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Not everything that can be counted counts: defining and evaluating tuberculosis mortality in Australia

Justin T Denholm on behalf of the National Tuberculosis Advisory Committee

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Justin T Denholm on behalf of the National Tuberculosis Advisory Committee

Background

Mortality is a critically important statistic recorded by healthcare services and tuberculosis (TB) programs globally and is used as a marker of the overall effectiveness of management and services.^{1,2} Data on TB mortality are compiled by the World Health Organization and other bodies, and targets for reduction in TB mortality are central to the End TB strategy.^{3,4} However, while death is an objectively defined outcome, there are concerns that classification whether a death is ‘TB-related’ may have significant variation between settings and practitioners.⁵ Although over-inclusive approaches to reporting—such as all-cause mortality within a period following TB disease onset—avoids some issues, it may limit recognition and correction of specific drivers of poor outcome, particularly in settings where TB is frequently co-existing with other potentially fatal conditions. The Australian National Tuberculosis Advisory Committee (NTAC)ⁱ considers accurate and consistent classification of TB-associated mortality to be a high priority for programmatic monitoring and strengthening, and this consensus statement has been developed to assist in optimising Australian classification and evaluation of death potentially associated with TB.

Classification of mortality in Australia

In Australia, cause of death certification is multi-tiered. A primary cause of death, and antecedent factors leading to the cause of death, are required to be reported.⁶ In addition, medical

practitioners certifying death may nominate other conditions present which are judged to have contributed to death, even if they were not directly related to the cause. In theory, such a classification system should allow for consideration of a range of factors relating to death associated with a TB notification. However, there are a variety of reasons jurisdictional TB mortality data may be inaccurate, and classifications vary. Assigning cause of death can be complicated, and frequently clinical judgement plays an important role. Cause of death may be centrally recorded by programmatic staff with a variable amount of direct involvement in management. In some published series with detailed review, up to half of deaths among notified TB cases were not considered primarily caused by TB, so incorrect classification may have substantial impact on mortality and case fatality estimates.⁷ While TB notification is mandatory in Australia, TB programs do not typically have routine access to individualised death certificates or data unless generated by program staff, and so death occurring after treatment completion or loss to follow up may be unrecognised.⁸

Empiric evaluation of TB mortality classification

Prior to developing policy regarding optimal classification, NTAC recognised that understanding variation in classification and the reason for differences was important for improving the reliability and consistency of reported TB-associated mortality. We therefore undertook a survey of clinicians and public health practitioners in Australia to explore variability in TB-associated death classification.⁹

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Respondents were presented with a series of hypothetical scenarios involving potentially TB-related death, and asked to classify mortality using several approaches. This survey identified broad consensus in classification where death was directly associated with TB disease progression, such as in the case of death from pulmonary haemorrhage in untreated pulmonary TB. It also found several areas where there was considerable variation in practice, including disagreement regarding the classification of death associated with medication adverse effects, non-microbiologically-confirmed TB, and cardiovascular death occurring during TB treatment.

