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

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

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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
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

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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**

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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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