Newborn Screening Quality Indicators for Inter- and Intra-Program Quality Assurance – Survey Results

November 8, 2011

Brad Therrell, Ph.D., Director

National Newborn Screening and Genetics Resource Center

Austin, Texas

U.S. Newborn Screening Data

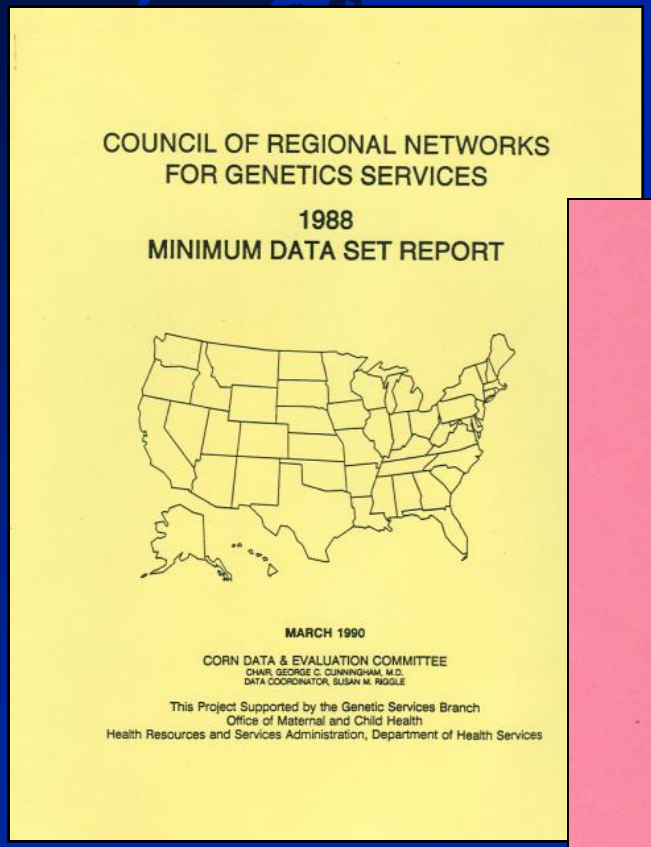
- Voluntary national data accumulation has occurred since 1989 as a HRSA-funded initiative.
- Primary Goal: To centralize valid and timely newborn screening data for evaluation, documentation and use in assuring quality access to care.
- Secondary Goals: To provide quality assurance information (quality indicators) for use by state programs for:
  (1) internal comparison over time
  (2) comparison to other programs.

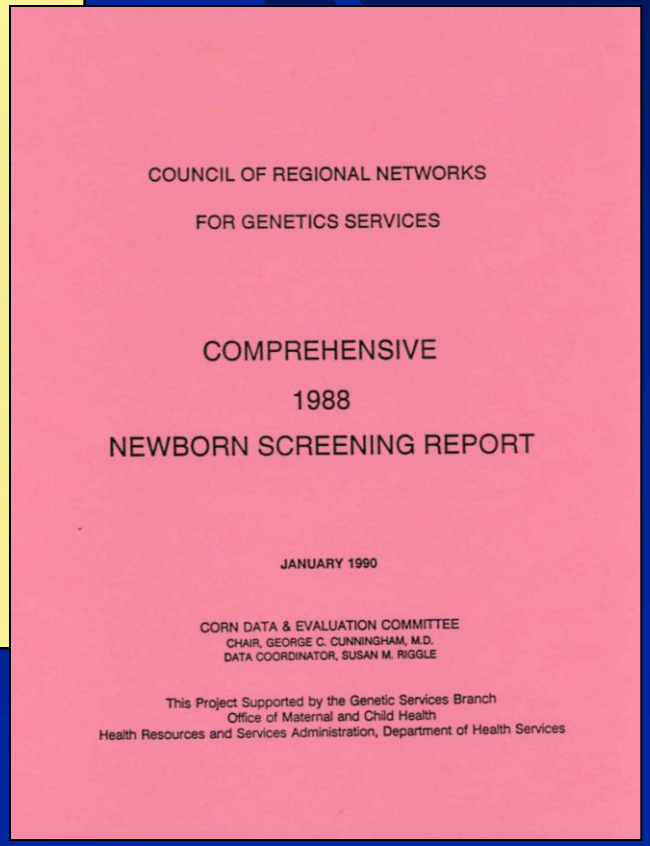
Focus on Previously Selected Indicators for Program Quality Assessment

