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Assessing the Impact of NCAA Sickle Cell Trait Screening on State Newborn Screening Programs

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SACHDNC meeting

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NCAA Sickle Cell Trait (SCT) Screening Mandate

- NCAA Division I Legislative Council
 - Proposal 2009-75-B
 - Amendment to Bylaw 13.11.3
- Approved April 13th, 2010
- Went into effect August 2010

The NCAA Mandate: Division I & Division II

Pre-participation Medical Evaluation

The examination or evaluation shall include a sickle cell solubility test unless documented results of a prior test are provided to the institution or the prospective student-athlete declines the test and signs a written release.

Amendment to Bylaw 13.11.3

History of NCAA Mandate



September 24, 2006

Dale Lloyd II collapses during football practice at Rice University

June 28, 2010

NCAA approves proposal to add mandatory sickle cell solubility test to medical examination for DI student athletes

June 28, 2009

Lloyd lawsuit is settled

October 11, 2010

SACHDNC publishes recommendation

SACHDNC's Recommendation

1. All individuals should **have the opportunity to find out their risk** for various medical disorders, including their carrier status for genetic conditions such as sickle cell disease.
2. Evaluation and testing for sickle cell disease and other genetic conditions should take place **within the individual's medical home**. That evaluation should include **counseling** regarding the implications of the information for the individual and assurance of the **privacy of genetic information**.

Genetic testing should not be a pre-requisite for participation in sports, unless deemed medically necessary

3. All potential athletes should receive **education on safe practices** for prevention of exercise and heat related illnesses.
4. The Secretary, HHS, instruct SACHDNC to work with the SCDA, relevant federal HHS agencies, athletic associations, community based and health care professional organizations to **develop guidelines and educational resources** about screening for sickle cell trait in all persons, including athletes.
5. The National Institutes of Health and the Centers for Disease Control and Prevention **conduct research** to ascertain if some athletes with sickle cell trait are at increased risk of exercise-related sudden death.

History of NCAA Mandate



September 24, 2006

Dale Lloyd II collapses during football practice at Rice University

June 28, 2010

NCAA approves proposal to add mandatory sickle cell solubility test to medical examination for DI student athletes

August 31, 2011

NCAA approves testing of all Division II student-athletes

June 28, 2009

Lloyd lawsuit is settled

October 11, 2010

SACHDNC publishes recommendation

January 19, 2013

NCAA approves Division III SCT testing requirement

DIII Waiver Stipulation

- Prior to signing a waiver, the institution provides the student-athlete with education regarding the implications of exercising the waiver option
- Student-athletes who have been tested, but do not yet have confirmed results documented or have signed a waiver shall be provided additional education regarding the risks, impact and precautions associated with sickle cell trait.

Potential Impact on NBS Programs

The examination or evaluation shall include a sickle cell solubility test **unless documented results of a prior test are provided to the institution** or the prospective student-athlete declines the test and signs a written release

Amendment to Bylaw 13.11.3

How to Provide Results of Previous Testing:

As of today, all 50 states have newborn screening programs that identify sickle cell trait status at birth, however not all states adopted screening in the same year. In the state of California, if your son or daughter was born after February 21, 1990, results may be available from your child's pediatrician by submitting this form ([UHS Med Records Release](#)) or **from the State** using this form at this link ([CA Newborn Screening Homepage](#)) **We suggest calling your pediatrician prior to submitting any request to ask if they have results on file, if not available, contact the state as noted above.**

Objective

- Assess impact of NCAA mandate on State Newborn Screening Programs
 - Demand placed on program resources?
 - Programmatic changes implemented?
 - Variation in impact across programs?
- Note: This issue is not up for Committee vote

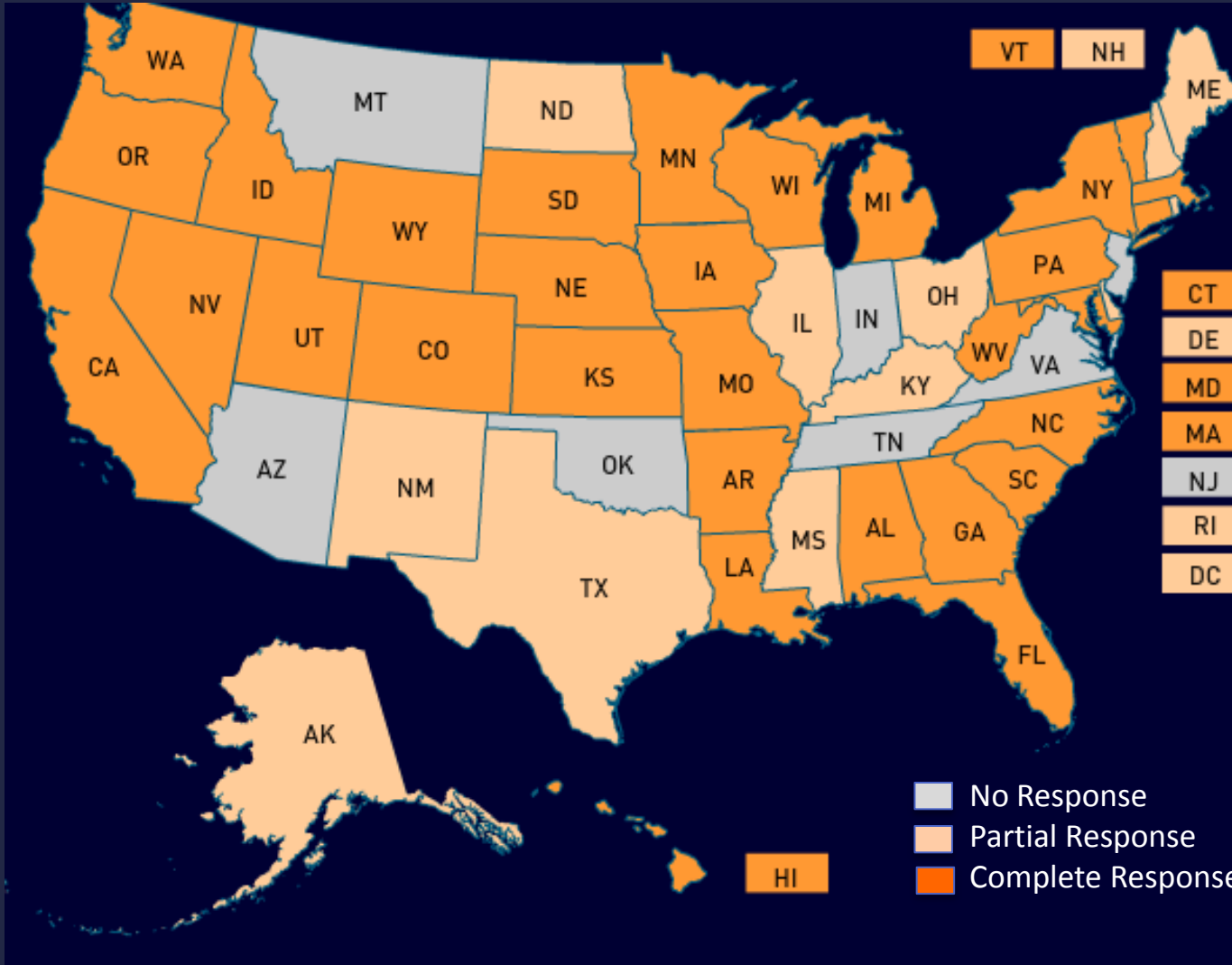
Methods

- Phone and written surveys (February – present)
- Recruitment: Snowball sampling method
- Stakeholder Interviews:
 - Laboratory Directors and personnel
 - Follow-up Directors and personnel
 - Hematologists & Genetic Counselors
 - Sickle Cell Community-Based Organizations
- State considered “complete” after speaking to Laboratory and Follow-up representatives
- Delphi method to validate each state’s results

