

Professor Chris Baggoley
Chief Executive
Australian Commission on Safety and Quality in Healthcare
GPO Box 5480
SYDNEY NSW 2001

27 June 2008

Dear Prof Baggoley,

Please find attached National Breast and Ovarian Cancer Centre's submission on the draft operating standards and technical design for Australian Clinical Quality Registries. We welcome the opportunity to review the draft documents and support this important health initiative to enhance national data capacity.

Please contact A/Prof Christine Giles on 02 9357 9404 or via email on christine.giles@nbocc.org.au should you require any further information about our response.

Yours sincerely



Dr Helen Zorbas
Director

Draft operating standards and technical design for Australian Clinical Quality Registries

Introduction

National Breast and Ovarian Cancer Centre (NBOCC) is Australia's independent national authority and information source on breast and ovarian cancer. Funded by the Australian Government, NBOCC works in partnership with health professionals, cancer organisations, researchers, governments and those diagnosed to improve outcomes in breast and ovarian cancer.

A key area of focus for NBOCC is enhancing national data capacity by improving the consistency, quality and timeliness of monitoring and reporting of key indicators in breast and ovarian cancer. High-quality and comprehensive data is essential for future health planning, financing and service decisions. Yet the collection of nationally consistent data and access to this data is currently constrained by a number of factors including differing practices in cancer registries, impediments to data linkage and significant data gaps across the public and private sectors. Enhancing national data capacity will result in a more effective overall response to cancer control issues and facilitate defined cancer control questions to inform future planning and service delivery.

NBOCC endorses the Australian Commission on Safety and Quality in Healthcare's (ACSQHC) *draft operating standards and technical design for Australian Clinical Quality Registries* and welcomes the opportunity to review the draft documents. NBOCC acknowledges the importance of the development of national guidelines to address the current inadequacies in clinical registries and to ensure the quality, value and consistency of data collection. This response will primarily address the issues of data quality and consistency, completeness, comparability, and timeliness as detailed in the *Guidelines for the establishment and management of clinical registries*.

Data quality and consistency

NBOCC supports ACSQHC's view that for data to drive change in practice it must be regarded as credible by clinicians. High quality and consistent data is the foundation of credible information. The *Guidelines for the establishment and management of clinical registries* are an ideal tool to reinforce the paramount importance of consistency and quality in data collection to ensure the ongoing value of data for clinical quality improvement.

NBOCC supports the proposed 'Attributes of clinical registries' detailed in chapter six of the Guidelines, ensuring clinical registries contain a core minimum data set (6.1), utilise systematic collection processes (6.2) and collect data that is uniformly accessible and epidemiologically sound (6.3).

Quality data is central to cancer control and NBOCC is a leader in promoting national consistency and quality in data collection. NBOCC has developed specialist minimum data sets in breast cancer and gynaecological cancer, including data definitions, to complement generic clinical cancer registration. The data items are recommended as best practice for breast and gynaecological cancer specific data collection and aim to facilitate national

consistency in defining, recording and monitoring information about patients with breast, ovarian, cervical and endometrial cancers. NBOCC will be conducting further work in this area as part of its upcoming business plan for 2008-09 to refine and implement the minimum data sets and to report on trends in breast and ovarian cancer.

Standardised data elements

NBOCC agrees that standard data elements and definitions should be used where they exist for particular diseases and conditions. NBOCC supports NEHTA's draft *Standards map for clinical registries* to improve the quality, consistency and use of clinical registry information through a suite of data specifications developed to standardise various clinical concepts. The standards are sufficient in nature to allow clinical registries to be robust depositories for clinical data representing a true picture of patient care patterns and outcomes.

NBOCC also endorses the classification process used to distinguish between registry types ranging from level one to level four. While level one stand alone registries may provide some use at a local level, they may not add value for clinical quality improvement at a broader public health level.

Data completeness

NBOCC acknowledges that for clinical registries to be regarded as important tools to monitor quality of care they should display the Registry attributes outlined in the Guidelines to ensure completeness of data including the collection of outcome data on a high percentage of patients (6.4), the collection of sufficient clinical information to allow basic risk adjustment (6.5) and the use of an 'all or none' policy to avoid introducing selection bias into the registry population (6.6).

The collection of a core minimum data set of information for individuals is also essential in ensuring completeness of data. While the Guidelines highlight the importance of collecting outcome measures (8.4), the collection of process measures should not be undervalued, for example, when looking at patterns of care. Process measures can be of great value as proxy measures when outcomes are only measurable in the very long term, for example, did the pathology report record the hormone receptor status of a breast cancer patient and if so, were anti-oestrogen therapies appropriately prescribed. Process measures can also be useful in explaining the results of measured outcomes.

Data comparability

For effective service monitoring, data needs to be able to be linked across the public and private sectors and across administrative jurisdictions. Data quality, consistency and completeness are essential components for data comparability and therefore the effective linkage of data from different sources. Without data comparability, comparisons with external benchmarks are unachievable.

Data linkage

NBOCC supports the linkage of data from separate administrative and clinical databases as an effective means of developing a de-identified national database that complies with privacy standards. NBOCC acknowledges that inappropriate and counterproductive use of ethics

and privacy legislation and guidelines can provide a barrier to the linkage of data and therefore undermine the effectiveness of data registries.

Clinical registries require complete coverage to avoid unacceptable levels of bias, i.e. health information about quality of care, not just quality of care in people who consent to be on a database. If too much emphasis is placed on secondary use of clinical records systems, where consent is integral, there is a possibility that clinical registration data will be biased. De-identified data cannot be used at the individual level; however, it can be useful in providing accurate statistics for quality monitoring.

The NEHTA draft Standards map and Architecture overview could provide more weight to data linkage as a means of extracting unbiased data. It is important to ensure there is a clear distinction made between consent issues around clinical record systems and clinical registry record systems.

Consideration could also be given to a broader legislative authority for clinical cancer registries. Apart from legislative mandation, legislative authorisation is commonplace, obviating the legal need for patient consent and Institutional Ethics Committee (IEC) approval.

Data timeliness

As identified in the Guidelines, the timely collection of data as close as possible to the point of care is essential in ensuring accuracy of data. Conversely, the timely reporting of data is essential to allow for monitoring of key outcomes. NBOCC supports ACSQHC's view that registries have a fundamental requirement to report without delay on the information they collect, both to institutions and individual clinicians contributing data and to the wider community. NBOCC supports the use of data outputs to evaluate quality of care by identifying gaps in best practice and benchmarking performance (14.2).

To avoid duplication in data collection and to improve the timeliness of reporting, NBOCC supports the use of existing administrative data where possible. Administrative data can be of value in high-level, all-of-population quality monitoring. Separate data collection could be considered when the quality of administrative data does not meet the set requirements or to add value by broadening the range of items available.

Conclusion

NBOCC recognises the value of high quality, consistent, timely and accessible data in both cancer control and the overall improvement of health service delivery. The current environment of data collection, analysis and access requires a dedicated stewardship and NBOCC supports the implementation of ACSQHC's *Guidelines for the establishment and management of clinical registries*. NBOCC appreciates the opportunity to have input into this important health initiative and looks forward to viewing the final document.