Brief History of NBS Data Collection

1988 CORN Minimum Data Set Report
1988 CORN Comprehensive NBS Report

Attempted to collect national data on genetic and newborn screening services.





1988 CORN Data and Evaluation Committee

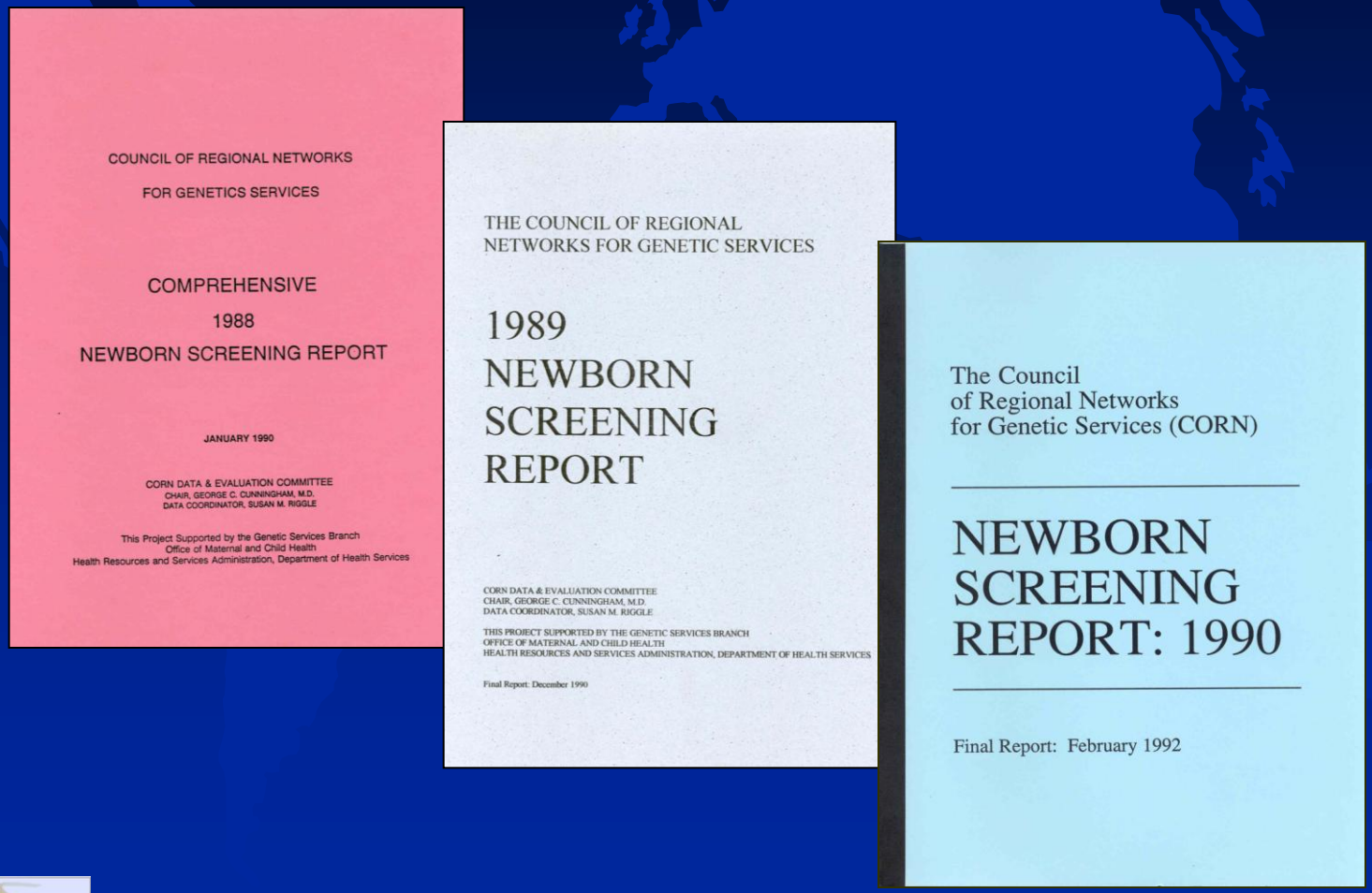
George Cunningham	Chair	PSRGN
Susan Riggle	Data Coordinator	PSRGN
Katharine Harris		GENES
John Waterson		GLaRGG
Paul Ing		GPSGN
Marion Robertson		MARHGN
Ryk Ward		MSRGSN
Mollie Jenckes		NERGG
Karen Novak		PacNoRGG
Sarah Wilding		SERGG
Kathleen Costello		TEXGENE

