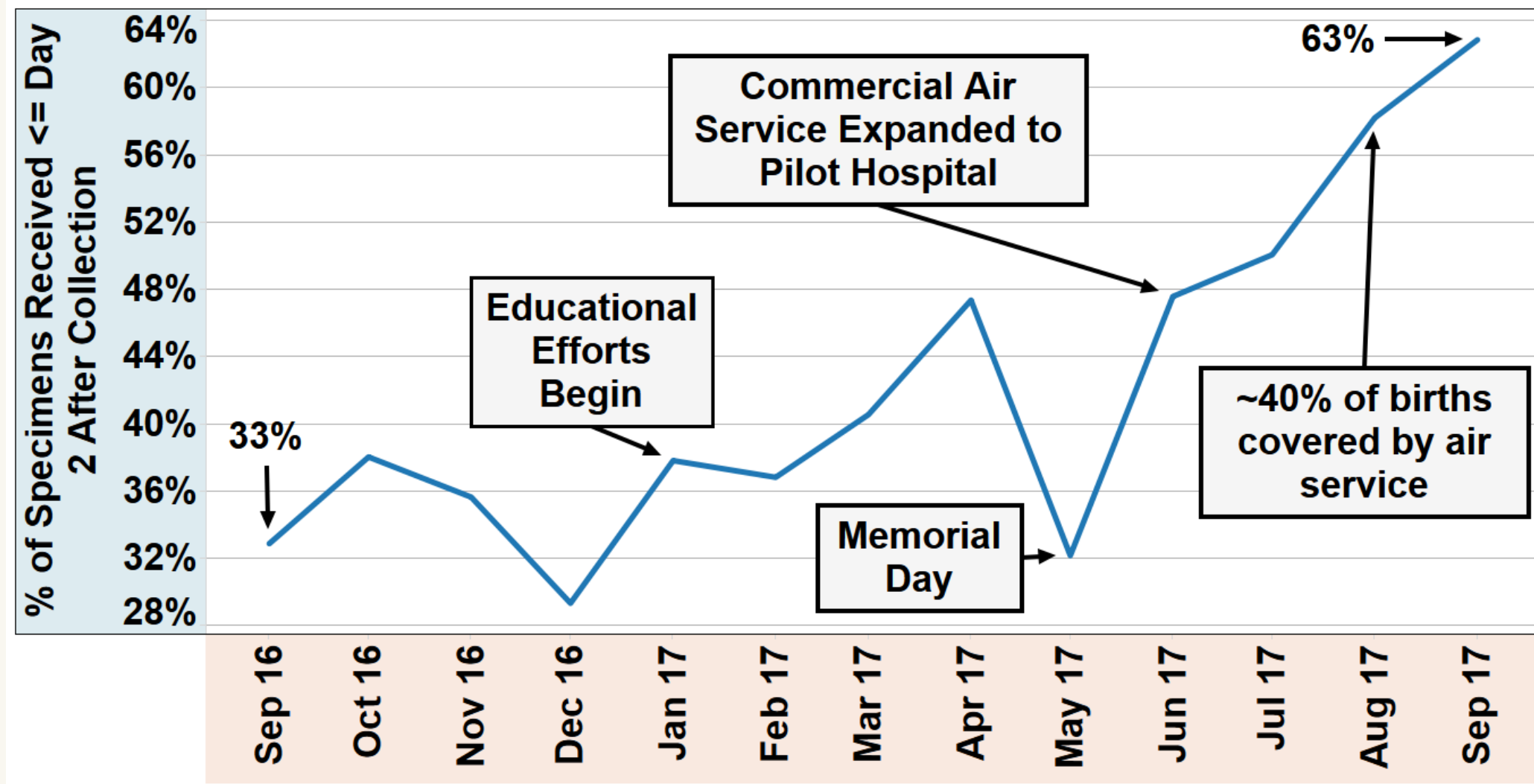
## Geographical Challenges

- 1/5 the size of the lower 48 states
- 1,800 named islands
- 39 mountain ranges containing 17 of the 20 highest peaks in the United States
- 5% of state covered by ice fields

