Improving Quality Indicators Associated with Newborn Screening Specimen Collection and Transport

Scott M. Shone, PhD

Program Manager – NBS Laboratory













Pilot Study of Quality Indicators for the Next Generation of Data Collection into a **National Newborn Screening Data Repository**

Scott Shone, PhD; Irwin Margolin; Suzanne Karabin, MS, CGC; Donna McCourt; Lori Garg, MD, MPH and Martha Smith

Newborn Screening Program, New Jersey Department of Health and Senior Services, Trenton, New Jersey



ABSTRACT

In June 2011, the Association of Public Health Laboratories (APHL) convened a Quality Indicators (QIs Vorkgroup consisting of stakeholders from State Newborn Screening (NBS) Programs, the APHL, the Health Resources and Services Administration (HRSA), the Centers for Disease Control and Prevention, the National Library of Medicine, and the Genetic Alliance. The goal of the workgroup was to summarize the utility of current NBS laboratory and short term follow up QIs and to develop and outline QIs that should be collected in the next generation national newborn screening data repository. The workgroup utilized data collected from State NBS
Programs, the Texas Newborn Screening Performance Measures Project, the Program Evaluation and Assessmen Scheme (PEAS), and the existing National Newhorn Screening Information SystemTM (NNSIS) to evaluate potential QIs based on their ability to improve the newborn screening system, their scientific merit, their levance to stakeholders, and their feasibility. Ten (10) QIs were selected for HRSA to recommend all State NBS ollect and to include in the future data repository.

The purpose of this pilot study is to determine the feasibility and utility of the 10 QIs selected by the workgroup. The New Jersey Newborn Screening Program and its Divisional Quality Assurance Program evaluated thes OIs, and the results are presented hereix

INTRODUCTION

- The New Jersey Newborn Screening Program routinely monitors several quality indicators (QIs) as part of Divisional quality improvement initiatives as well as Governor Christie's statewide program to track the operations and performance of each department of state government,. OIs monitored monthly include workload. pecimen quality, demographic data collection quality, and time for specimen transmittal from submitter to
- * The Ten (10) QIs selected by the APHL workgroup for HRSA to recommend all State NBS Programs collect
- 1. Percent of unsatisfactory specimens due to improper collection
 - Number of specimens on which labs cannot perform a complete newborn screening panel due to errors in collection divided by number of specimens submitted
- All cards with state-defined essential information divided by all cards received. 3. Frequency of condition detected at birth: First screen vs. Second screen
- umber of infants confirmed affected based on an out-of-range first (vs. subsequent) valid specimen divided
- by the number of infants screened 4. Rate of loss to follow-up: unsatisfactory & out-of range
- son (and no provious or later satisfactory enecimen) that were lost to follow-up per state protocols at 6 months of age divided by the total number of infants in the state with Number of babies with an out-of-range test result that were lost to follow-up per state protocols at 6 months of
- age divided by the total number of infants in the state with an out-of-range test result Percent of parental refusals
 Number of babies whose parents refused the complete newborn screening panel divided by total number of live
- 6. Percent of eligible infants receiving valid newborn screening test . Number of babies with a satisfactory and valid newborn screening result divided by number of live births in the
- A From hirth to specimen collection
- ♦B. From specimen collection to receipt by lab
- C. From specimen receipt to reporting out results
 D. From release of out-of-range results to notification of medical provider
- &E. From release of out-of-range results to medical intervention
- 8. Positive predictive value (PPV) of out-of-range screening results
- . Number of babies with a "not normal" screen with a confirmed diagnosis divided by number of all babies with · Number of babies referred for evaluation with a confirmed diagnosis divided by the number of all babie
- 9. Rate of out-of-range results, any referral to evaluation
- ned positive and need a repeat divided by total number of infants scr . Number infants with out-of-range result that need referral for evaluation divided by total number of infants
- - Number of babies with disease who were not identified on newborn screening (but had a valid NBS) divided by all the babies who were screened and diagnosed with disorder (true positives and false negatives combined

METHODS

Data from the Program's information system, Neometrics (Natus Medical Inc., San Carlos, CA) was exported using a variety of built-in and user-defined result filters and oueries.

