

DRAFT
**REPORT ON THE
REVIEW OF NATIONAL SAFETY
AND QUALITY
ACCREDITATION STANDARDS**

NOVEMBER 2007

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1. Review of Safety and Quality Accreditation

1.1 Introduction

This report brings together views and information collected over two phases of consultation with stakeholders on Safety and Quality Accreditation Standards undertaken by the Australian Commission on Safety and Quality in Health Care (the Commission) between July 2006 and November 2007. Australian Health Ministers requested that the Commission undertake this task with a view to developing an alternative model of accreditation of health services. It was intended that the model proposed operate across private, public, acute, ambulatory and primary care health services.

1.2 Reasons for Reform

Accreditation as a safety and quality strategy

In undertaking this review the Commission recognises that health services use a raft of mechanisms to ensure safety and improve the quality of care for consumers. Along with accreditation, mechanisms such as:

- incident analysis and investigation,
- registration of health professionals,
- credentialing of health professionals to define scope of practice ,
- use of quality improvement cycle to address identified issues,
- redesign of the patient journey,
- collection of clinical indicators,
- use of clinical registries and
- a focus on clinical audit.

are used to address the safety and quality of care. As accreditation is only one of these tools, neither the current accreditation system nor the Alternative Model (described in the *Draft An Alternative Model for Safety and Quality Accreditation: November 2007*) of accreditation is able to address all of the safety and quality issues facing health service in the delivery of care. However, making accreditation as effective as possible has the potential to deliver safety and quality improvements and is a key objective of this reform process.

Support for reform in previous reviews

The Australian system of safety and quality accreditation was the subject of review by the former Australian Council on Safety and Quality in Health Care. The Council

undertook consultation and published two papers¹ during 2003. The issues identified by the Council were reiterated in the Patterson report² where it was found that “stakeholders have legitimate concerns regarding the current accreditation of health care services ... [and] Ministers should be provided with a plan to transform accreditation arrangements”.

Following consideration of these reports, the Commission was tasked by Health Ministers with developing an alternative model of accreditation, following consideration in light of international experience and the strengths and weaknesses of the current system. This request took account of the fact that accreditation processes are well established in Australia and that it would be more practical and efficient to reform the system than to design a completely new system, given the maturity of and investment in existing accreditation systems.

The Paterson report³ states that accreditation is an important driver for safety and quality improvement and recommends a review of the following:

- Whether a national accreditation body is necessary and if so, what its role and function should be.
- The best mechanism to review existing standards that apply to the health sector, to determine opportunities for streamlining and reducing duplication.
- The best way to translate nationally agreed safety and quality improvement policies and standards into accreditation standards as a mechanism for implementation.
- Ways to address issues relating to the rigour and robustness of survey processes.
- The development of a mechanism to ensure appropriate action is taken in the event that an unacceptable threat to the safety and quality of care is identified by an accreditation agency.

These issues have all been considered in the development of the alternative model of accreditation.

Stakeholder support for reform

The strong interest and participation in the Council and Commission’s work on accreditation by stakeholders was evidenced by:

- The number of stakeholders self-selecting to participate in phase one consultation process – over five hundred and thirty (530) individuals nominated for focus groups nationally.

¹ Australian Council on Quality and Safety in Health Care. *Standards setting and accreditation literature review and report*, July 2003.

² Australian Council on Quality and Safety in Health Care. *Standards settings and accreditation systems in health: Consultation paper*, July 2003.

³ AHMC (2005) National Arrangements for Safety and Quality of Health Care in Australia: the report of the review of future of future governance arrangements for safety and quality in health care.

- The level of engagement of stakeholders – over four hundred and four (404) participated in forty (40) focus groups held nationally and ninety (90) written submissions were received by the Commission for phase one.
- The fact that twenty one (21) percent of the 351 respondents in the phase one focus groups rated the issue of accreditation reform as critical and sixty nine (69) percent rated the issue as significant.
- Fifty five (55) submissions were received in phase two.
- The willingness of stakeholders to continue to engage with the Commission to debate the issues and the reforms.

