



Tool for Assessing Health Needs

in relation to

Newborn Screening

Part of the PHG Foundation Toolkit
for Assessing Health Needs in
relation to Congenital Disorders

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PHG Foundation Needs Assessment Tool for Newborn Screening

Country/Territory of interest for present needs assessment on Newborn Screening

NBS-0 INTRODUCTION

Welcome to the PHG Foundation Congenital Disorders Needs Assessment Tool, for Newborn Screening (NBS). This Tool consists of five sections, which are explained briefly in the Guide:

- the Country Profile
- the Needs Assessment section
- the Situation Assessment
- the Initial Prioritisation
- the Summary Report.

The narrative and the written instructions are contained in the Tool, while numerical input and calculations are performed in the Calculator. The Tool and the Calculator should be used alongside one another. Where you need to put data into the Calculator, you will see an instruction.

Decision points

At certain points you will be prompted to decide whether it is necessary to continue with your present needs assessment. If the burden is low, for example, you may decide your efforts are better used on another topic, but this should be made explicit.

Subpopulations

If variation between population sub-groups is substantial, a whole-population needs assessment may not be appropriate. It may be necessary to conduct separate assessments for the individual groups, or to focus your assessment on a group that is particularly affected. At the minimum, you should ensure that substantially higher or lower rates in an identified population sub-group do not lead to inaccurate estimates for the whole population.

NBS-CP COUNTRY PROFILE

Demographic and health service factors are key determinants of the scale of congenital disorders and of the potential to provide care and prevention.

Note: If you or others conducting PHG needs assessments have already completed Demography and Health services sheets in another topic Calculator for this population, you can copy that data into the present Calculator.

Population definition: Briefly describe the population if you are not using the whole country.

Some sources containing data relevant to the Country Profile are given in Appendix 1, located at the end of this document.

NBS-CP1 Demography

Demographic factors in a population have important effects on the burden of congenital disorders. Variables such as maternal age and level of consanguineous marriage affect the incidence of disorder, while variables such as birth rate and contraceptive prevalence affect the absolute number of births. Other indicators are useful for understanding the general context.

In the sheet of the Calculator named 'Demography' there are estimates of various important demographic indicators. You can add data from your own sources.

>>> [Go to Calculator sheet Demography](#)

NBS-CP2 Health services

Ideally, activities related to the care and prevention of birth defects are well integrated into health services, and particularly into family planning, women's, maternal, newborn, child, genetic and public health services.

Please give a summary description of the operation of health services and programmes in the country or territory. Describe their accessibility and coverage, and who is responsible for them.

Please list relevant national health policies, legislation and guidelines in relation to the pre-conception period, pregnancy and childhood, including genetic services and screening for genetic conditions.

There are several variables that will be important to consider when assessing the potential for change and when completing the prioritisation process. Please now go to the Health Services sheet in the Calculator (HealthServices) and enter estimates of the health service indicators listed there.

>>> [Go to Calculator sheet HealthServices](#)

Please summarise the country profile, highlighting where the indicators are unsatisfactory. Comment on areas for improvement in the indicators.

NBS-NA NEEDS ASSESSMENT SECTION

NBS-NA1 Preliminary assessment of public health need

This section should help you to make an initial assessment of the level of need for NBS in your country or territory. You should complete the tables using epidemiological data where available. If data are not available, please enter a qualitative assessment using a rating system of 1-5, where 1 indicates that the risk factor is not significant in your population, and 5 indicates a highly significant risk factor.

Calculator NBS-NA1.1 deals with prevalence of conditions amenable to newborn screening. For each condition, identify if a newborn screening programme exists. Give estimates of the prevalence of the condition and of any significant variation in prevalence by region or sub-group population.

>>> Go to Calculator sheet NBS-NA1.1

Calculator NBS-NA1.2 addresses coverage of newborn screening programmes. Please enter information related to existing (components of) newborn screening programmes in your country/territory.

>>> Go to Calculator sheet NBS-NA1.2

Based on these tables and your experience, how do you rate the need for implementation or changes to effective newborn screening services as a public health issue in your country/territory?

Very low	Low	Medium	High	Very high	Do not know
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Explain your choice.

Decision point: If you do not consider this to be a significant public health problem and no specific policies and interventions are required as a priority, you may stop here and move to another topic. Otherwise, continue with section NBS-NA2.

