

Protocol for making a change to the National Notifiable Diseases List (NNDL) in Australia

Revision history

Version number	Endorsed by CDNA	Endorsed by AHPPC	Changes
1.0	17 June 2015	September 2015 out of session	Original version

Purpose

This document details the process for nominating and assessing a disease for inclusion on the national notifiable diseases list (NNDL) in Australia, for removing a disease from the list and for making minor amendments to diseases on the list. It also provides an overview of the process of approvals and changing the NNDL once approval is given.

Introduction

Australia has established a list of communicable diseases that are nationally notifiable (the NNDL). The NNDL is a legislative instrument under the *National Health Security Act 2007*. The Australian Government Minister for Health may vary the NNDL (add or delete a disease) following consultation with the Commonwealth Chief Medical Officer and each State and Territory Health Minister, or may make temporary additions without consulting state and territory health ministers. Temporary additions may not be subject to the usual assessment process.

For status as a nationally notifiable disease to have any practical effect, the disease must be notifiable in the states and territories, as this will provide the basis for laboratories and state and territories to collect the information under jurisdictional public health legislation.

In 2014, the Communicable Disease Network Australia (CDNA) endorsed a set of criteria (Appendix 1) to guide assessment of the need for inclusion of a disease on the NNDL, in order to advise the Minister for Health. The criteria are based on a system of scoring developed by the Public Health Agency of Canada (PHAC) which is designed to assist in determining surveillance priorities.¹ CDNA had previously developed and endorsed a system in 2008 based on the Centers for Disease Control and Prevention surveillance goals², but the system allowed too much variation in the way that diseases may be assessed, and the goals and criteria were vague and the criteria were never published.

Under CDNA criteria, diseases are ranked against 12 criteria that assess public health priority and feasibility of collection (Appendix 1). Public health priority criteria include: necessity for public health response, utility and significance of notification for prevention programs, vaccine preventability and, importance for Indigenous health. Feasibility criteria include: a case is definable, data completeness is likely to be acceptable and alternative surveillance mechanisms. The guide to how to assess and score the answers to each criterion will ensure consistency of scoring over time and between different assessors.

NNDL assessments and associated approval and legislative processes are co-ordinated within the Office of Health Protection (OHP) in the Australian Government Department of Health.

From time-to-time, it may be necessary to consider the removal of a disease from the NNDL, or to make a change to the name of a disease. The criteria for assessing the need to add a disease to the list may be used to assess the future need for national notification of a disease which is already on the list. A truncated consultation and approval process should be undertaken for changes to the list that are of a more minor nature, such as renaming, or separately listing a subset of notifications from one category into a new category.