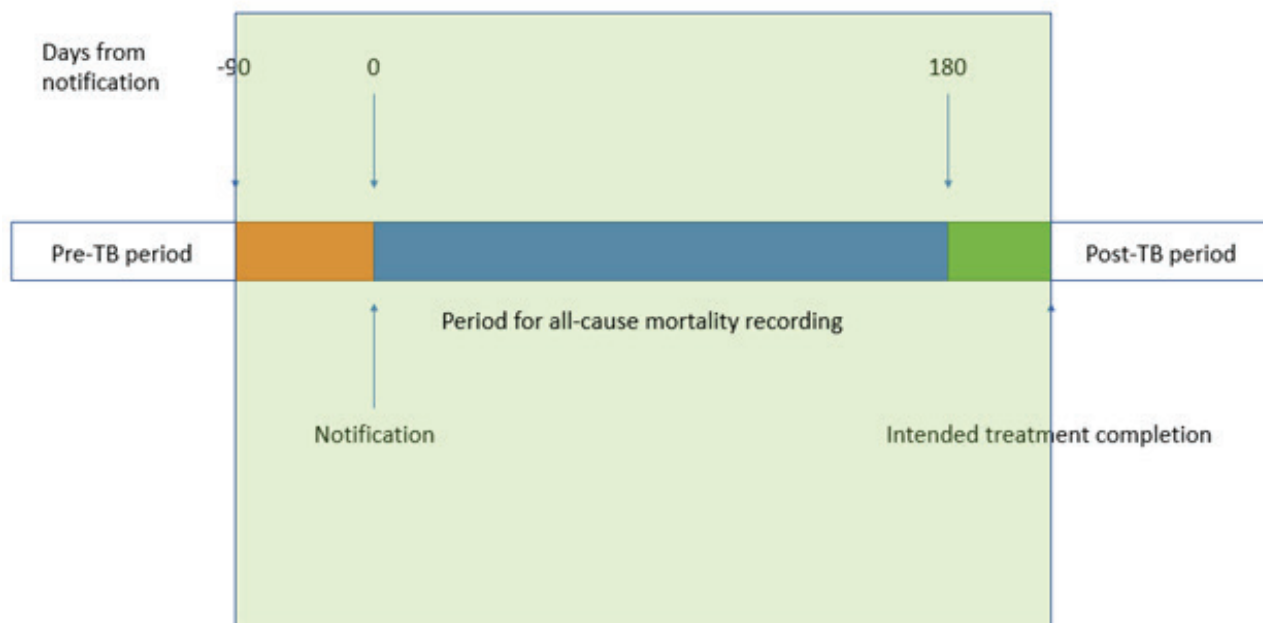
NTAC consensus statement

Collection of data regarding TB-associated death by programmatic services is primarily to allow opportunities for improvement of response and reduction in mortality. It follows, then, that to be maximally useful, potentially TB-associated death should not be excluded from classification without a clear basis. This committee therefore takes the view that collection of all-cause mortality, supplemented by expert review regarding likely primary cause and secondary contributors to death, is most appropriate.

Jurisdictional TB programs have most ready access to TB-related outcomes during the period of active disease management; that is, from the time of case notification to the intended completion date. The intended completion date may vary, based on factors such as drug susceptibility testing, adherence, initial burden of disease or interruptions to treatment, but will not be less than 180 days from treatment initiation (Figure 1). We intend to maintain this definition even in the event that future treatment protocols allow shorter durations of therapy than currently in use, to support maximal continuity of outcome monitoring. Death occurring during this period should be recorded, whether patients are actively receiving anti-TB therapy at the time of death or not. For programmatic purposes, deaths occurring up to 90 days prior to TB notification should also be included, such as may occur when mycobacterial cultures become positive after death, or where the findings of a post-mortem examination indicate TB.

This committee regards death occurring subsequent to completion of TB therapy as also being an important area for consideration. However, not all jurisdictions will have routine access to outcome data beyond successful completion of therapy, and data may be incomplete. While beyond the remit of this committee, we therefore

Figure 1: Timeframe for all-cause mortality recording of TB-associated deaths



encourage alternative approaches to assessment of post-TB outcomes in an Australian context including (but not limited to) mortality, such as by data linkage and/or longitudinal studies.

Committee plans for oversight/monitoring/review

Following from this consensus, NTAC will adopt several strategies for ongoing review of TB-associated mortality. This statement will be distributed to jurisdictional TB program managers, in order to support inclusion of all appropriate episodes. NTAC will convene an annual meeting in which a summary of TB-related deaths will be presented for expert review, including classification of whether TB should be considered as the cause of death, a contributor to death, or unrelated to death, and interjurisdictional review focused on potentially-avoidable deaths. A voluntary data collection instrument has been developed to support jurisdictions in this process, and is attached as Appendix A. TB will be considered the cause of death if due to adverse effects to TB medications. Following classification, NTAC will also consider themes and potentially-remediable issues which may support jurisdictional responses to reduce TB mortality in future. Periodically, NTAC will produce summary reports addressing overall and thematic issues relating to TB mortality and interventions to improve outcomes.

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Appendix A: Data collection instrument

TB MORTALITY ASSESSMENT FORM									
INSTRUCTIONS		When to complete this form							
		Death occurring during intended TB treatment period, or between 90 days prior and 180 days after notification							
Jurisdiction		Managing clinician or as otherwise programmatically determined. Forms will be used to inform jurisdictional and NTAC review of mortality							
Demographics									
Pt last name	Pt last name	First name	Unique identifier						
DOB	DOB	Date of notification							
Country of birth	Age at onset of event	Treatment initiation date							
Drug susceptibility results		Date of death							
		Intended completion date							
Relevant or major medical conditions / events (other than TB)									
Condition	Description/details (optional)	Date or year of onset if known	Continuing at time of death? (Y/N)	Date or year of recovery					
1. eg HIV, if none, please write 'none'	Description/details (optional)	Date of onset	Y/N	Date of recovery					
2									
3									
MEDICATIONS (taken in 30 days prior to death)									
	Dose	Frequency	Start date	Stop date	Continuing? (Y/N)				
1									
2									
3									
4									
5									
6									
OTHER Meds	Dose	Frequency	Start date	Stop date	Continuing? (Y/N)				
1									
2									
3									
4									
5									
Narrative description of events leading to death									
Description/narrative (include dates)									
Relevant lab results with dates	(LFTs, FBE, UEC, other) - attach with email if available								
Delayed diagnosis	Y/N	Communication error	Y/N	Adverse drug reaction	Y/N	Treatment adequacy	Y/N	Mental health issues	Y/N
Factors judged as contributing to death	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Record outcome	Y/N
Clinician assessed cause of death?									
Person completing form									
Institution	Name	Email	Phone						