NBS-NA2 Assessment of policies, services and information

NBS-NA2.1 Desired situation

First outline the desired situation ('where do we want to be?') in relation to the prevalence of specific conditions, availability of screening programme and coverage of newborn screening.

Now consider what policies and programmes would be optimal for delivering effective NBS in your country or region. Options include an integrated NBS programme providing advice, screening and support in the newborn period on the full range of risks and conditions that may affect the infant. Alternatively, or in addition, policies or programmes may focus on the prevention of particular conditions such as congenital hypothyroidism or single gene disorders.

Policies and programmes

Now consider services that may be delivered in the newborn period, such as screening, diagnosis of fetal abnormalities, counselling, care and treatment interventions.

Services and interventions

Please comment on the availability of information (e.g. registries, epidemiological information, health service indicators).

Desired outputs resulting from action (e.g. availability, coverage and quality of policies, interventions and services)

NBS-NA2.2 Current situation and gaps

Now please assess the current situation and unmet needs ('where are we now?'), giving indications on potential areas for action.

Table NBS-NA2 should help you to make an initial assessment of the level of unmet need for each component of the NBS programme in your country or region. Please enter level of met need for each component of the screening programme (physical examination, bloodspot, and hearing screening). Use a numerical code system from 1 to 5, to reflect (1) mostly unmet (high need) to (5) mostly met (low need), with '3' representing an intermediate level of met needs. Therefore '1' represents an unsatisfactory situation, and '5' represents an optimum situation. You may use the action areas listed below, and add items as you find appropriate.

Table NBS-NA2 Summary of levels of health needs related to newborn screening

Action areas	Programme areas		
	Newborn physical examination	Newborn hearing	Newborn bloodspot
Policies & guidelines			
Resources/funding			
Resources/personnel			
Resources/equipment			
Public education about newborn screening			
Professional education about NBS			
Workforce training			
Sample collection			
Transport of samples			
Lab processing			
Diagnosis confirmation			
Information on results			
Action on results			
Referral of affected children			
Care of affected children			
Associated counselling			
Population access			
Equitable access			
Population coverage			
Equitable coverage			
Programme governance			
Ethical conduct			
Data collection			
Data quality			
Surveillance			
Research			

NBS-NA2.2.1 Policy and programmes

Briefly list any national policies or programmes for the different components of newborn screening in your country or region. You may consider NBS, education, data collection and evaluation policies, protocols or guidelines. Please state who is responsible for them (e.g. Institution, Ministry or Department).

Newborn physical examination

Newborn hearing screening

Newborn bloodspot screening

Are there gaps or inadequacies in policies/programmes and in their implementation?
Give details.

If yes, are there plans to address them? Give details.

What else can be done to tackle unmet needs?

Comment on existing sources and adequacy of resources for the programme (financial, people and equipment).

If you follow any particular screening criteria in your country or locally, please give details.

NBS-NA2.2.2 Services and interventions

How is the delivery of programmes monitored and evaluated?

Are the newborn screening services being satisfactorily delivered?

Are the NBS services and interventions well integrated with other health services (e.g. preconception care and screening and prenatal screening, clinical services for the treatment and care or those affected)?

Are services and interventions delivered equitably across the country or territory, according to the needs of different populations?

Are there any gaps or inadequacies in the delivery of services and interventions?

If yes, what are the main reasons (e.g. lack of priority, planning, financial resources, facilities and equipment, trained personnel, managerial deficiencies)?

If there are gaps, are there plans to address them? Give details.

If not, is there a need for service changes or implementation of services or interventions? List what could be done and how.

NBS-NA2.2.3 Information needs

Comment on the quality of any existing surveillance, other epidemiological and research data that are relevant to the conditions that you screen newborns for, and also on data for programme monitoring.

Is there a need for implementation or changes in information systems in relation to NBS programmes?

If there are unmet information needs, how far does the absence of appropriate data hamper action? What can be done?

Is there a need for new research in relation to newborn screening?

What can be done?

If there are unmet research needs, how far does the absence of appropriate research data hamper action?

What can be done?

Summary of the main gaps or unmet needs

(Please refer to Tables NA1.1 and NA1.2 in the Calculator and NA2 above.)