Issues with the current accreditation system

The following concerns and issues were identified during the review:

1. **An awareness of the limitations of the current accreditation system** that resulted from:
 - There has been a lack of consensus about the purpose of accreditation.
 - A growing awareness of the potential risks inherent in health care have been developed.
 - Inter and intra assessor variability.
 - A system that has been characterised by duplication, fragmentation and lack of coordination.
2. **The value of the current accreditation system is under threat** because:
 - Of the growing cost and time requirements of compliance with safety and quality requirements, particularly where there are multiple accreditation processes with overlap and duplication.
 - Of the proliferation of standards with safety and quality components, but without a process to identify those which are essential to achieving safety and quality outcomes.
 - Despite accreditation, safety and quality is not consistently embedded as part of core business in day-to-day operations of health services.
3. **Accountabilities in the current accreditation system are inadequate** because:
 - There are gaps in accreditation coverage.
 - A number of public failures have occurred in the health system despite full participation by the organisation concerned in accreditation programs.
 - There is a lack of transparency in accreditation processes with no clear accountability or sanctions if standards are not met.
 - A greater range and number of high risk services are being provided outside of traditional acute care settings.
 - There is limited consumer focus.

- There is an absence of nationally consistent safety standards across all settings of care, despite a high level of consumer expectation.
- There is no mechanism to link accreditation to national safety and quality priorities.
- Ministers are held accountable by the community for the safety of the health system, but have limited influence on accreditation process and the standards that apply.

An analysis of the health sector accreditation literature undertaken in 2007 by Greenfield et al from the University of New South Wales, found that among the 39,900 published papers nationally and internationally there was little discussion of the process or outcomes of accreditation. A summary of findings noted that while accreditation promoted change in health organisations, this change was associated with “standardizing the organizing and decision making of care rather than producing care outcomes” (pg 16). There was however criticism of accreditation and the major concerns were listed in the paper as:

- “difficulties with interpreting and using the respective [accreditation] programs
- perception [accreditation] added little to patient care
- direct and indirect costs
- perceived inconsistencies among surveyors”

The findings of this literature analysis are consistent with the findings of the Commission’s review.

1.3 Purpose of Accreditation

The definition of accreditation used during this review is the one developed by the former Australian Council on Safety and Quality in Health Care which states “accreditation is the granting of recognition for meeting designated standards for structure, processes and outcomes, where outcome is the status of an individual, group of people or population which is wholly attributable to an action, agent or circumstance”. Like the Standards Australia⁴ definition of accreditation, it describes the process rather than the intent of accreditation.

In the first phase of consultation, stakeholders identified the lack of an agreed understanding of the purpose or intent of accreditation. Stakeholders suggested the purpose of accreditation could be to achieve one or more of the following:

- detection of poor performance to hold organisations or individuals accountable
- detection of poor performance in order to learn from failures and prevent recurrence
- promotion of best practice and continuous quality improvement.
- compliance with minimal standards

⁴ Standards Australia and ISO define ‘Accreditation’ as ‘third party-attestation related to a conformity assessment body conveying formal demonstration of its competency to carry out specific conformity assessment tasks’.

- effective risk management
- industry benchmarking
- public confidence that we have a safe, quality health system
- continuous quality improvement and compliance with standards to prevent adverse outcomes.

In the second round of accreditation, the Commission's Consultation paper sought to clarify the purpose of accreditation by suggesting that safer care could be achieved through the development and separate assessment of National Minimum Safety Standards. While this was not supported, there was agreement that the purpose of accreditation is to promote and support safe care for patients.