1990 CORN Data and Evaluation Committee

F John Meaney	Chair	CORN Exec Comm
Susan Riggle	Data Coordinator	PSRGN
Katharine Harris		GENES
John Waterson		GLaRGG
Paul Ing		GPSGN
Marion Robertson		MARHGN
Sundin Applegate		MSRGSN
Virginia Riley		NERGG
Karen Novak		PacNoRGG
George Cunningham		PSRGN
Sarah Wilding		SERGG
Jacqueline Hecht		TEXGENE
Millie Hillard, Ken Pass, Sydney Kling		NBS Comm Liaisons
James Bowman		Sickle Cell Liaison
Larry Edmonds, Muin Khoury		CDC Liaisons
Edward Duffy		HRSA Liaison

U.S. Newborn Screening Data

Initiated by: CORN Data and Evaluation Committee



National Newborn Screening and Genetics Resource Center
Austin, Texas USA
NNSGRC

1991 CORN NBS Committee

Brad Therrell	Lab	Chair	TEXGENE
Ken Pass	Lab		GENES
Sydney Kling	Follow-up		GLaRGG
Shari Kinney	Follow-up		GPGSN
Marion Schwartz	Follow-up		MARHGN
F. John Meaney	Follow-up		MSRGSN
Gretchen Landenburger	Follow-up		NERGG
Mike Glass	Lab		PacNoRGG
Fred Lorey	Follow-up		PSRGN
Emanuel Shapira	Medical		SERGG
Mary Ann Henson	Follow-up		SERGG
Charles Brokopp	Lab		ASTPHLD Liaison
James Eckman	Medical		CORN Liaison
Harry Hannon	Lab		CDC Liaison
Edward McCabe	Medical		AAP Liaison
Rudolph Hormuth			HRSA Liaison

