

National Safety and Quality Accreditation Standards Review

**The National Blood Authority's response to the
Australian Commission on Safety and Quality
in Health Care's Consultation Paper**

**“An alternative model for safety and quality
accreditation”**

Submitted 2 October 2007

Introduction

Thank you for inviting the National Blood Authority (NBA) to respond to the consultation paper “An alternative model for safety and quality accreditation of health care”.

One of the NBA’s key safety and quality roles under the *National Blood Agreement (2003)* is to *facilitate coordination, integration, cooperation and information exchange between the NBA and other bodies with a safety and quality role in the Australian blood sector, and between those other bodies*. Accordingly, the NBA sought and incorporated, where appropriate, the views of other key blood sector stakeholders during the compilation of this response.

While not responsible for developing or assessing against safety or quality standards, the NBA has an interest in promoting a national, uniform approach to blood utilisation and handling. Clinical practice in the blood sector is presently guided by a myriad of safety and quality guidelines, standards, accreditation requirements, circulars of information, safety and quality initiatives and regulation dealing with the prescription, sample collection, storage and transportation and administration of blood and blood components – all with a focus on safe and appropriate practice. Important contributors to safety and quality in the sector include:

- State and Territory health departments;
- hospital transfusion committees;
- professional societies and organisations, such as the Australia and New Zealand Society for Blood Transfusion (ANZSBT), the Australasian Society of Thrombosis and Haemostasis (ASTH), the Australian Red Cross Blood Service (ARCBS), and the Haematology Society of Australia and New Zealand (HSANZ);
- professional colleges, such as the Royal College of Nursing Australia (RCNA), the Royal College of Pathologists of Australasia (RCPA), and the Royal Australasian College of Physicians (RACP);
- accreditation bodies such as the National Association of Testing Authorities (NATA), the National Pathology Accreditation Advisory Council (NPAAC) and the Australian Council on Healthcare Services (ACHS); and
- Australian government agencies, such as the National Blood Authority (NBA) in consultation with Commonwealth, State and Territory Jurisdictional Blood Committee (JBC) members, and the National Health and Medical Research Council (NHMRC).

A great deal of effort has been expended, and continues to be directed, towards improvements in safety and quality in the sector, with variable impact on patient safety. There are risks to reform without first fully understanding the complexity of inter-relationships between the regulatory, business, safety and quality environments. For this reason, the NBA favours a cautious approach that has a clear objective of achieving real gains in patient safety through a full appreciation of the environment and subsequent prioritisation of safety efforts.

Comments on the options for the implementation of the alternative model

1. Separation of safety assurance and quality improvement assessment processes

The NBA supports in principle the concept of establishing a mandatory set of national minimum safety standards, but is cautious about the complete separation of safety standards setting and assurance processes from quality improvement standards setting and assurance processes.

As proposed, there is concern that the *alternative model* risks failing to align the expected minimum safety standards with the underlying quality improvement processes designed to achieve and maintain practice in accordance with those standards. The NBA believes that the concepts of safety and quality are inexorably linked – quality improvement activities (e.g. education, data driven quality improvement initiatives, guidelines and recommendations etc), support the attainment of minimum standards of safe practice. While the proposed national framework for quality improvement (page 16 of the Consultation Paper), helps to link safety standards to quality activities, this is not explicitly stated in the model and it is the NBA's recommendation that it should be (see Figure 1).

2. Separation between safety standards development and assessment of health services

The NBA has no experience or evidence of a conflict of interest arising out of accreditation bodies assessing health care providers against standards developed by the accrediting body. That said, there is value in the minimum safety standards being developed by a national body and being applied nationally. Presently in the blood sector, access to and assessment against blood-specific safety and quality standards is limited to those health-care institutions that subscribe to the accrediting body.

3. Accreditation of all settings of care where services are provided by registered health professionals

The NBA makes no specific comment on the appropriateness of this option with respect to all registered health providers. NBA however, notes the complexity and difficulty of standardising product management (e.g. blood storage) and procedures (e.g. phlebotomy) through the transfusion chain in all relevant health care settings. The enforcement of some standards across all relevant health care settings may require substantial capital investment (e.g. compliant blood fridges in all settings). It is envisaged that patient safety benefits would be derived in the blood sector through the inclusion of a mandatory safety standard against which accreditation is assessed, that addressed patient and sample identification in relation to the taking and administration of blood.

