



Special points of interest:

- Conditions the State of Kansas tests for through newborn screening.
- New test for Congenital Adrenal Hyperplasia (CAH) provides for fewer false positives.
- Kansas identifies 44 infants with an inheritable disorder through the expanded newborn screening.
- HHS recommends additional condition to core screening panel.

Kansas Department of Health and Environment
1000 Jackson St.
Topeka, KS 66612

Kansas Completes Second Year of Expanded Newborn Screening

The Kansas Department of Health and Environment’s Newborn Screening Program completed its second full year of testing for the American College of Medical Genetics’ core panel of 28 inherited disorders in newborns. In this second year the program experienced many updates and improvements, providing infants born in Kansas better outcomes. This annual report highlights some of those accomplishments and includes current and future challenges for the program.



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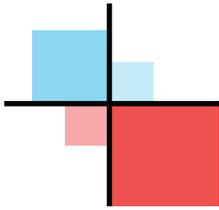
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Progress Made in Quality of Blood Spot Specimens Submitted For Testing

For SFY09 the annual rate of unsatisfactory blood spot samples submitted to the Kansas Health and Environmental Laboratories for newborn screening was 5.46%. Training programs were held in July 2009. (See page 6.) For SFY10, the annual rate of unsatisfactory blood spot cards dropped to 4.17% (a reduction of 23.5%). The ten facilities with the highest % reduction from SFY09 to SFY10 are listed below. (Facilities with more than 100 annual samples.) Performers with the highest % reduction in each number of samples submitted category are highlighted inside on page 8. Congratulations to KU Medical Center.

Facility Name	Facility ID	SFY09 BSC Unsat rate	SFY10 BSC unsat rate	SFY10 Total samples	SFY10 # of BSC unsats	Change
KANSAS UNIV MED CTR	2060	6.4	1.3	1692	22	-79.6
MERCY HOSPITAL - INDEPENDENCE	1230	4.4	1.1	277	3	-75.3
KEARNY CO HOSPITAL	880	4.6	1.3	154	2	-71.9
SUSAN B ALLEN MEM HOSP	170	8.2	2.4	340	8	-71.5
GEARY COMM HOSPITAL	610	13.5	3.9	355	14	-70.9
ALLEN CO HOSPITAL	20	14.3	5.2	116	6	-63.8
CENTRAL KANSAS MED CTR	90	7.6	2.8	290	8	-63.7
SALINA REG HEALTH CENTER	1610	2.6	1.0	1312	13	-62.3
CITIZENS MEDICAL CTR	1950	12.8	6.0	117	7	-53.1
NEOSHO MEMORIAL HOSPITAL	1330	9.1	4.4	344	15	-52.3



WHY NEWBORN SCREENING?

The goal of newborn screening is to identify and treat infants affected by one of these disorders so that disability, mental retardation and/or death can be prevented. All of the core metabolic disorders have treatments available. Although most of these disorders are rare, some occur as infrequently as 1:100,000, it remains important to screen, identify, and treat these infants early so that they can lead productive and healthy lives.

Newborn screening has been an integral part of an infant's health in Kansas since 1965 when testing for phenylketonuria (PKU) began. Since then the program has added additional tests, with the largest expansion beginning in July 2008 when Kansas added an additional twenty two disorders to their testing protocol. While testing for the 28 metabolic disorders recommended by the American College of Medical Genetics (ACMG) is not mandatory, most states now comply and test for the core panel of tests.



GOALS OF THE KANSAS NEWBORN SCREENING PROGRAM

Kansas has specific goals for its newborn screening program. These goals are:

- Ensure that each baby born in Kansas receives a newborn screening .
- Ensure that all infants with screened results that are outside of normal limits receive prompt and appropriate confirmatory testing.
- Ensure that all diagnosed individuals are referred for appropriate medical therapy.

How did we do in meeting our goals in SFY10?

- We tested 41,714 initial samples. Three parents refused testing for their child based on religious reasons (the only reason a parent can refuse testing in Kansas). Because the newborn screening program is not currently linked with Kansas Vital Statistics, we are unable to ensure that every child born in Kansas was provided a newborn screening test. Therefore, one goal for SFY11 is to have Kansas Health and Environmental Laboratories linked with the birth record to ensure that we test every child or a parent refusal form is obtained.
- 100% of the primary care physicians (PCPs) for the 1413 infants who had results outside of normal limits were notified by both the newborn screening follow-up program coordinator and the neonatal testing laboratory. Of these, only 21 infants (1.5%) were lost to follow-up or did not follow up as recommended by the program.
- Forty-four infants were diagnosed with a metabolic disorder in SFY10. Twenty one received services through the Children and Youth with Special Health Care Needs (CYSHCN) program at KDHE. All families with diagnosed infants are referred to CYSHCN, however not all families apply to this program, and not all families who apply are eligible to receive services through the program. Currently, Kansas does not have a formal long-term follow-up program to track infants identified with a genetic disorder through newborn screening. National organizations have identified newborn screening as an ideal case for the use of electronic health records. Kansas has challenges with its information reporting system as well as its capability to track long term outcomes for identified children.

PROGRAM OVERVIEW

The Kansas Newborn Screening (NBS) program is under the Kansas Department of Health and Environment (KDHE). The testing laboratory is located at Forbes Field in Topeka and the follow-up program is located at the Curtis State Office Building in downtown Topeka. The two sections of the program meet on a regular basis to discuss changes and to coordinate efforts within the program.

The laboratory is under the Health Chemistry section, lead by Stacey Sandstrom. Colleen Peterson is the manager of the laboratory and oversees the day-to-day operations. The laboratory technical staff includes June Carroll, Shawn Manos, Kathy Modin, Joyce Rich, Nestor Rodriguez, and Laura Ross. Customer service/Data Entry for the laboratory is done by Eugenia Akers, Laura Baer, Rebecca Banka, Stephanie Bryant, Amanda Metcalfe, Ron Peterson and Melanie Soza.

NBS follow-up is under the Bureau of Family Health, Children and Youth with Special Health Care Needs (CYSHCN) section at KDHE. CYSHCN is directed by Marc Shiff. The follow-up staff includes Jan Conklin and Diana Lopez, administrative assistants; Jamey Kendall and Linda Williams, follow-up coordinators; and Garry Kelley, epidemiologist.