Abbreviated assessment process for minor changes

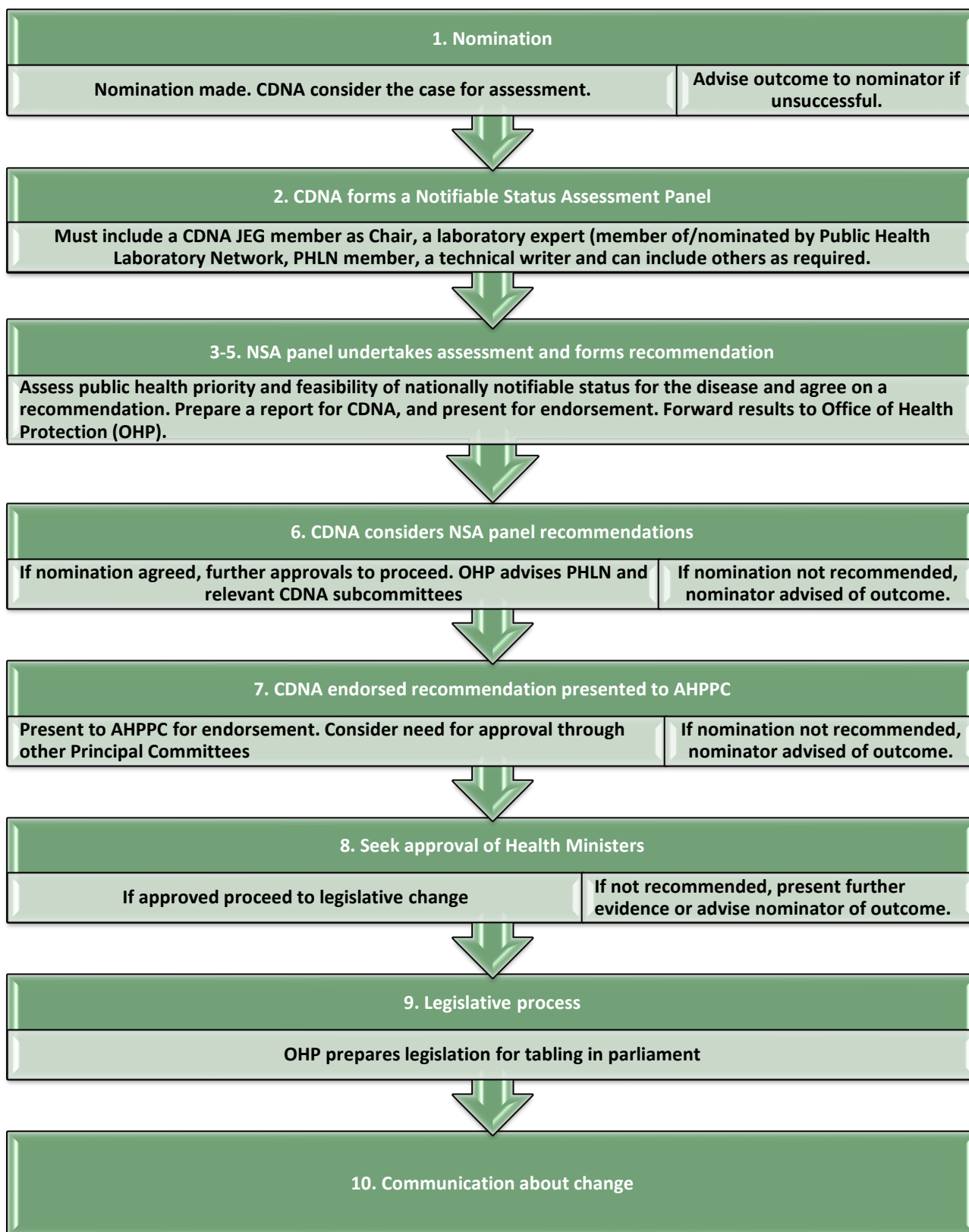
Changes that are administrative in nature, or which do not represent a change of priority or resource allocation usually require only consultation with affected stakeholders (usually through CDNA subcommittees). There is usually no need for the formation of a Notifiable Status Assessment (NSA) panel, or for a full assessment to be undertaken.

Examples of minor changes include changes of name (such as arbovirus NEC to flavivirus unspecified to match the case definition), or the moving of a given serovar, or of infection of unspecified duration, for a disease that is already notifiable to be notified under a separate disease code.

Once an administrative change is endorsed by CDNA, the approval process is the same as for major changes (steps 7 to 10 outlined in the process diagram and sections below).

Process summary diagram

Figure: Summary of the process of modifying the National Notifiable Diseases List¹



¹ Note that there is a separate abbreviated assessment and consultation process for changes of an administrative nature, which usually does not require the formation of an NSA Panel. See page 2.

Detailed nomination and assessment process for major changes

1. Nomination of a disease for national notifiable status

A CDNA member, an expert disease committee (sub-committee of CDNA), an AHMAC Principal Committee, a state or territory Chief Health/Medical/Public Health Officer, the Australian Chief Medical Officer or any State or Territory Health Minister can nominate a disease for assessment for addition or deletion from the list. Nominations are passed to CDNA in writing. Nominators would need to outline their reasons for nominating a disease, and how these reasons are informed by the NNDL criteria (Appendix 1).

Note: Temporary additions to the NNDL may not be subject to this assessment process and may not be nominated to CDNA.