1.4 Consulting for the Best Model

Review of accreditation has involved two comprehensive consultation processes. Phase one involved the development of an initial discussion paper which was the basis on which discussions were held with stakeholders in one-on-one meetings, focus groups and through written submissions. That consultation process included the following stages:

1. **Preliminary meetings** and teleconferences with peak health organisations and key stakeholders. A total of 58 preliminary meetings were held from June to November 2006.
2. **Focus group meetings with stakeholders.** There were 40 focus groups, (including two pilot groups). Meetings were held in all state and territory capitals and two regional centres. Over 530 people nominated to attend and over 420 individuals participated. More than 65% of people who participated identified themselves as currently working as a clinician or having been a clinician.
3. **Stakeholder comment on written submissions.** An invitation to stakeholders to submit written comment on the Discussion Paper was widely distributed and ninety proposals were received.

The second stage of the national review of safety and quality accreditation standards commenced with the development of a second consultation paper. This paper proposed a model to guide reform for the Australian safety and quality accreditation system. The phase two consultation process was also multi-faceted and involved:

1. **Preliminary meetings** with stakeholder groups potentially affected by the reform proposals. More than 25 preliminary meetings were held during August 2007.
2. **Forum meetings with stakeholders with shared interests.** Eleven were held in NSW, SA and Victoria.
3. **Stakeholder comment on written submissions.** An invitation to stakeholders to submit written comment on the Consultation Paper was widely distributed and fifty-five (55) proposals were received.

4. **National workshop on accreditation.** Over 180 stakeholders, representative of the health system, were invited to participate in a workshop to explore the Commission's recommendations on accreditation reform.

The purpose of the consultation process has been to seek stakeholder views at each stage of the development of policy options that are the basis of proposed reforms. Thus there was a process of identification of the limitations, barriers and opportunities that implementation of these reforms offered and alternatives where there was a basis for doing so.

In undertaking each round of discussions with stakeholders, the Commission employed a best practice consultation process, as outlined in the Best Practice Regulation Handbook (Office of Best Practice 2006). Although accreditation occurs in a quasi-regulatory environment rather than an explicitly regulatory environment, the Commission has aimed for consultation that would satisfy the more demanding requirements of a regulatory assessment process.

A final report, with recommendations for reform of the accreditation system, including an implementation plan, is to be forwarded to Health Ministers by March 2008.

Review Reports

This paper, a *Draft Report on the Review of National Safety and Quality Accreditation and Standards* is the fourth Commission publication from this review process. The first review document was the *Discussion Paper: National Safety and Quality Accreditation Standards* released in November 2006. It presented a range of options for reform focused on operational and process changes to the accreditation system. The concepts in the November 2006 Discussion Paper represented the Commission's early thinking on reform of the accreditation system. The Commission saw this consultation process as the first phase of engagement with stakeholders about possible reforms that would progressively become more detailed and specific as potentially good ideas progressed into a coherent reform package. Included among the recommendations for reform were mapping of standards, piloting of tracer methodology and unannounced surveys, developing or endorsing a best practice model of standards development and mutual recognition.

The feedback from phase one of the consultation process was presented in a second paper titled *Report on Initial Stakeholder Consultation on the Review of National Safety and Quality Accreditation Standards*, released in July 2007. This report summarises the broad range of issues identified during consultations on the 2006 Discussion Paper. The discussion generally supported the need for accreditation reform, however, there was concern expressed by stakeholders about the need for a more strategic reform proposal and consideration of the value, cost and impact of proposed changes for the health system.

The learnings from phase one were used to shape and refine the policy options and an alternative model of accreditation was presented to Australian Health Ministers at their meeting in June 2007. Without endorsing the model, they agreed it should form the basis of further discussions with stakeholders. The result was a third paper

published by the Commission in August 2007, titled a *Consultation Paper: An alternative model for Safety and Quality Accreditation of Health Care*. The alternative model evolved from the options and solutions identified by stakeholders to address issues with the current system. It took into account recommendations from stakeholders for strategic reform of the system and sought to address Ministerial concerns about the lack of a national, coordinated and integrated system.

