NewSTEPs
NEW DISORDER CHECKLIST

Phase 1

- Obtain approval
- Determine testing methodology and tiered testing strategy
- Identify lab and follow-up staffing needs
- Develop budget
- Procure vendor contracts for equipment

Phase 2

- Obtain equipment
- Perform validation(s)
- Identify and meet with sub-specialists to discuss notification strategy and follow-up algorithms
- Gain understanding of possible incidental findings
- Consider sub-populations that may affect results

Phase 3

- Integrate testing into current workflow
- Notify submitters of NBS report changes
- Identify website/brochure changes needed
- Develop fact sheets and follow-up letters
- Develop follow-up data needs (short and long)

Phase 4

- Build and test cut-offs/logic into LIMS (Lab and Follow-Up)
- Press release
- Notify health care practitioners of new disorder with expectations

Ongoing Internal Communication (biweekly or weekly)

Go Live / Post Go Live

NewSTEPs
NEW DISORDER CHECKLIST

Phase 1

- [ ] **Hold meetings with specialists/clinicians**
  - [ ] Form task force

- [ ] **Develop preliminary timeline to meet targeted "Go Live" date**

- [ ] **Obtain authority to test**
  - [ ] Fiscal note (budget costs)
  - [ ] Obtain spending authority
  - [ ] Obtain regulatory rules changes to increase fee if necessary

- [ ] **Testing methodology**
  - [ ] Select screening method addressing pros and cons identified by your state
  - [ ] Identify equipment needed
    - Consider buying versus reagent rental
  - [ ] Determine facility space needed
  - [ ] Determine additional power/construction needed
  - [ ] Determine use of tiered testing strategy
    - Consider biochemical versus molecular
    - Assess need for contracting/send-outs if using referral lab
    - Assess effect on timeliness
    - Procure contracts for 1st and 2nd-tier testing if needed

- [ ] **Lab and follow-up staff needs**
  - [ ] Hire new staff
  - [ ] Conduct training needed for new and existing staff
  - [ ] Consider weekend staffing needs

- [ ] **Develop budget**

- [ ] **Consider site visits to other states already screening**

NewSTEPs

NEW DISORDER CHECKLIST

Phase 2

- [ ] **Installation, training of staff and familiarization with assay and equipment**

- [ ] **Perform validations**
  - [ ] Prospective versus retrospective
  - [ ] Determine if identified, de-identified, or anonymized
  - [ ] Assess availability of known positive specimens, QA, reference, PT materials

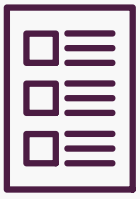
- [ ] **Identify and meet with sub-specialists**
  - [ ] Establish regular/ongoing meetings with Advisory Committee
  - [ ] Discuss need to test on weekends
    - Discuss buying versus reagent rental
  - [ ] Determine urgency of notifications and who should be contacted
  - [ ] Understand availability of appts for positive NBS
  - [ ] Determine barriers to timely follow-up testing
  - [ ] Develop and agree upon follow up algorithms

- [ ] **Gain understanding of incidental findings**
  - [ ] Determine how these will be reported

- [ ] **Consider sub-populations**
  - [ ] Premies/LBW/NICU
  - [ ] Early and late collected specimens
  - [ ] TPN
  - [ ] Transfusion

- [ ] **Assess changes to LIMS needed for implementation of screening/reporting**
  - [ ] Notify vendor and schedule project
  - [ ] Establish scope of work / draft specifications
  - [ ] Amend contract if necessary

- [ ] **Evaluating Continuity of Operations (COOP) needs**
  - [ ] Identify potential backup laboratories
  - [ ] Establish backup agreement documentation
  - [ ] Update COOP documents

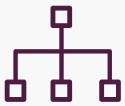


NewSTEPs
NEW DISORDER CHECKLIST

Phase 3

- [ ] **Outline pilot phase strategy**
  - [ ] Partial or full population pilot
  - [ ] Action algorithms during pilot

- [ ] **Integrate testing into current workflow**
  - [ ] Analyze how implementation affects other testing and timeliness
  - [ ] Write lab SOPs



- [ ] **Notify submitters of report changes**
  - [ ] Notify submitters of pilot study protocol
  - [ ] Determine how DNA/2nd-tier results will be reported
  - [ ] Determine how 2nd screen will be reported (if applicable) and how premature babies will be reported
  - [ ] Provide possible results, cut-offs, LOINC codes, other report changes

- [ ] **Identify website/brochure changes**
  - [ ] Make changes to website or general brochure as needed

- [ ] **Develop fact sheets and follow-up algorithms**
  - [ ] Create family fact sheet
  - [ ] Create medical fact sheet
  - [ ] Translate fact sheets as needed
  - [ ] Write follow-up SOPs
  - [ ] Develop follow-up letters as needed
  - [ ] Train follow-up staff

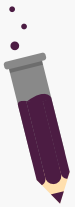
- [ ] **Develop follow-up data needs**
  - [ ] Determine diagnostic data fields needed
  - [ ] Determine long-term data fields needed

NewSTEPs

NEW DISORDER CHECKLIST

Phase 4

- [ ] **Build and test in LIMS**
  - [ ] Analyte cut-offs
  - [ ] Analyte reporting logic
  - [ ] Result comments
  - [ ] Follow-up logic and letters
  - [ ] Diagnostic forms and case definitions



- [ ] **Press release**
  - [ ] Work with communications group

- [ ] **Notice to health care practitioners**
  - [ ] Announce addition of new disorder and "Go Live" date
  - [ ] Announce increase in NBS fee, if applicable
  - [ ] Include announcement in laboratory/public health newsletter (work with communications)
  - [ ] Hold webinar with state hospital association
  - [ ] Discuss abnormal results

- [ ] **Notify accrediting body of testing changes**

- [ ] **Re-evaluate cutoffs**

NewSTEPs

NEW DISORDER CHECKLIST

Phase 5 - Post Go Live

- [ ] **Schedule follow-up meeting with specialists**
  - [ ] Determine how many months out to assess how program is going
  - [ ] Continue regular meetings of the specific new disorder work group

- [ ] **Assess notifications/report verbiage**
  - [ ] Discuss any confusing report language with providers
  - [ ] Address follow-up concerns

- [ ] **Assess heterogeneity of infants detected/spectrum of findings**
  - [ ] Determine what other conditions (secondary) are being detected
  - [ ] Determine if most cases are less severe than the expected/mind phenotypes

- [ ] **Assess medical system impact**
  - [ ] Determine the number of false positives
  - [ ] Determine any access issues that needs to be addressed

- [ ] **Assess expected or unexpected impact on special populations**

- [ ] **Check on the value, cost, and timeliness of second-tier tests, either done in-house or sent out**
  - [ ] Re-evaluate where these tests are being performed

This resource was developed by funding from the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) under grant number #U22MC24078 for $1,500,000. This information or content and conclusions are those of the author and should not be construed as the official position or policy of, nor should any endorsements be inferred by HRSA, HHS or the U.S. Government.