2. CDNA agreement to undertake an assessment and formation of Panel

If required, CDNA will discuss whether a sufficient case has been made for assessment and provide feedback to the nominator. Nominations are normally automatically assessed, unless there are compelling reasons not to undertake an assessment, such as if findings of a recent assessment recommending against national notification are thought to still apply.

If CDNA agrees to undertake an assessment, it will nominate an NSA panel. An NSA panel must include:

- a CDNA JEG member (chair);
- a laboratory expert from the Public Health Laboratory Network (PHLN) or nominated by PHLN;
- a public health unit representative (including people involved in frontline roles in jurisdictions such as Victoria with a centralised public health agency); and,
- a technical writer.

It may also include other experts and stakeholders drawn from CDNA or elsewhere and should ideally include at least one trainee who can gain experience through undertaking the assessment.

3. Operation of the NSA Panel

Background material is developed by the technical writer for the panel. The working group meets by teleconference to undertake an assessment against the CDNA criteria and prepare a report for CDNA on the outcomes of the assessment. Meetings are organised and documented by the technical writer, including the rationale for each criterion assessment, as per the reporting template (Appendix 2). The technical writer also drafts the report, which must be agreed by all members of the panel.

The technical writer should forward the results of the assessment to the OHP officer who coordinates NNDL assessments (via the CDNA secretariat for technical writers who are not OHP staff) for collation into a spreadsheet to facilitate the two year review (see section – Review of Criteria).

4. Guide to conducting the assessment

Diseases are ranked against 12 criteria that assess public health priority and feasibility of collection (Appendix 1). Public health priority criteria include: necessity for public health response, utility and significance of notification for prevention programs, vaccine preventability and, importance for Indigenous health. Feasibility criteria include: a case is definable, data completeness is likely to be acceptable and, alternative surveillance mechanisms. The guide to how to assess and score the answers to each criterion which are listed with the criteria ensure consistency of scoring over time and between different assessors.

The maximum score possible is 48. Following scoring, thresholds for action could be applied, and these have been set as:

- < 15 national notification not recommended
- 15 to 25 national notification to be considered further
- 26+ national notification recommended

5. Forming a recommendation

The panel utilises the thresholds for action, further discussion and their professional judgment in forming a recommendation regarding inclusion/non-inclusion on the NNDL. It is important to note that the score obtained for a disease may not direct the final recommendation of the panel. The expertise and judgement of the panel is required in making the overall assessment. There may be critical issues that should prevent/compel national notification, but which aren't reflected in the score obtained.

For diseases falling within the threshold requiring further consideration, the NSA panel could consult with the full CDNA committee if required, seek other expert opinion or input and could consider a range of factors specific to a particular condition and achieve consensus about whether or not to recommend notification. Any further considerations should be documented and justified. Disease specific considerations could include but not be limited to the following:

- AIDS – national notification would not be required because all cases are already notified for public health action under HIV.
- Flavivirus unspecified–low levels of public concern about these particular infections (although not for mosquito-borne diseases generally) along with low rates of infection and mild symptoms may lead to a low score, but monitoring the emergence of new flaviviruses is very important.
- Campylobacteriosis–a very high burden disease but with little to no follow-up currently feasible, however, monitoring notifications allows an understanding of the efficacy of controls at the primary production level, and future technologies such as whole-genome sequencing may enable outbreak detection.
- Emerging trends overseas could indicate a need for close monitoring of a disease which currently is of marginal interest to public health

Endorsement, approval and legislative process

6. Recommendation to CDNA and CDNA outcome

The findings of the NSA panel should be presented to CDNA at a meeting, with a recommendation about whether the disease should be included on the NNDL. The outcomes of CDNA discussion and next steps may be one of the following options, and the process may be iterative:

- CDNA endorses a recommendation that a disease should be made notifiable and consultation and approval continues; OR
- CDNA does not endorse the finding of an NSA panel and the NSA panel should be asked to reconsider the nomination in the light of CDNA's comments; OR
- CDNA decides that a nomination should not proceed (whether on the advice of the panel or against it) and the nominator will be provided with the outcomes of the assessment and any additional comments from CDNA, in the form of a letter from the Chair. PHLN and relevant CDNA subcommittees should be advised at this point, including provision of the assessment report.

