



**NewSTEPS**

A Program of the Association of Public Health Laboratories™

# New Disorder Readiness Scale: The Guide

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## Introduction

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, how these timelines vary by disorder, program and other variables.

NewSTEPS will use the New Disorder Readiness Scale to gain a national understanding of time and factors required for new disorder implementation, and to share this information to identify barriers and rate-limiting-steps. Ultimately, information garnered from the completed New Disorder Readiness Scale will inform policies regarding implementation of screening for new disorders and will enable NewSTEPS to better target and focus on areas for which additional technical assistance and resources are required.

The intent of this guide is to provide information on completing the New Disorders Readiness Scale. This is a living document that will be updated routinely as information is obtained from newborn screening programs to better refine this scale. Current iterations will be made available on [newsteps.org](http://newsteps.org).

Please direct all feedback and questions to Kshea Hale at [Kshea.Hale@aphl.org](mailto:Kshea.Hale@aphl.org)

## Disorder Selection

### New Disorder Readiness Scale

This scale is designed to track the progress of the Newborn screening program during the process of implementing screening for new disorders.

Date Started Tool: \_\_\_\_\_ Update1 Date: \_\_\_\_\_ Update2: \_\_\_\_\_ Update3: \_\_\_\_\_ Update4: \_\_\_\_\_

Please complete the table below for the following new disorder \_\_\_\_\_.

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.

Data fields have been placed so that progress may be tracked by NewSTEPS.

## General Notes for Completing the Table

	<b>Activity/Milestone</b>	<b>Not started</b>	<b>Date started</b> (MM/DD/YYYY) <i>*if exact day is unknown use 1<sup>st</sup> of the month</i>	<b>Date Completed/ Implemented</b> (MM/DD/YYYY) <i>*if exact day is unknown use 1<sup>st</sup> of the month</i>	<b>Not Applicable</b>	<b>Notes</b>
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- 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.

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- 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.

## Phase 1 – Authority to Screen

	<b>Activity/Milestone</b>	<b>Not started</b>	<b>Date started</b> (MM/DD/YYYY) <i>*if exact day is unknown use 1<sup>st</sup> of the month</i>	<b>Date Completed/ Implemented</b> (MM/DD/YYYY) <i>*if exact day is unknown use 1<sup>st</sup> of the month</i>	<b>Not Applicable</b>	<b>Notes</b>
<b>Phase 1 – Authority to Screen</b>	<b>Approval/ Authority to Screen</b>					
	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.					
	<b>Approval of Funding</b>					
	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.					

Each state has a different process for getting a condition approved to begin screening and in some cases for gaining approval. Phase 1 specific activity/milestone clarifications include:

- Obtaining approval can range from: 1) preparing a presentation for a governing body; 2) explaining the new disorder and why the state should consider screening for this disorder; 3) providing information so that the disorder can be voted on for inclusion if applicable; or 4) performing activities required to change state rules to add a new disorder.
- Multiple groups are captured here to ensure state-to-state variation is considered. Some states may start with their advisory committee prior to elevating the requests to the Board of Health.  
**Please specify the process where applicable, using the notes section.**

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- If your state is required to achieve a milestone or conduct an activity prior to gaining approval, please add this to the “other approval authority activities” line. Please also describe the activity or milestone in the notes section.
- “Mandate/approval to start screening/state approves disorder for NBS” is considered the result of obtaining authority to screen activities. We do not ask for a start date because we believe the other activities represent the start date. We would like the completed/implemented date because in some states there is a lag from gaining approval to actually receiving a mandate to start screening.
- If your state is required to achieve a milestone or conduct an activity prior to approval for funding or a funding increase, please add this to “other funding activities” with a description of the activity or milestone in the notes section.
- “Approval for fee increase” and “Fee increase implemented” are considered the results of having obtained approval for funding activities. We do not ask for a start date because we believe the other activities represent the start date. We would like the completed/implemented date because in some states there is a lag from gaining approval from the governing bodies to the time the fee increase being implemented.

