

Submission to the Australian Commission on Safety and Quality in Health Care regarding the discussion paper:

National Safety and Quality Accreditation Standards

Introduction

1. Improving the management and use of blood and blood components has been the focus of much activity in the blood sector. Blood sector stakeholders active in safety and quality improvements 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).

2. Relevant to the Australian Commission on Safety and Quality in Health Care's (ACSQHC) review of national safety and quality accreditation standards has been the blood sector's particular focus on initiatives to:

- i. improve the level of governance of blood handling and transfusion practice in hospitals, noting that in the absence of universally applied standards the current standard of transfusion practice is likely to be variable across hospitals and across the country; and
- ii. promote the uptake of guidelines to improve product use and transfusion practice.

3. This submission was compiled after consultation with key stakeholders in the blood sector and additionally records some of the comments made at an ACSQHC focus group meeting held in Canberra in March 2007.

Part 1: Accreditation standards

4. The problems associated with the proliferation of accreditation standards impacting the health sector are well recognised. Not the least of these include:

- the duplication of standards for the same subject area, potentially with differing requirements;
- the duplication of subject matter in standards covering different topics but with overlap at the fringes;
- standards that describe minimum acceptable practice versus best-practice approaches;
- maintaining the currency of standards;
- health facilities maintaining an awareness of the existence of standards and compliance requirements;
- an inconsistent approach to the language of standards, codes of practice, guidelines and the like.

5. The duplication of standards *per se* is not yet an issue for the blood sector (there would appear to be more gaps in standards' coverage than duplication). Some areas along the "transfusion chain" are devoid of clear standards or even guidelines. The absence of a well established, broadly accepted national approach to the safe management and use of blood leaves this area at risk of non-uniform safety and quality requirements.

6. This is evident in material that has been developed by various groups in order to fill these gaps. While most safety and quality requirements in these documents are framed as recommendations (or voluntary guidelines) rather than as standards, they are often perceived by users to be 'standards'.

7. There are guidelines available, developed by different professional bodies and covering various aspects of blood use and management. The alignment of everyday clinical transfusion practice with recommended best practice however is less than optimal and continues to be the focus of blood sector initiatives.

8. Only the production of blood and blood products, and transfusion laboratory processes are regulated or accredited in any detail at a national level. The Therapeutic Goods Administration (TGA) regulates the collection, manufacture and supply of blood and blood products. It also has responsibility for product safety and registration. The NPAAC, RCPA and the NATA provide laboratory accreditation services and good laboratory practice compliance monitoring.

9. For the hospital setting some national guidelines exist, however there is no nationally standardised oversight of transfusion-related activities outside the pathology laboratory. The Australian Council on Healthcare Standards (ACHS) has partially filled this gap with the release of the 4th edition of its Evaluation and Quality Improvement Program (EQulP 4).

10. EQuIP 4 was released in January 2007. It incorporates, for the first time, a patient safety standard (Standard 1.5) with a blood component (criterion 1.5.5 – The system for prescription, sample collection, storage and transportation and administration of blood and blood components ensures safe and appropriate practice). The intent of this criterion is that health-care organisations that deal with blood and blood components should have an effective system for ensuring that all aspects of the management of that blood are safe and appropriate.

11. Accompanying the EQuIP 4 standards are three blood-related clinical indicators within a hospital-wide clinical indicator set. The blood-related indicators are comparative rate based indicators addressing some aspects of the process and outcome of blood transfusion.

12. It could also be argued that these first iterations of the ACHS blood standards have a focus on systems, processes and policies rather than patient outcomes. These could be refined in subsequent releases so that there is better balance of process and outcome standards. It is however, important to retain some process standards as these provide specific and helpful direction to organisations on how to improve patient safety for transfusion care.

13. While the promulgation of a blood standard through the EQuIP 4 program is a major step forward, it is not a total remedy. While the ACHS “accredits the majority of health care organisations in Australia¹”, some health care organisations are either not accredited, or are accredited by another organisation that may or may not require compliance with blood related standards. Ideally, a ‘National Standard’ for the safe use and management of fresh blood and blood components and all related guidance material should be developed, accessible by, and required of all institutions that use blood, not just those accredited by the ACHS.

