NewSTEPs

Review of Changes to the NewSTEPs Quality Indicators

Sarah McKasson and Amanda Jenkins, APHL

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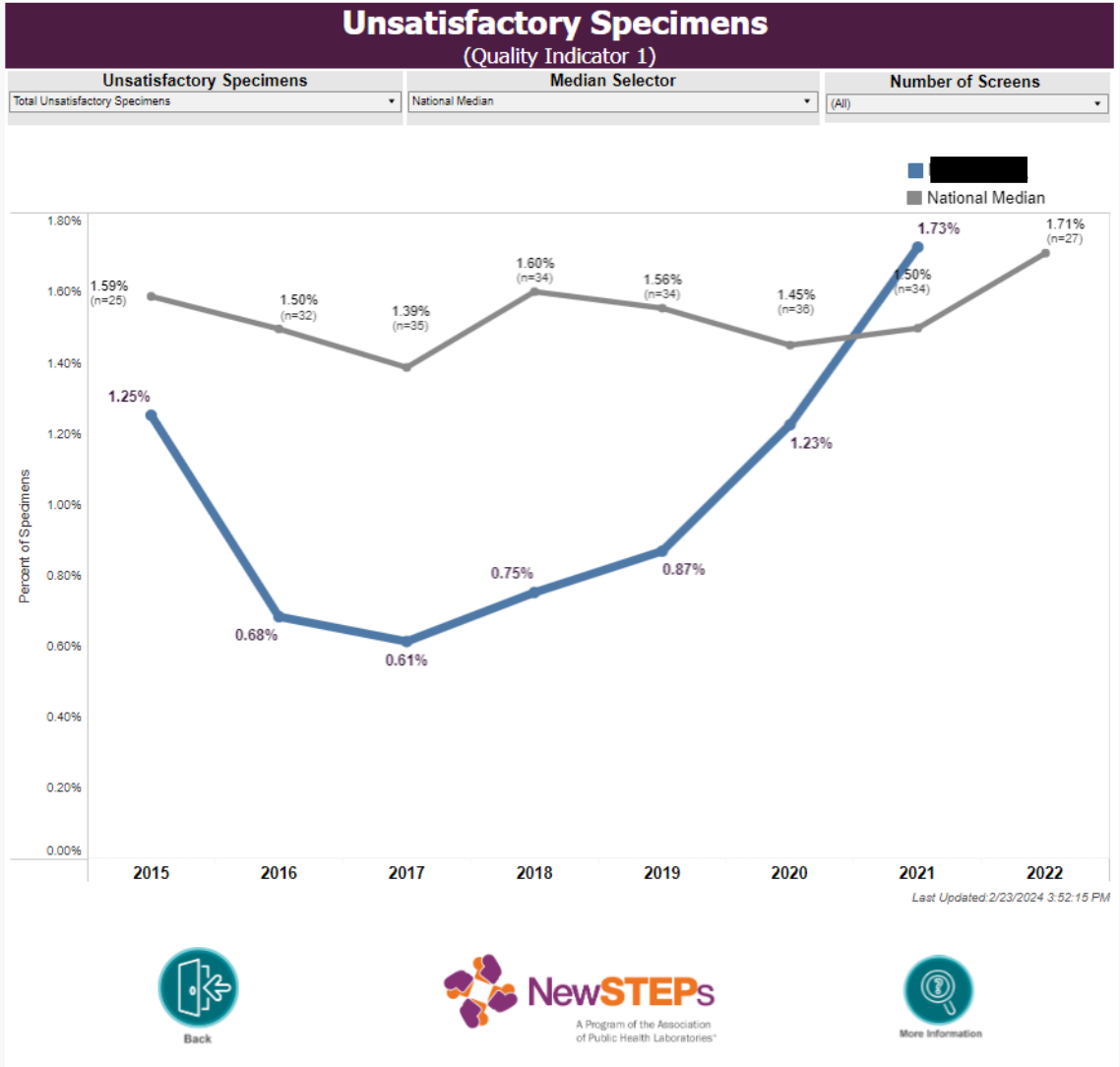
1. Why Quality Indicators?