7. CDNA endorsed recommendation presented to AHPPC

The Office of Health Protection will process the report and recommendation of CDNA through the relevant committee secretariats. The recommendation of CDNA, including the report of the NSA panel will be presented to AHPPC, where the scientific and technical aspects as well as the policy implications will be considered. For some diseases, it may be relevant to present a recommendation to other AHMAC Principal Committees for consideration.

8. Approval of the Commonwealth and State and Territory Health Ministers

Paragraph 38(e) of the *National Health Security Agreement 2008* provides for AHPPC to advise the Commonwealth on additions or deletions to the NNDL. If AHPPC (and other Principal Committees if relevant) endorses the CDNA recommendation, the Office of Health Protection will initiate consultations first with the senior health officials in all jurisdictions through a submission to the Australian Health Ministers' Advisory Council (AHMAC); and then with all jurisdictional Health Ministers through the COAG Health Council (CHC).

9. Legislative process

In consultation with the Office of Parliamentary Counsel, the Office of Health Protection prepares legislation for tabling in parliament.

Communication of change

10. Advising relevant stakeholders and publication

Communication about the progress of making a change to the NNDL should be made at various steps during the process. Where a disease is to be added, it may be necessary to develop new laboratory and surveillance case definitions and prepare the national notifiable diseases surveillance system for transmission of notifications for the disease. At a minimum the following groups should be advised during the process:

- National Surveillance Committee
- Case Definitions Working Group
- PHLN
- Other relevant CDNA sub-committees (e.g. National Arbovirus and Malaria Advisory Committee)
- All state and territory health departments (via updating CDNA and AHPPC on the process of making a change).

A brief summary report about the change should be published in *Communicable Diseases Intelligence* as a short report. This should be undertaken by the technical writer and the other panel members.

Review of the criteria

CDNA has recommended a review of the criteria be conducted two years after CDNA endorsement (July 2016). The review will be co-ordinated by the Office of Health Protection.

References

1. Doherty, J.A., Final report and recommendations from the National Notifiable Diseases Working Group Canada Communicable Disease Report 2006;32.
2. Guidelines Working Group., Updated Guidelines for Evaluating Public Health Surveillance Systems. MMWR 2001;50(RR13):1-35.

Appendix 1 – Criteria for NNDL assessments

Criterion	Score	Guide for use
Priority setting		
<p>1. Necessity for public health response</p>	<p>0= not important for public health to know about a case</p> <p>1= case reporting important for describing trends only</p> <p>2= case reporting important for detecting outbreaks that require investigating or contacts require routine intervention</p> <p>3= case reporting important to detect outbreaks of cases and investigate contacts that require immediate intervention to prevent fatalities or severe outcomes</p> <p>4= a single case can be considered an outbreak or having the potential to cause an outbreak and requires immediate follow-up</p>	<p>Subjectively ranked, based on the need and efficacy of a response by public health authorities to prevent other cases of the disease, e.g. case and contact management, including need for national level responses, e.g. national input to contact tracing, funding of vector control programs, funding of vaccination programs, nationally-coordinated foodborne disease investigations. Other aspects to consider are:</p> <ul style="list-style-type: none"> • For monitoring emerging diseases • For other diseases, where prevention programs or a public health response may be required if there is a significant change in epidemiology • The need for consistent longitudinal data • Alternative surveillance mechanisms

Criterion	Score	Guide for use
<p>2. Utility and significance of notification for prevention programs</p>	<p>0 = No national prevention program / international or national regulation</p> <p>1 = Need to establish burden of illness for monitoring or research purposes / priority setting</p> <p>2 = Notifiable to the WHO but no regional / global targets for elimination or eradication</p> <p>3 = National prevention programs in place or WHO Western Pacific Regional Office (WPRO) targets for elimination or eradication</p> <p>4 = Security sensitive biological agent (SSBA) or WHO global targets for elimination or eradication / critical for monitoring prevention programs</p>	<p>Note: National prevention programs do not include vaccination here; that is covered by question 3.</p>
<p>3. Vaccine preventability</p>	<p>0= No vaccine available</p> <p>2= Vaccine available, but no national immunisation program</p> <p>4= Vaccine available, national immunisation program in place (including programs targeted at particular sub-groups)</p>	

