Avant
By doctors for doctors

Avant Mutual Group Limited
ABN 58 123 154 898

Registered office
Level 6, Darling Park 3
201 Sussex Street, Sydney NSW 2000

Postal address
PO Box 746 Queen Victoria Building
Sydney NSW 1230

DX 11583 Sydney Downtown

avant.org.au

Telephone 02 9260 9000 **Fax** 02 9261 2921
Freecall 1800 128 268 **Freefax** 1800 228 268

29 March 2023

Dr Bernadette Aliprandi-Costa
Australian Commission on Safety and Quality in Health Care

By email: CQR@safetyandquality.gov.au

Dear Dr Aliprandi-Costa

Avant Submission to the Consultation Paper: National Consultation on Framework for Australian clinical quality registries

Thank you for the opportunity to provide a response to the consultation on the framework for Australian clinical quality registries conducted by the Australian Commission on Safety and Quality in Health Care.

Our submission is attached.

Please contact me on the details below if you require any further information or clarification of the matters raised in the submissions.

Yours sincerely

Georgie Haysom
General Manager, Advocacy, Education and Research
Email: georgie.haysom@avant.org.au

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Avant Submission to the Consultation Paper: National Consultation on Framework for Australian clinical quality registries

Avant is a member-owned doctors' organisation and Australia's largest medical indemnity insurer, committed to supporting a sustainable health system that provides quality care to the Australian community. Avant provides professional indemnity insurance and legal advice and assistance to more than 82,000 healthcare practitioners and students around Australia (more than half of Australia's doctors). Our members are from all medical specialities and career stages and from every state and territory in Australia.

We assist members in civil litigation, professional conduct matters, coronial matters and a range of other matters. Our Medico-legal Advisory Service provides support and advice to members and insured medical practices when they encounter medico-legal issues. We aim to promote quality, safety and professionalism in medical practice through advocacy, research and medico-legal education.

Avant supports the purpose of Clinical Quality Registries ("CQRs") to improve patient care, as articulated in the introduction to the Framework for Australian clinical quality registries (second edition) (the "Consultation Framework"). We acknowledge that there is much to be gained from improvements associated with the national collection of data in areas of clinical practice. It is an opportunity to ensure that clinical outcomes as well as morbidity and mortality rates can be benchmarked against acceptable standards and thresholds.

At the same time, it is important to ensure that necessary measures are in place to protect the data collected from misuse or manipulation. Misuse could undermine the aim of improving patient safety, generating reluctance or fear on the part of organisations and individuals contributing their data. It could result in under-reporting of complications or the "cherry picking" of low-risk patients at the expense of higher risk patients.

Our primary recommendations regarding the Consultation Framework are:

1. That it should refer to the findings of the *Legislation and regulation relating to clinical quality registries final report* and provide guidance for when a CQR should be subject to qualified privilege in accordance with Part VC of the *Health Insurance Act 1973* (Cth) (and/or the equivalent relevant state and territory legislation).
2. That the "outlier" approach (section 1.8) should be amended to ensure that the governing body liaises with the appropriate clinician or health service or entity before any "outlier" results are reported under those provisions.

Our recommendations aim to preserve the purpose of CQRs to improve the safety and quality of healthcare, while ensuring that there are no unintended negative consequences for the clinicians and health services delivering that care.

CQRs as quality assurance activities

The Consultation Framework refers to some CQRs being Declared Quality Assurance Activities (QAA)[1] and includes a requirement that all CQRs must have a "robust quality assurance plan". However, there is no direct reference to when or how a CQR should apply for a declaration that it is a QAA.

The reference to having a quality assurance plan is made in relation to data quality but the principles and purpose behind CQRs go beyond that. While the protections attached to the declaration under Part VC of the *Health Insurance Act 1973* (Cth) will not be relevant to all CQRs, we recommend the availability of that pathway should be made clear in the Consultation Framework.

We recommend that this could be included in section 1.3 regarding Governance. The section could refer to the legislation itself and the *Legislation and regulation relating to clinical quality registries final report*, which outlines when a CQR should be subject to qualified privilege. This will help preserve the purpose of CQRs.

Comments on 1.8. Outlier measurement and oversight

Avant supports the opportunity to recognise consistently excellent care as articulated in section 1.8 of the Consultation Framework. We support the recommendation in the Consultation Framework that a clinician or health service with "consistently excellent" performance is encouraged to "share their best practice processes so others can learn from them".

However, we are concerned about the potential unintended consequences that may result from the proposals for clinicians who are determined to be "outliers" as described in section 1.8. Specifically, section 1.8 suggests that, like a fire alarm system, the threshold for reporting should be relatively low to identify "*situations where patients may be possibly exposed to harm*"[2], and acknowledges that in setting a low threshold, there may be some false positive results. With a low threshold for "alarm" many clinicians and units will be identified as outliers even when their clinical care is to an acceptable standard.

The proposal fails to account for the risk associated with these false positives and does not build in any mechanisms to ensure the appropriate balance can be struck between the level of any false positives and the risk of those false positives to the clinicians involved. These risks include reputational damage which can have serious and long-term consequences for the clinician's ongoing employment and registration and also their health and well-being. Registries should not be used as an instrument to identify or apportion blame. If a practitioner is suspected of being an outlier and is found on further analysis to be meeting acceptable standards, it may be too late to repair this damage.

[1] See for example, Consultation Framework, 2nd edition, page 5 and page 31.
[2] Consultation Framework, 2nd edition, page 33.

Some clinicians or units may be identified as “outliers” in circumstances where there is a reasonable explanation for the variations in their data. For example, they may have an area of special interest where they manage patients with more severe conditions. In many cases, patients are referred to those clinicians by their peers because their additional expertise. Smaller hospitals and rural centres usually have less resources and sub-specialty support than larger metropolitan hospitals. Without appropriate safeguards on how “outlier” data is managed, it is possible that the CQR could become a barrier to clinicians providing otherwise appropriate care, for fear of the action taken in relation to their results captured in the CQR.

Therefore, we recommend that the CQR governing body should first raise any results regarding an “outlier” with the relevant clinician or health facility directly for discussion, before any further investigation or reporting take place. This would allow for relevant information to be gathered regarding the cause of the anomaly, or to inform a decision that further investigation is needed. Appropriate time needs be allocated for this information to be gathered as it may involve careful review of multiple patient files.

We support the recognition in the Consultation Framework regarding the role of peers and medical specialist colleges and societies in supporting clinicians who have had variations identified[3].

Depending on the model adopted, the CQR governing body is unlikely to be the appropriate entity to investigate the relevant activities at any given centre. Therefore, the first step should be to obtain further information directly from the clinician or health service involved. This would ensure there is a thorough and objective investigation of the cause for any “outlier” results. It would allow early identification of false positives in advance of release of details to a wider audience. Without this, the Consultation Framework could be regarded as not supporting a “just culture”: a culture that seeks to improve performance rather than apportion blame and isolate practitioners who may or may not be “outliers”.

Requiring immediate reporting of “outlier” results beyond the relevant health facility in the first instance may also result in a loss of clinician confidence in providing data to CQRs. If this occurred, it would have a detrimental impact on the primary objectives of the Consultation Framework, weaken the data's reliability and reduce its capacity to enable change and improvement. If there is a concern about a clinician’s results, this could then be addressed through the existing reporting pathways.

In summary, Avant supports the purpose of CQRs to improve the safety and quality of patient care. In order to achieve that purpose, it is important that clinicians have confidence in actively and honestly participating in the CQR process without fear of being unfairly identified or targeted.

Avant Mutual
29 March 2023

[3] Consultation Framework 2nd edition, page 33.