ADVISORY COUNCIL

Kansas statute 65-180 states that the Secretary of KDHE shall appoint an advisory council to advise on the implementation of newborn screening. This council meets quarterly in Topeka on the third Thursday of February, May, August and November. The meetings are open to the public. The current voting members are:

Lisa Butterfield, MS, CGC
Maternal Fetal Medicine, KU Medical Center

James Casey, MD
Pediatric Endocrinologist, Cotton-O'Neil Clinic

Dennis Cooley, MD
Pediatrician, Topeka

Diana Daldrup
March of Dimes

Majed Dasouki, MD—Council Chair
Pediatrics and Medical Genetics, KU Medical Center

Kenneth Dykstra, MD
Pediatric Endocrinologist, Wichita Clinic

Brenda Issa, MD
Pediatrics, KUMC—Wichita

Michelle Leeker
Parent/Advocate

Catherine Fox, MS, RD, LD—Council Vice-Chair
KU Medical Center

Vance Lassey, MD
Family Medicine, Holton

Greta McFarland, MD
Pediatrician, Chanute

Glenn Edwards McGee, Ph.D.
Center for Practical Bioethics

Rebecca Reddy, MD
Pediatrician, KUMC—Wichita

William Randall Reed, MD
Neonatologist, Wesley Medical Center

Maria Riva, MD
Pediatric Pulmonologist, KUMC—Wichita

Mitzi Scotten, MD
KUMC Cystic Fibrosis Center

Margaret Smith, MD
Kansas Health Policy Authority

Deborah Stern, RN, JD
Kansas Hospital Association

Jakica Tancabelic, MD
Pediatric Hematologist, Cotton-O'Neil Clinic

Leona Therou, MD
Pediatrician, KUMC

Suzanne Wikle, MSW
Kansas Action for Children



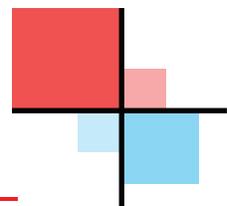
Laboratory Staff: L to R: Joyce Rich, Nestor Rodriguez, Colleen Peterson, Shawn Manos, Laura Ross, Kathy Modin, June Carroll, Stacey Standstrom.



Customer Service Staff: Front row: Eugenia Akers, Stephanie Bryant Back row: Laura Baer, Melanie Soza, Rebecca Banka, Ron Peterson, Amanda Metcalfe.



Follow-up Staff: L to R: Garry Kelley, Linda Williams, Jamey Kendall, Jan Conklin and Diana Lopez.



A SYSTEMS APPROACH TO NEWBORN SCREENING

Newborn screening involves many partners to provide our newest citizens a quality newborn screen. Without these elements in place, the system may fail to provide the excellent service that Kansans have come to expect from newborn screening. These systems include:

- Education of healthcare providers and parents
- Collection of a quality sample
- Timely transport of specimen to the state laboratory
- Rapid and reliable testing methodology
- Timely notification of healthcare providers and parents of any unexpected result
- Timely repeat sample collection
- Appropriate referral of infant to specialists for diagnosis, treatment and counseling services
- Assuring access to programs that help our most vulnerable citizens
- Continuous quality improvement within the program

The Kansas Newborn Screening Program is committed to these systems and encourages our partners to develop, enhance and implement these systems as well.



NEWBORN SCREENING TESTS PERFORMED IN KANSAS—AMERICAN COLLEGE OF MEDICAL GENETICS CORE PANEL

MISC. DISORDERS

BIO - Biotinidase Deficiency
CAH - Congenital Adrenal Hyperplasia
CH - Congenital Hypothyroidism
CF - Cystic Fibrosis
GALT - Galactosemia

AMINO ACID DISORDERS

ASA - Argininosuccinic Acidemia
CIT - Citrullinemia
HCY - Homocystinuria
MSUD - Maple Syrup Urine Disease
PKU - Phenylketonuria
TYR - Tyrosinemia Type I

ORGANIC ACID DISORDERS

IVA - Isovaleric Acidemia
GA-1 - Gluteric Acidemia Type I
HMG - 3-hydroxy-3-methylglutaryl-CoA lyase deficiency
MCD - Multiple Carboxylase Deficiency
MMA (MUT) - Methylmalonic Acidemia - Mutase Deficiency
3MCC - 3-Methylcrotonyl-CoA Carboxylase Deficiency
MMA (CBL A,B) - Methylmalonic acidemia - cblA & cblB
PROP - Propionic Acidemia
BKT - Beta-ketothiolase Deficiency

HEMOGLOBINOPATHIES

SCA - Sickle Cell Anemia
HB S/TH - HB-S/Beta Thalassemia
HB S/C - HB-S/C Disease

FATTY ACID DISORDERS

CUD - Carnitine Uptake Defect
LCHAD - Long Chain 3-OH Acyl-CoA-Dehydrogenase Deficiency
MCAD - Medium Chain Acyl-CoA Dehydrogenase Deficiency
VLCAD - Very Long Chain Acyl-CoA Dehydrogenase Deficiency
TFP - Tri Functional Protein Deficiency



POSITIVE SCREENING RESULTS

In SFY10, Kansas screened 41,714 infants. Of these 3,027 had presumptive positive or inconclusive results and required further testing. Most often, this meant the newborn screen had to be repeated. However, for certain presumptive positives, immediate consultation and additional blood work or urine analysis was indicated. Sweat chloride testing was recommended after two positive IRT results were obtained.

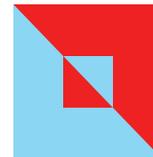
Six hundred fifty three infants had an initial positive immune reactive trypsinogen (IRT) result. IRT is the initial screen for cystic fibrosis. Of these 114 repeated positive and were referred for a sweat chloride test—ninety eight were sweat chloride normal, 10 were diagnosed with cystic fibrosis, 2 were deceased before testing could be performed and 4 infants have a sweat chloride test pending.

Nine hundred one infants had positive results for congenital hypothyroidism (CH) - 30 were presumptive positive and 871 were borderline. Eighteen were diagnosed, including two with transient CH. Of the 18 diagnosed, 9 of those had initial borderline results (including 1 of the transient diagnosis).