Why are the Quality Indicators Important?

- Performance metrics
- Tracks trends over time
- Informs quality improvement initiatives
- Standardization and harmonization→see QI definitions

Why should I enter my QI data?

- Access to your own state's data plus regional and national aggregate data
- NBS programs can explore data to identify challenges and meet needs
- Access to reports and dashboards



2. Quality Indicator Overview

What are the Quality Indicators?

Quality Indicator	Level	Submission
1-Unsatisfactory Specimens	Specimen	Monthly and Annual
2- Missing Essential Information	Specimen	Monthly and Annual
3- Unscreened Newborns	Baby	Annual
4-Lost to Follow-up	Baby	Annual
5-Timeliness	Specimen and Baby	Monthly and Annual
6-Screen Positives	Baby	Annual
7-Confirmed Cases	Baby	Annual
8-Missed Cases	Baby	Annual

General Notes

- Annual time interval (Jan 1-Dec 31)
  - Specimen-level QIs: use year (or month) the specimens were received
  - Baby-level QIs: use the birth year of the infant
- No longer collecting quality indicators for **CCHD** and **EHDI**
- True zero vs. null

First vs. Requested Subsequent Specimens

First Specimen

- Earliest specimen received at the laboratory for testing.
- A first specimen can only be received at the laboratory once per screen.

CHANGE: Revised the language to align with the Clinical and Laboratory Standards Institute (CLSI):

- ***Requested*** subsequent specimens
- ***Routine*** second specimens

Requested Subsequent Specimens

- Unacceptable specimen
- Repeat for a borderline or out-of-range result from the first specimen
- Specimens collected as part of the NICU protocol
- Routine second specimen collected in two-screen states
- Requested repeat specimen following the second screen due to unacceptable, borderline or out-of-range second screen

QI 1 | Unsatisfactory Specimens

CHANGE: Stratified by “first specimens” and “requested subsequent specimens”

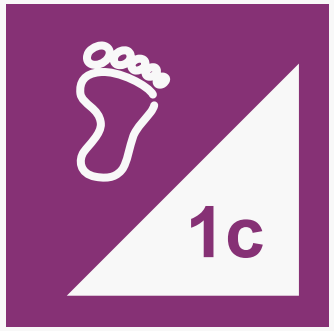
First Specimens

Improper Collection
Percent of first dried blood spot specimens that were unacceptable due to improper collection.

Improper Transport
Percent of first dried blood spot specimens that were unacceptable due to improper transport.

Requested Subsequent Specimens

Improper Collection
Percent of requested subsequent (including routine second) dried blood spot specimens that were unacceptable due to improper collection.



Improper Transport
Percent of requested subsequent (including routine second) dried blood spot specimens that were unacceptable due to improper transport.

New Metrics

QI 1| Unsatisfactory Specimens

Improper Collection (QI 1a, 1c)

- Insufficient quantity of blood (QNS)
- Clotting or smearing
- Contamination
- Inadequately filled circles
- Oversaturation or layering of blood
- Use of capillary tubes and scratching or abrading by capillary tube spotting
- Incomplete drying before shopping
- Specimens collected or expired dried blood spot devices

Improper Transportation (QI 1b, 1d)

- Any specimen received after the state-defined length of time from collection that deems a specimen unacceptable for testing
- Any specimen that is damaged in transport
- Specimens placed in an airtight or sealed plastic bag with or without a desiccant

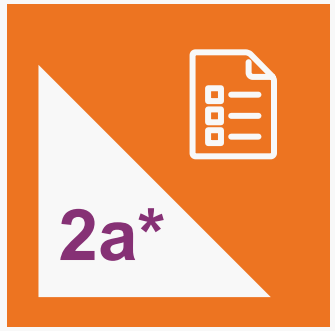
NOTE: If it is unknown whether unacceptable specimens were due to improper collection or transport, they should be counted under improper collection only (QI1a*, QI1c)

QI 2 | Missing Essential Information

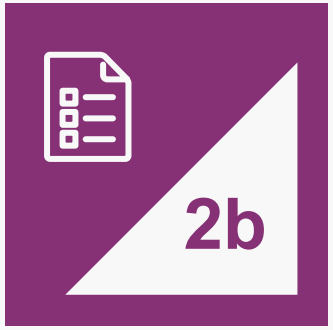
CHANGE: Stratified by “first specimens” and “requested subsequent specimens”

First Specimens

Priority Indicator
Percent of first dried blood spot specimens with at least one missing state-defined essential data field upon receipt at the newborn screening laboratory.