## Phase 2 – Lab & Follow-up Logistics

	<b>Activity/Milestone</b>	<b>Not started</b>	<b>Date started</b> (MM/DD/YYYY) <i>*if exact day is unknown use 1<sup>st</sup> of the month</i>	<b>Date Completed/Implemented</b> (MM/DD/YYYY) <i>*if exact day is unknown use 1<sup>st</sup> of the month</i>	<b>Not Applicable</b>	<b>Notes</b>
<b>Phase 2 – Lab &amp; Follow-up Logistics</b>	<b>Laboratory</b>					
	<b>Establish the Algorithm:</b>					
	Identify screen methodology/assay for (first -fifth) testing.					
	Please specify the methodology for (first-fifth) testing. <i>(select one from dropdown menu)</i> <ul style="list-style-type: none"> <li>• MS/MS</li> <li>• LS-MS/MS</li> <li>• Digital Microfluidics</li> <li>• Molecular Methodology, specify</li> <li>• Other, specify</li> </ul>					
	Develop/validate assay for (first-fifth) tier testing.					
	<b>External Lab Contracts</b>					
	Add testing to outside lab contract (Phase 2b)					
	<b>Facility/Infrastructure Readiness</b>					
	Describe and ensure adequate space for testing.					
	Develop adjusted workflow to accommodate new test.					

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Phase 2 of the New Disorder Readiness Scale is stratified by laboratory, follow up, and information technology, with subsections under laboratory and information technology indicated in italics. Phase 2 specific activity/milestone clarifications include:

- Laboratory:
  - Under *Establish the Algorithm*, we ask about methodology used for testing the newborn screening disorder for which you are completing the Readiness Scale. You will need to **complete this section for each level of testing (e.g., first tier, second tier, third tier, etc.)**. Further this section contains an item “develop/validate of assay for testing”, which includes: 1) assay identification; 2) development and placement of quality improvement activities, including proficiency testing; and 3) implementation of controls, including cost estimates.
    - Note that when selecting “molecular” methodology, the “date started” should include when readiness for molecular testing was initially assessed.
  - Under *External Lab Contracts*, there is an item “Add testing to outside laboratory contract,” which captures instances where your laboratory is not performing this screen, but another laboratory is performing it for the newborns in your state. If this is the case, you might need to check “Not applicable” above for “Establish the Algorithm” category. When considering date started and implementation dates for “Add testing to outside laboratory contract,” please include notes on steps taken to identify a screening laboratory, development of contract, development of system for information exchange, and mechanisms for specimen transport, etc.
  - Under *Staffing* the item “Develop staffing plan and ensure adequate staffing” relates to the process to add staff, shift staff responsibilities, or the decision to make no changes. Please share the timing of activities to decide whether current staffing is adequate, when changes are necessary and how long it will take to bring on adequate staffing. Further, the item “Train staff to begin testing for the new condition” can refer to in-house training, external courses or workshops, including those provided by the Centers for Disease Control and Prevention (CDC) and other laboratories. All such training activities can be included in this milestone.
  - Laboratory Readiness Complete

<b>Overall Laboratory Readiness</b>	Check Box if your NBS Laboratory (public health, regional, or private lab) is ready to screen for this condition.	Yes, we are ready <input type="checkbox"/>
Earliest start date and latest completion date of lab readiness activities.		

To help with analysis, we added a section for you to indicate if your lab is ready to screen for this condition. This means that all the necessary laboratory activities are complete. If you use an outside laboratory then lab readiness is that your program has a contract in place AND that lab can begin screening for this condition on your behalf.

For this piece you need to check the box to indicate your lab is ready. If the box is checked, we ask you to provide the earliest start date for your lab readiness activities. This is typically the first date you have listed anywhere in the lab readiness section of the Readiness Tool.

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Next, we ask for the last completion data of the lab readiness activities. Again, this is most likely the most recent completion data of all the activities in this section.

- Follow Up

- Develop staffing plan and ensure adequate staffing” relates to the process to add staff, shift staff responsibilities, or the decision to make no changes. Please share the timing of activities to decide whether current staffing is adequate, when changes are necessary and how long it will take to bring on adequate staffing. For example, weekend staff may need to be shifted if a specific condition requires immediate call-out.
- “Develop and gain buy-in” on short-term/long-term follow-up protocols for abnormal screens can include any activities required to obtain approval for new staffing patterns and for working with providers to determine when an abnormal screen should be called out.
- “Identify medical specialists and/or treatment center to work with/refer to and establish contract/agreement to follow infants” refers to the specialists or center who would perform confirmatory testing and treatment. This includes both identification and development of a formal arrangement/contract with providers such that follow-up activities following an abnormal screen are conducted.
- Follow-Up Readiness Complete

<b>Overall Follow-Up Readiness</b>	Check Box if your NBS Follow-Up program is ready to screen for this condition.	Yes, we are ready	<input type="checkbox"/>
Earliest start date and latest completion date of follow-up readiness activities.			