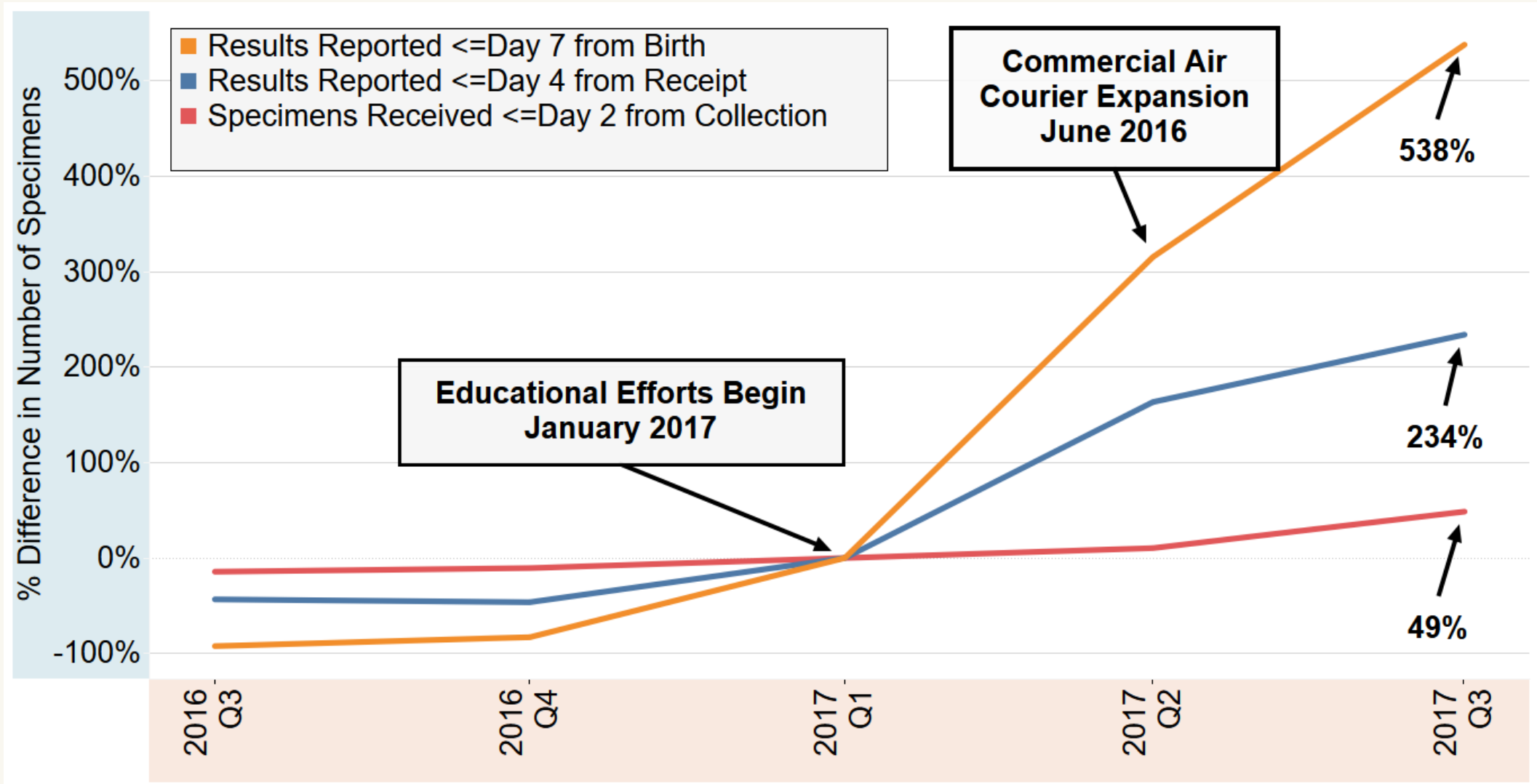
## Process Challenges

- NBS Program located in Anchorage
- Only 10 of 20 birthing hospitals connected by road system
- 4 of these 10 are a 1 to 6 hour drive to nearest airport
- All specimens tested at the Oregon NBS laboratory
- 2,455 mile specimen travel distance

**Alaska:** The percent of Alaskan specimens received at the Oregon NBS laboratory within 2 days of collection improved from 33% in September 2016 to 63% in September 2017 due to educational efforts and commercial air courier expansion



**Alaska:** Alaska educational efforts and courier expansion, in addition to internal Oregon laboratory process improvements such as hiring a quality improvement specialist, refining the HgB screening process, and reallocating resources produced a 538% increase in the percent of specimens with all results reported within 7 days of birth