Criterion	Score	Guide for use
4. Importance for Indigenous health	0= Low 2= Medium 3 = High 4 = Very high	<p>Low: Disease rates in Indigenous community similar to in non-Indigenous people, not an Indigenous health priority</p> <p>Medium: Disease rates similar or somewhat higher in Indigenous and non-Indigenous people, but severity higher in Indigenous people e.g. influenza</p> <p>High: Significantly higher disease rates in Indigenous people than in non-Indigenous people e.g. shigellosis</p> <p>Very high: Almost exclusively occurs in Indigenous communities and/or identified as a priority for prevention e.g. trachoma</p>
5. Emerging or re-emerging disease	0= has been stable, absent or declined in incidence over past 5 years 2= slowly re-emerging or increasing incidence/prevalence disease over the past 5 years 3= risk of emergence in Australia due to ecological or epidemiological change or importation 4= new, rapidly emerging disease in Australia	<p>Consider whether it is a newly appeared disease or an unexpected/unusual event and the factors that could modify its clinical and/or epidemiologic characteristics. These factors might include:</p> <ul style="list-style-type: none"> • Changes in demographic features, • Appearance/reappearance of the disease • Accumulation of susceptible people • Environment/climate factors • Changes in the ecology of vectors (including incursions of exotic vectors that would make local transmission possible). <p>Emergence may be overall, or in certain subgroups, and there may be concerns about strain replacement for vaccine preventable diseases.</p>

Criterion	Score	Guide for use
6. Communicability and potential for outbreaks	0= Not communicable or no outbreak potential 1= Low 2= Medium 3= High 4= Very high	<p>None: Not communicable, or no potential to cause outbreaks</p> <p>Low: Very high infectious dose, not environmentally stable, seldom transmitted to even close (e.g. sexual) contacts, enteric organisms <i>not known</i> to be transmitted person-to-person and vectorborne diseases. Conditions for transmission do exist in Australia, or previous outbreaks known to have occurred.</p> <p>Medium: Transmissible to very close contacts (including sexual contacts) only; respiratory pathogens that require prolonged (e.g. household) contact; enteric pathogens that may be transmitted via high dose in food or water. Small infrequent outbreaks possible.</p> <p>High: Transmissible to casual contacts; respiratory pathogens that are transmitted by droplets and may be passed to persons sharing the same airspace for several hours; enteric pathogens that require a low dose to be transmitted by food OR may be passed person to person via the faecal-oral route (e.g. hepatitis A; <i>Shigella</i>). Large or frequent outbreaks possible.</p> <p>Very high: Respiratory pathogens that are transmitted through fine aerosol and are potentially transmitted to anyone sharing the same airspace with the case. Potential to cause large, widespread, ongoing, devastating outbreaks.</p>

Criterion	Score	Guide for use
7. Severity and socioeconomic impacts	1= low severity and socioeconomic impacts 2= medium severity and socioeconomic impacts 3= high severity and socioeconomic impacts 4= very high severity and socioeconomic impacts	<p>Considered on a per case basis, without considering incidence or prevalence. The cost and severity of a single case, if there were one.</p> <p>Low: Short-term illness, and/or complete recovery in majority of cases, and/or case-fatality close to 0%/ low cost to community or health care system.</p> <p>Medium: Short or somewhat longer-term illness, and/or lengthy recovery in some cases, and/or case-fatality = 0% to 1%/low to medium cost to community or healthcare system.</p> <p>High: Long-term disability, and/or recovery rare, and/or death more likely, and/or case-fatality = 1% to 10% and/or medium to high cost to community or healthcare system.</p> <p>Very high: Severe illness, and/or death is most likely outcome, and/or case fatality = 10% to 100% and/or high cost to community or healthcare system.</p>