4. National minimum safety standards that apply across all settings of care

The NBA recommends that national minimum safety standards are developed in consultation with consumers and key stakeholders. There are likely to be significant challenges to overcome in harmonising regulatory and technical standards to enable mutual recognition. This will require an extended process of consultation with not only the

regulators but also the technical standard setting bodies (to avoid overlap), the health care providers and assessment and accreditation organisations.

The NBA would see value in prioritising the development of mandatory national safety standards to cover those areas where incident reporting data suggests significant problems presently exist.

Table 1 indicates the safety issues that would probably apply across all health sectors where incident reporting data in the blood sector suggests safety improvements are necessary.

Table 1. Safety elements and how they relate to the blood sector

Safety element	Examples of errors in the blood sector
Misidentification (of patient, product, specimen)	<ul style="list-style-type: none"> • blood taken from wrong patient. • blood specimen tube labelled incorrectly. • blood given to wrong patient. • incorrect blood product given to patient.
Infection	<ul style="list-style-type: none"> • failure to follow infection control procedures resulting in patient infection. • failure to follow infection control procedures resulting in staff infection.
Informed consent	<ul style="list-style-type: none"> • informed consent either not sought or received.
Incorrect procedure	<ul style="list-style-type: none"> • patient receives blood or blood products via the incorrect route and/or using the incorrect equipment.

5. Assessment of non-clinical and technical compliance

The separate assessment of non-clinical and technical compliance of a health service is supported. In fact, this model could be extended to clearly segregate the 4 (or more) essential/mandatory areas of assessment and the assessment bodies responsible. It reasonably follows that the absence of clear demarcation between the assessment of health service providers against the increasing number of non-clinical, technical, minimum safety and quality improvement requirements has contributed to the need for reform. Many of the reasons for reform listed on pages 4 and 5 of the Consultation Paper flow from the failing of the present system to identify the reasons for/drivers of compliance and whether, and for what purpose, compliance is mandatory.

The purpose of assessment against these areas should be clearly defined to bring some clarity as to why or for what purpose a health service provider must comply. The value of compliance should be transparent and obvious.

The categories for assessment/compliance/accreditation then would include:

- national minimum safety standards (mandatory);
- quality improvement framework (mandatory/non-mandatory components);

- jurisdictional regulatory requirements (e.g. fire, chemical storage/handling, food safety) – non-clinical (mandatory);
- requirements of funders/insurers – compliance with technical standards (mandatory/non-mandatory);

6. Development of a national framework for quality improvement

The NBA recommends that the national quality improvement framework elements support and are linked directly to the national minimum safety standards (see Figure 1). The NBA also recommends that further consultation be conducted in the development of this framework to take into consideration existing knowledge to assist with the identification of priorities and targets. These priorities should be focused in a way that yields rich safety improvement rewards whilst avoiding adding to unnecessary administrative burden. For example, the NBA has developed a program, “Blood Counts”, which includes a number of initiatives that aim to improve the safe and appropriate use of blood and blood products. Research, including the review of haemovigilance information, has been, and is being undertaken, to identify and target clinical and technical practices that would benefit from quality improvement initiatives. Further, the ANZSBT has recently established a Clinical Practice Improvement Committee to facilitate shared learning and the implementation of practice improvement initiatives such as national audits. It is recommended that the criteria for inclusion of elements in the national quality improvement framework take into consideration, not only the linkages to the national safety standards, but also the experiences of these stakeholders.

7. Establishment of a National Entity to lead and coordinate changes

The NBA supports the establishment of a National Entity to undertake the roles described in the Consultation Paper.