NBS-NA3 Qualitative assessment of interventions

For each condition where you have NBS programme, consider whether local or WHO criteria* for screening are met (please state 'local' or 'WHO'). Indicate the effectiveness, cost-effectiveness, and impact of the **current** NBS programmes in Table NBS-NA3a, and of the **expected** programmes in Table NBS-NA3b. Use a numerical code system from 1 to 5, to reflect (1) mostly unmet (high need) to (5) mostly met (low need), with '3' representing an intermediate level of met needs. Therefore '1' represents an unsatisfactory situation, and '5' represents an optimum situation.

Table NBS-NA3a Qualitative assessment of the impact of **current** interventions

Condition	Meets local/WHO screening criteria*	List any screening criteria unfulfilled	Effectiveness	Cost-effectiveness	Impact
Newborn physical examination					
Basic examination**					
Exam. for gross abnormalities**					
Detailed physical examination**					
Hearing screening					
Hearing test					
Newborn bloodspot					
Congenital hypothyroidism					
PKU					
Cystic fibrosis					
Sickle cell disease					
Thalassaemia					
G6PD deficiency					
Congenital adrenal hyperplasia					
MCADD					
Other					

PKU = phenylketonuria

MCADD = medium-chain acyl-CoA dehydrogenase deficiency

G6PD = glucose-6-phosphate dehydrogenase

* World Health Organisation criteria for deciding whether or not to screen for a condition in the context of resources limited countries are given in the NBS Background document

** For definitions, see the NBS Background document, Newborn Screening Tests section.

Table NBS-NA3b Qualitative assessment of the **expected** impact of changes and interventions

Condition	Meets local/WHO screening criteria*	List any screening criteria unfulfilled	Effectiveness	Cost-effectiveness	Impact
Newborn physical examination					
Basic examination**					
Exam. for gross abnormalities**					
Detailed physical examination**					
Hearing screening					
Hearing test					
Newborn bloodspot					
Congenital hypothyroidism					
PKU					
Cystic fibrosis					
Sickle cell disease					
Thalassaemia					
G6PD deficiency					
Congenital adrenal hyperplasia					
MCADD					
Other					

PKU = phenylketonuria

MCADD = medium-chain acyl-CoA dehydrogenase deficiency

G6PD = glucose-6-phosphate dehydrogenase

* World Health Organisation criteria for deciding whether or not to screen for a condition in the context of resources limited countries are given in the NBS Background document

** For definitions, see the NBS Background document, Newborn Screening Tests section.

NBS-NA4 Quantitative assessment of interventions

The following sheets in the Calculator allow you to estimate the effects of newborn screening programmes and treatment/management on the burden of various conditions.

Note: If you or others conducting PHG needs assessments have already completed the intervention(s) sheets in another topic Calculator for this population, you can copy that data into the present Calculator.

- >>> Go to Calculator sheet NBS-CHT
- >>> Go to Calculator sheet NBS-G6PD
- >>> Go to Calculator sheet NBS-RHD
- >>> Go to Calculator sheet NBS-SCD
- >>> Go to Calculator sheet NBS-THAL
- >>> Go to Calculator sheet NBS-OFC
- >>> Go to Calculator sheet NBS-PKU
- >>> Go to Calculator sheet NBS-CF

NBS-NA5 Situation assessment

Now consider your environment and describe the **Strengths**, **Weaknesses**, **Opportunities** and **Threats** in relation to policies and services, using the SWOT diagram in Table NBS-NA5.

Table NBS-NA5 SWOT diagram

Internal environment	External environment	
Strengths	Opportunities	+
Weakness	Threats	-

NBS-NA6 Initial prioritisation: Comparing interventions

The prioritisation team and processes

List the people and organisations invited to and involved in the initial prioritisation process in Table NBS-NA6a, and briefly explain how they were chosen.

Table NBS-NA6a The prioritisation team

Person invited	Organisation represented	Accepted (Y/N)

Brief explanation of choice of participants and give any other comments.

Now consider in the group your ground rules, prioritisation criteria and action areas and complete Tables NBS-NA6b to NBS-NA6d. Start with the ground rules.

Table NBS-NA6b Ground rules for the prioritisation process (add rows if needed)

Now list in Table PNS-NA6c the prioritisation criteria you will use. You may wish to add weights to each criterion (from '0' to '1') in the table.