Seven hundred fifty six hemoglobin results were reported to physicians for follow-up. Of these sixteen were presumptive hemoglobin diseases and seven hundred forty were hemoglobin traits. Approximately 20% of the traits have been confirmed, while another five hundred eleven are still pending. The recommendation is to do confirmatory testing at the one year exam, so this pending number is not unexpected.

Condition Screened	Number of Presumptive Positive or Inconclusive Results on Initial Screen	Number of Pending Confirmation Testing	Number of Positive Screens Lost to Follow-Up	Number of Deceased Prior to Confirmation or Diagnosis	Number of Confirmed Positive/ Diagnosed (classical or partial with treatment)
Biotinidase Deficiency	3	0	0	0	1
Cystic Fibrosis	653	0	13	5*	10
Endocrine Disorders					
Congenital Adrenal Hyperplasia	163	0	1	4	2
Presumptive Congenital Hypothyroidism	30	0	0	0	8 + 1 transient
Borderline Congenital Hypothyroidism	871	8	56	0	8 + 1 transient
Galactosemia	7	0	0	0	1 Duarte
Hemoglobinopathies					
Sickle Cell Anemia	7	0	1	0	4 Sickle Cell 1 sickle trait 1 (see below) **
Sickle C Disease	2	1	0	0	1
Sickle/ β Thal Disease	0	0	0	0	0
Other Hemoglobin Diseases	8	1	0	0	5 Hgb E Disease 1 Hgb E/ β Thal
Hemoglobin Traits	740	511	82	0	83 sickle trait 64 other traits
Amino Acid Disorders	370	1	3	11	1 CIT
					2PKU
					1 Transient Tyr
Fatty Oxidation Disorders	50	0	1	1	1 CUD
					3 MCAD
					1 VLCAD
Organic Acid Disorders	123	1	2	3	1 MMA
*includes 2 released to hospice					
** = β Thal/ Osu-Christiansborg trait					

NEWBORN SCREENING INITIATIVES IN FY10



Education

- Regional trainings for collection facilities were completed with four trainings held in July 2009. The training locations were Topeka (St. Francis Hospital), Hutchinson (Promise Regional Medical Center), Kansas City (Providence Medical Center) and Overland Park (Overland Park Regional Medical Center). Seventy-six professional staff members from thirty-three facilities attended the trainings. Included in the three-hour sessions was an overview of newborn screening, how to properly collect a blood spot card, an introduction to the newborn screening laboratory, an overview of the disorders we screen for, and how follow-up tracks abnormal results.
- Jamey Kendall and Linda Williams presented at the Kansas Association of Osteopathic Medicine in April. Approximately 75 attendees learned about the Kansas Newborn Screening Program and the expansion of testing that began in July 2008.

Staff Development

- Four staff members, Colleen Peterson, June Carroll, Jamey Kendall and Linda Williams attended the Association of Public Health Laboratories Newborn Screening Symposium in Orlando, FL. This four day symposium included information about emerging technologies, outcomes, information systems and education.
- Jamey Kendall was awarded an Advanced Certificate in Public Health Genetics/Genomics from Sarah Lawrence College.
- Linda Williams completed the Kansas CORE Public Health Program.
- Laura Ross attended “Newborn Screening Molecular Training Workshop: Using Cystic Fibrosis as a Model” at the Centers for Disease Control and Prevention.
- Colleen Peterson attended an HPLC seminar sponsored by Waters and a hemoglobin workshop in Oakland, CA.

Laboratory Improvements

- On October 18th, 2009 the use of the new PerkinElmer Kit for 17-OHP with a new antibody was implemented. The new antibody in the Perkin Elmer kit has improved specificity and sensitivity for 17-OHP. Cut offs were revised and the new kit resulted in a significant reduction number of false positive results. Prior to the implementation of the new kit, the false positive rate was 0.80%. From October 18th, 2009 to June 30th, 2010 the false positive rate dropped to 0.46%. With the implementation of this new kit approximately half as many infants are having a second specimen drawn due to a false positive 17-OHP for Congenital Adrenal Hyperplasia.
- On April 24, 2010 the lab participated in an emergency drill with Missouri. See full details on page 7.

Heartland Genetics and Newborn Screening Collaborative

- The KS NBS program continues to be an effective participant with the Heartland Genetics and Newborn Screening Collaborative (HGNBSC). Staff members participate in monthly conference calls. Jamey Kendall is a member of the HGNBSC Advisory Council.
- Four program staff attended the annual HGNBSC meeting in Little Rock, AR in September 2009. The meeting was an opportunity to network with other newborn screening programs within the Heartland region.
- Work is on-going to harmonize the states’ efforts in newborn screening. The region’s members goal is to have blood spot acceptance criteria and blood spot card information harmonized so that samples can be tested at any of the region members’ laboratories.

KANSAS NEWBORN SCREENING PROGRAM HOLDS FIRST EMERGENCY MANAGEMENT DRILL

On April 27th, a plane trying to make an emergency landing at Forbes Field lost part of its wing, which crashed into the roof of Building 740, right above the newborn screening laboratory. The rooftop HVAC system and exhaust system were damaged and part of the ceiling tiles in the Neonatal Laboratory were dislodged, disabling the two MS/MS instruments and both of the AutoDelfia instruments. That was the scenario for the first emergency management drill for Kansas Newborn Screening. The Heartland Genetics Collaborative states have been working on emergency management drills for the past two years and it was Kansas' turn to put a full drill into action. With the help of the Missouri Newborn Screening Program, Kansas was able to demonstrate its capability to respond to an actual emergency, if needed.

The exercise not only involved the newborn screening programs of both states, it also involved the Metropolitan Topeka Airport Authority, the Bureau of Public Health and Preparedness, and the Office of the Governor. An Emergency Management Assistance Compact (EMAC) was implemented and pertinent staff were convened in the Department Operations Center (DOC), just as if this was a real emergency.

Three hundred samples, which were tested the previous week at the KS lab and known to be acceptable samples, were shipped overnight to the MO lab. They were tested the day they arrived and follow-up received results via a phone call and fax, that followed protocols for first time testing of samples. Missouri's laboratory results for the three hundred specimens were compared to the results the Kansas Laboratory had reported. All results from the two laboratories fell within acceptable ranges of each location and support the accuracy and correlation of the two facilities. The exercise was a huge success and provided vital experience and information to all agencies involved.

