s22

From: s22 on behalf of CQR Policy
Sent: Monday, 20 November 2017 1:39 PM
To: s22
Subject: FW: Request for Feedback: Cardiac Devices Register [DLM=For-Official-Use-Only]
Attachments: CQR - Information Brief - CDR Contract for Services.docx

FYI

From: s22
Sent: Friday, 17 November 2017 3:57 PM
To: s22 CQR Policy
Subject: FW: Request for Feedback: Cardiac Devices Register [DLM=For-Official-Use-Only]

Hi s22

I could not meet the 2 pm deadline you have set due to a number of competing deadlines.

The minute is well written and I don't have editorial comments. Here are some substantive comments.

About this line: "ACOR has not considered TGA advice on the dataset requirements for the CDR."

It is a fact that the CDR as it is currently set up will not generate information that will meet our data requirements, but I don't know that they have not "considered our (the TGA's needs". The story is more complicated. However the minute presents this as a key finding of the Health Consult Review, not as the view of the TGA itself, so I think that it's OK to leave it as it is.

s22

Regards

s22
Principal Scientific Adviser
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Phone s22
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From: s22 **On Behalf Of** CQR Policy
Sent: Friday, 17 November 2017 12:51 PM
To: s22
Cc: CQR Policy
Subject: Request for Feedback: Cardiac Devices Register [DLM=For-Official-Use-Only]

Good afternoon s22

Thank you for your time on the phone. The Clinical Quality Registries Policy Section is developing a Ministerial Submission for the Cardiac Devices Register (CDR). The Contract for Services for the CDR ends on 31 December 2017. The Department has developed options for the progression of the CDR following an independent review of the CDR. The independent review, conducted by HealthConsult, assessed the effectiveness of current arrangements, identified options to improve or modify the arrangements, provide advice on strengthening future performance.

We would very much appreciate your feedback or input on the Ministerial Submission being prepared for the Minister. Please see attached a copy for your review.

If possible, and we apologise for the short notice, could you please provide your feedback or input by 2pm today? If you are unable to please let me know for planning purposes.

Thank you for your assistance, it is greatly appreciated. If you have any questions please feel free to contact me

Kind regards
s22

Clinical Quality Registries Policy Section | Performance, Evaluation and Quality Branch
Australian Government Department of Health
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MDP 10-12, PO Box 9848, Canberra ACT 2601

To: Minister Hunt
Subject: Cardiac Devices Registry
Critical date: 7 December 2017.

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Recommendation/s:	
1. Note	**1. Noted**
2. Agree to progress option 1	**2. Agreed/Not agreed/Please discuss**
3. Note	**3. Noted**
Signature …..……	**Date:** / /
Comments:	

Contact Officer:	*Nicholas Hartland*	*First Assistant Secretary, Research, Data and Evaluation*	Ph: (02) 6289 8776 Mobile: s22
Clearance Officer:	*Mark Cormack*	*Deputy Secretary, Strategic Policy and Innovation*	Ph: (02) 6289 3348 Mobile:

Issues:

1. An independent review of the Cardiac Device Registry (CDR) has identified that ACOR has not met its contractual requirement to establish a clinical quality registry (CQR) for cardiac devices that complies with the CQR principles and guidelines developed by the Australian Commission on Safety and Quality (the Commission).

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Independent Review

In accordance with the Contract for Services, an independent review of the Australian Breast Device Registry (ABDR) and the CDR was undertaken to assess the effectiveness of the current arrangements, identify options to improve or modify the arrangements, and provide advice on strengthening future performance. The Department contracted HealthConsult Pty Ltd to undertake the review in June 2017 and a final report was provided on 26 October 2017.

Note: ACOR was actively engaged in the review but have not yet been provided with the final report.

The key findings of the review include:

- The data collection is not consistent and does not align with the Framework for Australian clinical quality registries (the Framework) developed by the Commission.
- ACOR has not considered TGA advice on the dataset requirements for the CDR.
- There is a low level of stakeholder engagement and less than five percent of eligible sites (mainly public and private hospitals) are contributing data to the CDR.
- ACOR has not effectively engaged with their State and Territory counterparts (Victorian Cardiac Outcomes Registry, the Coronary Angiogram Database of South Australia or the Australian and New Zealand Society of Cardio Thoracic Surgeons), to promote greater participation in the CDR and leverage the success of State and Territory based registries.
- The CDR does not include outcomes and procedures data and therefore is unable to analyse device data in a way that is relevant for stakeholders.

[1] Australian Commission on Safety and Quality in Health Care (2014) *Framework for Australian clinical quality registries* p.7

- Stakeholders (particularly clinicians and hospitals) raised incentive payments, requirements for consent and the intellectual property of data as barriers to participation in the CDR.

A list of all the key findings resulting from the independent review is at **Attachment B**.

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Background

Independent Review of the Cardiac Devices Register

- In June 2017, the Department engaged HealthConsult to undertake an independent review of the CDR.
- The purpose of the review was to assess the extent to which the registry met or is likely to meet its objectives.
- HealthConsult is a member of the Department's evaluation panel.
- The final report will be provided to the Australasian Cardiac Outcomes Registry Ltd (ACOR) who manages the CDR.
- Total payment for the contracted review will be $199,870 (GST inclusive).
- A review has also been undertaken on the ABDR, which has shown it is performing well.

