New Disorder Readiness Scale (updated May 2021)

The NewSTEPs New Disorder Readiness Scale is intended to track progress toward full implementation of screening for a new disorder, as well as to provide data to NewSTEPs on how long the different phases and milestones of the implementation process take, and how these timelines vary by disorder, program and other variables.

Timing of activities and milestones achieved may differ by disorder. Therefore, we request that you complete a separate scale for each new disorder. If you are initiating implementation for more than one disorder, please complete a new scale for each. Here are some general notes for completing the tables:

- Phases 1, 2, and 4 represent implementation activities and Phase 3 represents education related activities.
- Your state may not need to conduct each activity/milestone listed. If the activity does not apply to your state, please check "not applicable" for that line.
- Start and completion dates are estimates. NewSTEPs would like to capture whether the activity takes three months or twelve months, and as such exact dates are helpful, but not required. If you are unsure, please use the first of the month.
- If a required activity has not yet been initiated, please mark "not started." If preparations for an activity have been initiated, please select "started" and enter the month and year preparation was initiated.
- Use the notes field to capture feedback or other information that is important to understanding the time required to complete a given activity.

For more information and instructions on how to complete the New Disorder Readiness Scale, including clarification about the activities/milestones included, please see the New Disorders Readiness Scale Guide.

Date Started: _____ Update 1 Date: _____ Update 2: _____ Update 3: _____ Update 4: _____

Please complete the table below for the following disorder _____.

Activity/Milestone	Not started	Date started (MM/DD/YYYY) *if exact day is unknown use 1st of the month*	Date Completed/ Implemented (MM/DD/YYYY) *if exact day is unknown use 1st of the month*	Not Applicable	Notes
Approval/Authority to Screen					
Obtain approval from the NBS Advisory Committee (from initial presentation/meeting to final approval).					
Obtain approval from the Board of Health/Commissioner/other leaders (from initial presentation/meeting to final approval).					
Other approval authority activities.					Specify:
Mandate/approval to start screening/ state approves disorder for NBS.	■■■■■■	■■■■■■			
Obtain approval from the Institutional Review Board (IRB) to initiate pilot testing, if needed.					
Approval of Funding					
Develop a budget to show costs for screen, including laboratory testing, follow-up, information technology, etc.					
Obtain approval by NBS Advisory Committee for increase in funding.					
Obtain approval by the State Budget Authority.					
Other funding activities.					Specify:
Approval for fee increase.	■■■■■■	■■■■■■			
Fee increase implemented.	■■■■■■	■■■■■■			

Phase 1 – Authority to Screen

Activity/Milestone	Not started	Date started (MM/DD/YYYY) *if exact day is unknown use 1st of the month*	Date Completed/ Implemented (MM/DD/YYYY) *if exact day is unknown use 1st of the month*	Not Applicable	Notes
Laboratory					
Establish the Algorithm[1]					
Identify screen methodology/assay for (first through fifth) testing.					
Please specify the methodology for (first-fifth) testing. *(select one from dropdown menu)* • MS/MS • LS-MS/MS • Digital Microfluidics • Molecular Methodology, specify • Other, specify					
Develop/validate assay for (first-fifth) tier testing.					
External Lab Contracts					
Add testing to an outside lab contract (Phase 2b).					
Facility/Infrastructure Readiness					
Describe and ensure adequate space for testing.					
Develop adjusted workflow to accommodate new test.					

Phase 2 – Lab & Follow-up Logistics

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[1] In the online survey, you will be asked how many screening tiers your state will use for each disorder; REDCap will automatically generate the appropriate number of fields for each tier.

Activity/Milestone	Not started	Date started (MM/DD/YYYY) *if exact day is unknown use 1st of the month*	Date Completed/ Implemented (MM/DD/YYYY) *if exact day is unknown use 1st of the month*	Not Applicable	Notes
Laboratory					
Equipment					
Identify the need for additional equipment and procure any needed equipment.					
Identify laboratory space, modify space, and install needed equipment.					
Calibrate equipment.					
Staffing					
Develop staffing plan and ensure adequate staffing.					
Train staff to begin testing for the new condition (initiation of staff training through all staff being trained).					
Reporting					
Develop a system to determine cut-off values.					
Implement call-out algorithm.					
Overall Laboratory Readiness	Check Box if your NBS Laboratory (public health, regional, or private lab) is ready to screen for this condition.			*Yes, we are ready*	☐
Earliest start date and latest completion date of lab readiness activities.	■			■	