14. To improve safety and quality in the management and use of blood and blood components the blood sector would benefit from:

- standards and an accreditation process accessible (at an affordable cost) to all health care providers that use blood and blood products (including both public and private institutions) irrespective of their affiliations. There is a view that these should be mandatory;
- a uniformly accepted standard of blood management and use applicable across all jurisdictions developed and regularly revised by a respected professional body(ies). Defining ‘blood management’ and agreeing the scope of any standard would be an important first step;
- a comprehensive set of evidence-based national clinical practice guidelines for blood products, blood related products and blood related services to ensure best practice in the management and use of such products and services, available to all institutions that use blood, that provide guidance, worked examples, checklists and other

¹ ACHS website: <http://www.achs.org.au/Whatisanachsmember/>; accessed 27 March 2007.

tools to assist institutions to meet the requirements of the standard. These guidelines should be promoted broadly and their use encouraged and monitored;

- an accreditation process that assesses institutions that use blood against a single standard or standard set.

Specific questions relating to accreditation standards

What are the barriers to standardisation of language and definitions (in standards)? Who needs to be involved in this standardisation process?

15. The use of non-uniform definitions in standards across similar subject areas is a contributing factor to the fragmentation of the accreditation system and the duplication of standards. The use of different terms for the same thing, and the same term for different things is certainly confusing.

16. There needs to be developed a clear and nationally recognised understanding of the differences between standards, guidelines, codes of practices, guidance notes and other such documents: what their intended uses are and the level of detail provided in each. Presently there are 'standards' written as guidelines, and vice-versa. It would also be worth agreeing some standard descriptions of 'performance based' approaches versus 'prescriptive' standards and when each type may be most appropriate.

17. Standardisation of definitions is desirable and ought to be achievable, in particular where there are well established international standards and an international approach to definitions in particular subject areas.

18. Standardisation of language will be more difficult. For example, technical and scientific standards such as Australian Standards necessarily use more technical language compared to performance-based standards which may be more descriptive. Identifying "classes" of standards and standardising the language within each class may be worth exploring.

19. Employing a nationally agreed standard development methodology would contribute to the standardisation of the language and structure of standards and improve the efficiency of the uptake and implementation of standards. The 'standardisation' of the standard development process is supported.

Should compliance with 'environmental' standards be part of an accreditation process?

20. The question of whether compliance with standards that do not relate directly to health care should be part of the accreditation process is an interesting one. On the one hand, inclusion of 'environmental' standards (e.g. food safety, fire safety, storage and handling of dangerous goods) ensures additional focus on these important areas; on the other, it diverts attention

from those services directly related to health care and the improvement of patient outcomes.

21. Compliance with environmental standards is often mandated by law and subject to other compliance activity. The interaction between regulation and standards in the accreditation process should be carefully considered. Perhaps a guiding principle could be that where there is evidence to suggest patient outcomes are adversely impacted by non-compliance with environmental standards then the assessment of an institution against those requirements should be part of the accreditation process (unless the institution is already assessed, in which case a linkage to that assessment should be made in order to avoid duplication).

It is proposed that a detailed process of analysis and mapping of all existing Australian health care safety and quality standards be undertaken. Who needs to be involved in this process?

22. The increase in number and complexity of standards across the health sector generally increases the compliance burden on health service providers. To avoid this in the blood sector it is important that the development of standards for blood is well managed.

23. A mapping process applied to the blood sector would focus on any gaps in the standard and/or accreditation environments and clearly identify those areas requiring development. Blood donors and recipients alike should be assured that all processes in the transfusion chain are covered by a standard.

24. For the blood sector the following professional colleges, societies and organisations would be some of the principal players to inform the mapping process:

- Australasian Society of Thrombosis and Haemostasis (ASTH)
- Australian Council on Healthcare Services (ACHS)
- Australian and New Zealand Society for Blood Transfusion (ANZSBT)
- Australian Red Cross Blood Service (ARCBS)
- Haematology Society of Australia and New Zealand (HSANZ)
- National Association of Testing Authorities (NATA)
- National Blood Authority (NBA) and Jurisdictional Blood Committee (JBC)
- National Health and Medical Research Council (NHMRC)
- National Pathology Accreditation Advisory Council (NPAAC)
- Royal Australasian College of Pathologists (RACP)
- Royal Australasian College of Physicians (RACP)
- Royal College of Nursing Australia (RCNA).

25. Jurisdictional programs with expertise in safety and quality for transfusion are also well positioned to comment on the mapping process, for example, BloodSafe and the Better Safer Transfusion (BeST) program.