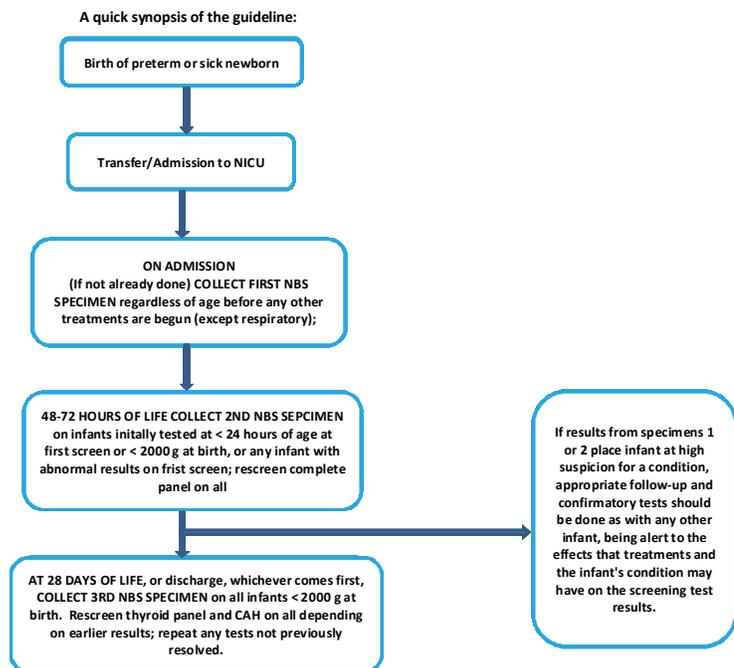


NEW STANDARDS FOR NEWBORN SCREENING OF PRETERM, LOW BIRTH WEIGHT AND SICK NEWBORNS

The Clinical and Laboratory Standards Institute published the first approved guideline for newborn screening of preterm, low birth weight and sick newborns in October 2009. The guideline is a culmination of several years work by experts in newborn screening and neonatology. The advisory council recognized the importance of getting this guideline out to Kansas hospitals that care for these special infants and recommended that all hospitals with a Neonatal Intensive Care Unit (NICU) receive a copy. With a generous contribution from the March of Dimes, we were able to provide twenty facilities with a copy of this important guideline.

Currently, KU Medical Center NICU is the only facility that is following the guideline. Because the guideline is not mandatory, each NICU facility should determine what's in the best interest of their patients.

One challenge for the KS state laboratory and follow-up staff is to keep track of repeat samples and previous results. Because the laboratory information system is sample based and not patient based, it is important that each repeat sample is linked to a previous sample, and that all results are conveyed to the follow-up staff when reporting abnormal results.



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QUALITY ASSURANCE AND PROCESS IMPROVEMENT REPORTS—FY10

Blood Spot Quality

Several areas for improvement were identified during the year, most importantly the quality of the blood spot card (BSC) samples submitted to the laboratory for testing. The FY09 annual unsatisfactory blood spot percent was 5.46. The unsatisfactory rate dropped to 4.17% through continued training and communication with our collection facilities. When analyzing this data, it is helpful to compare similar sized facilities. The unsatisfactory goal of less than 2.0% has not been met, therefore, continued efforts are being made in this area. Below are facilities that had a 25% or greater decrease in the number of unsatisfactory blood spot samples submitted for testing.

FACILITIES WITH > 999 SAMPLES IN SFY10						
Facility Name	Facility ID	SFY09 BSC unsat rate	SFY10 BSC unsat rate	SFY10 Total samples	SFY10 # of BSC unsats	Change
KANSAS UNIV MED CTR	2060	6.4	1.3	1692	22	-79.6
SALINA REG HEALTH CENTER	1610	2.6	1.0	1312	13	-62.3
LAWRENCE MEMORIAL HOSPITAL	430	5.3	2.7	1198	32	-49.9
PROVIDENCE MEDICAL CENTER	2040	2.8	1.5	1074	16	-46.4
SHAWNEE MISSION MED CTR	850	3.2	1.8	4041	74	-42.4
MERCY REGIONAL HEALTH CENTER	1570	5.0	2.9	1078	31	-42.1
OVERLAND PARK REG MED CTR	870	3.1	2.0	3603	72	-36.4
ST LUKE'S SOUTH HOSPITAL	868	2.6	1.7	1037	18	-33.3
IRWIN ARMY COMM HOSPITAL	600	6.6	4.9	1015	50	-25.5

FACILITIES WITH 500 - 999 SAMPLES IN SFY10						
Facility Name	Facility ID	SFY09 BSC unsat rate	SFY10 BSC unsat rate	SFY10 Total samples	SFY10 # of BSC unsats	Change
SAINT FRANCIS HOSPITAL	1760	3.1	1.5	977	15	-50.5
HAYS MEDICAL CENTER	6660	2.3	1.3	765	10	-43.2
ST CATHERINE HOSPITAL	520	11.6	7.7	871	67	-33.7

FACILITIES WITH 50 - 99 SAMPLES IN SFY10						
Facility Name	Facility ID	SFY09 BSC unsat rate	SFY10 BSC unsat rate	SFY10 Total samples	SFY10 # of BSC unsats	Change
GREELEY CO HOSPITAL	660	5.1	0.0	50	0	-100.0
MEDICAL CTR LABORATORY	6530	0.5	0.0	99	0	-100.0
GOVE CO MEDICAL CENTER	620	6.0	1.8	55	1	-69.5
SCOTT CO HOSPITAL	1630	10.8	3.5	57	2	-67.4
KU CHILDREN'S CENTER - KC	6850	13.0	5.5	73	4	-57.9
BIRTH & WOMENS CENTER - YODER	8203	13.0	5.9	51	3	-54.8
MEMORIAL HOSP - ABILENE	410	9.6	5.2	97	5	-46.1
NEMAHA VALLEY COMM HOSPITAL	1290	12.7	8.5	59	5	-33.4
GOODLAND REGIONAL MEDICAL CTR	1850	13.3	9.2	65	6	-30.8