Analyses were performed using Microsoft Excel, Microsoft Access, and Crystal Reports (Seagate Tech., Scotts

RESULTS

OI1: Percent of Unsatisfactory Specimens Due to Improper Collection

- · Results include all initial and repeat specim there is no way to currently differentiate. Red bars indicate percent of specimens rejected per CLSI guidelines.
 - Pumle hars indicate first specimens collected <24h after birth or following a transfusion including those that were collected too soon due to State protocol. There is no way to currently identify these specimens.
 - Spike in March due to lost package from one

QI2: Percent of Specimens Lacking Essential Information



- Results include all initial and repeat specimens that were received missing essential demographic information even if the data was ultimately
- OI was calculated to show cards lacking essential information.
- States that require fewer demographic fields are more likely to have better compliance

QI3: Frequency of a Condition Detected at Birth: 1st Screen vs. 2nd Screen



- Table shows the initial results and frequency of detection on first screen for all confirmed classic cases for babies born in 2010 New Jersey does not have a mandatory 2nd screen
- for all newborns, therefore, no results are shown for these specimens 11 of the 13 cases with initial result that were
- WNL for CH were out of range on the 2nd screen (NICU protocol). All 4 CH unsat specimens, which include those collected <24 hours after birth, were out of range
- on the second specimen. For CF, the unsat specimen was out of range on the second screen and the WNL specimen was a

missed case (see OI10)

QI4: Rate of Loss to Follow-up: Unsatisfactory & Out of Range



- Table 1 shows number of newborns born during the 1st quarter of 2011 who had an initial specimen that was unsatisfactory and who did not have a satisfactory repeat by 6 months of age.
- Results may be greater than expected as expired newborns and newborns transferred out of state prior to repeat collection are not easily identified in the current system.
- instead of 6 months should be considered
- Table 2 shows number of newborns born during the 1st quarter of 2011 with an out of range result
- who were lost to follow-up. · The "narrow" category includes newborns for whom no contact was confirmed
- . The "broad" category includes newborns in the 'narrow" category and newborns for whom contact was made with the family or physician but have no final disposition (confirmed or cleared).

QI5: Percent of Parent Refusals

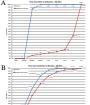
Jnable to calculate as this is currently monitored by the hospitals and physicians and not by the State Program

QI6: Percent of Eligible Infants Receiving Valid NBS



- · Table shows number of births reported to the State's electronic birth certificate (EBC) system for the 1st quarter in 2011, the number of 1st specimens received by the laboratory, the number of unrepeated unsatisfactory 1st specimens, the number of "valid" 1st specimens (1st spec minus unrepeated), and percent of births screened.
- · First specimens include initials specimens, repeat specimens with no previous specimen in the laboratory information system (LIS), and out of state births. In addition, actual patient data is not matched between the EBC and LIS. Therefore this is the best available approximation of the OI

OI7: Time from X to Y









. Overall, average time is not as useful as graphs of the data buckets.

- Chart A shows the time from birth to specimen collection for initial specimens and repeat or unsatisfactory specimens from the 3rd quarter in State protocol dictates that specimens should be
- collected between 24 and 48 hours of life. 92% of initial specimens are collected in this time frame The >7d spike in collection of repeat specimens is a
- likely result of the State's NICU protocol. Time of receipt is not recorded in hours, therefore,
- all data in Chart B is presented in days. State protocol dictates that specimens must be transmitted to the NBS Laboratory within 24 hours of collection. In addition, for initial specimens, the
- State provides overnight delivery services Transmittal times greater than 2 days for initial specimens suggests the potential holding of specimens at the hospitals and indicates a need for
- Repeat specimens sent by physicians are often transmitted via USPS, which is likely contributing to the difference in time to receipt, however this level of stratification is not currently possible.
- Chart C is also presented in days and represents the time from receipt until a written report is issued by the laboratory. The immediate notification of critical results is not represented on this chart.
- Specimens received on Friday have a minimum of 3 days from receipt to written report · Report date changes in information system when
- duplicate reports are issued requiring timely review · The date of notification of medical provider data in
- Chart D is not recorded electronically therefore a 10 day sample of cases was reviewed for this study This chart includes both borderline cases (mailed letter) and presumptive cases (phone call).
- . The longer turn around times seen are likely a result of a State holiday that occurred during the pilot

QI7: Average (cont.)