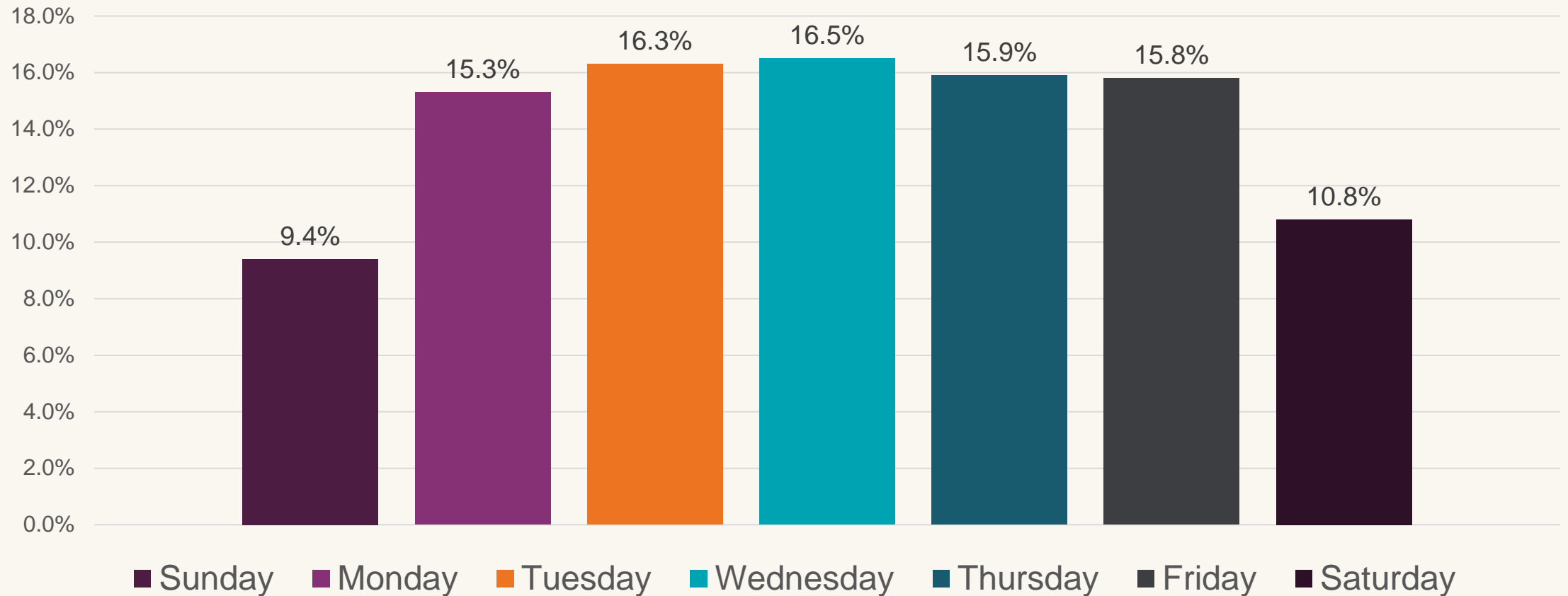


# Iowa: Improving Timeliness by Reducing Disparity

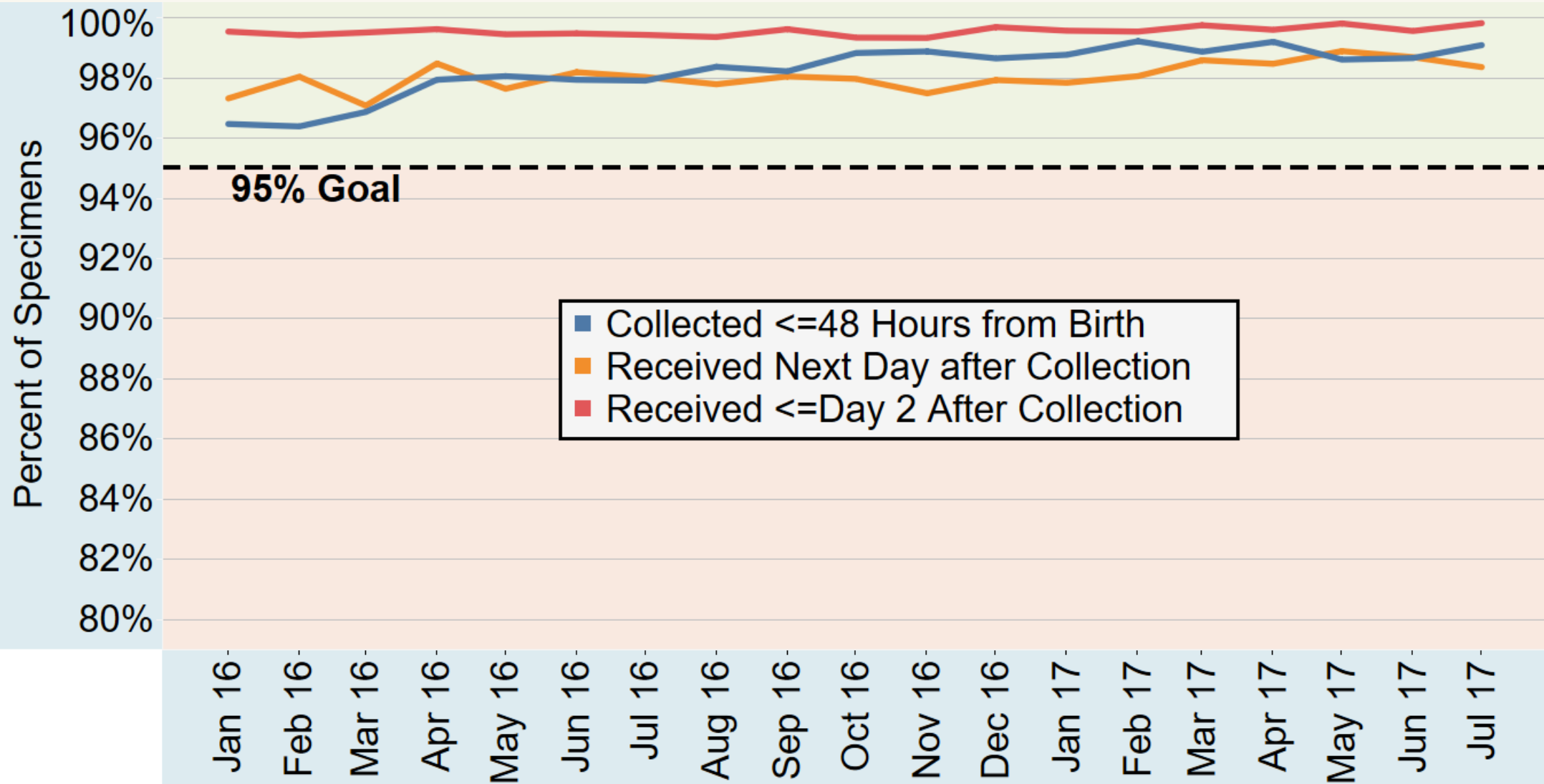
- Disparity caused by the disconnection of the birth continuum and the Monday-Friday lab operating model
- Compounded by the fact that the distribution of births by day-of-week is NOT random
- Therefore, all babies should receive the same benefit everyday regardless of the day of the week they were born