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Attachment B

List of Findings

Below are the findings that have resulted from this Review.

Aims and objectives of the CDR

F1 The aims and objectives of the CDR are well documented and align with the relevant Operating Principles within the ACSQHC Framework for Australian Clinical Quality Registries, reflecting best practice.

F2 There is strong support across all stakeholder groups involved in the implantation of cardiac devices for the documented aims and objectives of the CDR.

F3 There are mixed and conflicting views amongst stakeholders on the purpose of the CDR. One view (majority of stakeholders) is that the CDR has been set up as a recall registry and the other view is that the CDR should be a fully functioning CQR. The latter view is clearly reflected in the Contract for Services and the associated CDR documentation.

F4 The CDR is not a CQR, as it does not include the required outcomes and procedure data. The addition of procedures and outcomes data would result in a more comprehensive dataset that is consistent with a fully functioning CQR, and would provide greater ability to analyse cardiac device data in a way that is more relevant to stakeholders.

Effectiveness of the design, development, implementation and operation of the CDR

F5 The data collection approach implemented at each of the contributing sites is different. This practice does not adhere to the relevant Operating Principles for CQR development. Adopting a more consistent approach would assist the collection of high quality and complete datasets.

F6 The CDR is operated in parallel with the CPR to minimise workload at sites. The information in the two Registries is manually transferred and can be manually linked. The process is not efficient. It is time consuming for Registry staff and has also resulted in issues around poor data quality.

F7 The process for contributing data to the CDR creates a high resource burden at participating sites of up to 10 minutes per procedure. Current efforts to make the data collection process more efficient should be pursued.

F8 The CDR meets the data security requirements as specified in the relevant Operating Principles for CQR development. Access to the Registry information is restricted through the Secure Report Depot, and data access and reporting requires Steering Committee endorsement.

F9 The CDR data quality assurance activity is in its infancy and is further evolving with the development of the Registry. There is evidence that the processes for monitoring the accuracy and completeness of data are in place, and it is expected that they will be implemented and further refined as the dataset grows.

F10 The CDR reporting processes are still in the development phase, due to the infancy of the Registry. There is evidence of a structured process, which is likely to produce the information required. There is also evidence that Registry has consulted with contributing sites to understand their needs for performance monitoring reports.

Registry support and infrastructure

F11 The CDR provides adequate support to participating sites when required and for the most part, the supporting documentation for the CDR serves its purpose.

F12 The layout of the paper based data collection forms can be improved without compromising the data collected. This opportunity is evidenced by one of the contributing sites, which has developed a two page form that collects all data elements required (although it also covers the CPR).

Data Collected

F13 The CDR has a well-developed minimum dataset with associated data definitions to support the provision and interpretation of the required data. However, these documents are currently only available through the Secure Report Depot, and are not available to the general public.

F14 Input into the development of the minimum dataset was limited to a select number of clinicians and stakeholders. Not all of the relevant stakeholders were consulted, and in some instance, it appears that advice provided was not addressed by the Registry.

F15 The lack of a shared understanding around the aim and objectives of the CDR is reflected in the conflicting views on whether the data elements collected meet the aims and objectives of the CDR.

F16 The CDR does not meet the relevant Operating Principles of a CQR or the requirements of the Contract for Services in respect of the adequacy of the data collected. Currently, sufficient data for risk adjustment and outcomes reporting can only be obtained through the use of a secondary data source (i.e. existing procedures/outcomes registries).

Organisation and governance arrangements

F17 The CDR has a governance structure that is set up in line with the relevant CQR Operating Principles. Operationally, Registry staff have identified the opportunity to improve and optimise the output of the CDR Management Committee, and are in the process of implementing changes.

F18 The CDR Steering Committee should consider expanding its membership to include representatives from each of the State-based registries and Registry custodians (SAHMRI) to promote greater participation and provide immediate access to additional Registry development and operational expertise.

Level of registry skills and experience

F19 The CDR, particularly through the SAHMRI, has access to staff with the required level of Registry skills and expertise.

F20 The addition by the SAHMRI of Registry staff with the Joint Replacement Registry experience is a positive, and the learnings gained from establishing and running a highly successful registry will assist the SAHMRI in the development and delivery of the CDR.

Stakeholder engagement with the CDR

F21 The CDR has not met the participation targets as set in the Contract for Services. Less than five percent of eligible sites are currently contributing data, with representation from only NSW, QLD, SA and the ACT.

F22 The CDR has a low level of engagement from the ANZSCTS. Currently, there is no surgical valve data available in the CDR.

F23 The CDR has a low level of engagement from clinicians, particularly those contributing to State-based registries. Whilst there is evidence to suggest clinicians are willing to contribute to the CDR, this interest has not been reflected through site or clinician recruitment and participation.

Contract progress reporting requirements

F24 The CDR has met the progress reporting requirements required under the Contract for Services.