Domains Assessed

- History and procedure of NBS screening for Hb
 - Laboratory Procedure and History
 - Availability of SCT results
 - Reporting SCT status
- Direct effects of NCAA mandate
 - Volume and nature of requests
 - Procedure for providing results
 - Qualitative assessment of programmatic changes

Participation-to-date



States contacted:
44/51 = 88%

States completed:
31/51 = 62%

Made using
<http://usmapgenerator.com/>

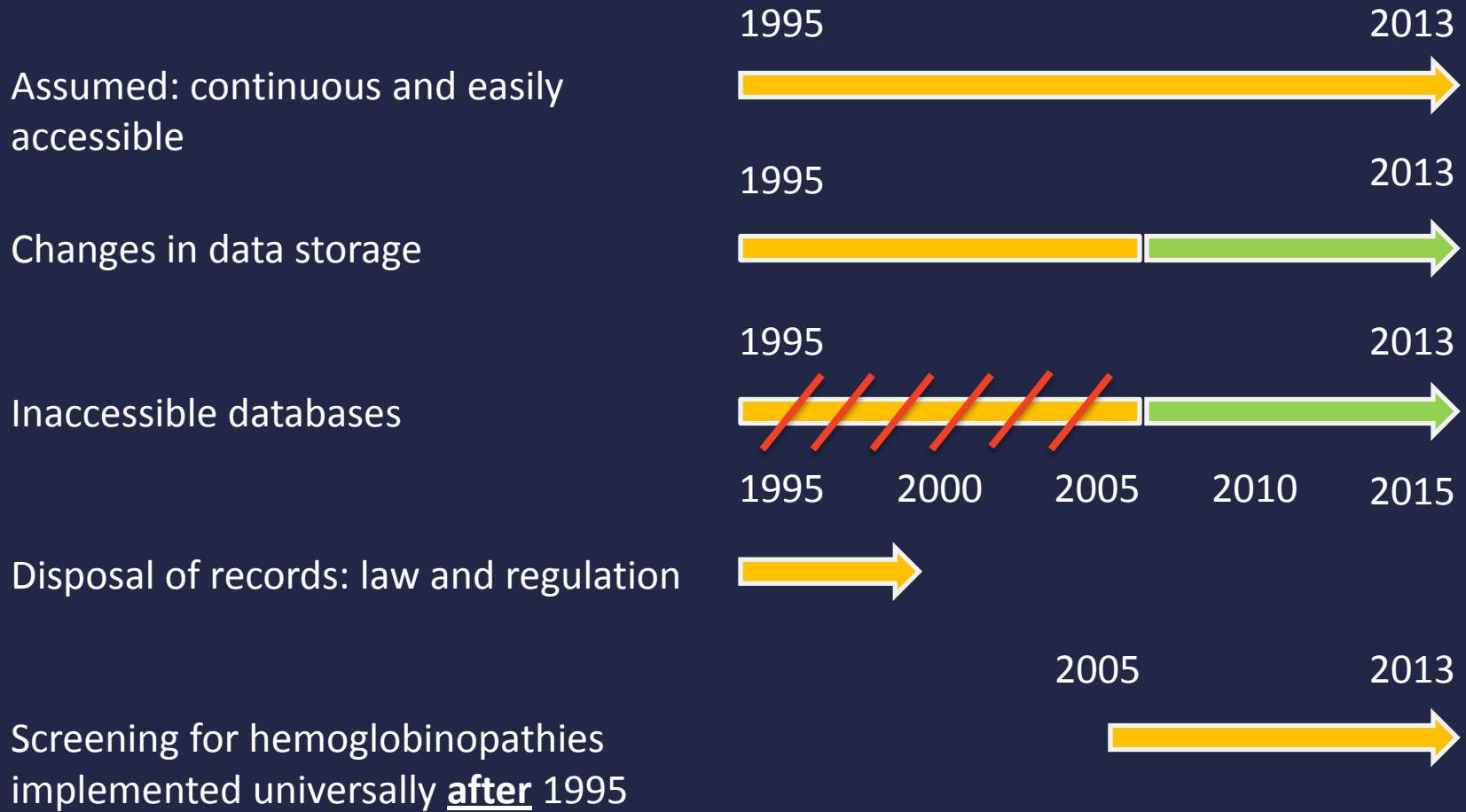
Results

History & Procedure of NBS for Hb

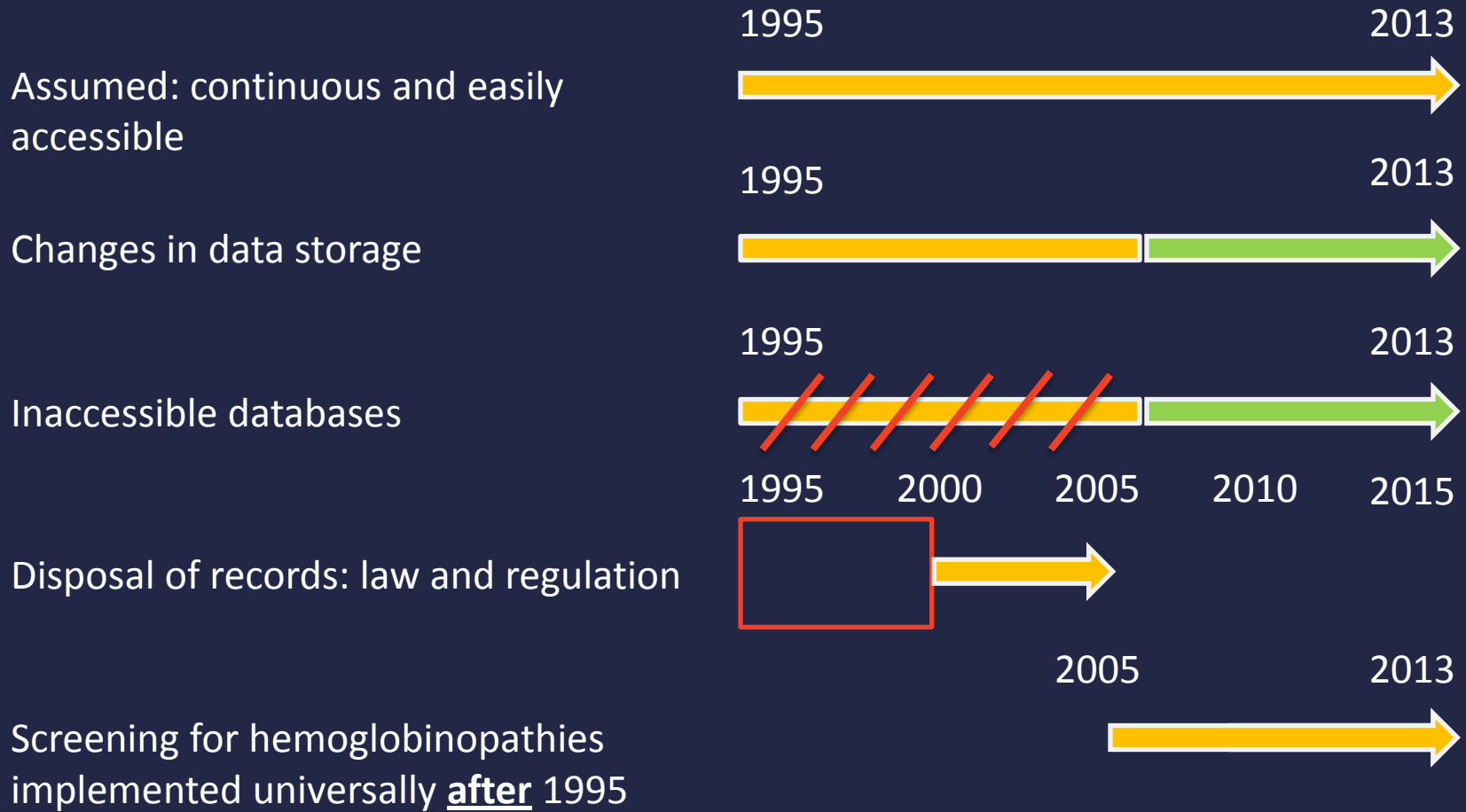
History of NBS for Hb Screening

- Years states have been Hb screening
 - (1990, range: 1975-2005)
- Methods used
 - Isoelectric Focusing (IEF), High Performance Liquid Chromatography (HPLC), DNA testing, Electrophoresis
- Procedures
 - Single testing (14%, 6/43 states)
 - Two-step reflexive testing (86%, 37/43 states)