**Iowa:** Being born on a Wednesday or Thursday increases the risk of exposure to process delays if Iowa were to operate on a Monday-Friday operating schedule, compounded by the fact that there are ~80% more births those days than on a weekend day

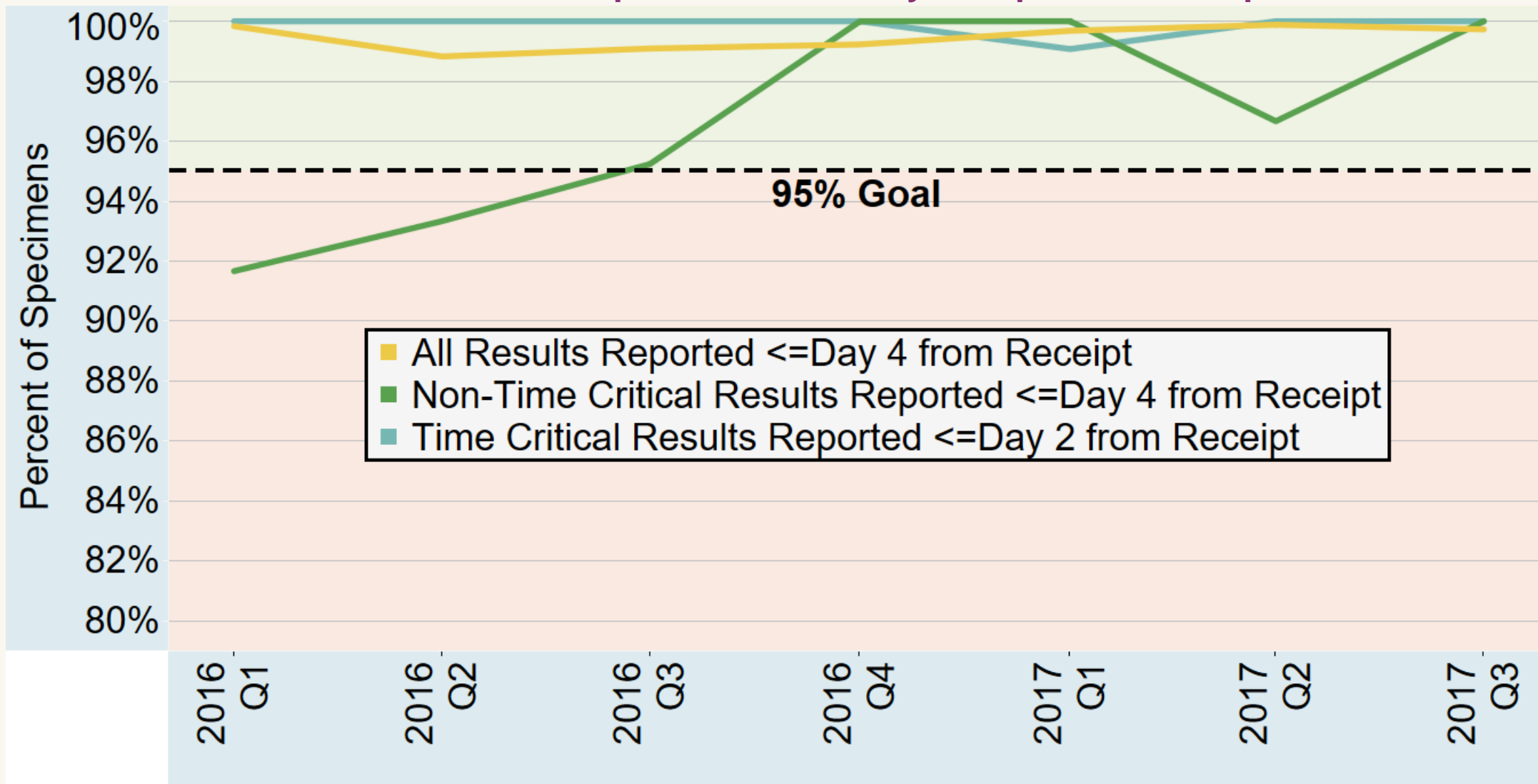
Percentage of 2016 Iowa Births by Day of the Week



**Iowa:** Educational efforts focused on “The Why”, same day courier provided 7 days a week 365 days a year, and laboratory hours of 20 hours per day every day of the year eliminates disparity between the birth continuum and the Monday-Friday model. Iowa collects >96% of specimens within 48 hours of birth and receives >96% of specimens within 1 day of collection

