NewSTEPs Data Repository Data Elements

1. **Case Level Data**
   - **Demographics**: State Unique ID; Date of Birth*; Gestational Age; Birth Weight; Biological Sex, Race, Ethnicity
   - **Screening information**: Was prenatal testing done; Which newborn screen result indicated this infant was at risk for the disorder; Was this individual diagnosed later in life (not identified by newborn screening); Screening dates* (initial/subsequent) – date of specimen collection, receipt by lab, release of out of range results; Date of intervention by appropriate medical provider; Date of confirmation of diagnosis
   - **Case definition information**: diagnostic information (post newborn screen) – varies by disorder. Please see the case definition worksheets for more details

2. **Quality Indicators (QIs)**
   - Aggregate data for 8 QIs that are described in the quality indicators source document

3. **State Profiles**
   - Program Overview
     - o Annual births by year
     - o Name of state NBS program
     - o Region of state NBS program
     - o Website of state NBS program
     - o Number of required screens
     - o Responsibly laboratory by name and type
     - o Screening card image document and/or link
     - o Hearing screening form document and/or link
   - Disorders Screened (Core, Secondary, Other)
     - o Category of disorder screening - not screened, universally screened, likely to be detected and reported due to screening of another disorder, offered to select populations
       - ▪ Subcategory of disorder screening - required by law or rule, not required by law or rule
     - o Testing methodology for first and second screen– first tier, second tier, third tier
       - ▪ Testing method's target – first tier method target, second tier method target, third tier method target
     - o Testing equipment
     - o Proposed/ actual implementation date for universal screening
   - Policies

Case Definitions Worksheets: https://www.newsteps.org/sites/default/files/case-definitions/case_definitions_master_0.pdf
Quality Indicators Source Document:
https://www.newsteps.org/sites/default/files/quality-indicators/qi_source_document_version_2_1_-_march_23_2017.pdf

- Specimen collection
  - Recommended initial screening age
  - Recommended second screening age
  - Second screen policy
  - NICU CLSI guideline adoption status
  - NICU CLSI guideline adoption description
- Specimen transport, receipt, storage, and retention
  - Courier service usage status
  - Definition of specimen receipt at lab
  - Recording of specimen receipt at lab
  - Dried blood spot retention time
  - Dried blood spot storage conditions
  - Data retention policy exists?
  - Data storage period for normal specimen data
  - Data storage period for abnormal specimen data
- Consent
  - Consent for newborn screening
  - Opt out policy
  - Opt out recording method
  - Consent recording method
  - Residual specimen uses
  - Specimens consented for research?
  - Specimen sharing policies
- Follow-up
  - Short-term follow-up definition
  - Short-term follow-up description
  - Unique follow-up methods
  - Follow-up period for inconclusive diagnosis
  - Long-term follow-up activities?
  - Long-term follow-up description
- Analysis
  - Process for reporting missed diagnoses?
  - Missed diagnosis reporting process
  - Matching NBS records to find unscreened babies?
  - Matching data system?
  - Result matching method

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- Unsatisfactory specimen testing policy
  - o Operations
    - Provide emergency/disaster support
    - Provide emergency/ disaster agreement in place?
    - Provide emergency/ disaster plan written?
    - Provide emergency/ disaster plan testing frequency?
    - Receive emergency/ disaster support policy?
    - Receive emergency/ disaster support policy description
    - Receive emergency/ disaster support agreement in place?
    - Receive emergency/ disaster support plan written?
    - Receive emergency/ disaster support plan testing frequency?
    - Continuity of operations plan (COOP) exists?
    - COOP exercised?
- Adding to the NBS Panel (General Info, Lab, POC)
  - o National recommendations followed?
  - o National recommendation implementation time frame
  - o Pilot studies required before implementation?
  - o Feasibility study done?
- Fees:
  - o Funding
    - Newborn screening funding sources
    - Fee collection method
    - Fee holding location
  - o Fees – initial screen fee, repeat screen fee, second screen fee
  - o Fee use details
  - o Fee notes
- Program Structure
  - o NBS system organizational chart
  - o Shared duties
  - o Follow-up on unsatisfactory specimens
  - o Follow-up on borderline results
  - o Laboratory test performance evaluation
  - o Formal communication structure
  - o Lab operating hours
  - o Weekend lab activities
  - o Holiday lab activities
  - o Inclement weather work policy

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- o NBS program staffing level
- o STFU responsible parties
- o Certification program
- o Proficiency tests
- o Program information
- o NBS educational information languages
- Contacts (Program, Director, Program Manager, Lab, Follow-Up, EHDI, CCHD, HIT)
  - o Main contact
  - o Alternate contact
- Advisory Committee
  - o Existing advisory committee?
  - o Advisory committee voluntary?
  - o Committee structure
  - o Charge/ bylaws
  - o Meeting frequency
  - o Meeting minutes link
- IT Support
  - o Lab information system
  - o Follow-up information system
  - o Staffing levels
  - o IT support description
  - o NBS data backup frequency?
  - o Data loss amount from database failure?
  - o Data loss amount from instrument failure
  - o IT infrastructure recovery time
  - o Disaster recovery hardware
  - o IT part of COOP
  - o Redundant off-site operations exists?
  - o Redundant on-site operations exists?
- HIT Elements
  - o HL7 order messages accepted?
  - o Number of birthing centers submitting HL7 orders
  - o Number of HL7 orders received for specimen testing
  - o HL7 results messages sent?
  - o Number of birthing centers receiving HL7 results
  - o Number of HL7 specimen results sent
  - o HL7 implementation guide used
  - o Terminology standards used

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- o Web portal for sharing data related to the NBS present?
- o Web portal for DBS test orders and demographic data entry present?
- o Number of birthing centers using DBS order and demographic data entry web portal
- o Number of specimens entered into DBS order and demographic data entry web portal
- o Web portal for NBS results reporting present?
- o Number of birthing centers using NBS results retrieval portal?
- o Submitter performance feedback portal present?
- o Submitters performance feedback portal description
- o Alternative performance feedback method present?
- o Alternative performance feedback method description
- o Databases integrated with NBS information systems
- o How are hearing results integrated with DBS results?
- o How are CCHD results integrated with DBS results?
- o What is the implementation status of a statewide HIE?
- o What is the status of your NBS program exchanging data with the statewide HIE?
- o HIE interfacing funds received?
- o Who can access NBS results sent to/through the HIE?
- o How are NBS results shared via the HIE sent to birthing facilities/ pediatric providers?
- o What other databases interface with the HIE?

* Please note that dates are collected only in the browser for the purpose of calculating differences in dates (i.e., days elapsed between birth and screening) – aside from birth year, no date is stored in the system

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