All four published papers, written submissions and facts sheets produced as a result of this review process are available on the Commission's website www.safetyandquality.gov.au.

2. Feedback on Phase Two Consultations

This section of the paper analyses the outcome of stakeholder feedback on the Australian Commission on Safety and Quality in Health Care Consultation Paper *An Alternative Model for Safety and Quality Accreditation of Health Care* convened during August and September 2007.

Two key strategies were employed to gain feedback. Firstly, key stakeholders with similar interests were invited to attend a series of forums. These forums aimed to identify barriers and opportunities in the alternative model from the perspective of particular groups. Forums were held for:

- Accrediting bodies (2 meetings)
- Allied health organisations
- Victorian/Tasmanian health services
- South Australian/Western Australian health services
- Dental practitioners and therapists
- NSW, ACT and Queensland health services
- Consumers
- Medical colleges and other standard setting organisations
- Practitioners of cosmetic procedures, and chinese medicine practitioners
- Health insurers

A nursing forum was planned but was unable to proceed due to issues with participant availability.

A Consultation Paper was publicly released in August 2007 and stakeholders were invited to provide written comment on the direction of the reform proposals or individual proposals by 5 October 2007. Fifty-five (55) proposals were received and available for review on the Commission's website at www.safetyandquality.gov.au.

Support for Reform

Overall there was support from stakeholders for elements of the alternative model of accreditation with some qualifications. Stakeholders considered that the reforms could offer a range of benefits, including:

- a uniform national approach to safety and quality assessment
- simplification of a complex and fragmented system
- reduction in duplication of effort and processes
- opportunities for greater efficiency
- a better balance between compliance requirements and quality improvement processes
- accreditation requirements proportional to the risks to patients
- establishment of an overarching framework for consistent safety and quality improvements
- enhanced credibility for the health care system
- decision making based on a partnership approach

- encouragement for the use of comprehensive, transparent, accessible, evidenced based, consumer informed, innovative, measurable and valid standards that and have a clinical outcomes focus
- improvements in surveyor competency and inter-assessor reliability
- opportunities for collection and analysis of core safety and quality data

Opposition to Reform

There were a number of stakeholders who did not support the proposed alternative model of accreditation, in whole or in part. The reasons given for opposition to the reforms included:

- Their restriction to the health sector, which is an artificial distinction for consumers who are seeking continuity of care across health, community, ambulatory and aged care sectors.
- A view that a regulatory model is considered inflexible and unresponsive to changes in evidence and the needs of health services.
- Fear that the cost of implementation of the model would be disproportionate to the benefits of the proposals.
- Suggestions that the changes will result in duplication of the regulation, guidelines and standards that already apply to health services.
- Whilst there may be accountability reasons to give Ministers a role in standards endorsement, they were seen to lack the expertise to ensure the currency and appropriateness of clinical standards.
- Other safety and quality tools may be more effective at organisational change to achieve better safety and quality patient care.
- That there was insufficient evidence of harm occurring to patients for an accreditation system to be warranted in small professional practices.
- There was inadequate enunciation of the issue of accountability.
- That reforms do not address key safety and quality issues such as workforce shortages, increasing workload and increased work hours due to increased demand facing health services.
- The risk that reforms may not result in a national system if the changes to be implemented are an agreed course of action that is separately interpreted and implemented by states and territories.

2.1 Separation of safety and quality assessments

This issue was discussed in detail at all eleven (11) stakeholder forums and in forty (40) of the fifty-five (55) written responses received by the Commission. Twenty-four (24) written respondents directly opposed the proposal and many of the others raised concerns. The separation of safety and quality was opposed by almost all stakeholder forum participants.

Respondents who opposed this reform proposal argued that safety and quality are part of a single continuum and any separation would be arbitrary and unhelpful. There was a perception that the proposal could lead to a reduction in focus on quality and it was noted that minimum safety standards do not drive improvement in service, but could promote minimal compliance with little incentive for performance improvement organisational learning. It was noted that a separation of safety assurance and quality improvement has the potential to create duplication and thus result in greater costs for health services.