To help with analysis, we added a section for you to indicate if your follow-up program is ready to provide follow-up care for this condition. This means that all the necessary follow-up activities are complete. We expect that if this box is checked your program is not working on preparation of any major follow-up activities to work with families who have a positive screen for this condition.

For this piece you need to check the box to indicate your follow-up program is ready. If the box is checked, we ask you to provide the earliest start date for your follow-up readiness activities. This is typically the first date you have listed anywhere in the follow-up readiness section of the Readiness Tool, but we recognize the readiness tool may not be capturing all the necessary follow-up steps right now. Next, we ask for the last completion data of the follow-up readiness activities. Again, this is most likely the most recent completion data of all the activities in this section, but it may not be.

- Information Technology:

- For this section, each activity/milestone is stratified into five sections: *Disorder is Integrated into LIMS Testing & Reporting; Disorder is Integrated into Follow-up Reporting System; Disorder is Integrated into Electronic Order Protocol, Disorder is Integrated into Electronic Results Protocol, and Other IT activities.*
- Each section, with the exception of *Other*, asks about the following activities/milestones:

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- “Describe and develop specifications” includes identifying, creating, and adding any new data fields to the information systems.
- “Identify required coding changes and implement changes” includes applying the developed specification to the information systems.
- “Validate the changes” includes testing changes to the information systems with pilot data or other data to ensure the information systems are working correctly
- Any large Information Technology (IT) activity or milestone that is not listed should be added to *Other IT Activities*. Please describe the activity or milestone in the notes section.
- Laboratory Readiness Complete

<b>Overall IT Readiness</b>	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	<input type="checkbox"/>
Earliest start date and latest completion date of IT readiness activities.			

To help with analysis, we added a section for you to indicate if your newborn screening IT is ready to screen for this condition. This means that all the necessary IT activities are complete. We expect that if this box is checked your program is not working on preparation of any major IT activities around IT integration into LIMs, Follow-Up reporting system(s), electronic ordering, and/or electronic reporting as applicable to your program.

For this piece you need to check the box to indicate your IUT is ready. If the box is checked, we ask you to provide the earliest start date for your IT readiness activities. This is typically the first date you have listed anywhere in the IT readiness section of the Readiness Tool. Next, we ask for the last completion data of the IT readiness activities. Again, this is most likely the most recent completion data of all the activities in this section.

## Phase 3 – Education

	<b>Activity/Milestone</b>	<b>Not started</b>	<b>Date started</b> (MM/DD/YYYY) <i>*if exact day is unknown use 1<sup>st</sup> of the month</i>	<b>Date Completed/ Implemented</b> (MM/DD/YYYY) <i>*if exact day is unknown use 1<sup>st</sup> of the month</i>	<b>Not Applicable</b>	<b>Notes</b>
<b>Phase 3 – Education</b>	<b>Education for Families</b>					
	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.					
	<b>Education for Providers</b>					
	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.					
	<b>Education for the General Public</b>					
	Identify and modify education materials for the general public to be state specific.					
	Initiate a strategy for general public					

As with Information Technology, there are four responses repeated here under each category of education. Education materials can include all mediums such as brochures, posters, videos, ACT sheets, presentations, etc. Phase 3 specific activity clarifications include:

- “Identify and modify education materials” includes any time spent researching what already exists, gaining access to those materials, and making any modifications needed so that the materials are state-specific. If state-specific education materials are developed, those activities would be included in “Initiate a strategy for education materials.”
- “Identify or create measures to track impact” would be any activity involved in gathering or analyzing data to see if the education led to an increase in knowledge or understanding; or the desired behavior change based on your education goals and objectives. **If there are no education goals or objectives, mark “Not Applicable.”**
- There is currently no option to list an end date for “Materials being distributed” given that this is an ongoing process. The intent of this scale is to capture time needed to initiate early education with the acknowledgement that education is ongoing by nature.

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## Phase 4 – Full Implementation

	<b>Activity/Milestone</b>	<b>Not started</b>	<b>Date started</b> (MM/DD/YYYY) <i>*if exact day is unknown use 1<sup>st</sup> of the month</i>	<b>Date Completed/ Implemented</b> (MM/DD/YYYY) <i>*if exact day is unknown use 1<sup>st</sup> of the month</i>	<b>Not Applicable</b>	<b>Notes</b>
<b>Phase 4 – Full Implementation</b>	<b>Screening</b>					
	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.					

Phase 4 specific activity clarifications include:

- “Pilot population testing” includes if an outside lab is conducting the pilot test for you; please describe in the notes section.
- Select populations may include opt-in/optional screenings, or populations within states/territories that are screened differently than full population.