Criterion	Score	Guide for use
8. Preventability	0= no preventive measure 1= preventive measure available but low efficacy and/or uptake or acceptability 2= preventive measure with moderate efficacy /low acceptability or uptake 3= preventive measure with moderate efficacy/low side effects/acceptable uptake 4= preventive measure with high efficacy/low side effects/high acceptability and uptake	<p>Subjectively ranked, based on the efficacy (including risk/benefit) of available preventive measures, including, but not restricted to, vaccines. Consider the efficacy, acceptability but also uptake of available preventive measures.</p> <p>For diseases such as hepatitis C unspecified, this can be assessed as the efficacy of preventive measures to stop incident cases from becoming chronic. Hepatitis D is directly preventable as hepatitis B vaccination prevents against hepatitis D. A disease may be rated as having no preventive measure where a vaccine is not (yet) available in Australia.</p>
9. Level of public concern and/or political interest	1= no to low public concern or political interest 2= low to medium public concern or political interest 3= medium to high public concern or political interest 4= high public concern/perceived “crisis” situation if cases identified	<p>Subjectively ranked, based on the level of public concern and/or political interest associated with the disease, including media attention. Diseases where there is an unknown or unclear disease mechanism, immediacy of the effect of disease, fear of the unfamiliar/unknown, diseases mainly affecting mainly children, “identifiable victims” and not controllable by the public tend to be of increased concern. This is not measuring public perception of the chance of acquiring the disease.</p>

Criterion	Score	Guide for use
Feasibility of collection		
10. A case is definable	0= Case is difficult to define, or agreement between stakeholders on definition cannot be reached 2= A case is definable, but with complexities 4= Case has an acceptable laboratory definition without or without a clinical definition	
11. Data completeness is likely to be acceptable	1= Data likely to be incomplete, representing only a very small fraction of community cases 2= Data represent an proportion of community cases with a known undercount 4= Data likely to represent a high proportion of cases, or all cases.	
12. Alternative surveillance mechanisms	0=Robust, comprehensive and continuing alternative national surveillance mechanism in place e.g. HPV 2= Alternative surveillance mechanism in place, but not nationally co-ordinated, only sentinel sites or surveys, significant gaps or weaknesses e.g. rotavirus 4= No alternative surveillance mechanisms in place.	Where a robust alternative surveillance mechanism is in place, the need for national notification may be lower so diseases that are not covered by any current system score more highly on this criterion, regardless of any public health priority consideration.

Appendix 2-Template Report

Assessment of the need for national notification of [DISEASE]

[INSTRUCTIONS: This template provides the basic framework for reporting to CDNA on the outcomes of an NSA panel. Instructional text is in red, and should be replaced with relevant wording, or options chosen or deleted if not relevant]

Notifiable status assessment (NSA) Panel for the Communicable Diseases Network Australia (CDNA)

[DATE]

Summary

An NSA Panel nominated by CDNA assessed the need for national notification of [DISEASE] in Australia against CDNA and PHLN endorsed criteria. The NSA panel considered that [FINDING] [RATIONALE]. Using the current CDNA-endorsed criteria for assessing the need for national notification, [DISEASE] scored within the threshold for action “national notification recommended/national notification to be further considered/national notification not recommended”. National notification is [recommended/not recommended], and [should be progressed through AHPPC and the State and Territory and Australian health ministers with the endorsement of CDNA] [AHPPC should be advised of the outcome of the assessment for noting].

Introduction

The Australian Government Minister for Health may include a disease in the NNDL if the Minister considers that an outbreak of the disease would be a public health risk. In 2014, the Communicable Disease Network Australia endorsed a set of criteria (Appendix A) to guide assessment of the need for inclusion of a disease on the NNDL, in order to advise the Minister for Health. The criteria are based on a system of scoring developed by the Public Health Agency of Canada (PHAC) which is designed to assist in determining surveillance priorities.¹ CDNA had previously developed and endorsed a system in 2008 based on the Centers for Disease Control and Prevention surveillance goals², but the system allowed too much variation in the way that diseases may be assessed, and the goals and criteria were vague and the criteria were never published. These assessments are carried out by an NSA panel, consisting of a CDNA jurisdictional executive group member (Chair); a laboratory expert nominated by the Public Health Laboratory Network (PHLN); a local public health unit representative; a technical writer; and other experts drawn from CDNA or elsewhere, when required. On 30 July 2014, CDNA endorsed a revised set of criteria that enables assessment of the public health priority and feasibility of national notification for a disease, and result in a score that guides

further action. The NSA panel assess the disease against the CDNA endorsed criteria, and then develop a discussion paper for CDNA and PHLN with recommendations about whether surveillance for the condition would be useful, and the best method of surveillance as compared to other methods of disease monitoring (e.g., surveys, notifications, using existing datasets).