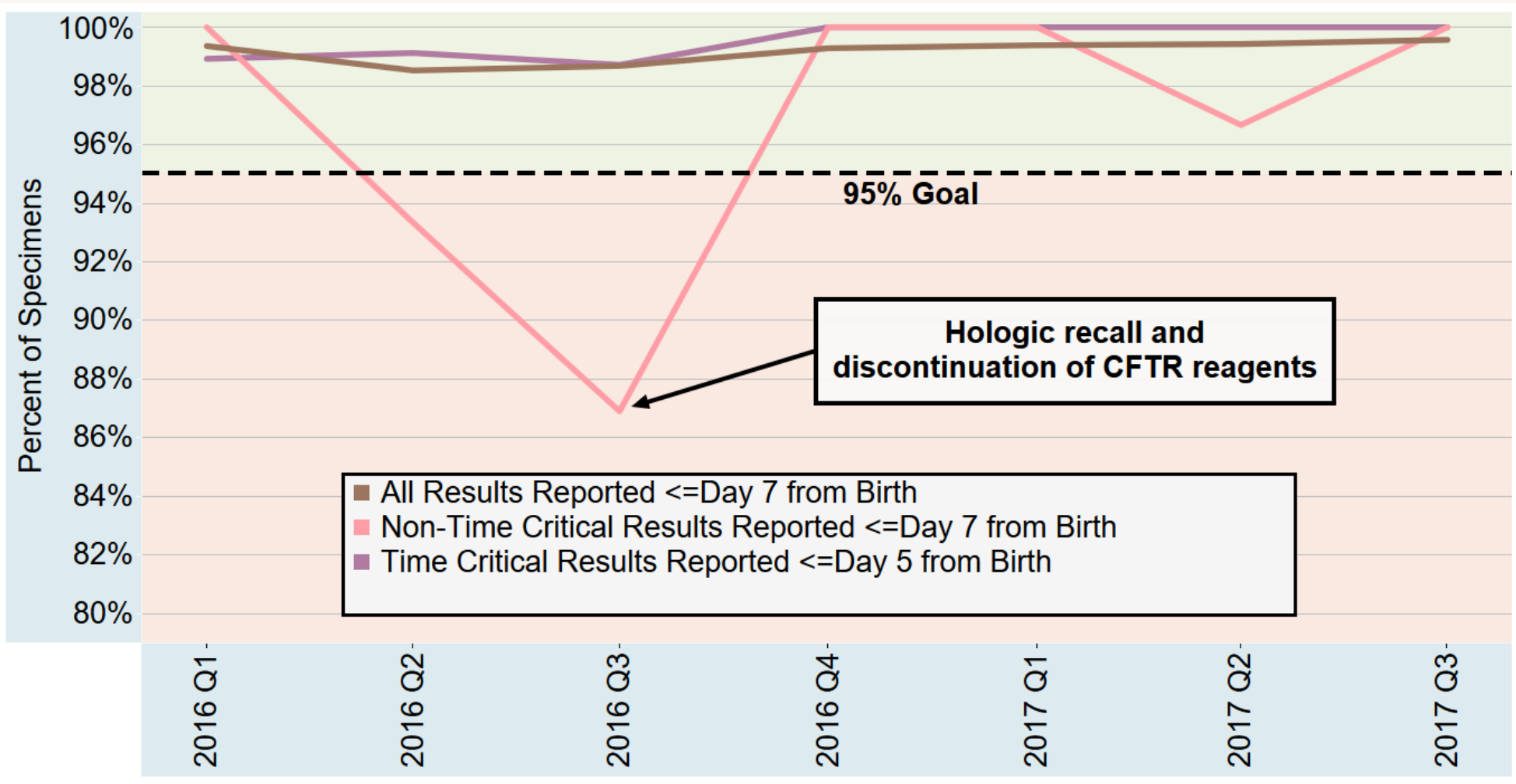


**Iowa:** The 24/7/365 continuous courier and operating hours model also eliminates laboratory specimen “batching” created by limited or no laboratory activities on weekends. The result is >98% of time critical results reported within 2 days of specimen receipt, and >96% of non-time critical results and all results reported within 4 days of specimen receipt





**Iowa:** Eliminating disparity between the birth continuum and the Monday-Friday model allows all specimens to be delivered the same day as pick-up and tested the same day as delivery, and allows results to be reported the very next day no matter what day of the week. The result is >99% of time critical results reported within 5 days of birth and >96% of non-time critical results reported within 7 days of birth.



# Important Timeliness Take-Aways to Grow On

Important take-away messages from efforts to improve timeliness thus far

# Take-Aways from Efforts Thus Far

1. Combination of educational activities, expanding courier services, expanding operating hours, and improving laboratory processes positively impacts timeliness
2. Improvements appear small at the aggregate level, but are quite large at the program level
3. Incremental improvements can require a lot of time and effort
4. Barriers can be specific and unique to a state
5. States may want to examine their data to assess differences in the percent of births by day-of-the-week