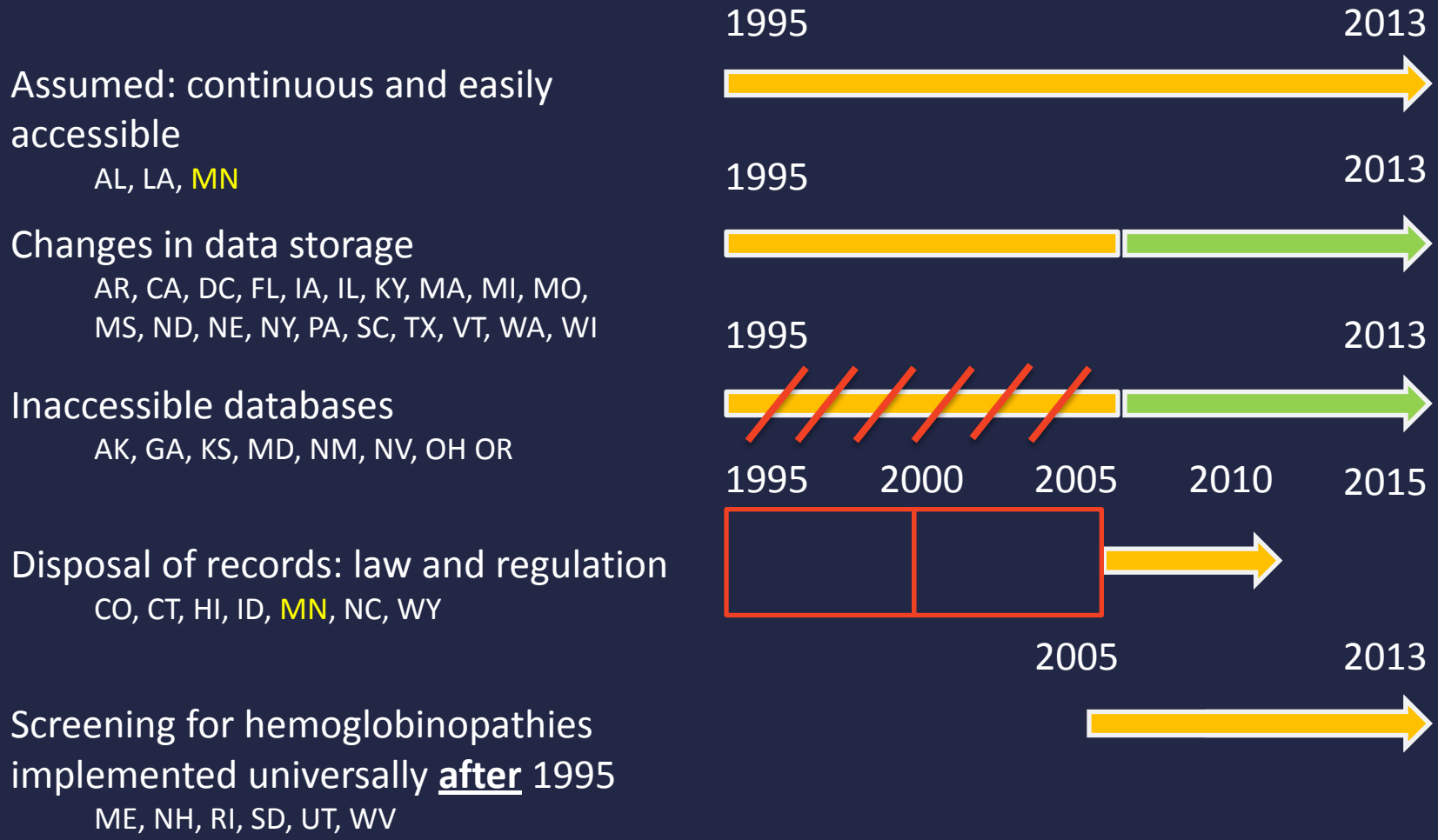
Availability of Results Since 1995



Availability of Results Since 1995



Availability of Results Since 1995



Availability of Results Since 1995

Assumed: continuous and easily accessible

AL, LA, MN

1995

2013



Changes in data storage