Quality Indicators for Inter- and Intra-Program Quality Assurance

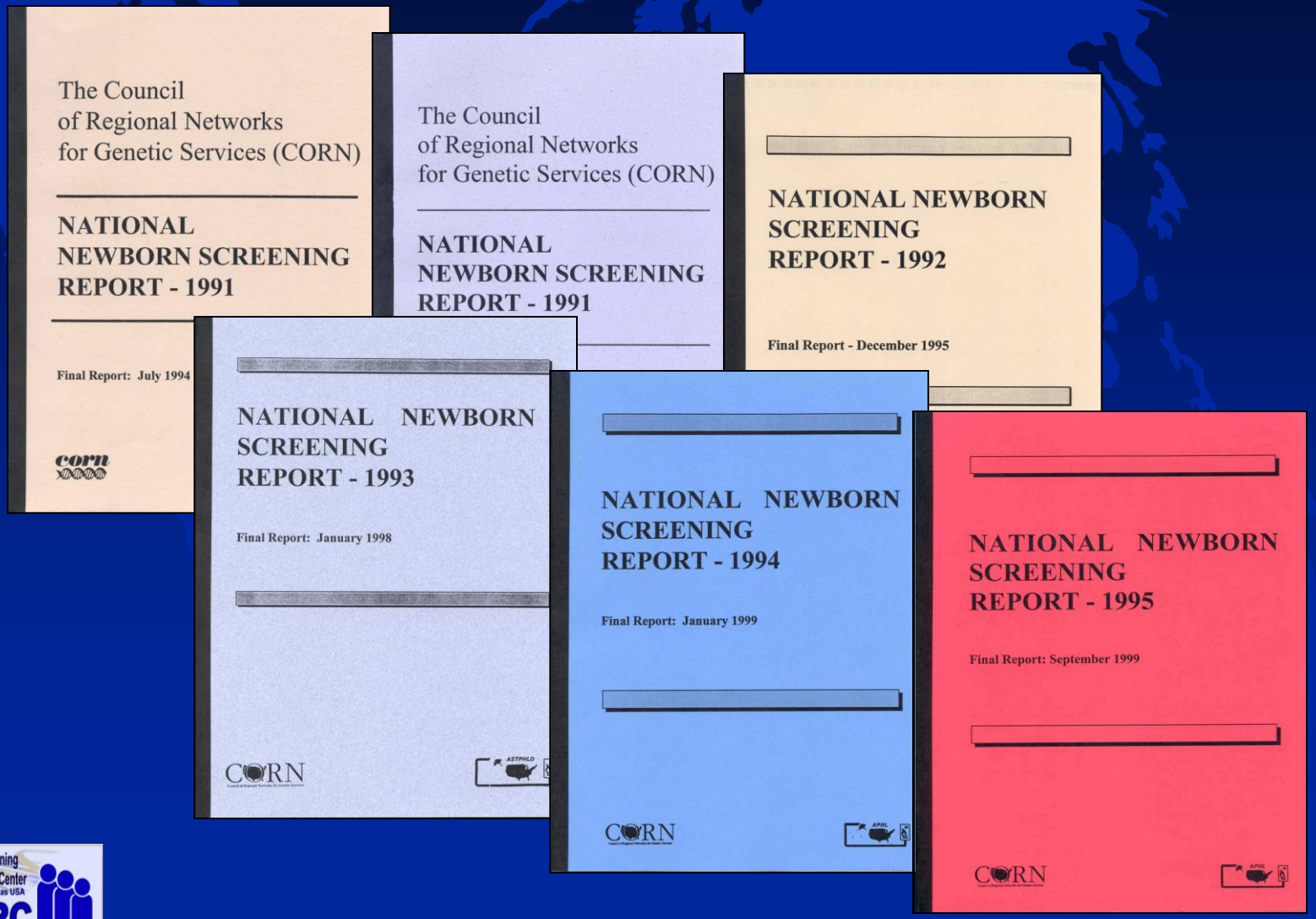
1. Number of disorders screened in each state (classified by requirement – required in all, some, none (voluntary)
2. Percentage of newborns screened
   a. Number of births (official NCHS occurrence records by race/ethnicity)
   b. Number of unduplicated (initial) screens (and time of screen)
   c. Number of subsequent screens [routine, non-routine (clarification)]
3. Age at time of screening (time from birth to screen)
4. Percentage of unsatisfactory specimens
   a. Initial
   b. Subsequent
5. Predictive value of screening
   a. 'Not normal' screens (requiring follow-up of any kind)
   b. Cases confirmed (including race/ethnicity, sex)
6. Time to physician notification
7. Time to treatment
8. Percentage of 'not normal' screens lost to follow up
9. Percentage of cases detected on second screen (normal 1st)

Other Program Information to be Monitored

1. Contact person for laboratory questions in each program
2. Contact person for follow-up questions in each program
3. Definitions of screened disorders for each program
4. Age criteria for screening (<24 h, <36 h, <48 h)
5. Number of screening laboratories within the jurisdiction
6. Components included in follow-up (how reported, confirmation of additional testing, confirmation of treatment, annual follow-up)