- addition, date of written report is used as a proxy for time of release. Treatment well in advance of report date was due to symptoms noted at birth or as a result of a critical result called prior to the written report Delays in treatment were most often related to
- hemoglobin results or NICU babies already under close observation with multiple ongoing treatments . Data shown in Chart E is from the first half of 2011 and includes both cleared and confirmed
 - cases as well as initial and repeat specime Time to diagnosis varies significantly by disorder and stratification of results would be beneficial for the OI measure.
 - The difference between the time to confirmation and the time to clearance would also be of interest

QI8: Positive Predictive Value for Out of Range Results

	A	8	c	D	E			
10	# Initial Out of	# Initial Presumptive	Classic		Classic Cases from			
110	Range Results	Results	Cases	Cases	Initial Presumptive	D/A	t/s	
	1861	102	57	62	25	3.33%	24.51%	
Ü	11	6	2	6	2	54.55%	33.33%	
LT	92	43	2	22	2	23.91%	4.65%	
н	670	276	2	5	2	0.75%	0.72%	
	194	33	10	15	8	7.73%	24.24%	

- Calculations of PPV will vary based on a laboratory's results categories/definition of out

QI9: Rate of Out of Range Results



- . For newborns born in 2010, 103 798 first specimens were tested with 4,006 out of range results and 810 presumptive results. Stratifying results by disorder will give a better idea of assay performance and workload for future etudies
- · It is not currently possible to stratify by confounders such as NICU or TPN.

QI10: Rate of Missed Cases

2010	СН	CF	All
false negatives	3	1	4
total diagnosed cases	62	15	227
e/	A 0.40/	C C70/	1 760/

- . For newborns born in 2010, a total of 4 cases out of 227 confirmed classic cases were not detected by NBS
- The definition of a confirmed CH case is debated by the State's pediatric endocrinologists and diagnoses will and may change over time.

CONCLUSIONS

- All of the OIs selected by the workgroup are relevant and useful
- Not all of the QIs are easy to calculate, which could hinder wide-spread analyses. Feasibility will strongly depend on the configuration of the Program's information ystem and retrievability of the data
- Pilot results for NJ indicate areas of need for education as well as gaps in data collection.
- (i.e. parent refusals) that need to be addressed. Time frame observed is important and plays a different role in different QIs
- Routinely monitoring the proposed QIs and acting on results should improve Program











Pilot Study of Quality Indicators for the Next Generation of Data Collection into a National Newborn Screening Data Repository

- 1. Percent of unsatisfactory specimens due to improper collection
- 2. Percent of cards with all essential information
- 3. Frequency of condition detected at birth: First screen vs. Second screen
- 4. Rate of loss to follow-up: unsatisfactory & out-of range
- 5. Percent of parental refusals
- 6. Percent of eligible infants receiving valid newborn screening test
- 7. Average time:
 - a) From birth to specimen collection
 - b) From specimen collection to receipt by lab
 - c) From specimen receipt to reporting out results
 - d) From release of out-of-range results to notification of medical provider
 - e) From release of out-of-range results to medical intervention
 - f) From birth to diagnosis
- 8. Positive predictive value (PPV) of out-of-range screening results
- 9. Rate of out-of-range results, any referral to evaluation
- 10. Rate of missed cases (false negatives)





Sign Out

Welcome to the NewSTEPs Data Repository

The repository is now ready for data entry for basic state profiles, cases and quality indicators. We anticipate updates to occur on a quarterly basis, or sooner if needed. Please continue to check this page for announcements of new features. FAQs for the NewSTEPs Data Repository can be found linked **here**. To consult the General User Guide please click **here**. The State Administrators User Guide can be found **here**.