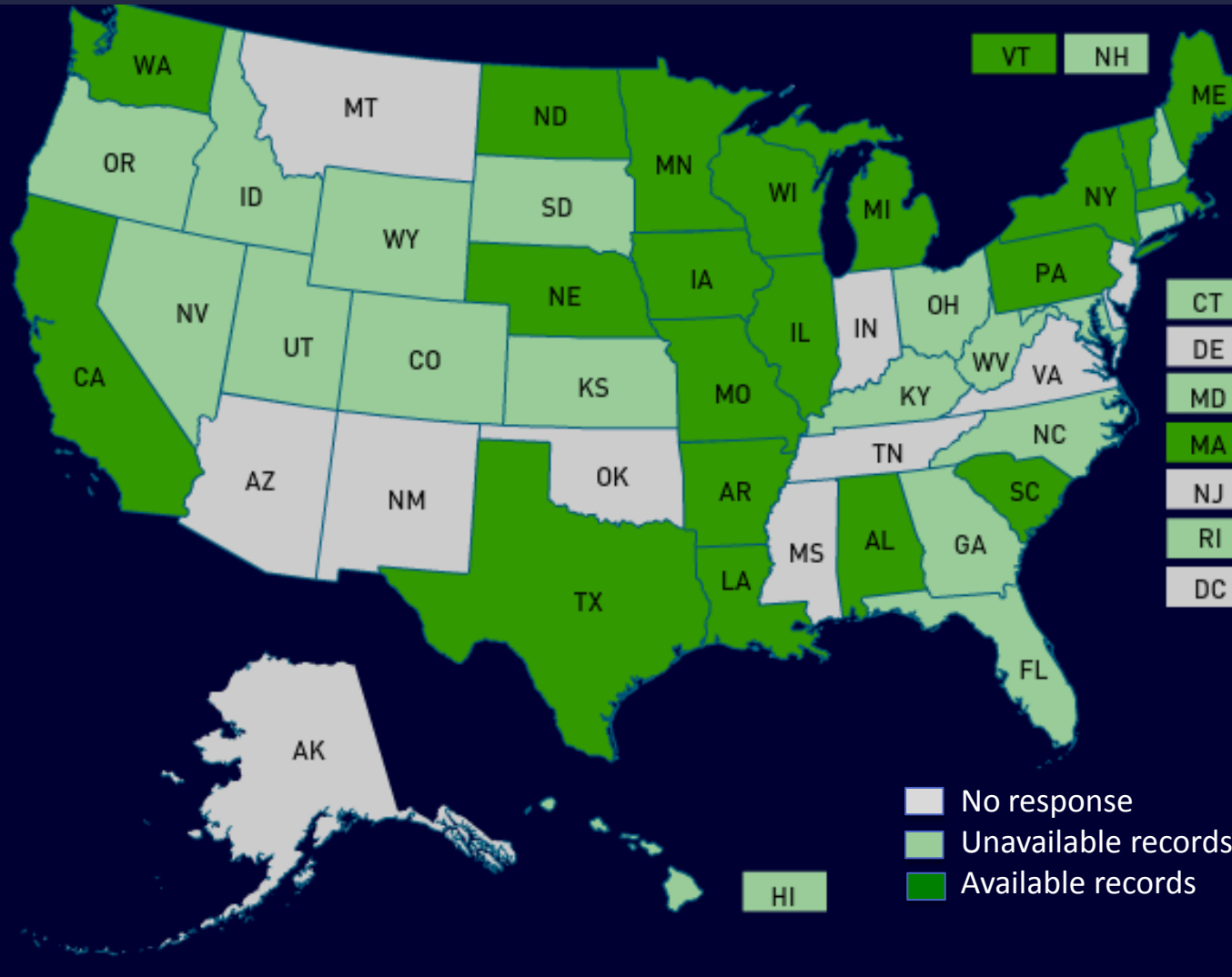
AR, CA, DC, FL, IA, IL, KY, MA, MI, MO,
MS, ND, NE, NY, PA, SC, TX, VT, WA, WI

1995

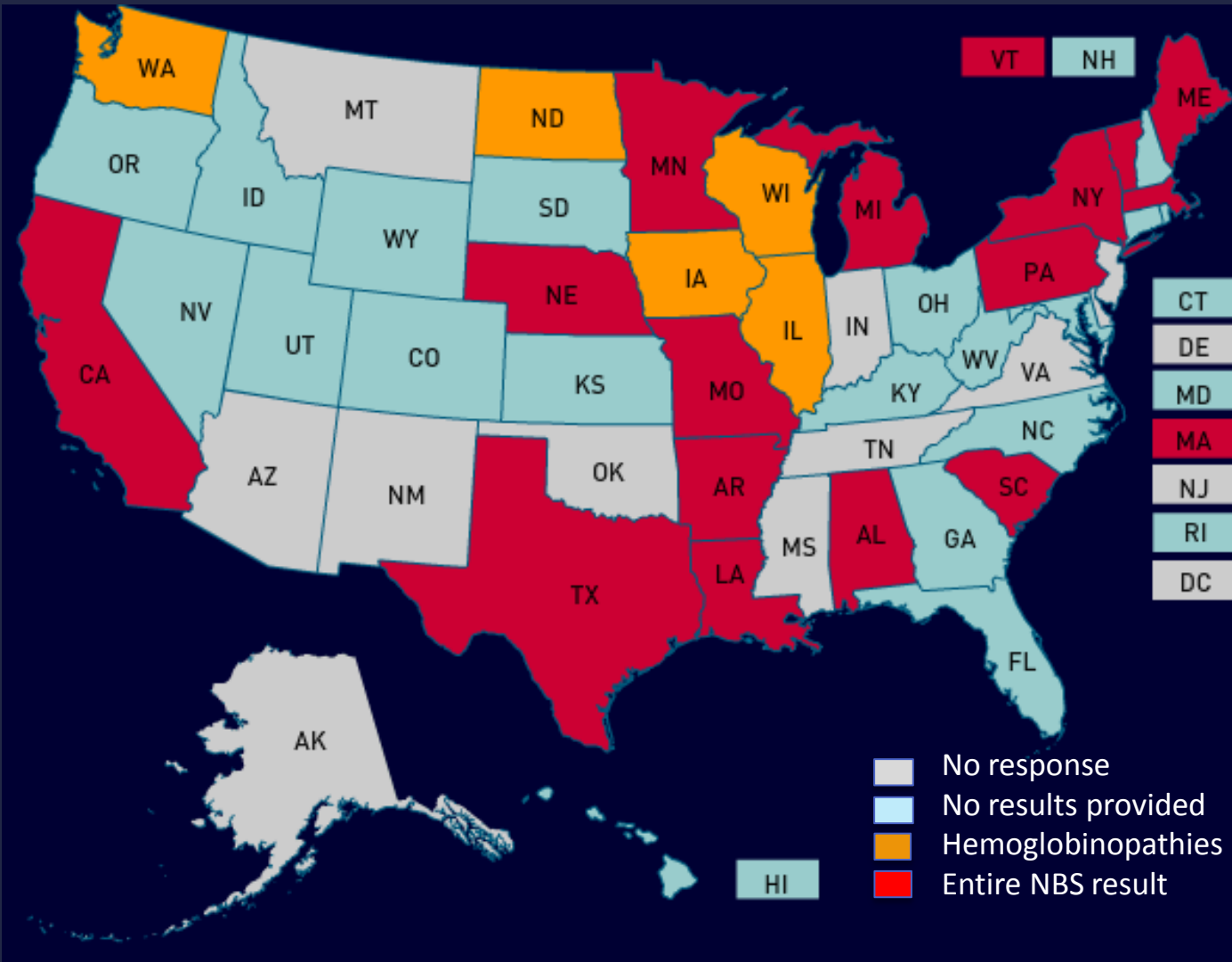
2013



States Currently Providing Results



Information Provided by NBS Programs



States providing entire NBS result:
38% (15/39)