New Metric



Percent of requested subsequent (including routine second) dried blood spot specimens with at least one missing state-defined essential data field upon receipt at the newborn screening laboratory.

Requested Subsequent Specimens

QI 2| Missing Essential Information

Data elements considered essential

- Patient identification number
- Infant first and last name
- Date and time of birth
- Date and time of specimen collection
- Birth weight
- Sex
- Mother first and last name
- Mother address
- Mother phone
- Submitter identification
- Submitter address
- Physician name
- Physician phone

NOTE: Do NOT tally how many fields are missing; only count the number of specimens if at least one field is missing.

Denominators for QI 1-2

QI 1| Unsatisfactory Specimens
QI 2| Missing Essential Information

First Specimens (QI 1a-b, 2a)

Number of first dried blood spot specimens received at your designated newborn screening laboratory.

This includes first specimens collected from the first screen only.

Requested Subsequent Specimens (QI 1c-d, 2b)

Number of requested subsequent dried blood spot specimens received at your designated newborn screening laboratory.

This includes requested subsequent and routine second specimens (for two-screen states).

QI 3 | Unscreened Newborns

NOTE
QI 3a ≥ 3b +3c

3a | Number of newborns in your state/territory without a valid dried blood spot screen*	
	3b | Number of newborns born in your state/territory without a valid dried blood spot screen due to **parental refusal**
	3c | Number of newborns born in your state/territory without a valid first dried blood spot screen due to **pre-analytic error**
3d | In two-screen states, the number of newborns born in your state/territory without a valid first and routine second screen due to a missing or unmatched dried blood specimen	

NOTE: Only includes newborns that only received one out of the two required screens

Examples of Pre-Analytic Error (QI3c)

- Unacceptable specimens that never had a subsequent specimen
- Specimens lost in transit
- Specimens for which hospital personnel forgot to collect or ship the specimen

Updates to QI 3: Unscreened Newborns

CHANGE: No CCHD and EHDI Collection

CHANGE: No longer need to enter a denominator; annual births is now pulled from CDC vital statistics

CHANGE: Updated language for QI 3d for clarification purposes

CHANGE: Removed QI 3e

QI 4 | Lost to Follow-Up

Percent of infants that have no recorded final resolution with the newborn screening program by 12 months of age following:

4a*

Receipt of an unacceptable DBS Specimen

Denominator

Number of infants with an unacceptable DBS specimen

4b*

A borderline result

Denominator

Number of infants requested to have a subsequent DBS specimen following a borderline result

4c*

Out-of-Range Result

Denominator

Number of infants with an out-of-range result from a DBS screen requiring clinical diagnostic workup

QI 5 | Timeliness





Birth to Collection (5a)

i. First dried blood spot specimens
ii. Routine second screen
iii. Requested subsequent specimens

Collection to Receipt (5b)

i. First dried blood spot specimens
ii. Requested subsequent specimen
iii. Routine second screen **(NEW)**

Reporting

From Receipt (5c)
From Birth (5d)

i. Time critical disorders
ii. Non-time critical disorders
iii. First specimen
iv. Requested subsequent specimens
v. Routine second screen

Intervention & Diagnosis (5e and 5f)

5e | Time from reporting out-of-range results to medical intervention for infants with a confirmed diagnosis

5f| Time from birth to confirmation of clinical diagnosis

False Positives (5g)

For infants with an out-of-range newborn screen, time from birth to determining if the result was a false positive **(Definition Added)**