Phase 2 – Lab & Follow-up Logistics

Activity/Milestone	Not started	Date started (MM/DD/YYYY) *if exact day is unknown use 1st of the month*	Date Completed/ Implemented (MM/DD/YYYY) *if exact day is unknown use 1st of the month*	Not Applicable	Notes
Follow-Up					
Develop staffing plan and ensure adequate staffing.					
Develop and gain buy-in on short-term follow-up protocols for abnormal screens.					
Develop and gain buy-in on long-term follow-up protocols for abnormal screens.					
Identify medical specialists and/or treatment center to work with/ refer to and establish contract/agreement to follow infants with abnormal screens.					
Overall Follow-Up Readiness	Check Box if your NBS Follow-Up program is ready to screen for this condition.			*Yes, we are ready*	☐
Earliest start date and latest completion date of follow-up readiness activities.	■			■	
Information Technology					
Disorder is Integrated into Laboratory Information Management Systems (LIMs) for Testing & Reporting					
Describe and develop specifications for LIMs.					

Phase 2 – Lab & Follow-up Logistics

Activity/Milestone	Not started	Date started (MM/DD/YYYY) *if exact day is unknown use 1st of the month*	Date Completed/ Implemented (MM/DD/YYYY) *if exact day is unknown use 1st of the month*	Not Applicable	Notes
Identify required coding changes and implement changes to the LIMs.					
Validate the changes to the LIMs and re-test as needed.					
Disorder is Integrated into Follow-Up Reporting System					
Describe and develop specifications for the follow-up reporting system.					
Identify required coding changes and implement changes to the follow-up reporting system.					
Validate the changes to the follow-up system and re-test as needed.					
Disorder is Integrated into Electronic Order Protocol					
Describe and develop specifications for the electronic order protocol.					
Identify required coding changes and implement changes to the electronic order protocol.					
Validate the changes to the electronic order protocol and re-test as needed.					
Disorder is Integrated into Electronic Results Protocol					
Describe and develop specifications for the electronic results protocol.					
Identify required coding changes and implement changes to the electronic results protocol.					
Validate the changes to the electronic results protocol and re-test as needed.					

Activity/Milestone		Not started	Date started (MM/DD/YYYY) *if exact day is unknown use 1st of the month*	Date Completed/ Implemented (MM/DD/YYYY) *if exact day is unknown use 1st of the month*	Not Applicable	Notes
Other IT Activities						
Other IT activities.						Specify:
Overall IT Readiness	Check Box if this disorder is integrated into all applicable IT systems for your NBS Program (LIMs, follow-up reporting system, electronic ordering, electronic reporting, etc.)				*Yes, we are ready*	▢
Earliest start date and latest completion date of IT readiness activities.		███			███	

Activity/Milestone	Not started	Date started (MM/DD/YYYY) *if exact day is unknown use 1st of the month*	Date Completed/ Implemented (MM/DD/YYYY) *if exact day is unknown use 1st of the month*	Not Applicable	Notes
Education for Families					
Identify and modify family education materials to be state specific.					
Initiate a strategy for family education materials and create own family education materials.					
Identify or create measures to track impact of family education materials.					
Family education materials are distributed.			███████		
Education for Providers					
Identify and modify provider education materials to be state specific.					
Initiate a strategy for provider education materials and create own provider education materials.					
Identify or create measures to track impact of provider education materials.					
Provider education materials are distributed.			███████		
Education for the General Public					
Identify and modify education materials for the general public to be state specific.					
Initiate a strategy for general public education materials and create own					

Phase 3 – Education

Activity/Milestone	Not started	Date started (MM/DD/YYYY) *if exact day is unknown use 1st of the month*	Date Completed/ Implemented (MM/DD/YYYY) *if exact day is unknown use 1st of the month*	Not Applicable	Notes
education materials for the general public.					
Identify or create measures to track impact of education materials for the general public.					
Education materials for the general public are distributed.			███████		

	Activity/Milestone	Not started	Date started (MM/DD/YYYY) *if exact day is unknown use 1st of the month*	Date Completed/ Implemented (MM/DD/YYYY) *if exact day is unknown use 1st of the month*	Not Applicable	Notes
Phase 4 – Full Implementation	**Screening**					
	Pilot population testing (if outside lab is conducting pilot test, please describe in the notes).					
	Implement statewide screening (including follow-up, reporting, and education) for select population(s).	■				
	Implement statewide screening (including follow-up, reporting, and education) for all newborns.					