What is Available Now?

Each state has the ability to review and revise basic state profile data, enter cases and quality indicator data through one designated state contact.

Reports

Sample Reports depicting fictional data summaries demonstrating the range of responses in quality indicators throughout newborn screening systems in the country while protecting the confidentiality of each state newborn screening program can be found linked here: Sample Reports

Quality Indicators

The 8 Quality Indicators that will be used to provide longitudinal comparisons within a program as well as comparisons to aggregate data across programs can be found linked here. Quality Indicators. Worksheets demonstrating data that will be requested to populate the Quality Indicators can be found linked here.

Current Activities

State Profile data can be entered prior to the ratification of the MOU. NewSTEPs has convened a series of webinars detailing the Memorandums of Understanding (MOUs) that will be entered into between APHL and newborn screening programs. NewSTEPs has contacted state representatives to help facilitate signatures. We request that all Quality Indicator and Infant level data entry be held until the MOUs are fully ratified.





Pilot Study of Quality Indicators for the Next Generation of Data Collection into a National Newborn Screening Data Repository

- 1. Percent of unsatisfactory specimens due to improper collection
- 2. Percent of cards with all essential information
- 3. Frequency of condition detected at birth: First screen vs. Second screen
- 4. Rate of loss to follow-up: unsatisfactory & out-of range
- 5. Percent of parental refusals
- 6. Percent of eligible infants receiving valid newborn screening test
- 7. Average time:
 - a) From birth to specimen collection
 - b) From specimen collection to receipt by lab
 - c) From specimen receipt to reporting out results
 - d) From release of out-of-range results to notification of medical provider
 - e) From release of out-of-range results to medical intervention
 - f) From birth to diagnosis
- 8. Positive predictive value (PPV) of out-of-range screening results
- 9. Rate of out-of-range results, any referral to evaluation
- 10. Rate of missed cases (false negatives)





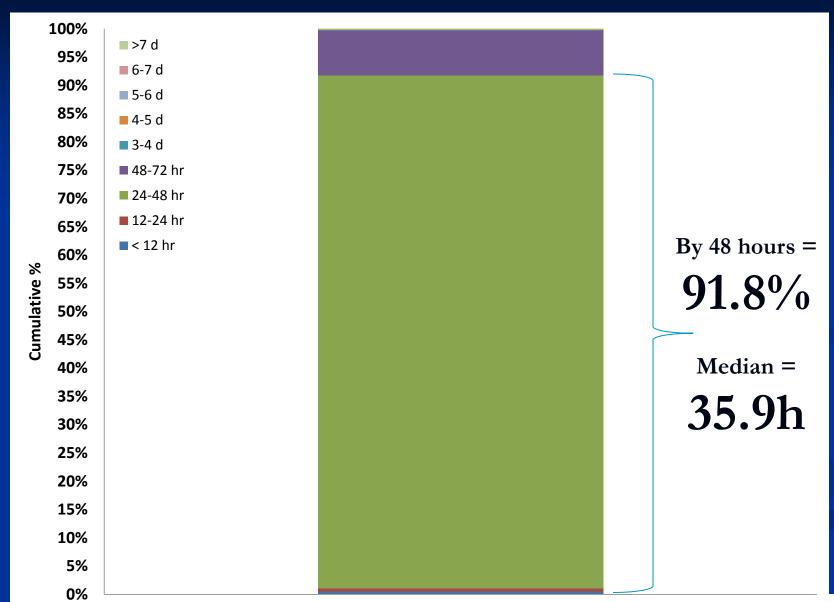
Specimen Collection and Submission

- N.J.A.C. 8:18-1.4(a)
 - Responsibilities of the chief executive officer
 - 9. Assure that specimens are taken before the infant is 48 hours old. If an infant is transferred or discharged from a facility prior to 48 hours of life, a specimen shall be collected prior to discharge unless there are medical reasons to prevent specimen collection