States providing only hemoglobinopathies result:
13% (5/39)

- CT
- DE
- MD
- MA
- NJ
- RI
- DC

States providing no results:
49% (19/39)

Answered by 39/44 responding states

Concerns that Prevent NBS Programs from Providing SCT Results

- Privacy of genetic information
- NBS program policy
- Cost to NBS program
- Accuracy matching record to individual
- Accuracy of SCT “diagnosis”
- Results for athletes this age do not exist
- Inconvenience retrieving results
- Use of NBS resources
- Other

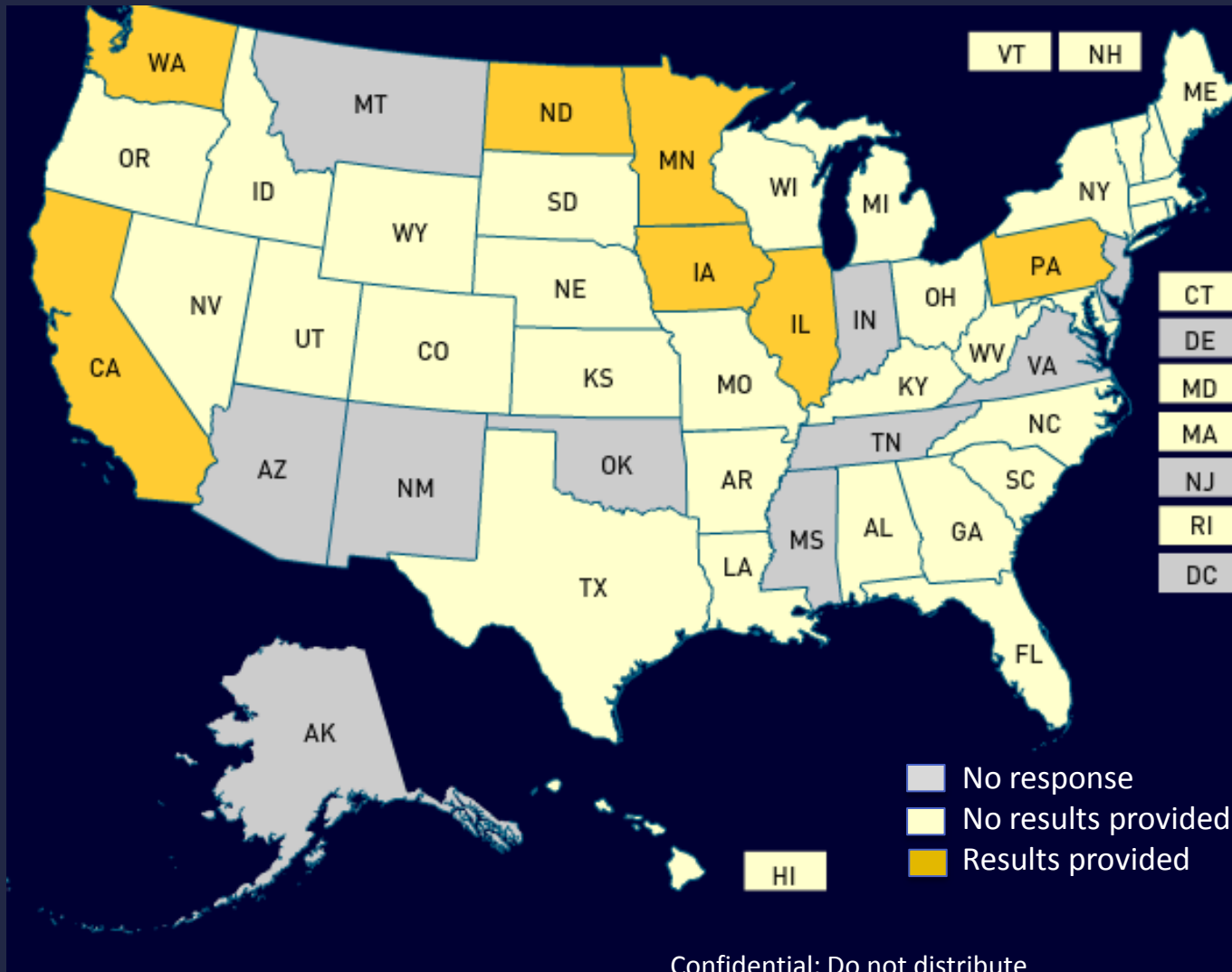
“Other” Concerns: Qualitative Summary

- “Providing SCT results is not a worthwhile public health initiative. This is not the mission of the newborn screening program.”
- “Public trust in the program would be undermined if people found out that we were sharing information collected when you were a newborn.”

Provide Results to Whom?

- Primary care physicians
- Athletes or Parents
- Athletic Department
- Team Physicians
- NCAA