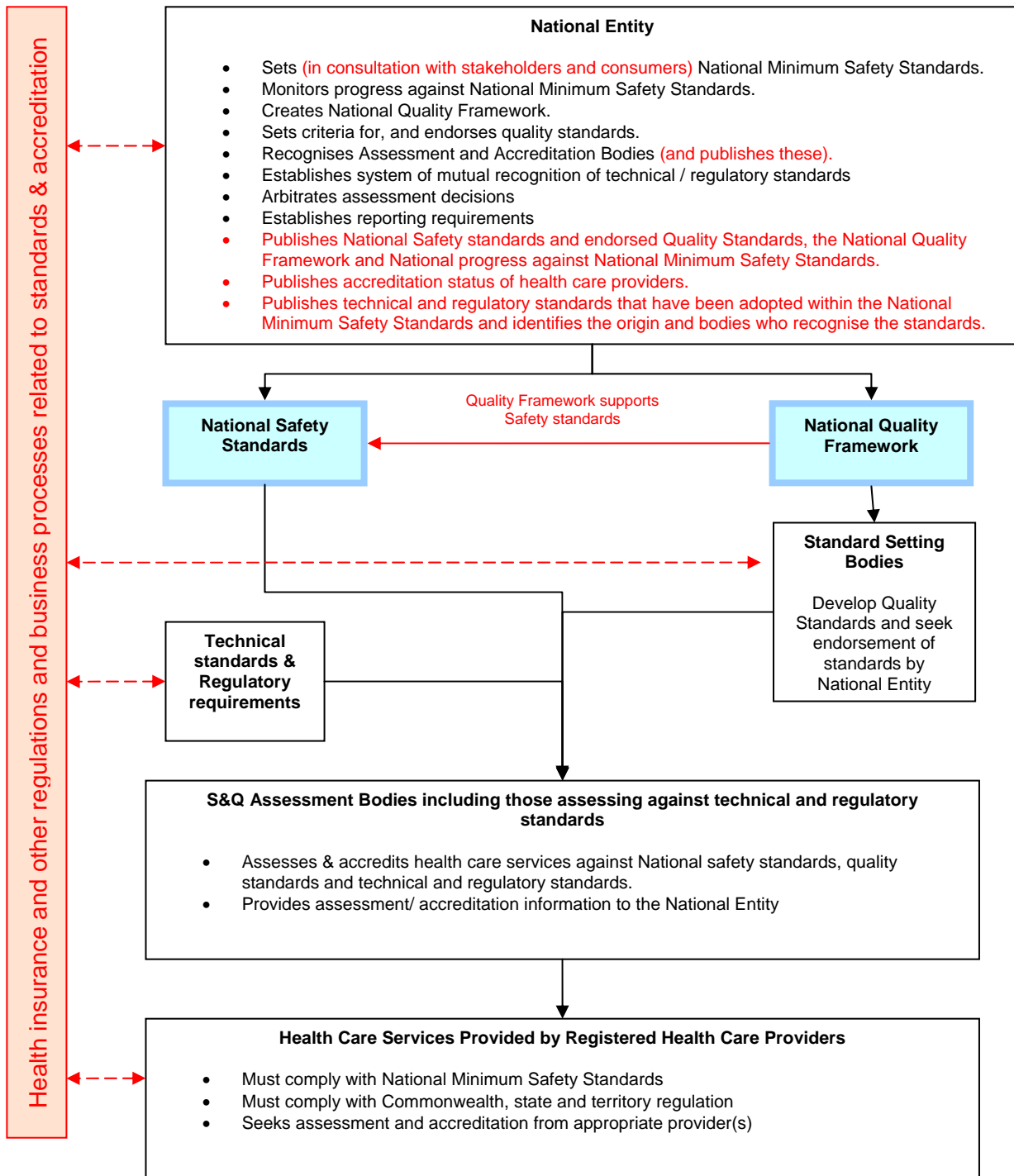
It is noted that the proposed National Entity will be responsible for, among other things, collecting and analysing data about accreditation outcomes and providing it to health services for the purposes of benchmarking, as well as to consumers to instil confidence in service providers, and regulators and funders for use in policy, decision making and resource allocation.

The NBA recommends that the National Entity makes publicly available:

- the national minimum safety standards
- national and state and territory progress reports against these standards
- recognised/registered assessment/accreditation bodies
- details of the national quality improvement framework
- endorsed quality improvement standards
- the accreditation status of health care providers against national minimum safety standards
- the technical standards and non-clinical regulatory requirements to be met by health services.

Figure 1 is a diagrammatic representation of the NBA’s interpretation of the *alternative model*. Additional suggested functions of the National Entity are shown in red.

Figure 1: Representation of the *alternative model*.



Dotted lines indicate inter-relationships that the NBA recommends should be investigated and incorporated into the *alternative model*.

8. Review of surveyor training

The NBA generally supports the notion of standardised surveyor training but makes no specific comment about the proposal for a review of surveyor training and assessment across the range of accreditation programs.

9. Associated reforms

Each of the listed, associated proposals would contribute positively towards the reform of the accreditation of health care by variously providing tools for assessment; assistance with standardisation and avoidance of duplication; or provision of information to governments, funders and consumers. The NBA believes these should be incorporated into the reform agenda.

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