Time from Birth to Collection







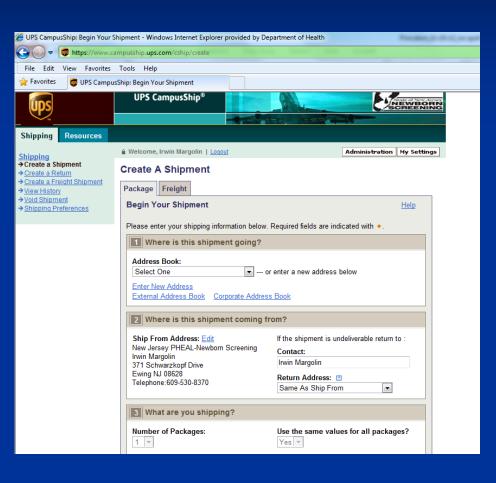
Specimen Collection and Submission

- N.J.A.C. 8:18-1.4(a)
 - Responsibilities of the chief executive officer
 - 16. Assure that all specimens are forwarded to the testing laboratory within 24 hours of collection by next day delivery, or in the event service is unavailable with respect to Sundays and Federally designated holidays, then as soon thereafter as is practicable, using an account number the Department shall establish with an overnight package delivery service, which number the Department shall make available upon request





UPS CampusShip



- Printing a shipping label
- Scheduling pickups
- Selecting Saturday delivery
- Tracking Packages



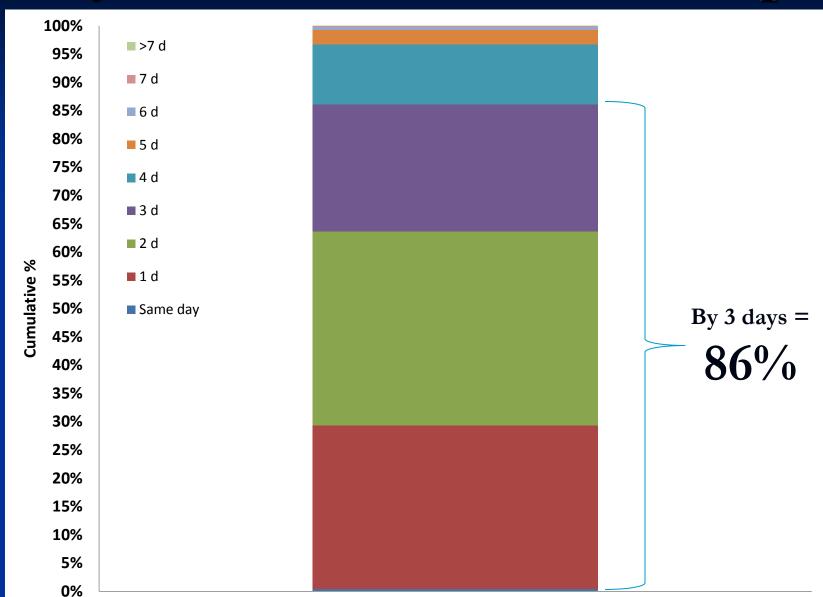


- The NJ NBS Laboratory is open Monday through Saturday and Holidays
 - Except New Year's Day, Memorial Day, Independence Day, Labor Day, Thanksgiving, and Christmas.
 - On Saturdays and Holiday, the most time sensitive procedures are performed with reduced staff.
 - Critical abnormal results are also reported on Saturdays and Holidays.
- The NJ NBS Laboratory works during all winter (and non-winter) states of emergency to ensure continuity of this critical testing service.
- Hospitals who do not follow these requirements are referred to HFE&L for investigation





Days from Collection to Receipt







Transmittal >3 days

_															
CODE	HOSPITAL	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC	TOTALS	% of all Transmittal
XXX	Α	83	72	57	51									263	7.5%
	S	46	58	123	27									254	7.2%
XXX	В	81	39	51	57									228	6.5%
XXX	С	59	36	43	49									187	5.3%
XXX	D	38	38	36	21									133	3.8%
XXX	E	53	27	21	31									132	3.8%
XXX	F	46	38	25	20									129	3.7%
XXX	G	29	26	30	41									126	3.6%
XXX	Н	36	2	29	33					·			·	100	2.8%
XXX	I	18	18	34	19									89	2.5%