Providing Results Directly to Athletes or Parents

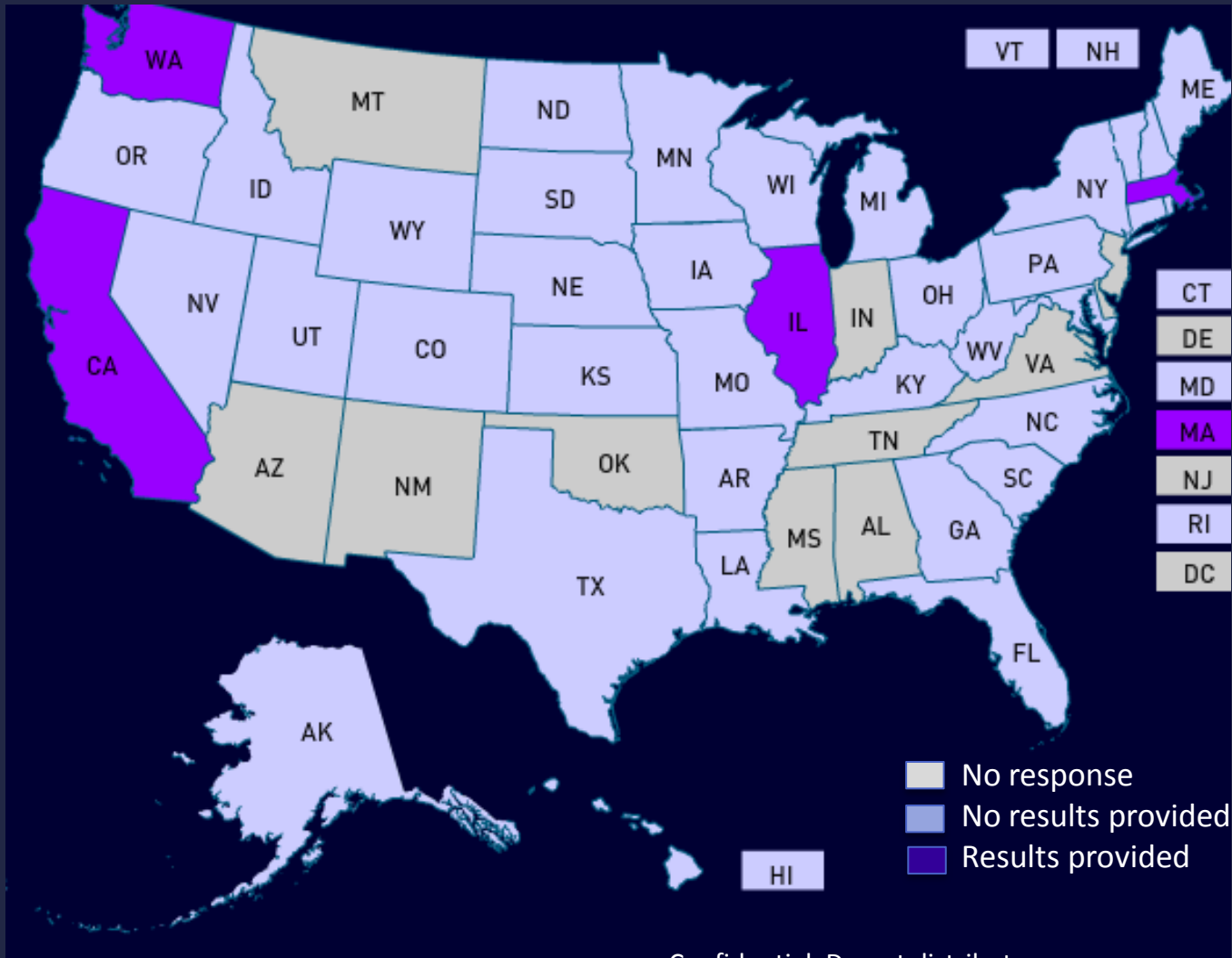


States providing results to athletes/parents: 18% (7/39)

States not providing results to athletes/parents: 82% (32/39)

Answered by 39/44 responding states

Providing Results to Athletic Department

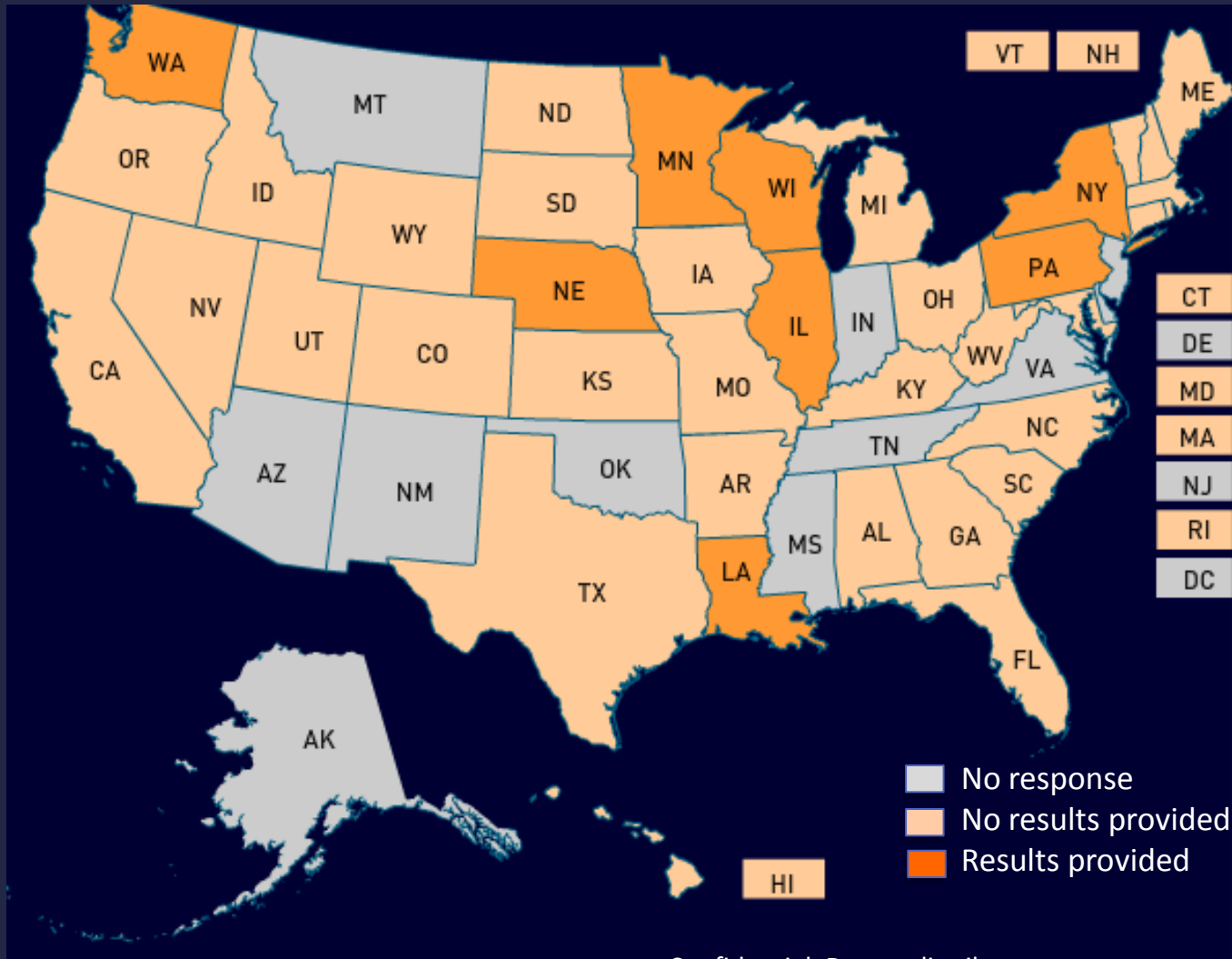


States providing results to athletic department: 10% (4/39)

States not providing results to athletic department: 90% (35/39)