PRIORITY INDICATORS Completed: 100%

5b.i | First dried blood spot specimens

20	Same day as collection (Day 0)	2.12	%
49	Day after collection (Day 1)	5.2	%
139	Day 2 after collection (Day 2)	14.76	%
250	Day 3 after collection (Day 3)	26.54	%
141	Day 4 after collection (Day 4)	14.97	%
132	Day 5 after collection (Day 5)	14.01	%
112	Day 6 after collection (Day 6)	11.89	%
98	Greater than or equal to Day 7 after collection (>=Day 7)	10.4	%
1	Time elapsed unknown	0.11	%

QI 5c	QI 5d
Receipt to Reporting	Birth to Reporting

i. Number of DBS specimens with out-of-range results for **time critical disorders**

ii. Number of DBS specimens with out-of-range results for **non-time critical disorders**

iii. Number of **first** DBS specimens with **normal or out-of-range** results for any disorder

iv. Number of **requested subsequent** DBS specimens with normal or out-of-range results for any disorder

v. Number of **routine second** DBS specimens with normal or out-of-range results for any disorder

NOTE: Date of report out is when:

- A medical provider is notified of actionable results (5c.i, 5c.ii, 5d.i, 5d.ii)
- Report is released back to the submitter for normal results

NOTE: Sum of QI5c.i = QI5d.i | Sum of QI5c.ii = QI5d.ii | Sum of QI5c.iii=QI5d.iii

List of Time Critical Disorders

Organic Acid Conditions	Fatty Acid Oxidation Disorders	Amino Acid Disorders	Endocrine Disorders	Other Disorders
Propionic acidemia - PROP	Medium-chain acyl-CoA dehydrogenase deficiency - MCAD	Argininosuccinic aciduria - ASA	Congenital adrenal hyperplasia - CAH	Classic galactosemia - GALT
Methylmalonic acidemia (methylmalonyl-CoA mutase) - MUT	Very long-chain acyl-CoA dehydrogenase deficiency - VLCAD	Citrullinemia, type I - CIT		Glycogen Storage Disorder, type II-Infantile Pompe
Isovaleric acidemia - IVA	Long-chain L-3 hydroxyacyl-CoA dehydrogenase deficiency - LCHAD	Maple syrup urine disease - MSUD		
3-Hydroxy-3-methyglutaric aciduria - HMG	Trifunctional protein deficiency - TFP			
Holocarboxylase synthase deficiency - MCD	Glutaric acidemia, type II– GA II			
β-Ketothiolase deficiency - BKT	Carnitine acylcarnitine translocase deficiency—CACT			
Glutaric acidemia, type I – GA 1	Carnitine palmitoyltranferase, type II deficiency – CPT II			

NEW

Reporting "Time Critical" and "Non-Time Critical" Disorders (QI 5c.i, 5c.ii, 5d.i, 5d.ii)

- Calculate time to report out using the first specimen if:
  - An out-of-range result was detected on the first specimen
  - An out-of-range result was detected on the first specimen and confirmed on the requested subsequent specimen
  - A borderline result was detected on the first specimen and an out-of-range result was detected on the requested subsequent specimen during repeat testing
  - A first specimen was unsatisfactory, *tested*, and detected the out-of-range result (i.e., unsatisfactory first specimen detected an out-of-range result)
- Calculate the time to report out using the **requested subsequent specimen** if the first specimen was unsatisfactory and *not tested*, and the subsequent specimen detected out-of-range result during repeat testing
- For **two-screen states**, calculate the time to report out using the specimen from which the out-of-range result was detected

QI 5 |Time to Medical Intervention & Diagnosis

5e

Time to Medical Intervention

Time from reporting out-of-range results requiring clinical diagnostic workup by an appropriate medical professional to medical intervention for infants with a confirmed diagnosis

5f

Time to Diagnosis

Time from birth to confirmation of clinical diagnosis

NOTE: QI 5e and QI 5f requires infants with a confirmed clinical diagnosis to be entered as an individual case in the NewSTEPs Repository.