FACILITIES WITH 100 - 499 SAMPLES IN SFY10						
Facility Name	Facility ID	SFY09 BSC unsat rate	SFY10 BSC unsat rate	SFY10 Total samples	SFY10 # of BSC unsats	Change
MERCY HOSPITAL - INDEPENDENCE	1230	4.4	1.1	277	3	-75.3
KEARNY CO HOSPITAL	880	4.6	1.3	154	2	-71.9
SUSAN B ALLEN MEM HOSP	170	8.2	2.4	340	8	-71.5
GEARY COMM HOSPITAL	610	13.5	3.9	355	14	-70.9
ALLEN CO HOSPITAL	20	14.3	5.2	116	6	-63.8
CENTRAL KANSAS MED CTR	90	7.6	2.8	290	8	-63.7
CITIZENS MEDICAL CTR	1950	12.8	6.0	117	7	-53.1
NEOSHO MEMORIAL HOSPITAL	1330	9.1	4.4	344	15	-52.3
BIRTH & WOMENS CENTER - TOPEKA	1820	33.3	19.6	163	32	-41.1
COFFEY CO HOSP	310	12.1	7.2	111	8	-40.7
MEMORIAL HOSPITAL - MCPHERSON	1140	8.2	5.2	211	11	-36.6
ATCHISON HOSPITAL	40	9.7	6.2	178	11	-36.3
BOB WILSON MEM GRANT CO HOSP	640	14.9	9.9	111	11	-33.6
RANSOM MEMORIAL HOSPITAL	590	5.7	3.8	157	6	-32.6
SAINT JOHNS HOSPITAL	970	12.9	9.5	105	10	-26.3

FACILITIES WITH 10 - 49 SAMPLES IN FY10						
Facility Name	Facility ID	FY09 BSC unsat rate	FY10 BSC unsat rate	FY10 Total samples	FY10 # of BSC unsats	Change
ARBOR CREEK FAMILY CARE	10502	12.5	0.0	10	0	-100.0
HOLTON COMMUNITY HOSPITAL	790	13.9	0.0	33	0	-100.0
MICHELLE RUEBKE MIDWIFE	8060	6.1	0.0	25	0	-100.0
WEST WICHITA FAMILY PHYSICIANS	6070	5.9	0.0	38	0	-100.0
HUTCHINSON CLINIC	6040	17.4	3.0	33	1	-82.6
MINNEOLA DIST HOSP	270	11.9	2.5	40	1	-79.0
OSBORNE CO MEM HOSPITAL	1380	21.7	5.9	17	1	-72.9
WICHITA CLINIC - CARRIAGE PKWY	5060	16.0	4.5	22	1	-71.6
MORRIS CO HOSPITAL	1260	6.5	2.0	49	1	-68.7
BRENDA FRANKENFIELD	8370	50.0	23.1	13	3	-53.8
CLOUD CO HEALTH CTR	290	10.4	5.6	36	2	-46.7
CHEYENNE COUNTY HOSPITAL	250	10.0	6.7	15	1	-33.3

Forty-nine of the 154 (31.8%) submitting facilities had a 25% or greater reduction in their blood spot errors. However, 55 facilities (35.7%) had an increase in the number of unsatisfactory blood spots when compared to FY09. This latter group includes two of the larger birthing facilities in the state and twelve facilities that had less than 10 samples submitted in FY10.

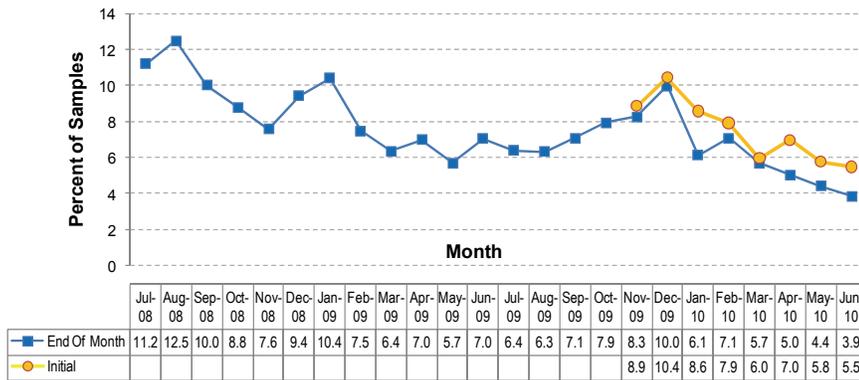
Of the 46,605 samples submitted for testing (includes repeat samples), 1,938 samples were unsatisfactory due to the quality of the blood spots. In addition, 808 samples had missing demographic information and 612 were drawn at <24 hours (235 in NICU).

Monthly Unsatisfactory Samples

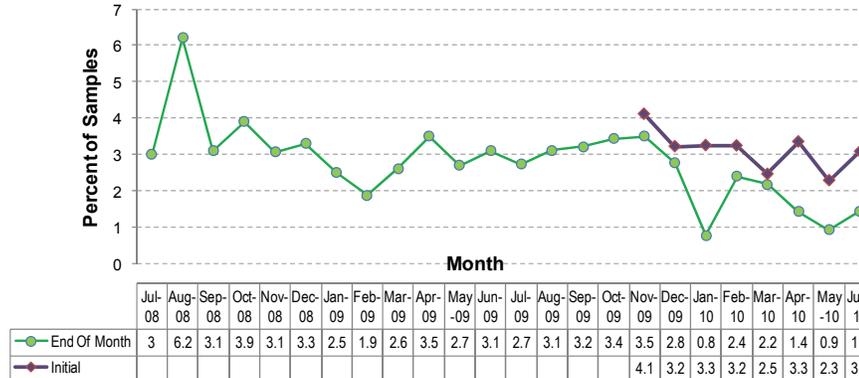
Overall, the total percentage of unsatisfactory samples dropped over each of the two previous fiscal years. In July 2008 the overall unsatisfactory rate was 11.2%. In June 2010, the overall unsatisfactory rate was 3.9%. Blood spot errors continue to drop. In July 2008, the blood spot error rate was 8.2% and in June 2010 the rate was 2.4%. The goal of maintaining an overall unsatisfactory rate of under 2.0% remains unattained. The NBS staff will continue to educate and communicate with collection facilities in FY2011 to support meeting this goal.