Answered by 39/44 responding states

Providing Results to Team Physicians



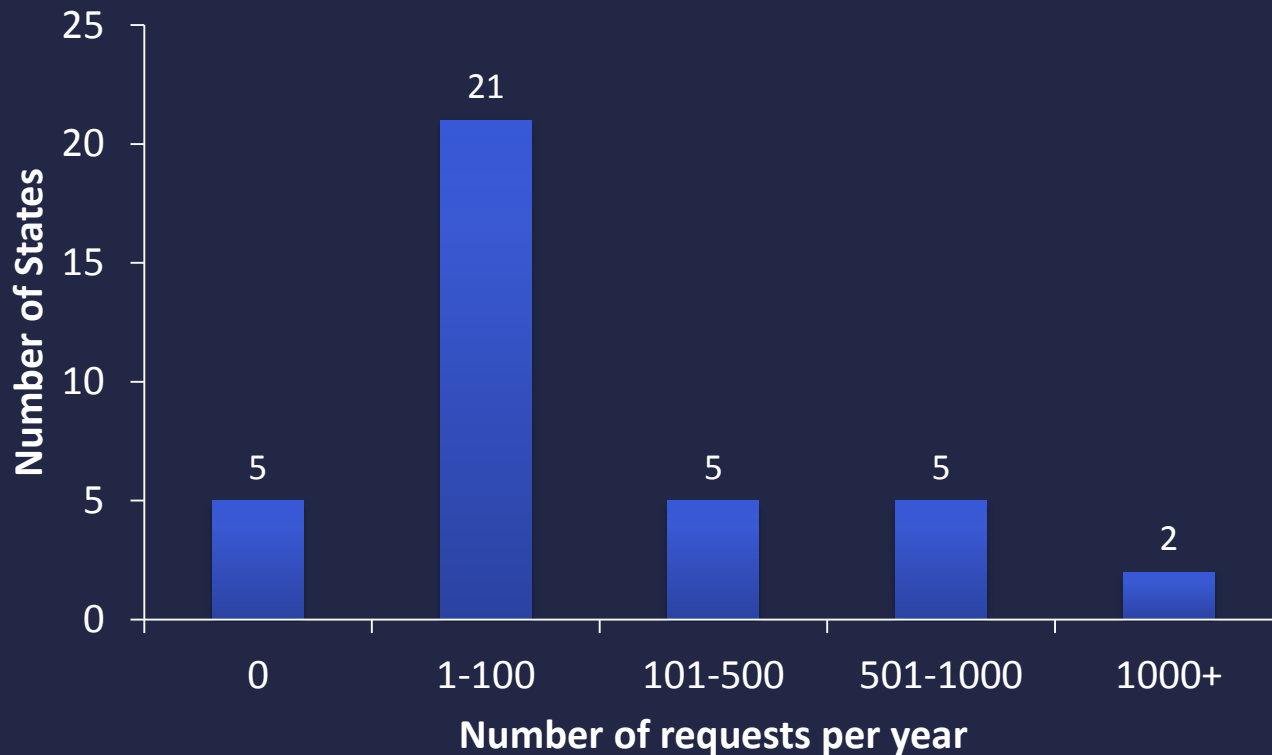
States providing results to team physicians:
20% (8/39)

States not providing results to team physicians:
80% (31/39)

Answered by 39/44 responding states

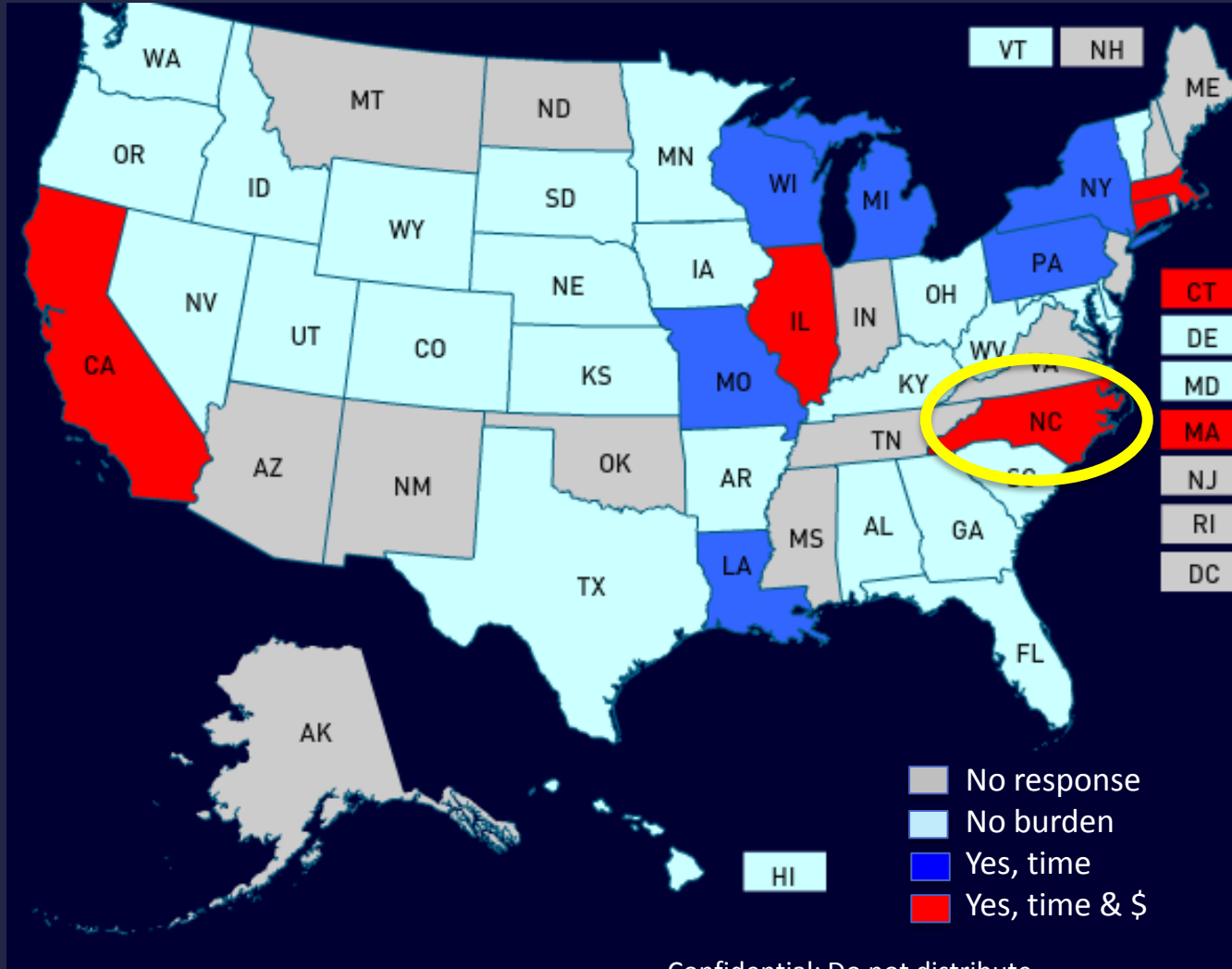
Effect of NCAA Mandate

Reported Volume of SCT Requests Directly to NBS Program (per year)*



- * Ranged from 0 – 6000 requests per year
- * Most requests received between May and August
- * Does not include record retrieval through web-based portals