# Take-Aways from Efforts Thus Far

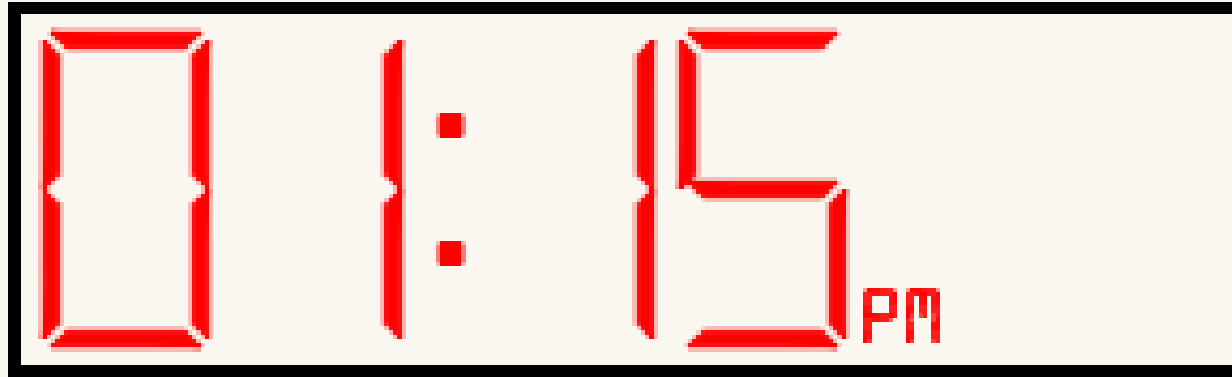
6. Midwives, NICUs, and other out-of-hospital births pose a challenge for all NBS programs
- 7. Sustainability efforts to continue the momentum and maintain high timeliness performance once achieved will need to be addressed moving forward**
- 8. Programs are learning from one another via collaboration**
- 9. Timeliness requires constant and continuous attention and effort!**
- 10. Competing priorities, implementing new conditions, limited resources, and limited staff capacity can negatively impact timeliness**

# Saving a Baby in a Timely New York Minute

An example of saving a newborns life through timely actions that occur in every state across the country on a daily basis

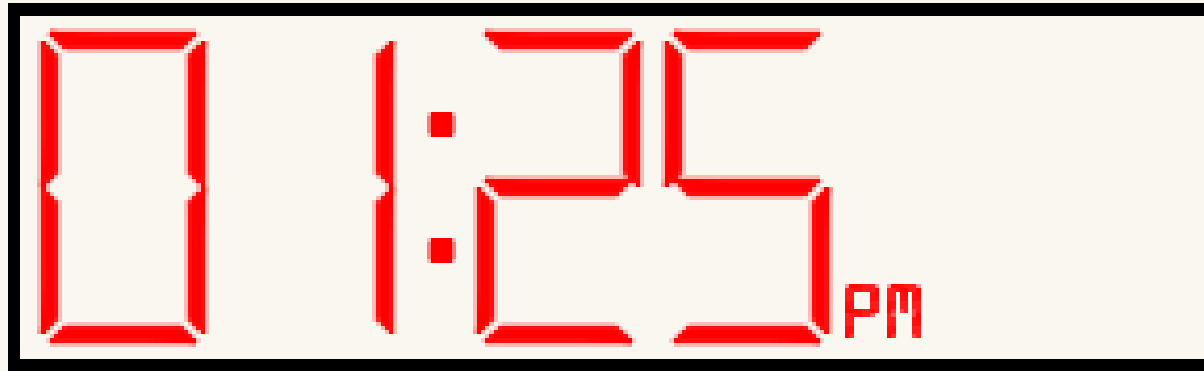


# Day 0



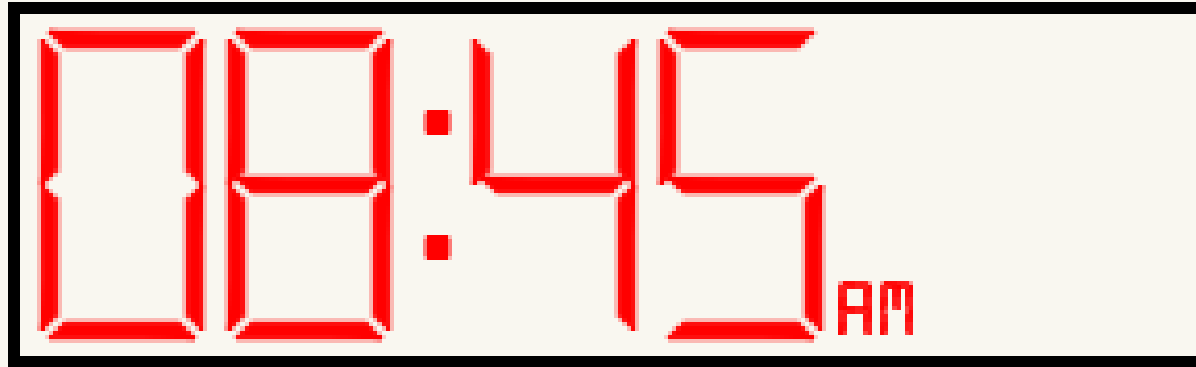
- A baby girl is born
- Born during Sukkot (week long Jewish holiday)