In November 2009, follow-up staff began tracking demographic unsatisfactory samples received by the lab. The monthly collection facility reports are completed two weeks after the close of the month. By this time, many of the demographic errors have been resolved so the initial unsatisfactory rate is not reflected in the report. The graphs below show the monthly unsatisfactory rates, including the initial and end of month (reported) rates.

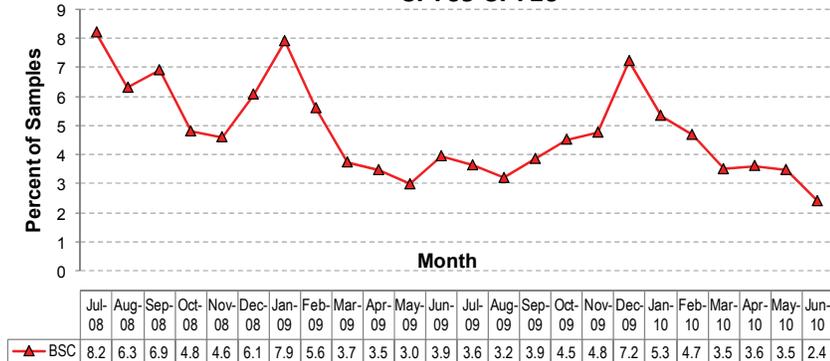
**The Percent of Total Unsatisfactory Samples
SFY09-SFY10**



**The Percent of Samples with Demographic Errors,
SFY09-SFY10**



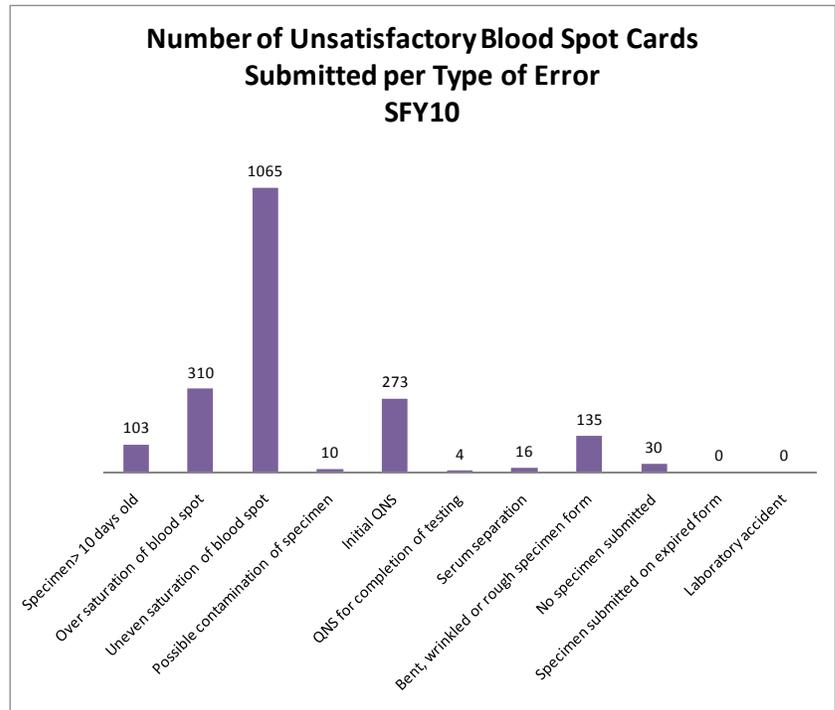
**The Percent of Samples with Blood Spot Card Errors
SFY09-SFY10**



Reasons For Unsatisfactory Blood Spot Samples

The most common reason for an unsatisfactory blood spot is the uneven saturation of the blood sample. The laboratory currently uses thirty reason codes when rejecting a sample; those codes can be grouped into eleven common reasons.

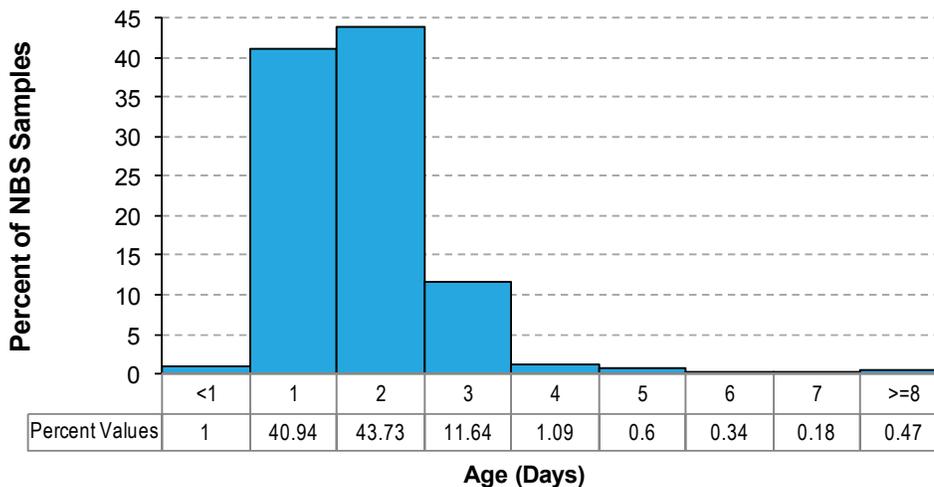
- 1) Specimen > 10 days old
- 2) Oversaturation of blood spot
- 3) Uneven saturation of blood spot
- 4) Possible contamination of specimen
- 5) Initial quantity not sufficient for testing (QNS)
- 6) Quantity not sufficient for completion of testing
- 7) Serum separation
- 8) Bent, wrinkled or rough specimen form
- 9) No specimen submitted
- 10) Specimen submitted on expired form
- 11) Laboratory accident



Age of Infant at Time of Initial Sample Collection

The Kansas Newborn Screening Advisory Council recommends that the initial sample for newborn screening be collected between 24 and 72 hours after birth. In March 2010, 96.3% of initial samples were collected within this time frame.

