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
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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

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*NewSTEPs is a Program of the Association of Public Health Laboratories*
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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
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**
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

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