It is proposed that registration of sets of health care standards become mandatory. What needs to be in place to make this approach feasible? Which organisation is best placed to manage the longer term register of standards? What minimum information should be publicly available on accreditation standards?

26. The list of benefits identified on page 29 of the Commission's discussion paper makes this an attractive proposal.

27. There are likely to be fewer problems actually developing and operating such a register if its purpose was to provide a readily accessible data-base of applicable standards and guidance material, rather than as a regulatory register. In either case, it would be difficult for such a register to impose a frequency of review of standards, both from the view point of the burden of cost to the reviewer, and the willingness of international standard setting bodies to comply with the register's review requirements. Other practical problems would include the replacement of standards that become outdated, or no longer meet required standards, when the owner organisation is unable or unwilling to review them in a timely way.

What priority areas should be included in core safety and quality standards?

28. The specification of a set of core safety and quality standards broadly applicable across the health sector for accreditation purposes is supported. Standards for patient identification, blood sample collection, medication/blood and blood product storage, privacy issues, informed consent and infection control, for example, are areas critical to the safe management and use of blood as they are for other health services. Compliance with core standards could set a minimum requirement for accreditation purposes.

29. Alternatively, 'patient centric' core elements could be identified as foundation components of all safety and quality related standards for the health sector. Specific examples of how these core elements would be observed in particular applications could be provided. For example, informed consent for a blood transfusion could be part of a standard for blood administration. Subject specific requirements could be built onto the core elements within each standard.

30. It is recognised that there might be limited capacity to require standards developed overseas to comply with the inclusion of universal/core elements.

Part 2: Accreditation process

31. As far as we are aware, 2007 will be the first year health facilities are assessed against a standard specifically relating to the prescription, sample collection, storage and transportation and administration of blood and blood components. This standard has been developed by the ACHS and is introduced as part of EQuIP 4. While the standard focuses on processes and policies rather than direct patient outcomes, its introduction will nonetheless focus hospitals on transfusion practice and likely bring about improvements in governance.

32. Prior to EQuIP 4, some health services were assessed by the ACHS against EQuIP 3 for blood and blood product management, which linked national blood component guidelines to accreditation requirements. EQuIP 4 introduces a blood specific standard that is more advanced and significantly broader in scope.

Specific questions relating to accreditation process

It is proposed that a range of regulation, funding and policy levers be used to ensure all health services participate in a registered accreditation and quality process. Which health services should be accredited as a priority, and how can this be best achieved?

33. Accreditation of public sector health service providers is already mandatory in some jurisdictions and, while not mandatory in a legislative sense, appears widespread in the private sector. According to information provided by the Australian Private Hospitals Association the majority of private and public hospital beds in Australia are accredited. Funding levers are already used extensively in the private sector – every health fund contract with a private hospital requires current accreditation. In addition, any private hospital unable to secure a contract with a health fund can apply for eligibility to receive a 2nd tier default benefit. Eligibility for this benefit similarly requires current accreditation. Accreditation is also a pre-condition of membership of the Australian Private Hospitals Association.

34. In addition, under quality assurance requirements of the Private Health Insurance Bill (2006) presently in the Federal Parliament, the Commonwealth's intention is that from 1 July 2008 private health insurance benefits should only be paid for hospital treatment where the hospital has met the accreditation requirements of an 'appropriate' accrediting body. This will be required under the Private Health Insurance (Accreditation) Rules.