U.S. Newborn Screening Data

Prepared by: CORN Newborn Screening Committee



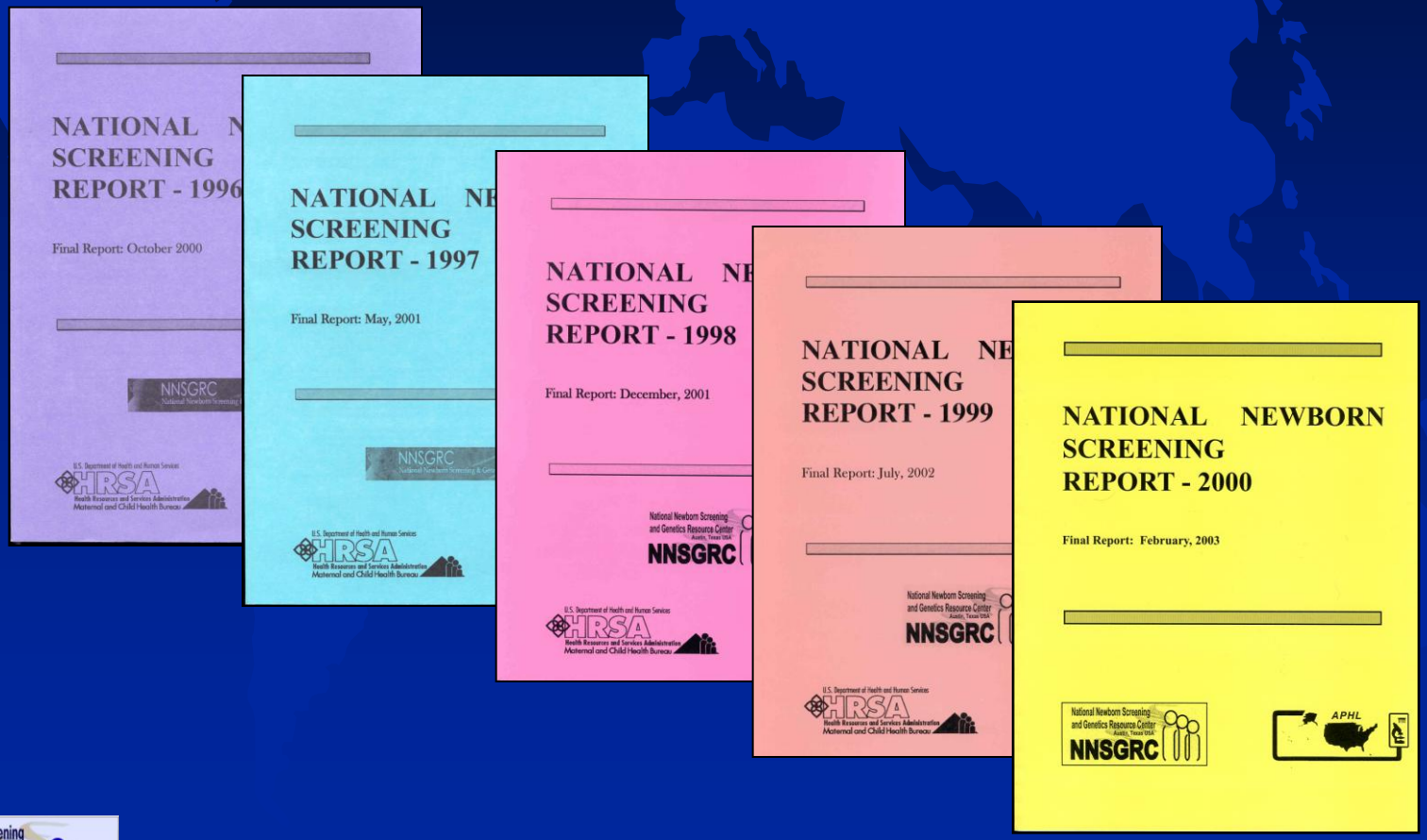
National Newborn Screening and Genetics Resource Center
Austin, Texas USA
NNSGRC