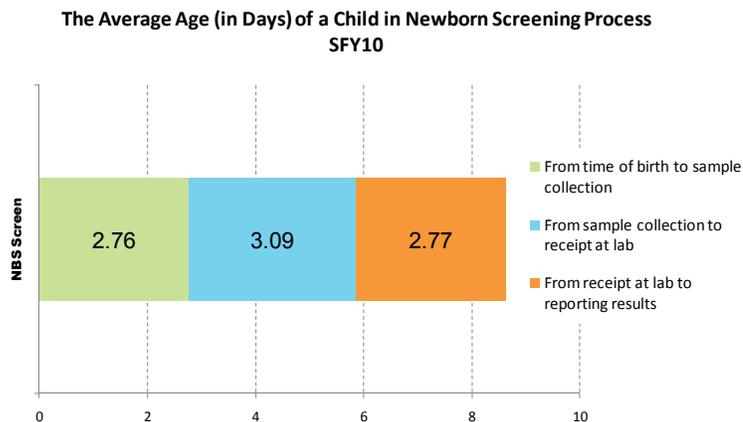
Percent of Initial Samples by Child's Age in Days March 2010 (9,622 samples)



Turn Around Times

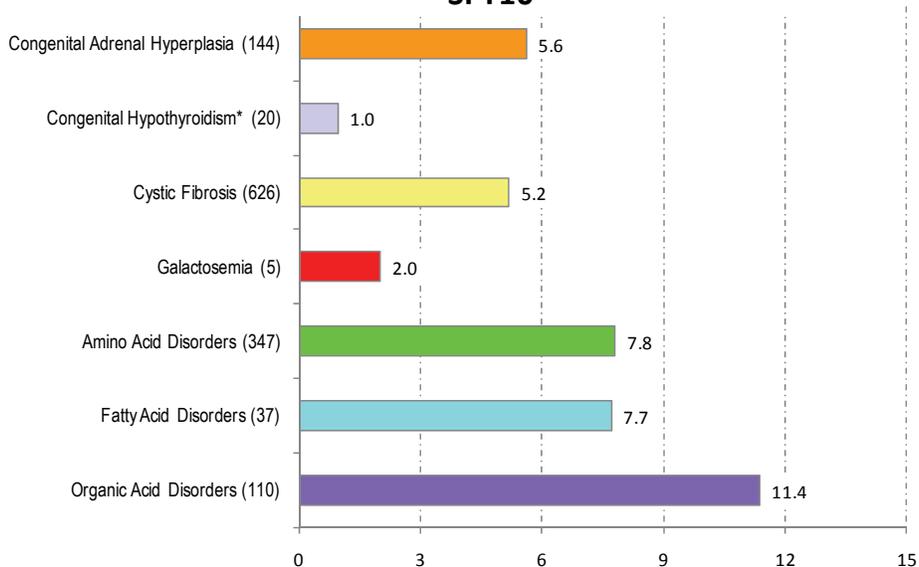
Time can be critical in newborn screening. This is why it's important to (1) track the time it takes to collect a sample at the birthing facility, (2) how long it takes to get that sample to the laboratory, and (3) how long it takes the lab to get abnormal results to the follow-up team.

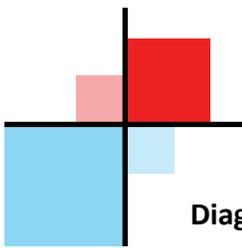
In FY10, the average age at sample collection was 2.76 days. It took an average of 3.09 days from date of collection to date of receipt at the laboratory. Once the lab took receipt of the sample, it took an average of 2.77 days upon the lab receipt of the sample to report an abnormal result to the follow-up team.



A second important timeframe is the length of time it takes the provider to get a requested repeat sample collected for retest when the initial result is abnormal. In the table below, the amino acid, fatty acid, and organic acid disorders have a longer turn around time for the second specimen. This could be due to infants in the NICU who are on Total Parenteral Nutrition (TPN). Because this can affect results, it is recommended that the infant be off TPN for at least 48 hours prior to retest. For congenital hypothyroidism, many of the positive results have already had a second sample collected prior to notification of the abnormal result. This, again, is because the infants are in the NICU, where the initial sample was collected at birth and a second sample was collected after 24 hours.

The Average Number of Days from Provider Notification to Retest Date by Disorder Group for SFY10

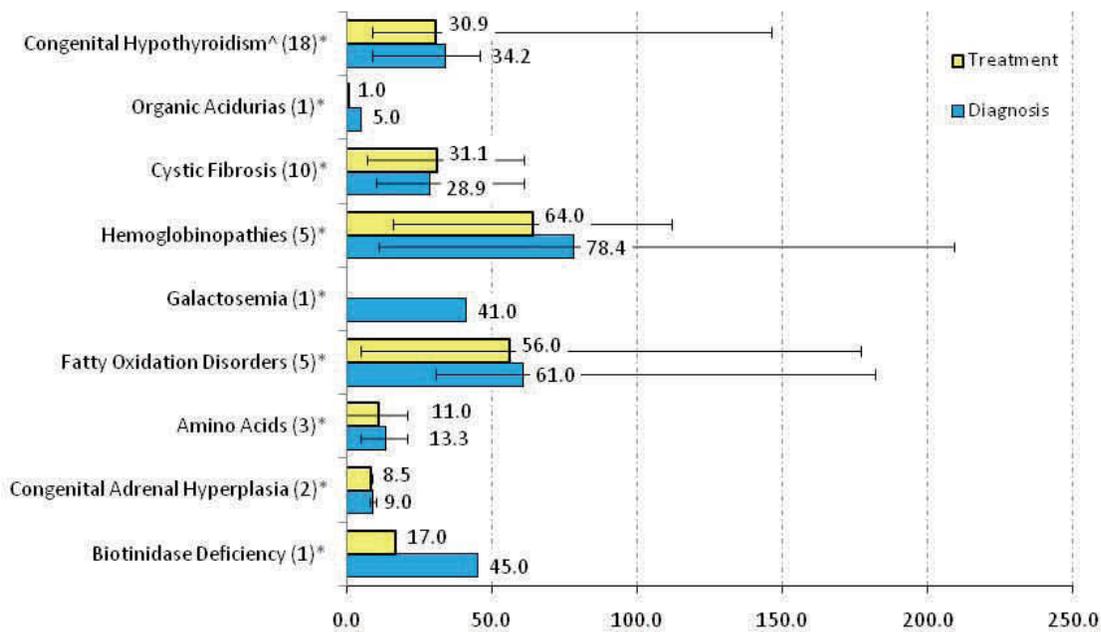




Diagnosis and Treatment

When an infant is identified with an abnormal newborn screen, typically the screen is repeated prior to recommending diagnostic testing. Some presumptive positives go directly to diagnostic testing. The goal of the program is to quickly identify those infants who need treatment for a diagnosed condition. Treatment often begins prior to the completion of all diagnostic testing, as seen in the chart below; especially if a diagnostic test needs to be sent to a reference lab.