NOTE: Use the Definitions of Medical Intervention and Diagnosis document for standardization

QI 5 |Time to Medical Intervention & Diagnosis

Confirmed Case Online Form

1 — 2 — 3 — 4 — 5 — 6 — 7

ARIZONA | 3-METHYLCROTONYL-COA CARBOXYLASE DEFICIENCY - 3-MCC

Date and time of birth are used to calculate time elapsed between birth, specimen collection(s), and diagnosis. They are not stored in the system. Year of birth is stored, to calculate Quality Indicators. If the time of birth is not available, enter only the date.

5. Intervention, Follow-Up and Diagnosis

Intervention by Appropriate Medical Provider

Date (mm/dd/yyyy)	Time (hh:mm AM/PM)	Time Elapsed Since Birth (in days)

Confirmation of Diagnosis

Date (mm/dd/yyyy)	Time (hh:mm AM/PM)	Time Elapsed Since Birth (in days)

QI 5g |Time from Birth to Determination if a Result was a False Positive

5g | For infants with an out-of-range newborn screen result requiring a clinical diagnostic workup by an appropriate medical professional, time from birth to determining if a result was a false positive ⓘ

200	Number of infants with an out-of-range result from a dried blood spot screen requiring clinical diagnostic workup by an appropriate medical professional (QI 4c, QI 5g)

Disorder Category	Amino Acid Disorders	Endocrine Disorders	Fatty Acid Disorders	Hemoglobin Disorders	Lysosomal Storage Disorders	Organic Acid Disorders	Other Disorders
No false positives called out	☑	☑	☑	☑	☑	☑	☑
PRIORITY ITEM Total false positives	Enter %	Enter %	Enter %	Enter %	Enter %	Enter %	Enter %
Less than 7 days after birth	Enter %	Enter %	Enter %	Enter %	Enter %	Enter %	Enter %
7-14 days after birth	Enter %	Enter %	Enter %	Enter %	Enter %	Enter %	Enter %
15 days to 1 month after birth	Enter %	Enter %	Enter %	Enter %	Enter %	Enter %	Enter %
Greater than 1 month to 2 months after birth	Enter %	Enter %	Enter %	Enter %	Enter %	Enter %	Enter %
Greater than 2 months to 6 months after birth	Enter %	Enter %	Enter %	Enter %	Enter %	Enter %	Enter %

NOTE: A false positive is a screen positive result indicating that an individual is at increased risk for the primary target disease when the individual is found to be later unaffected.

APHL

NewSTEPs
A Program of The Association of Public Health Laboratories

QI 6 | Screen Positives*

Reported by disorder or disorder category

Numerator

Number of newborns with an out-of-range result from the dried blood spot screen requiring clinical diagnostic workup, reported by disorder/disorder category.

NOTE: Denominator excludes refusals, deaths, or blank collection devices

Denominator

Number of newborns born in your state/territory that received a dried blood spot screen whose specimen was received at your designated NBS laboratory.

QI 6| Screen Positives

Breakout of Disorder/Disorder Categories

- Organic Acid Disorders
- Fatty Acid Disorders
- Amino Acid Disorders
- Endocrine Disorders
  - CAH
  - CH
- Hemoglobin Disorders
- Lysosomal Storage Disorders
  - MPS I
  - MPS II
  - Pompe
- Other Disorders
  - BIOT
  - CF
  - GALT
  - GAMT
  - SCID
  - XALD
  - SMA