Variety of Issues

Collection

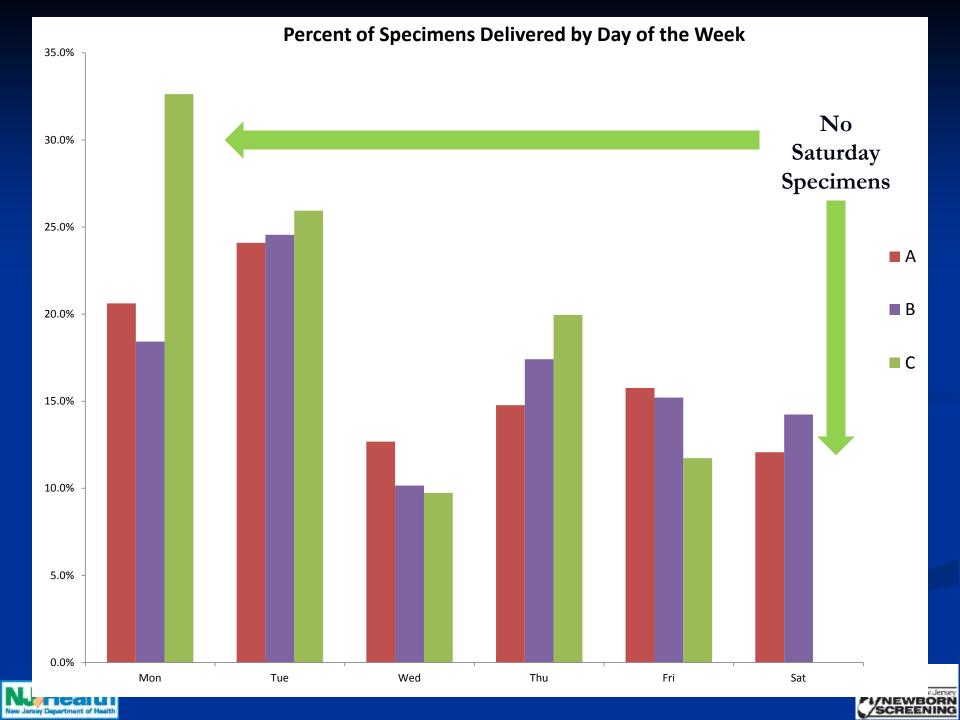
- Did not know.
- Errors in reporting
- Medical issues
- Transferred

Transportation

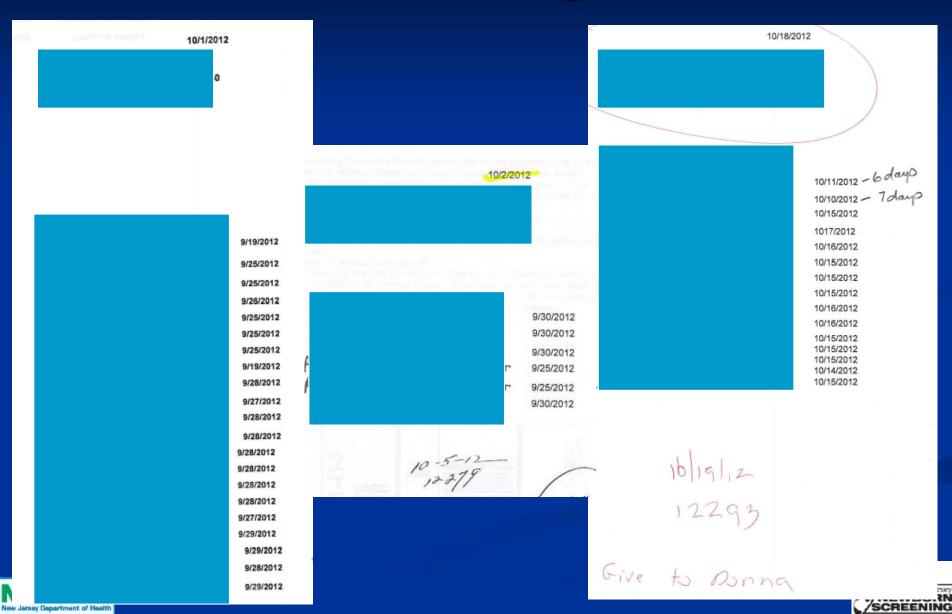
- Saturday deliveries/Saturday pickups
- Batching specimens
- Timing of collection
- Incorrect use of UPS CampusShip system
- UPS delivery problem