The Average Age of Child (in Days) and Age Range (error bar) for Treatment and Diagnosis by Disorder Group - SFY10



Note: ^ For congenital hypothyroidism, borderline cases were excluded from the analysis

* Number in parenthesis is number of cases



STATE GENETICS PLAN

Throughout the past year many stakeholders convened to develop a state genetics plan for Kansas. This was made possible through a grant from the Heartland Regional Genetics and Newborn Screening Collaborative. The Kansas Department of Health and Environment invited stakeholders and worked in conjunction with DNAXPRT Consulting, LLC (Lenna M. Levitch, MS, CGC; Molly M. Lund, MS, CGC) to create a draft State Genetics Plan. EnVisage Consulting, Inc. contacted medical experts throughout the state and region to complete a final draft, and convened medical experts for a final review of the State Genetics Plan.

Stakeholders met in November 2009 for the kick-off meeting. During the year over 40 stakeholders worked through the four goals to develop objectives and actions plans for each of the goals. The four core goals of the state genetics plan are:

1. To improve the state's capacity to respond to advances in genomic medicine and technology
2. To promote collaborative partnerships in support of genetic services in Kansas
3. To develop a genetics literacy agenda for the public and policymakers
4. To assess the impact of heritable conditions on public health and sustain a statewide partnership of genetic services

The complete plan is available at:

http://www.kdheks.gov/newborn_screening/download/State_Genetics_Plan.pdf



“Genetics and genetic disorders impact the lives and health of all Kansans. Along with healthy behaviors and environmental conditions, genetics plays an important role in our health. Today almost everyone knows someone whose health has been affected by genetic conditions.”

Kansas Governor Mark Parkinson

NEWBORN SCREENING ANNUAL BUDGET AND EXPENDITURES

In FY10 the Kansas Newborn Screening Program received funding from three sources: 1) Children's Initiative Fund (CIF), 2) Maternal Child Health Block Grant (MCH) and 3) State General Funds (SGF). The laboratory and follow-up programs have separate budgets within the program. The newborn screening laboratory receives funding only from CIF and not the other two sources. Each year the CIF conducts an evaluation of the program through the University of Kansas to ensure that the program is effective and a good steward of the funds received through CIF. The table below indicates the funding source, amounts and whether it was allocated to the laboratory or follow-up program.

FY10 NEWBORN SCREENING BUDGET AND EXPENDITURES									
Funding Source	Budgeted			Expended			Balance		
	Laboratory	Follow-up	Total	Laboratory	Follow-up	Total	Laboratory	Follow-up	Total
State General Funds	\$ -	\$ 155,000	\$ 155,000	\$ -	\$ 148,302	\$ 148,302	\$ -	\$ 6,698	\$ 6,698
Children's initiative Fund	\$ 1,901,764	\$ 322,342	\$ 2,224,106	\$ 1,900,087	\$ 322,136	\$ 2,222,223	\$ 1,677	\$ 206	\$ 1,883
Maternal Child Health Block Grant	\$ -	\$ 112,215	\$ 112,215	\$ -	\$ 91,231	\$ 91,231	\$ -	\$ 20,984	\$ 20,984
Total of Sources	\$ 1,901,764	\$ 589,557	\$ 2,491,321	\$ 1,900,087	\$ 561,669	\$ 2,461,756	\$ 1,677	\$ 27,888	\$ 29,565

NEW CONDITION ADDED TO CORE PANEL—SEVERE COMBINED IMMUNE DEFICIENCY (SCID) DISORDERS

On January 21, 2010, the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (SACHDNC) unanimously voted to recommend severe combined immune deficiency (SCID) to the core newborn screening panel. Secretary Kathleen Sebelius, Health and Human Services (HHS), signed the recommendation on May 21, 2010. SCID is the first condition to be added to the panel since the recommended expansion of newborn screening in September 2005.

SCID is a group of disorders that are characterized by a lack of immune system, which, if left undetected and untreated leads to early death. The treatment for SCID is a bone marrow transplant, preferable prior to any infection in the infant. Therefore, adding this condition to the NBS core panel would be effective in early identification and treatment to save these children's lives.

The Kansas Newborn Screening Advisory Council discussed the addition of SCID to the Kansas panel at two of their meetings this year. At this time, the council has decided to wait to see how other states implement this testing protocol and follow-up program. SCID presents two challenges for the Kansas NBS program. The first is the cost of the test itself. Since the testing protocols are relatively new, each test costs approximately \$5.00 per sample. In addition, Kansas does not currently have easy access to a pediatric transplant center, where identified infants would have to go for their transplant. The council feels that in the early stages of implementation, many of these challenges will be resolved by early adopters and that Kansas should wait until more states have implemented testing for SCID. Secretary Sebelius has asked the SACHDNC to report back to HHS in May 2011 regarding how states have responded to the addition of SCID to the recommended core panel and challenges the states face regarding implementation of testing for SCID.

UPCOMING INITIATIVES/GOALS FOR SFY11

Education

- Further education and outreach will be done with NICU facilities regarding the CLSI guidelines
- Education and outreach will be done with OB/GYN facilities and birthing classes so parents are informed about newborn screening prior to the birth of their child
- Continued education for collection facilities to lower the number of unsatisfactory blood spot card submissions.

Information Systems

- Get laboratory information system (Informix) integrated with Vital Statistics so the NBS program can track every child born in Kansas
- Continue to improve the follow-up program with the use of enhanced Access database

Laboratory

- Implement DNA testing for cystic fibrosis confirmatory testing. This will reduce the number of repeat tests for confirmation and ultimately reduce the number of infants who are referred to sweat chloride testing.

KANSAS NEWBORN SCREENING PROGRAM
WWW.KDHEKS.GOV/NEWBORN_SCREENING
1-785-296-1650 (LABORATORY)
1-785-296-0109 (FOLLOW-UP)