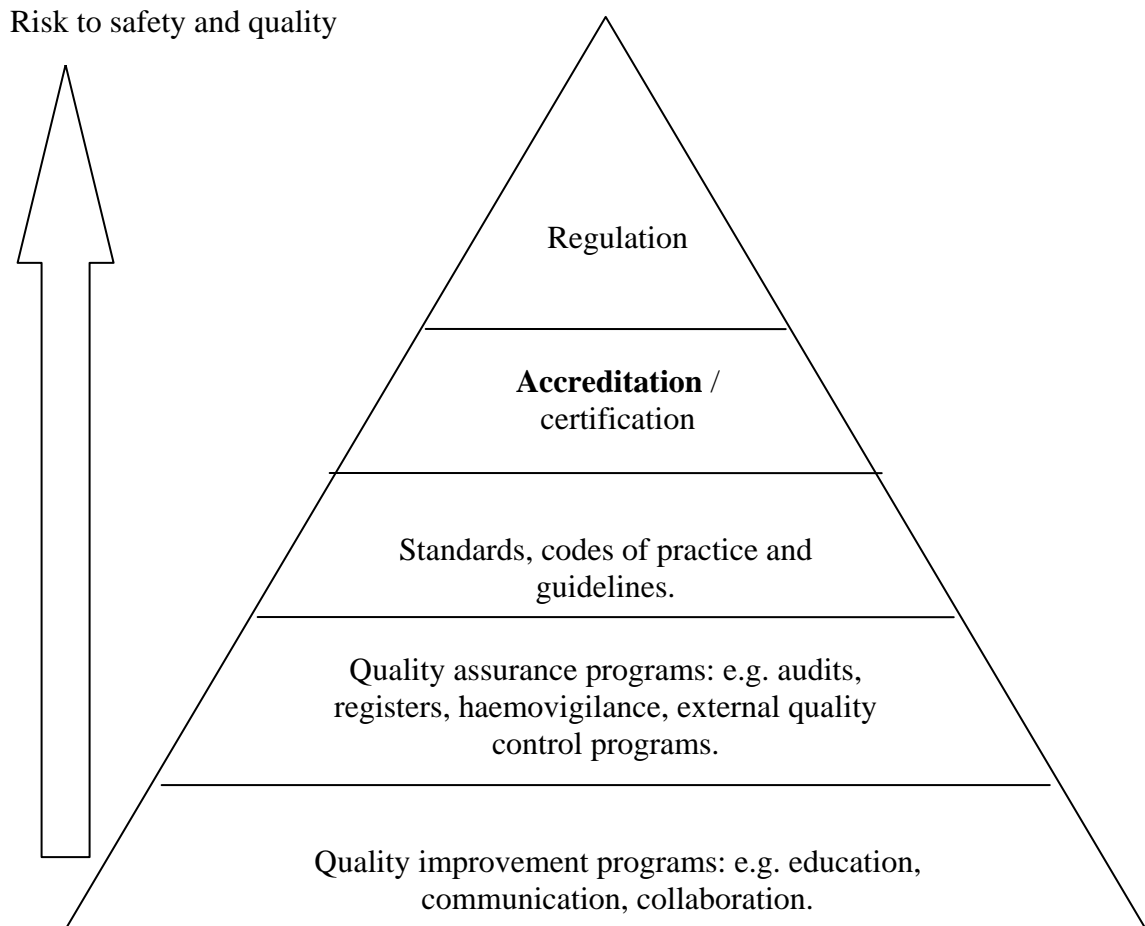
35. However, it is likely to be impractical to subject ALL health services to an accreditation process. For example, patients administering blood products at home could not be surveyed (although training and education programs for home administration should). There may be a need to distinguish between patient self-management and 'hospital in the home' care where treatment is provided or supervised by an accredited health facility.

36. The focus of ‘mandatory’ accreditation should be on where practices are controllable and where system failures will result in the highest risk to recipients of care.

37. It is also important to recognise that in some instances accreditation is treated as a ‘paper exercise’ and does not always result in safety and quality improvements.

38. If accreditation was to be positioned in some sort of ‘hierarchy of controls’ for ensuring safety and quality in health care it may well be positioned as shown in Figure 1 below. Those services in which system failures could result in a commensurate risk to safety and quality could be those subject to accreditation processes.

Figure 1: Hierarchy of measures to ensure safety and quality in health care.



It is proposed that registration of health care accrediting bodies becomes mandatory. What needs to be in place to make this approach feasible? Which organisation is best placed to manage the registration of accreditation bodies?

39. There would be certain advantages to developing a register of accrediting bodies for health service providers. For example, such a register would be useful to consumers and those seeking accreditation – to understand who was in the marketplace for accreditation. The register may also be able to identify accrediting bodies specialising in particular areas of health care.

40. There could be specific requirements for accrediting bodies to get onto the register: for example, they themselves could be required to be accredited to a certain standard. The standard that would be used, and who would do the accreditation are some important issues to be resolved before this could go forward.

What needs to be done to integrate and streamline overlapping accreditation processes? How can accreditation be made more cost effective and efficient?

41. The proliferation of health care standards and to a lesser degree accrediting bodies/systems has made the business of accreditation increasingly time consuming and expensive. A reduction in the duplication of standards and the number of accrediting bodies surveying overlapping areas could assist in making accreditation more cost effective and efficient. The mutual recognition of accrediting standards, bodies and systems would assist in this regard.

