

**MTAA Comments to the Australian Commission on Safety and Quality
in Health Care (ACSQHC) Consultation on the
Framework for Australian Clinical Quality Registries:
Prioritisation of Clinical Quality Registries Discussion Paper**

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MTAA welcomes the opportunity to attend the Australian Commission on Safety and Quality in Health Care (ACSQHC) consultation workshop on clinical quality registries to participate in the discussion of the Framework for Australian Clinical Quality Registries.¹

In relation to clinical quality registries in Australia, MTAA continues to hold the view that well-designed registries can provide postmarket *'safety and effectiveness data which in turn would enable a less burdensome premarket approval process for high risk implantable devices without compromising the overall safety and wellbeing of patients'*.² MTAA recommends that government consider these factors in determining their priorities for future establishment of clinical quality registries and that registries are established based on clinical need and operates in accordance with the principles for Australian Clinical Quality Registries.

MTAA acknowledges the ACSQHC's effort in developing the Framework and for providing various relevant stakeholders the opportunity to discuss and provide comment on the Discussion Paper ('Paper') *'Prioritisation of Clinical Quality Registries'*.³

The Paper, as presented, includes a set of prioritisation criteria for Australian Clinical Quality Registries, which is to identify a list of clinical domains for potential development of national clinical quality registries that involves a cost burden analysis (for costed infrastructure model for clinical quality registries), clinical practice guideline identification and environmental scans.

MTAA shares ACSQHC's view in that *'clinical quality registries offer a better model of measuring quality of care' and that there are existing 'barriers to national reporting include restrictions on the disclosure, collection, and use of patient-level data, varying hospital and jurisdictional data governance arrangements'*.¹

In response to the Framework and Paper, MTAA expresses the following key issues and concerns in relation to the processes and prioritisation of the clinical quality registries:⁴

- **The process and outcomes to achieve are unclear: aim, objectives and methodology are unclear**
 - What problems are we trying to solve?
 - The methodology as described in Table 2 of the Paper⁵ is unclear. Although the methodology was discussed at the stakeholder meeting, the method to developing the list of prioritisation criteria remains unclear - as many stakeholders expressed at the meeting.
 - The method used to develop the criteria (Clinical Domains) is also not clear. This was not explained clearly at the stakeholder meeting.
 - The objective to developing the list of 'Clinical Domains' and 'Prioritisation Criteria' needs to be explained clearly - in the Paper and at stakeholder consultation.
 - MTAA is pleased that a broad range of stakeholders (including representation from the medical technology industry) have been invited to participate as part of the consultation of the Discussion Paper. Relevant stakeholders including MTAA however, were not consulted for the development of the lists of 'Prioritisation Criteria' and 'Clinical Domains'. Further opportunity to review the developed lists should be provided to all relevant stakeholders.

1 Australian Commission on Safety and Quality in Health Care (ACSQHC). Framework for Australian clinical quality registries. Sydney. ACSQHC, March 2014.

2 MTAA Submission to the Medicines and Medical Devices Review Taskforce - September 2015. Available: www.mtaa.org.au/docs/submissions/mtaa-submission---mmdr-taskforce---sept-2015---final.pdf?sfvrsn=2