Batching



Let Us Help You!

CODE	HOSPITAL	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC	TOTALS
XXX	Α	11	14	13	12	14	14	10	8	3	4			103





CLSI -Clinical and Laboratory Standards Institute www.clsi.org

- LA04-A5 Blood Collection on Filter Paper for Newborn Screening Programs;
 Approved Standard - Fifth Edition
- LA04-A5-DVD Making a
 Difference Through Newborn
 Screening: Blood Collection
 on Filter Paper

Blood Collection on Filter Paper for Newborn Screening Programs; Approved Standard—Fifth Edition

This document addresses the issues associated with specimen collection, the filter paper collection device, and the application of blood to filter paper, and provides uniform techniques for collecting the best possible specimen for use in newborn screening programs.

A standard for global application developed through the Clinical and Laboratory Standards Institute consensus process.



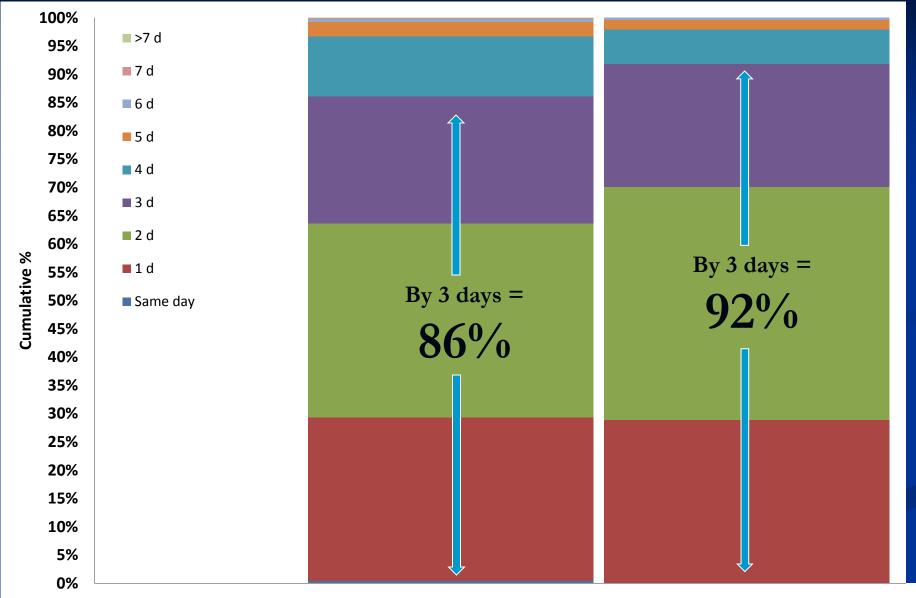
Time from Birth to Collection



SCREENING

2014

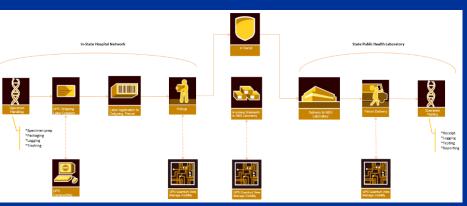
Days from Collection to Receipt



vdersey DRN SCREENING

What's Next? NJ NBS NYMAC









QI 5f. Birth to confirmation of diagnosis