Reported Burden on NBS Program



No burden:
67% (24/36)

Time burden only:
19% (7/36)

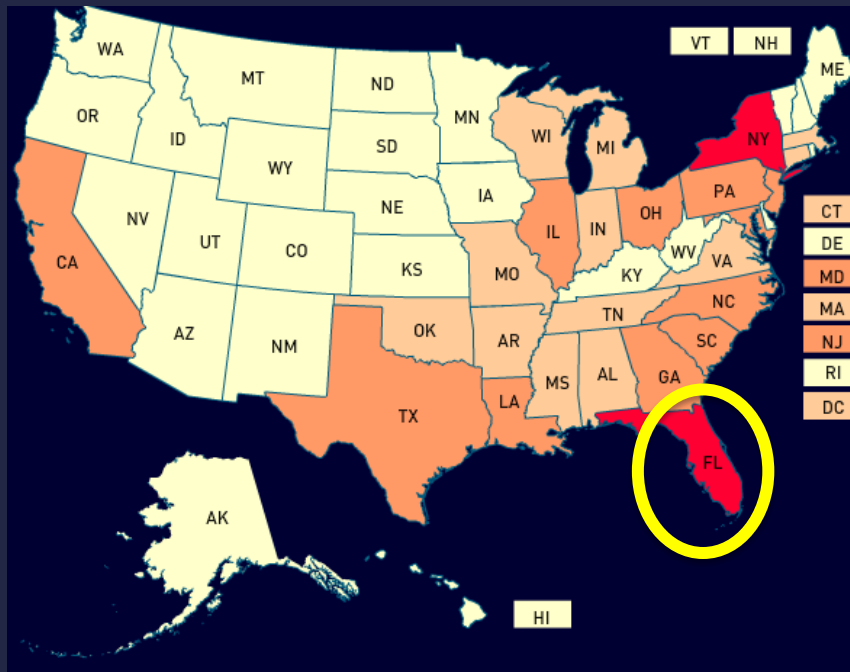
\$ burden only:
0% (0/36)

Burden of \$ AND time:
14% (5/36)

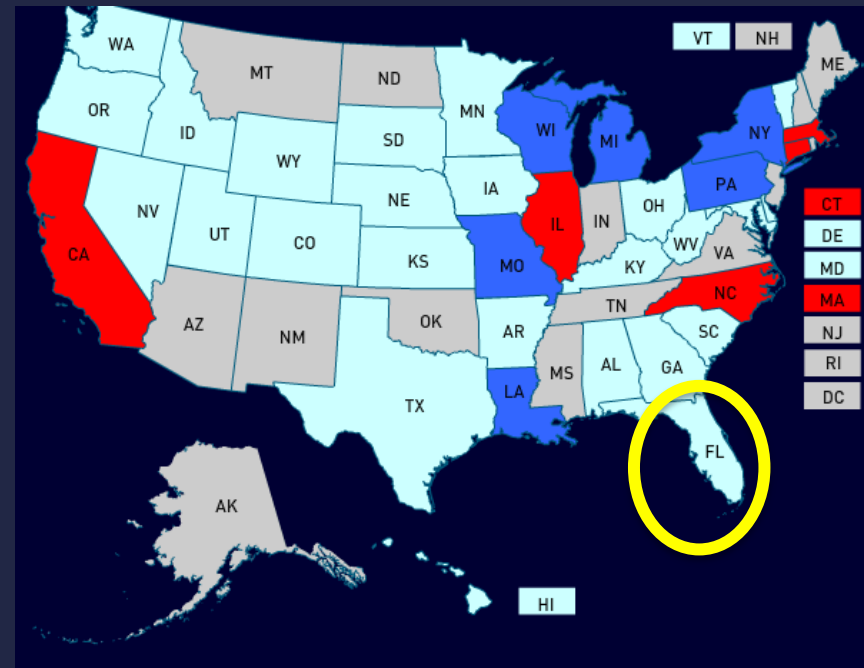
Answered by 36/44
responding states

Relationship Between Reported Burden and Estimated SCD Prevalence

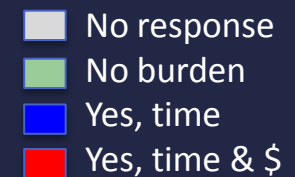
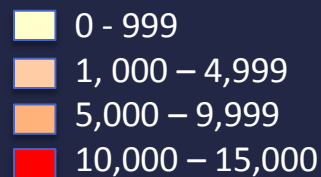
Estimated Sickle Cell Disease Prevalence



Reported Burden on NBS Program



NNSIS-based total birth cohort
(2005–2007)
Hassell, 2010



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Burden Reported by NBS Programs

- \$
 - “We would hire someone just to handle these calls but we don’t have the resources.”
 - “Since our system is fax-based, we are killing our fax machine. We don’t have funds to buy office equipment.”
- Time
 - “All of the requests come in a narrow time period in early summer so it is like cramming 40 weeks worth of work into a 25 week window.”
 - “Providing information to a NICU where one of our newborns is in treatment is a higher priority than this, and that is where we try to spend our time.”
 - “We spend so much time just explaining to parents what the screening is for and why they are being required to get this information.”
 - “I could have a little tape recording that explains where to go to get results because I have to give that speech so often.”

Programmatic Changes within NBS: Qualitative Assessment

- Procedure for reporting results
 - “We were not used to providing results to individuals. We had to make a new form for individuals to request their newborn screen.”
- Policy on release of information
 - Who can request results
 - Ensuring student-athlete’s consent
- Retention of results
 - “This mandate pushed the debate [within our state] to destroy samples older than 5 years to the brink.”
- Review of educational materials
 - Brochures, websites, trait letters sent to families
- Staffing changes
 - Reassigning duties, need for additional FTE

Discussion Generated Within NBS Programs: Qualitative Assessment

- IT changes
 - “The influx of requests has helped us to make a stronger case for an online portal system.”
- Implications for releasing other NBS results
 - “How long should we be keeping results for sickle cell? If we keep results for sickle cell, why not all other diseases? Should there be an age limit or should we just keep records for a lifetime? Do we have the funding and staffing to do all of this?”

Conclusions

- Not all states are capable of providing SCT results to student-athletes
- States have varying practices on sharing SCT results
- Those states that are willing and able to give SCT results have reported variable impact of this mandate, ranging from no impact to significant impact

Acknowledgements

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- Collaborators:
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