QI 7 | Confirmed Cases

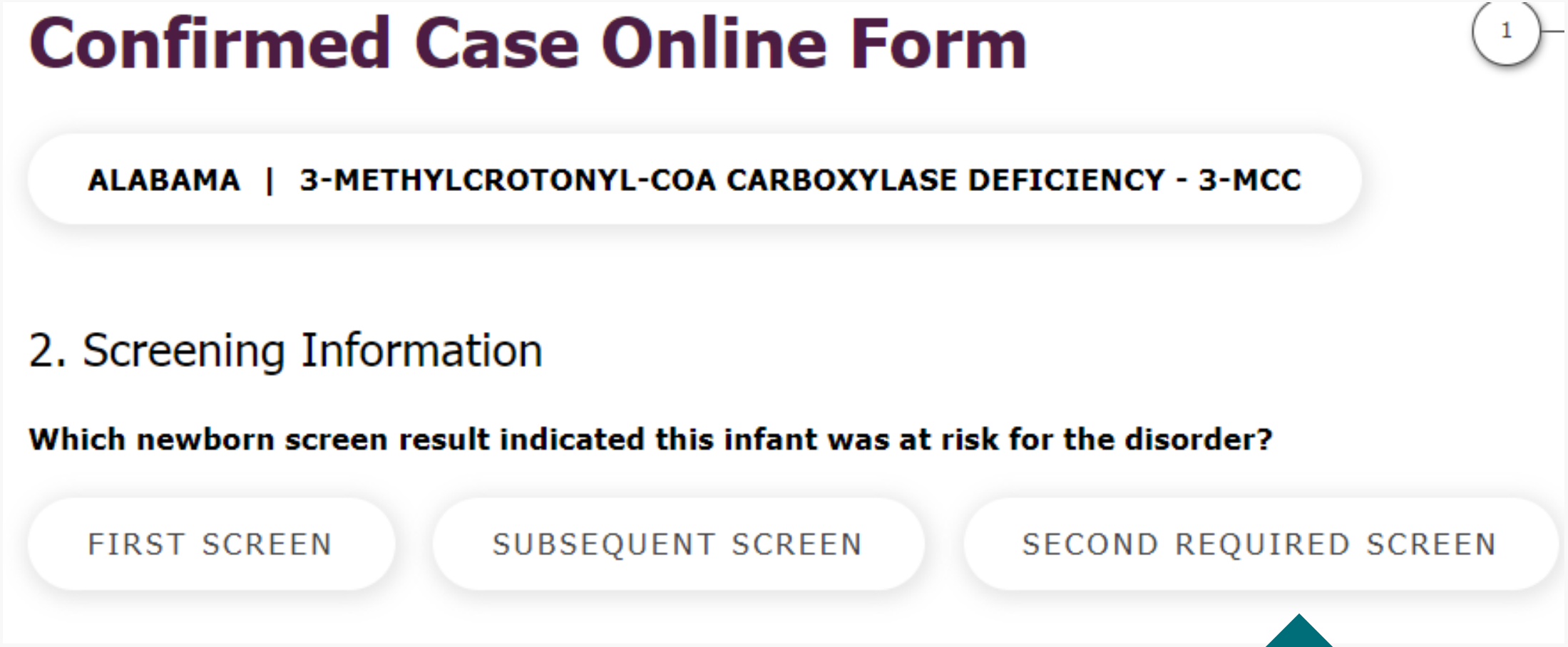
CHANGE: Removed denominator collection as prevalence will be determined by annual births

Total Confirmed Cases	=	From First Screen	+	From Requested Subsequent	+	From Routine Second Screen
7a*		7b		7c		7d
Number of infants with an out-of-range result from **any** DBS specimen and with a confirmed diagnosis of a disorder on your NBS panel, reported by disorder		Number of infants with an out-of-range result from the **first** DBS specimen and with a confirmed diagnosis of a disorder on your NBS panel, reported by disorder		Number of infants with an out-of-range result from a **requested subsequent** DBS specimen and with a confirmed diagnosis of a disorder on your NBS panel, reported by disorder		In **two-screen states**, number of infants with an out-of-range result from the **routine second screen** that did not have an out-of-range result from the first screen and with a confirmed diagnosis of a disorder on your NBS panel

Pulled from aggregate cases

Pulled from individual cases

QI 7| Confirmed Cases



For two-screen states only!

QI 8 | Missed Cases

NOTES: Missed case only if your program was screening for the disorder at the time of birth; follow-up time for missed case is up to 18 years of age.

8a

Number of infants with a confirmed diagnosis by a physician for a specific NBS disorder, but did **NOT** have an **out-of-range result** on a valid DBS screen, reported by disorder

8b

Number of infants with a confirmed diagnosis by a physician for a specific NBS disorder, but did not have an out-of-range result because they did not have a **valid DBS screen due to error**, reported by disorder

CHANGE: Removed denominator as the number of missed cases is small

QI 8 | Missed Cases

QI 8a

Was this individual diagnosed later in life (not identified by newborn screening)?

