



Tool for Assessing Health Needs

in relation to

Teratogens

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

Version 1.1, September 2013

PHG Foundation Needs Assessment Tool for Teratogens

Country/Territory of interest for present needs assessment on Teratogens:

TER-0 INTRODUCTION

Welcome to the PHG Foundation Congenital Disorders Needs Assessment Tool for Teratogens (TER). 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.

Please note this tool looks at teratogens broadly and encompasses all teratogen related congenital disorders. You may specify a particular teratogen if you wish to consider a narrow subset. In addition, if you would like to carry out a needs assessment with regards to specific teratogens, documents relating to alcohol, rubella, syphilis and nutritional deficiencies (folic acid and iodine) are listed under specific clinical topics.

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 there is substantial variation in burden or service factors between population sub-groups, 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.

TER-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.

TER-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 disorders, 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

TER-CP2 Health services

Ideally, activities related to the care and prevention of congenital disorders 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.

TER-NA NEEDS ASSESSMENT SECTION

TER-NA1 Preliminary assessment of public health need

This section should help you to make an initial assessment of the level of need for services and structures to mitigate risk from teratogens 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 TER-NA1.1 deals with a range of maternal and environmental teratogenic risk factors for congenital disorders. Please enter estimates, including an indication of variation within your population.

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

The Calculator sheet TER-NA1.2 contains tables which allow you to record epidemiological data with relation to teratogens if these are available. You may populate this table with data for teratogens broadly or you can create similar tables for specific sub-groups of teratogens as appropriate.

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

Based on this preliminary assessment and your experience, how do you rate the need for effective services with respect to teratogens as a public health issue in the country or region?

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 TER-NA2.

TER-NA2 Assessment of policies, services and information

TER-NA2.1 Desired situation

First outline the desired situation ('where do we want to be?') in relation to the epidemiology, care and prevention with relation to congenital disorders caused by teratogens in the following areas:

Teratogenic risk factors and congenital disorders

Now consider what policies and programmes would be optimal for reducing congenital disorders due to teratogens in your country or region. Options include an integrated programme providing advice, screening and support in the preconception period on the full range of risks and conditions that may affect a future pregnancy and infant. Alternatively (or in addition) policies or programmes may focus on the reduction in exposure to particular teratogens.

Policies and Programmes

Now consider services that may be delivered such as women's and reproductive health services, preventive services, and interventions aimed at reducing teratogen exposure or providing information on teratogens.

Services and Interventions (e.g. education on risk, preconception and prenatal review of medications)

Please comment on the availability of information (e.g. teratogen information services, registries of congenital disorders linked to exposures in pregnancy)

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

TER-NA2.2 Current situation and gaps

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

TER-NA2.2.1 Policy and programmes

Briefly list any policies or programmes for the care and prevention of Teratogen-induced congenital disorders in your country or territory, and who is responsible for them (e.g. Institution, Ministry or Department).

Care

Prevention

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

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

What can be done to tackle unmet needs?

TER-NA2.2 Services and interventions

List services and interventions for prevention and care, and comment on their quality and who provides them.

In Table TER-NA2, list and describe current services aimed at reducing congenital disorders caused by teratogens. Describe any significant variations in the availability or delivery of services

Component	Tick if available*	Description	Variation**
Public education			
Professional education			
Legislation and regulation: Environmental			
Legislation and regulation: Occupational			
Legislation and regulation: Prescribed drugs			
Legislation and regulation: Non-prescribed drugs			
Workforce training			
Screening for teratogen exposure: environment			
Screening for teratogen exposure: workplace			
Information on teratogen effects and exposure risk			
Prenatal screening			
Prenatal diagnosis			
Termination of pregnancy			
Newborn screening			
Referral care plan			
Long term clinical care and related interventions			
Social care for those born with teratogen-induced congenital disorders.			
Disability support			
Education in schools			
Education in workplace			
Surveillance of exposures			
Surveillance of cases			
Research into teratogens			

* Or enter n/a if not relevant for your population.

** Describe any significant variations in the programme coverage across the country/region and any sub-groups of the population who are underserved by the programme.

Comment further on significant variations in the coverage of services and interventions in the country/territory, and on any sub-groups of the population who are underserved.

How is the delivery of these interventions monitored and evaluated?

Are the services being satisfactorily delivered?

Are the above services and interventions well integrated with other health services (e.g. maternal and child health services, occupational health services, teratogen information services)?

How do these target people at different life stages (i.e. before and during pregnancy and after birth)?

Are there appropriate and integrated pathways for prevention and care? (e.g. communications between health service staff, and referral mechanisms)

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 or legal regulation)?

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

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

TER-NA2.2.3 Information needs

Comment on the quality of any existing surveillance and research data on exposure to teratogens and on congenital disorders caused by them.

Is there a need for implementation or changes in surveillance systems for exposure to teratogens and related congenital disorders?

If there are unmet information needs, how much does the absence of appropriate **surveillance data** impede action?

What can be done?

Is there a need for new research in relation to teratogen exposure and the related incidence of congenital disorders?

If there are unmet information needs, how much does the absence of appropriate **research data** impede action?

What can be done?

