

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 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)

Ongoing Internal Communication (biweekly or weekly)

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 4

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

Go Live / Post Go Live



NEW DISORDER CHECKLIST

Phase 1

Hold meetings with specialists/clinicians

- Form task force



Develop preliminary timeline to meet targeted "Go Live" date



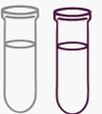
Obtain authority to test

- 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



NEW DISORDER CHECKLIST

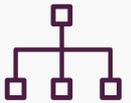
Phase 2

- 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

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



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**



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/mild 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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