YES | NO | UNKNOWN

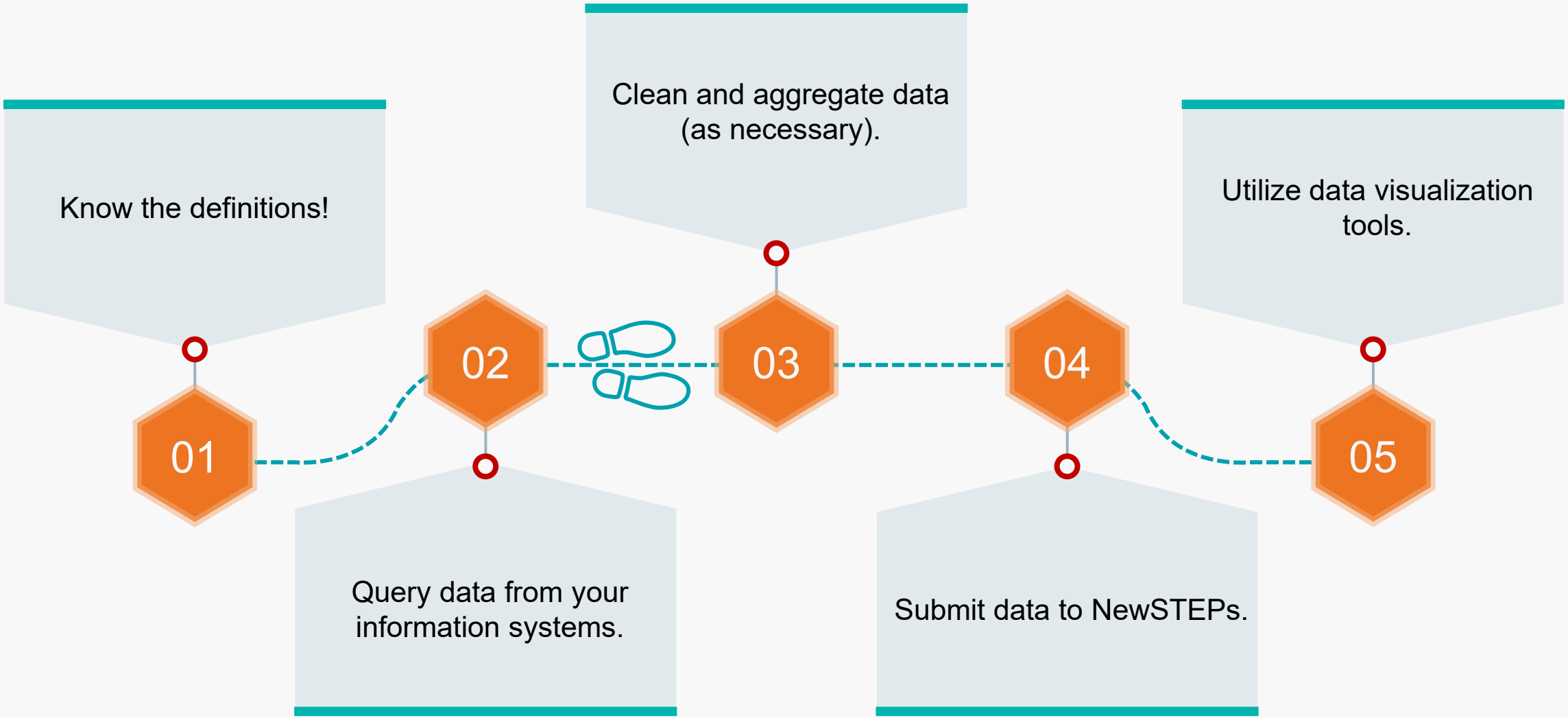
QI 8b

What was the reason the infant was missed?

- Parental Refusal
- Lost to follow-up after unsatisfactory specimen
- Biologic false negative / result within normal range
- **Did not have a valid screen due to error**
- Other (please describe below)

Demo of QI Data Entry

Data Submission Process



Questions?