

Professor Chris Baggoley,
Chief Executive Officer
Australian Safety and Quality in Healthcare Commission

Dear Professor Baggoley,

Thank you for the opportunity to provide feedback on "Guidelines for the establishment and management of clinical registries Draft version 2"

The Australian Blood Cancer Registry (ABCR) is a coalition of stakeholders including consumers, clinicians, researchers supported by healthcare and pharmaceutical organisations that aims to provide sufficient and appropriate information to achieve best practice in clinical care and policy development for blood cancers and associated conditions.

ABCR has been working for more than three years to a position where:

- Standards for the collection and classification of blood cancers and related diseases exist, are in use by all nationally, and there is a respected system for their maintenance.
- Data is collected efficiently and in sufficient detail and accuracy to be used for clinical practice and policy development
- The best available information is readily accessible and used by clinicians, therapeutics manufacturers, diagnostic services, patients and their carers in making decisions for better outcomes

The ABCR supports the development of standards for the establishment and management of clinical registries and commends ACSQHC both for commissioning this paper and for the consultative approach taken to its further development.

While we accept that many of the quality characteristics of a clinical registry are common, we believe that there is good reason for considering haematological cancers as a focus for early standards development. This is because:

- There is already a broad-based, well organised and committed group that has been working on realising this vision
- Innovative work has been done on the efficient collection of clinical data as a part of the clinical work process and on reporting that to a registry using existing communications channels using pathology practices – the Lymphoma Wizard Project (<http://abcr.net.au/content/view/13/14/>)

- National consensus standards and guidelines for some conditions (such as the most common one - lymphoma) exist and have been incorporated into electronic decision support within patient management systems using new international standards
- Work is underway nationally on developing a structured pathology report that would facilitate the collection of relevant clinical data for blood cancers
- Blood cancers are important because:
 - They are prevalent and some are increasing in Australia at a rate which is neither understood nor well researched
 - Our understanding of the molecular biology of these diseases is increasing rapidly leading to new and effective therapies
 - These therapies are expensive and their optimum effectiveness and efficiency are not well understood for patients in the general community
- There is consensus among the stakeholders that a clinical registry for blood cancers is an essential tool in fighting these cancers and that a sound business case can be developed to support this

In terms of the ACSQHC Report the ABCR group makes the following specific comments:

- The report does not give the emphasis the ABCR would like to see on the more timely collection and analysis of data for decision support by patients and their clinicians in day-to-day practice – as opposed to the development of policy, important as this is accepted to be. With the experience that we have had with the Lymphoma Wizard Project we are confident that this such an approach is both achievable and desirable
- The report needs to address how any extension of the current incidence and death reporting to a more detailed and clinically-oriented database could be done at a national level. This is especially true of the collections around cancer where there is already a substantial knowledge resource and regulatory environment that could provide greater value
- This further development of data needs to be harmonised with and linked to any national strategy or plan for eHealth in Australia especially as it relates to public health - the standardisation of terminology and informatics needs to be emphasised
- The document includes reference to the work of NEHTA. The Commission would be aware of the current activity to establish a national strategy and to review standards development, conformance testing and certification in the eHealth arena. There may be some value then in being more generic in the report and instead refer to relevant national standards and programs in these areas

- The report should advocate that this data collection be seen as a part of the ordinary business of the provision of health services in Australia and requires long term planning and funding
- The report would be strengthened by taking the approach that other standards developers such as ISO, the National Pathology Accreditation Advisory Council and the Australian Council on Healthcare Standards have for the structure of the document where a principle is enunciated and then the practical approach that might be taken to achieve that principle is described.
- While it is recognised that these are written as guidelines it would be sensible to write the standard so that it can be used for inspection, certification and accreditation. The careful use of the words 'should' (optional) and 'must' (mandatory) needs to be addressed to do this.

The ABCR would welcome the opportunity to meet with ACSQHC and to help progress this important initiative and we commit to provide our expertise and resources to that end.

Yours sincerely

A handwritten signature in blue ink, appearing to read 'Michael Legg', with a stylized flourish at the end.

Michael Legg,
for the Australian Blood Cancer Registry

1 August 2008