Summary of the main gaps or unmet needs

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

TER-NA3 Qualitative assessment of interventions

Now consider existing interventions and their coverage, effectiveness, cost-effectiveness, and their current impact (Table TER-NA3a) and expected impact (Table TER-NA3b). Use numbers from '1' (very low) to '5' (very high). Please add rows as appropriate.

Table TER-NA3.2a Qualitative assessment of the impact of **current** interventions

Interventions	Coverage	Effectiveness	Cost-effectiveness	Impact
Before pregnancy				
Family planning, education				
Occupational health monitoring				
Environmental health monitoring				
Interventions to reduce risk				
Information on risks and exposures (including teratogen information services)				
During pregnancy				
Education on risks				
Targeted prenatal screening based on exposure				
Prenatal diagnosis				
Termination of pregnancy				
Maternal protection legislation				
Information on risks and exposures (including teratogen information services)				
After birth				
Newborn screening				
Newborn diagnosis				
Clinical and related interventions				
Social care and support				
Education interventions				
Compensation legislation				

Now consider the potential for the implementation of new interventions or changes to existing ones, in relation to their achievable coverage, effectiveness, cost-effectiveness and potential impact. Use numbers between '1' (very low) and '5' (very high). Please enter or delete rows as appropriate.

Table TER-NA3.2b Qualitative assessment of the expected impact of interventions

Interventions	Achievable coverage	Effectiveness	Cost-effectiveness	Impact
Before pregnancy				
Family planning, education				
Occupational health monitoring				
Environmental health monitoring				
Interventions to reduce risk				
Information on risks and exposures (including teratogen information services)				
During pregnancy				
Education on risks				
Targeted prenatal screening based on exposure				
Prenatal diagnosis				
Termination of pregnancy				
Maternal protection legislation				
Information on risks and exposures (including teratogen information services)				
After birth				
Newborn screening				
Newborn diagnosis				
Clinical and related interventions				
Social care and support				
Education interventions				
Compensation legislation				

TER-NA4 Quantitative assessment of interventions

The following sheets in the Calculator allow you to estimate the potential reduction in birth prevalence of congenital disorders through reducing specific teratogenic risk and prenatal screening.

Please use this section if you are interested in a specific teratogen and have data in relation to it. If you would like to consider a broad range of teratogens or you have no data, please skip this section.

>>> Go to Calculator sheet TER-Interv1

>>> Go to Calculator sheet TER-Interv2

Here, you should fill in data relating to the prevalence of specific Teratogens in different intervention scenarios: in the absence of interventions, in the current situation, and in the desired situation.

Table TER-NA3a in Calculator sheet TER-NA3 relates to 'potential cases' – expected numbers of cases and rates in the absence of any interventions (if coverage = zero).

Please note: there is no Calculator sheet NA2. This is deliberate!

>>> Go to Calculator sheet TER-NA3

Tables TER-NA3b to NA3g in Calculator sheet TER-NA3 refer to the current and target (desirable) situations for interventions before birth, during pregnancy and after birth. Please enter data in these tables. You may add or delete rows as appropriate.

>>> Return to Calculator sheet TER-NA3

Table TER-NA3h in Calculator sheet TER-NA3 refers to outcomes. Figures for 'current situation' come from Tables TER-NA1a and NA1b.

>>> Return to Calculator sheet TER-NA3

TER-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 TER-NA5.

Table TER-NA5 SWOT diagram

Internal environment	External environment	
Strengths	Opportunities	+
Weakness	Threats	-

TER-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 TER-NA6a, and briefly explain how they were chosen.

Table TER-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 TER-NA6b to TER-NA6d. Start with the ground rules.

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

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

Table TER-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 TER-NA6d action areas for consideration.

Table TER-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 this in a more systematic way (see the Prioritisation document). Show your results in Table TER-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 TER-NA6e List of priority action areas and interventions for Teratogens

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

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

TER-NA6 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 burden of Teratogens, the present state of interventions and the potential to improve care and reduce incidence.

Briefly describe the population, teratogens considered and conditions arising from exposure to the teratogen(s)

Briefly describe how the relevant services are organised and their link with maternal and child health services¹.

List the main services and interventions currently available for the care and prevention of congenital disorders caused by teratogens²

Are there any threats to the continuation of services?³

¹ Possible reference section: CP2

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

What are the unmet needs as assessed by the Toolkit?⁴

Is it feasible to meet the identified needs?⁵

³ For example, in relation to resources, acceptability, and 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 prevalence rates (both at birth and population level) as low as they can be?; vi) Is prevention before pregnancy being delivered effectively, cost-effectively and according to need?; vii) Is prevention during pregnancy being delivered effectively, cost-effectively and according to need?; viii) Is prevention and care after birth being delivered effectively, cost-effectively and according to need?; ix) Are prevention and care activities being delivered fairly (equitably)? 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 findings

List the planned activities and how they will be evaluated

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

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

2. WHO Statistical Information System (WHOSIS)

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

3. Indicator definitions. (WHO)

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

4. UNICEF country statistics

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

5. UN Demographic Yearbook (UNDY) series

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

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

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

7. WHO data and statistics (various links)

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

8. Global health Observatory (GHO)

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

9. Countdown to 2015 (profiles for selected countries)

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

10. Health of Nations

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

11. Consanguinity

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

12. Immunisation

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

13. UN Statistics Division

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

Please list your own sources of data below

- 1.
- 2.
- 3.