1995 CORN NBS Committee

Ken Pass	Lab	GENES
Gary Hoffman	Lab	GLaRGG
Robert West	Medical	GPGSN
Marion Schwartz	Follow-up	MARHGN
Daniel Gray	Lab	MSRGSN
Ellie Mulcahy	Follow-up	NERGG
Judi Tuerck	Follow-up	PacNoRGG
Fred Lorey	Follow-up	PSRGN
Charles Myers	Follow-up	SERGG
Brad Therrell	Lab	TEXGENE
David Carpenter	Lab	APHL Liaison
Susan Panny	Mecical	ACMG Liaison
Harry Hannon	Lab	CDC Liaison
Kay Vander Ven		HRSA Liaison

U.S. Newborn Screening Data

Prepared by: NNSGRC Staff
Assisted by Newborn Screening Advisory Committee



National Newborn Screening and Genetics Resource Center
Austin, Texas USA
NNSGRC

2000 NNSGRC NBS Advisory Committee

Brad Therrell	Lab	Texas
Ken Pass	Lab	New York
Gary Hoffman	Lab	Wisconsin
Robert West	Medical	Arkansas
Wanda Andrews	Follow-up	Virginia
Daniel Gray	Lab	Colorado
Jim Eckman	Medical	Georgia
Judi Tuerck	Follow-up	Oregon
Fred Lorey	Follow-up	California
Charles Myers	Follow-up	Louisiana
Nate Bauer		Parent
David Mills	Lab	APHL Liaison
Susan Panny	Medical	ACMG Liaison
Harry Hannon	Lab	CDC Liaison
Marie Mann		HRSA Liaison

Additional Program Information to be Monitored

1. Date screening began for each condition
2. Cumulative number of cases diagnosed
3. Length of time specimens stored
4. Storage conditions for stored specimens
5. Storage and disposal policy – yes or no
6. Computerized evaluation of submitters (report card)
7. Screening method for each condition
8. Is there routine submitter education?
9. Program fee information
    a. Amount of fee
    b. Program components covered by fee
    c. Is Medicaid billed? Amount?
    d. Fee collection mechanism
10. Second screen criteria
11. Laboratory criteria for follow-up (cutoffs) by condition

National Newborn Screening and Genetics Resource Center - Windows Internet Explorer

http://genes-r-us.uthscsa.edu/

National Newborn Screening and Genetics ...

NNSGRC

National Newborn Screening & Genetics Resource Center

Contact Us | Events | Parents/Families | Professionals | NNSIS

Welcome to the National Newborn Screening and Genetics Resource Center web site: GeNeS-R-US, (Genetic and Newborn Screening Resource Center of the United States).

Health Improvement Institute
AESCULAPIUS AWARD
WWW SITE
2008 Award of Excellence

The National Newborn Screening and Genetics Resource Center (NNSGRC) is a cooperative agreement between the Maternal and Child Health Bureau (MCHB), Genetic Services Branch and the University of Texas Health Science Center at San Antonio (UTHSCSA), Department of Pediatrics.

We provide information and resources in the area of newborn screening and genetics to benefit health professionals, the public health community, consumers and government officials.

Google™ Custom Search | Search

Search our site

Links of Special Interest

Papers and Reports----------

NEW! **Message Board:** A discussion forum for consumers of newborn screening services including healthcare workers, parents, and others affiliated with newborn screening programs.

NEW! **SACGHS Report: Oversight of Genetic Testing** (2008)

ACT Sheets (ACMG)

Related Links----------

NEW! **Newborn Screening Use Case** Use case documents developed by ONC

-Draft Use Case

-Draft Resource Guide

-**Resource Database** a web-based tool to allow

start | Microsoft Outloo... | National Newbor... | Microsoft Power... | 9:10 PM

National Newborn Screening Information System (NNSIS)

National Newborn Screening & Genetics Resource Center

National Newborn Screening Information System

Home NNSGRC Home Contact NNSGRC

Welcome Guest

General Reports | Customized Reports | Disorder Reports | Login | User Manuals

Welcome! You are currently using the

NATIONAL NEWBORN SCREENING AND GENETICS RESOURCE CENTER'S

National Newborn Screening Information System (NNSIS™)

A project of the University of Texas Health Science Center at San Antonio

Data displayed in this system have been voluntarily contributed by state newborn screening programs for use in assessing inter- and intra-program quality over time. Where data questions exist, please contact the national data coordinator at 512-454-6419.