# Day 1



- Age = 24.2 Hours
- Newborn screening specimen collected

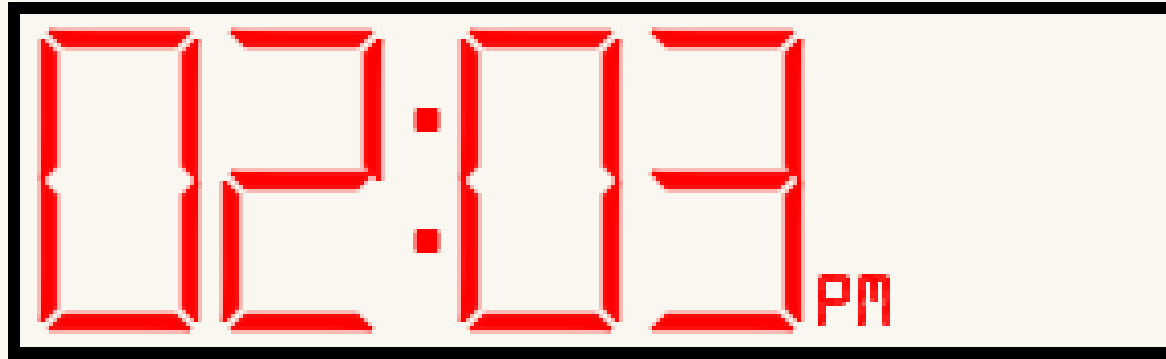
# Day 2



- Age = 43.5 Hours
- Specimen arrives at NY laboratory

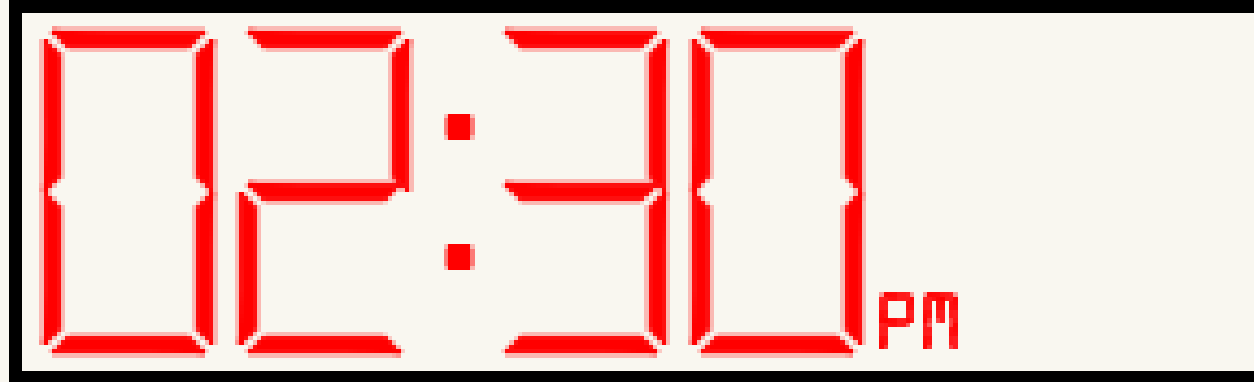


# Day 2



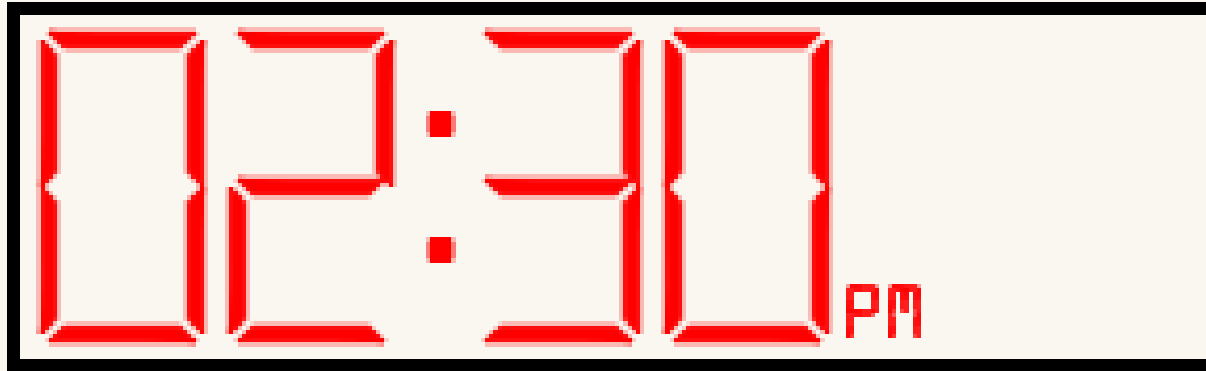
- Age = 48.8 Hours
- Total lab time = 5.5 Hours!
- Screened positive for Galactosemia
- Lab staff creates referral

# Day 2



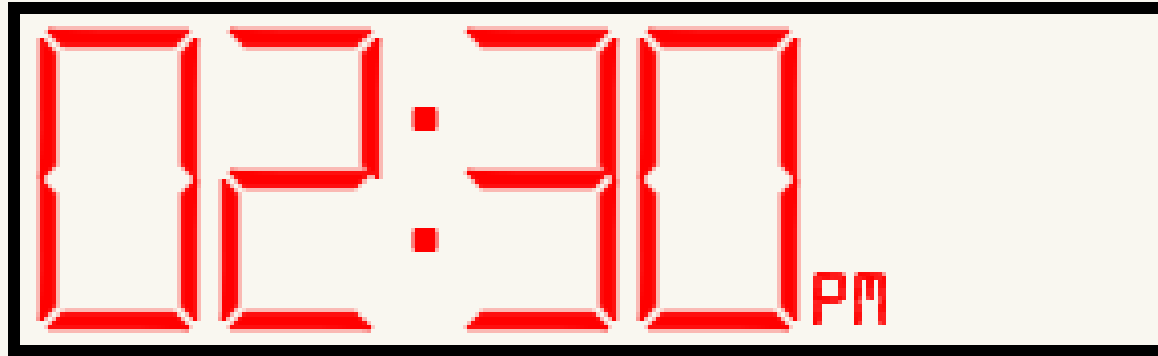
- Age = 49.3 Hours
- Follow-up calls out result to Specialty Care Center
- Cannot get ahold of family