Table NBS-NA6c List of criteria for prioritisation of interventions (add rows if needed)

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Based on your assessment of needs, please consider and list in Table NBS-NA6d action areas for consideration.

Table NBS-NA6d List of action areas for consideration (add rows if needed)

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Based on the criteria selected, compare the action areas and rank them from the highest to the lowest priority. You may enter the results directly, following your discussions. You may find it helpful to use decision analysis software, so as to do it in a more systematic way (see the Prioritisation document). Show your results in Table NBS-NA6e, by entering the selected 'Action Areas' from the highest priority (1) onwards, using as many rows as appropriate. Tick the last column for all action areas that you consider are of sufficient priority to carry over to the later stages of the prioritisation process. This will enable these results to be compared with those for other conditions or topics at a later stage.

Table NBS-NA6e List of priority action areas and interventions for newborn screening

Priority	Action Area	Carry over
1. highest		
2.		
3.		
4		
5		

You have completed this Section! Now please proceed to the Summary Report.

NBS-NA7 Summary report

It is now time to bring together the main findings of your needs assessment into a summary report. This will present in one place the basic information about the need for Newborn Screening Services, the present state of interventions and the potential to improve care and reduce incidence.

Briefly describe the population and topic covered by this health needs assessment.

Briefly describe how the relevant services are organised¹.

List the main service activities and interventions in relation to newborn screening².

¹ Possible reference sections: CP2, NA1.2

² You may wish to include an assessment of the effectiveness, cost-effectiveness, coverage, quality and level of satisfaction with the interventions or services. Possible reference sections include NA2.2.

Are there any threats to the continuation of services³?

What are the unmet needs as assessed by the Toolkit⁴?

Is it feasible to meet the identified needs⁵?

³ For example, in relation to resources, acceptability or competing priorities.

⁴ You may wish to consider the following questions: i) What are the main needs? ii) Is appropriate information available? iii) Are appropriate legislation, policies and programmes in place? iv) Are appropriate services and interventions in place? v) Are the main risk factors being addressed? vi) If appropriate, are prevalence rates, e.g. at birth and population level, as low as they can be? vii) Is prevention and care being delivered effectively, cost-effectively and according to need? viii) Are prevention and care activities being delivered fairly (equity)? Possible reference sections: NA3 and NA4

⁵ You may wish to consider strengths, weaknesses, opportunities and threats. Possible reference section: NA5

What actions may be required to respond to the unmet needs?

Describe how the prioritisation has been done and the main findings⁶.

List the planned activities and how they will be evaluated⁷.

⁶ Possible reference section: NA6

List the proposed next steps.

APPENDIX 1 – SOURCES OF DATA FOR THE COUNTRY PROFILE

For demographic, socio-economic and other indicators for your country or world regions, you may use the links below or other sources available to you.

1. Countdown to 2015 (profiles for selected countries)

http://www.childinfo.org/countdown_638.htm

2. Global health Observatory (GHO)

<http://www.who.int/gho/en/index.html>

3. Health Indicators database. Pan American Health Org (PAHO)

<http://ais.paho.org/hip/viz/basicindicatorbrowser.asp>

4. Health of Nations

<http://www.healthofnations.com/countries/map/outcomes/life>

5. Indicator definitions. (WHO)

<http://www.who.int/whosis/indicators/en>

6. Information on consanguinity

http://www.consang.net/index.php/Global_prevalence_tables

7. Information on immunisation

http://apps.who.int/immunization_monitoring/en/globalsummary/countryprofileresult.cfm

8. UN Demographic Yearbook (UNDY) series

<http://unstats.un.org/unsd/demographic/products/dyb/dyb2.htm>

9. UN Statistics Division

<http://unstats.un.org/unsd/demographic/products/socind/health.htm>

10. UNICEF country statistics

http://www.unicef.org/statistics/index_countrystats.html

11. UNICEF reports on The State of the World's Children

<http://www.unicef.org/sowc08/statistics/statistics.php>

12. WHO data and statistics (various links)

<http://www.who.int/research/en/>

13. WHO Statistical Information System (WHOSIS)

<http://www.who.int/whosis/whostat/2010/en/index.html>

Please list your own sources of data below.

- 1.
- 2.
- 3.