The database is hosted by the

National Newborn Screening and Genetics Resource Center (NNSGRC)

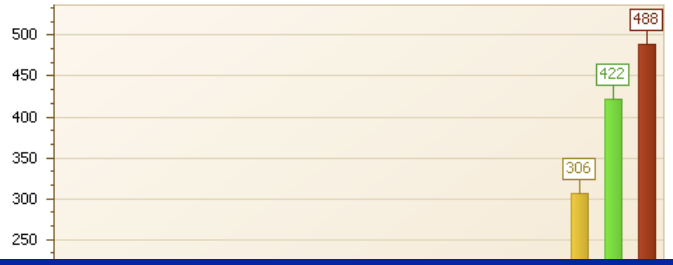
and is designed to provide a secure, Internet based, real-time, information collection and reporting system for capturing state and territorial newborn screening information

The system uses existing reporting requirements specified in the former National Newborn Screening Annual Report

States Where Reported % Unsat >1 for 2010

Days Since Last Update

(have we heard from you lately?)



NNSIS Indicator Survey – 2011

(n=67 of ~100)

Indicator	Yes	No	Score
1. Total number of births (NCHS)	60	0	100
2. Number of initial specimens rec'd	59	3	95
3. Number of newborns with 'not normal' results lost to follow-up	58	3	95
4. Number of confirmed cases (initial screen) by condition	59	4	94
5. Time from birth to physician notification	55	5	92
6. Time from birth to treatment	52	5	91
7. Number of specimens globally unsatisfactory	52	7	88

NNSIS Indicator Survey - 2011

(n=67 of ~100)

Indicator	Yes	No	Score
8. Number of specimens 'not normal' by condition	52	7	88
9. Positive predictive value (confirmed cases x 100/ 'not normal reports'	47	7	87
10. Number of confirmed cases (subsequent screen) by condition	50	8	86
11. Case demographics - sex	48	8	86
12. Number of subsequent specimens rec'd	48	9	84
13. Number of newborns screened by age at time of first screen	53	7	83
14. Case demographics – race and ethnicity	47	11	81

NNSIS Descriptor Survey – 2011

(n=67 of ~100)

Indicator	Yes	No	Score
1. Testing method for each disorder	61	2	97
2. Screening laboratories within jurisdiction	60	3	95
3. Amount of fee ……Items covered by fee	57 57	3 3	95 95
4. Second screening criteria (when a second screen is required either by statute or algorithm)	56	5	92
5. Date screening began for each condition	51	6	90
6. Disorder definitions (diagnostic criteria)	55	7	89
7. Definition of ‘not normal’ for each condition [cutoffs and algorithms (MS/MS]	55	7	89

NNSIS Descriptor Survey - 2011

(n=67 of ~100)

Indicator	Yes	No	Score
8. Length of time specimens stored	55	7	89
9. Written policy for storage and disposal of residual specimens	52	8	87
10. Fee collection mechanism	45	8	85
11. Components included in follow-up	49	10	83
12. Computerized evaluation of submitter compliance (report cards)	47	10	82
13. Routine education to submitters	47	11	81
14. Medicaid billing information	39	11	78

Items with 100% Agreement (No Responses of 'No Opinion')

Indicator	Yes	No	Score
1. Contact person for laboratory issues	67	0	100
2. Contact person for follow-up issues	67	0	100

Comments were solicited throughout along with suggestions for other indicators.

The comments generally centered around improved definitions and there were no substantive suggestions for additional data elements to be collected. Possibility of two types of PPV in future.


Thank You!!
http://genes-r-us.uthscsa.edu
National Newborn Screening and Genetics Resource Center
Austin, Texas USA
NNSGRC