3 ACSQHC. Prioritisation of clinical quality registries Discussion (paper by Clayton Utz). March 2016.

4 MTAA expressed at the Sydney Stakeholder meeting held on March 29, 2016.

5 ACSQHC. Prioritisation of clinical quality registries Discussion paper by Clayton Utz). March 2016 Page 6.

- **List of Clinical Domains: Inappropriate and limited**
 - The role of clinical quality registries is to: provide measurement and benchmarking of high significance clinical procedures, monitor the safety of new devices, drugs and surgical procedures, and collect minimum dataset from patients at participating hospitals/sites. *'Outcomes reported by registries are measured in a systematic way using identical definitions across all sites'*.⁶
 - High cost data as presented in the Paper is not an accurate reflection of the high burden of cost (disease) in Australia. Further, the prioritised list, as presented currently, is not a 'true' reflection of the Australian high burden of disease. For example, overweight and obesity, which is the second highest contributor to the Australian burden of disease⁷, was not included in the list, however, 'road traffic accidents', which is not considered clinically as 'disease', is included.
 - Use of only 'Assessment of burden of disease' and the 'National Health Cost Data Collection' - to identify the clinical domains and indication for cost analysis – is highly inappropriate and quite limiting. The use of only two prioritised criteria would be inadequate to highlight the purpose and the benefits clinical quality registries provide to improving patient outcomes and the safety and quality of healthcare to drive quality improvement.
 - The clinical domains as presented only capture hospital separations i.e. hospital admissions, and therefore out-patient data (i.e. patient outcomes) would not be captured. Furthermore, treatment and management of many chronic diseases, e.g. diabetes, are usually not performed in a hospital setting.

- **Feasibility and sustainability of new and existing registries in Australia is important**
 - Registries offer 'value for money' to the Australian healthcare system – based on preliminary data of 5 existing registries in Australia.⁸
 - *'Well-designed registries are extremely costly and careful consideration needs to be given to defining areas of high risk for selection and implementation of a registry. The indiscriminate use of registries is not only costly and burdensome but can also stifle innovation and be unachievable for niche technologies and low revenue technologies'*.²
 - Despite the key purpose of clinical quality registries and the cost/benefits (patient outcomes and 'value for money') registries provide to the Australian healthcare system, the 'funding' of registries was not included in the Discussion Paper and will not form part of the scope of the consultation.
 - The Paper states that 'high-cost, high-volume clinical domains is insufficient include cardiology and cardiac surgery, stroke and hip fracture' and discusses the existing registries in Australia and overseas. However, in Australia, there is expectation that registries involving medical technology should be funded solely by the industry. For example, orthopaedic companies with devices listed on the Prostheses List and tracked by the National Joint Replacement Registry (NJRR) must pay a registry levy to the Department of Health but are unable to recoup these costs through charges.²
 - Cost of developing, operating and maintaining registries is high. With the use of the proposed methods and lists as presented in the Paper, the results and outcomes are unlikely to be useful to develop an appropriate cost infrastructure model to support the sustainability of existing and new Australian clinical quality registries.
 - In other jurisdictions, sustainability of registries is achieved due to multi-stakeholder funding. Feasibility and sustainability models for registries developed overseas should be explored and adopted to ensuring sustainability of registries in Australia and that registries continue to provide benefits to the Australian healthcare system and patients.
 - MTAA recommends that the Framework and Paper include the funding process of registries to ensure the appropriate feasibility and sustainability models are implemented, and that the industry should not be left to bear all costs.

- **Transparency of registry process including data collection and access**

⁶ Monash University. Clinical Registries. Available at: www.med.monash.edu.au/epidemiology/units-centres/registries/

⁷ AIHW. Overweight and obesity. Available at: <http://www.aihw.gov.au/overweight-and-obesity/>

⁸ Presentation by Ms Catherine Katz, ACSQHC at the Sydney Stakeholder consultation meeting held on 29 March 2016.

- Transparency of the process and methodology to data collection and access i.e. ownership vs custodians of registry data, needs improvement.
- The Framework and the prioritisation (lists and processes) of clinical quality registries in relation to data collection, should ensure 'all aspects of patient treatment and care, including patient selection, treatment protocols, physicians' technique and learning curve, and hospital factors such as infection control' is captured appropriately and will be useful i.e. as holistic healthcare system approach.

MTAA wishes to recommend to the ACSQHC that future establishment of clinical quality registries should be based on need (clinical) and established in accordance with ACSQHC's guidelines and operating principles. Importantly, funding for registries should be considered as part of the Framework – to ensure that clinical registries in Australia remain sustainable and equitable.

MTAA trusts the ACSQHC considers these recommendations for implementation of the proposed Framework and Prioritisation of Australian Clinical Quality Registries.

We look forward to continue to work with ACSQHC on registry matters and participation in future consultations.