[DISCUSSION OF EPIDEMIOLOGY, PUBLIC HEALTH IMPACT, KNOWLEDGE GAPS, OBJECTIVES OF SURVEILLANCE (INCLUDING AS DEFINED IN SONG WHERE RELEVANT), DESCRIPTION OF CURRENT SURVEILLANCE MECHANISMS, LEVEL OF PUBLIC CONCERN]

At the CDNA teleconference on [date], members agreed to form a NSA panel to assess and make recommendations about whether [DISEASE] should be made nationally notifiable. [INSERT ANY FURTHER DETAILS ABOUT HOW AN NSA PANEL CAME TO BE NOMINATED e.g. LETTER FROM THE PUBLIC TO CDNA CHAIR]

For status as a nationally notifiable disease to have any effect, the disease must be notifiable in the states and territories, as this will provide the basis for laboratories and state and territories to collect the information under jurisdictional public health legislation. As at [DATE], [DISEASE] was notifiable in [LIST STATES AND TERRITORIES].

Other issues that may be discussed include the history of past assessments for the disease.

Composition of the Panel

The NSA panel comprised:

- [NAME], CDNA jurisdictional executive group member [JURISDICTION]
- [NAME],[EXPERTISE/REPRESENTATION/ROLE]
- [NAME],[EXPERTISE/REPRESENTATION/ROLE]
- [NAME],[EXPERTISE/REPRESENTATION/ROLE]
- [NAME],[EXPERTISE/REPRESENTATION/ROLE]
- [NAME],[EXPERTISE/REPRESENTATION/ROLE]
- [NAME],[EXPERTISE/REPRESENTATION/ROLE]

Assessment against CDNA endorsed criteria 2014

The NSA panel assessed the need for national notification against the 12 criteria endorsed by CDNA in 2014. The scoring matrix, the assessed scores for [DISEASE] and the explanation for each of the scores is at appendix A. Possible scores under the revised criteria range from 0 to 48, with thresholds for action set as <15 national notification not recommended, 15 to 25 national notification to be considered further, and 25+ national notification recommended (unless there are compelling reasons not to recommend this). The score for [DISEASE] was [SCORE], thus [national notification is recommended/to be considered further/not recommended].

[SUMMARISE AREAS WHERE DISEASE SCORED HIGHLY OR OTHER IMPORTANT FEATURES]

International public health significance and notification practices

[RELEVANT INFORMATION]

Further considerations (if required)

This is particularly relevant where a score for a particular disease fell within the range 15 to 25, “further consideration required” but can also be relevant where there are critical issues that prevent/compel national notification, but which aren’t reflected in the score. The score should not be considered an absolute guide to the outcome. The overall assessment still relies on the expertise and judgement of the panel members.

Recommended monitoring

This is particularly relevant where the NSA panel has assessed that national notification is not recommended. Alternatives to national notification or additional monitoring (if required) should be described here.

References

[INSERT]

Other sources of information

[LINKS]

Appendix A – Reporting template- Assessment against CDNA criteria for national notification of [DISEASE]

Criterion	Score	Notes/explanation for scores given
Priority setting		
1. Necessity for public health response		
2. Utility and significance of notification for prevention programs		
3. Vaccine preventability		
4. Importance for Indigenous health		
5. Emerging or re-emerging disease		

6. Communicability and potential for outbreaks		
7. Severity and socioeconomic impacts		
8. Preventability		
9. Level of public concern and/or political interest		
Feasibility of collection		
10. A case is definable		
11. Data completeness is likely to be acceptable		
12. Alternative surveillance mechanisms		