42. Mutual recognition may be possible in some areas and effort ought to be focused on identifying where this will be beneficial to hospitals and not compromise on quality.

43. However, as pointed out during discussions at a focus group meeting held in Canberra, mutual recognition may be problematic in some areas.

44. For example, in the blood sector pathology laboratory processes are accredited in the main by NPAAC/NATA. NPAAC/NATA's interests extend beyond the pathology laboratory when there is off-site equipment (fridges, laboratory analysers, etc) serviced and maintained by the laboratory. Sometimes fridges and other equipment are shared by a hospital and/or one or more laboratories. The responsible body for accreditation purposes may not be clear-cut. As the ACHS surveys processes outside of the laboratory it may 'accredit' an off-site blood fridge. NATA may not be able to recognise this ACHS accreditation as, though they refer to the same standard (Australian Standard AS-3864), there may be an issue around the competency of ACHS surveyors to interpret technical standards.

45. There is a view that the accreditation of specialised technical areas needs to be retained by the organisation with the relevant expertise. Mutual

recognition is irrelevant in the situation where there is only one technically competent accrediting organisation. Where the competency of surveyors to assess compliance against technical standards is assured mutual recognition may be possible.

46. Another barrier to mutual recognition could be whether the accrediting body is itself accredited and to what standard. Some accrediting bodies pride themselves on being accredited and may not want to mutually recognise others that are not.

It is proposed that the Commission explore opportunities to use data from a number of collections to provide a more comprehensive picture of health service outputs and outcomes. How can the available data sets be best used to inform accreditation processes?

47. De-identified, aggregated national data could be very useful in identifying those areas in particular need of safety and quality improvements. Key performance indicators are already collected in laboratories for this purpose. This would be a valuable resource when outputs are measurable and comparable objectively and data could be collected easily and without imposing significant resource demands.

It is proposed that unannounced surveys be introduced by all accreditation providers. What needs to be done and by whom to introduce unannounced surveys in a timely and effective way?

48. For regulatory agencies, unannounced visits are a powerful tool for addressing persistent non-compliance.

49. For accreditation purposes, while unannounced visits would likely be more successful in discovering gaps in quality processes that might otherwise be covered-over in a planned visit, opinion is divided as to whether they could be implemented practicably. There is potential for unannounced visits to be highly disruptive and cause delays in otherwise critical processes. The style of assessment may need to be modified to ensure that they add value for patient care and take account of the fact that the organisation visit may occur at peak work times.

50. The potential for unannounced surveys to cause delays should not preclude such a process but this should be balanced against the needs of an organisation to get on with its day-to-day activities without negative impacts on quality and timeliness. It was suggested that unannounced surveys could be reserved for areas or organisations of high risk.

It is proposed that tracer methodology be implemented nationally by all bodies accrediting health services. What needs to be done and by whom to introduce tracer methodology in a timely and effective way?

51. One issue would be the establishment of clear ‘borders’ of responsibility for accreditation bodies as a patient moved through the system. Could one accreditation agency be responsible for surveying the entire route?

52. Presently in blood, quality and safety aspects are assessed from the viewpoint of where a blood unit or blood product is in the system. Typically, this is described as a journey from the vein of a donor to the vein of a recipient – that is, from “vein-to-vein”. This is a convenient way of looking at quality and safety aspects concerned with donor selection, collection, processing, testing, transport and storage, compatibility testing, prescription, administration of the blood and post-transfusion care.

53. Tracer methodology applied to the “vein-to-vein” approach should be used judiciously to ensure that duplication of assessment is not occurring without adding value from a patient quality and safety perspective.

54. Tracer methodology applied to a particular patient’s interaction with a health service (say, from admission-to-discharge) would potentially examine only one or two elements of safety and quality as applied to blood – namely the prescription and administration.

It is proposed that training and assessment requirements of surveyors be reviewed across the sector with a view to ensuring all surveyors are suitably qualified and trained with the skills necessary to implement new accreditation methodologies. What are the essential skills, competencies and attributes that surveyors need?

55. Surveyor training needs to be closely aligned with the technical and scientific knowledge needed to understand and assess a health care facility against a particular standard. Some technical and scientific standards require specialised knowledge.

56. General skills, competencies and attributes of surveyors could be assessed through a nationally accepted assessment instrument.

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