# Day 2



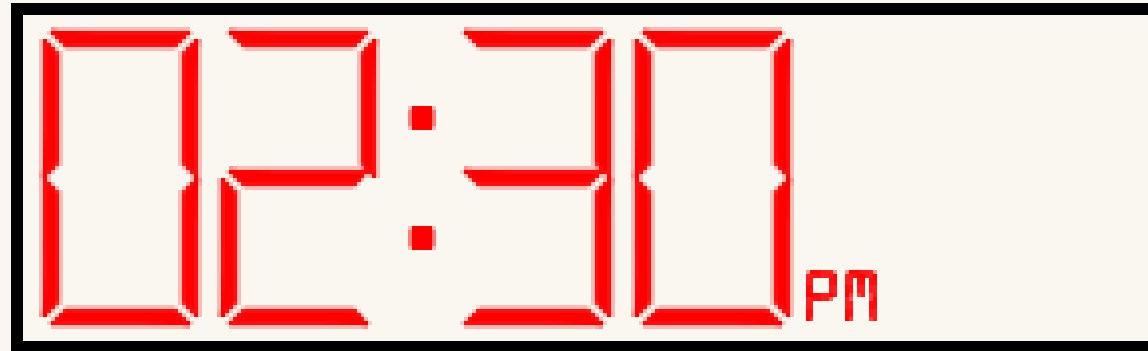
- In the following 3 hours:
  - Contacted birth hospital, but discharged
  - Contacted specialty care center nurse handling referrals and provided all numbers available from the birth hospital
  - Voicemails and texts left at all numbers

# Day 2



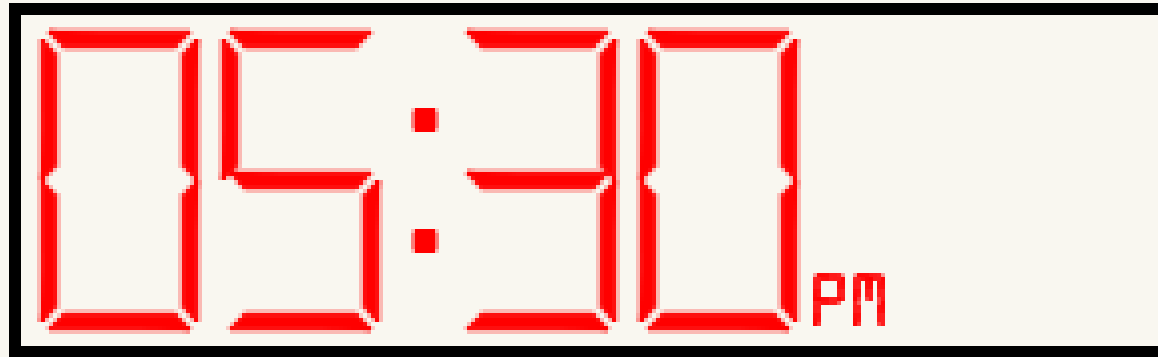
- In the following 3 hours (cont):
  - Follow-up calls pediatricians office which is closed for the Sukkot holiday
  - Call transferred to answering service and on-call doctor was paged
  - After no response called office again and was connected with office secretary
  - She requested they fax the result and that the doctor would return their call in a few days after the holiday

# Day 2



- In the following 3 hours (cont):
  - Fax was sent as requested and in bold stated “**THIS RESULT IS LIFE THREATENING. ACT QUICKLY.**”
  - Also included Galactosemia fact sheet
  - Police, on second request, went to family’s house for a “well-check”, but no one home; asked neighbors how baby was and where family might be
  - Re-contacted hospital for any emergency numbers
  - Reached family at grandma’s house

# Day 2



- Age = 52.3 Hours
- Ambulette sent to grandma's house
- Arrives at emergency department at Specialty Care Center.
- Baby admitted to PICU and survives!
- SCC: "If it had been one more day the outcome would have been bad"



# Conclusion

- Every newborn screening program participating in NewSTEPS 360 has made great improvements in timeliness
- Since January 2016:
  - **74,355 additional newborns** have had specimens collected within 48 hours of birth
  - **62,326 additional newborns** have had specimens received within 2 days of collection
  - **378 additional newborns** have had a presumptive positive result for a time critical disorder reported within 5 days of birth
  - **1,983 additional newborns** have had a presumptive positive result for a non-time critical disorder reported within 7 days of birth
  - **117,143 additional newborns** have had all results reported within 7 days of birth
- And now we need to continue this momentum and sustain success



# Acknowledgements

- A **GIANT** thank you to **ALL** the newborn screening programs for doing all the incredible things you do every day to save lives!
- Thank you to all the newborn screening programs that provided timeliness data for the NewSTEPs Timeliness Report to the GAO
- Thank you to the wonderful newborn screening programs participating in NewSTEPs 360 who continue to provide us with endless amounts of information despite their busy schedules
- Thank you to the NewSTEPs/NewSTEPs 360 team. This was, is, and always will be a **TRUE TEAM EFFORT** 😊

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