Those stakeholders who supported this proposal considered that this was an opportunity to re-orientate the system to a patient focus, increase links to patient outcomes and create an open and standardised process.

There was general acceptance about the need for a particular focus on a small number of key safety issues. Participants tended to prefer the idea of introducing national standards through inclusion in a quality framework.

It was noted that if implemented, this change would require a comprehensive education program to explain the intent and extent of the changes and training for the full range of stakeholders involved in this area.

2.2 Separation of standards development and assessment

The issue of separation of safety and quality standards development and the assessment against those standards was discussed at all eleven (11) forums and by forty (40) of the written respondents. Twenty three (23) of the thirty four (34) written respondents addressed this issue and many of the forum participants supported this proposal.

Supporters of this reform proposal accepted that good governance requires a separation between standards development and assessment. Their concerns were based on a recognition that bodies which both set standards and assess against those standards have no incentive to either reduce the number of standards used to assess services or to fail those that do not meet standards. Stakeholders have reaffirmed the need for appropriate professional, technical and consumer involvement in standards development. It was noted this proposal supports the development of a single national set of standards, therefore promoting consistency in the assessment of health services.

It was suggested that the process of developing national standards should be independent of, but accountable to governments. Criticisms of the direct involvement of government in standard setting related to the timeliness and responsiveness of government to shifts in evidence and / or service delivery. For many respondents the

level, coverage and relevance of the standards was more important than who set the standard. Consumers were seen to support strategies such as this with potential to improve the transparency and reliability of safety assessment.

Those stakeholders opposed to this reform proposal saw the separation of standards development and assessment as adding to costs of standards development. The ‘capture’ of the accreditation system by regulation was feared, as it suggested that processes might supplant the legitimate ownership of professional standards by relevant professional bodies. It was suggested that the focus should be on the accreditation agencies:

- Demonstrating that their processes are transparent.
- Ensuring accountability for their activities.
- Guaranteeing a rigorous approach to standards setting with lessons from successes and failures embedded in standards development.
- Ensuring assessment methods and reporting are appropriate for time, place and service.
- Demonstrating that expenditure on the development and operation of assessment programs is justified.

2.3 Accreditation of services provided by registered health professionals

This reform proposal was discussed in all of the forums held, and in thirty five (35) written submissions.

Stakeholders have expressed concerns about the Commission’s proposed approach to the scope of accreditation. Stakeholders considered that the proposal in the first phase of consultation to base accreditation on service types was problematic. Similarly, stakeholders are not satisfied that the more recent proposal to base accreditation on health practitioner registration is the right approach.

From the Commission’s perspective, both proposals have benefits and limitations. Health services exist with a wide variety of organisational structures, in service networks and under a range of different service descriptions. The extent of this variation makes it difficult to accurately or consistently describe the services to be accredited. Recommending all services provided by registered health professionals be accredited also has limitations because it excludes a range of services provided by non-registered health practitioners with the potential to cause harm to consumers.

There was a mixed reaction to the registration-based proposal, with some respondents suggesting this represented the right approach to determining the scope of the alternative accreditation model. Some participants were prepared to accept the proposal as a starting point, and others wanted accreditation to span the continuum of specific services such as the blood supply chain. Still others considered that accreditation should be expanded on the basis of risk and either exclude a range of practice settings that were considered low risk (no evidence of patient harm) or include non-clinical services that had the potential for harm, e.g health food shops and beauticians. Health funds suggested that some quality standards for individual

practitioners, whether registered or not, would be useful and avoid the need for individual assessments by funds.

It was noted that the number of registered health professionals and the diverse range of settings and service types would make accreditation of all services where a registered health practitioner practices a substantial task. Some stakeholders have therefore suggested that the initial focus should be on institutions rather than low risk, small practice settings.

For low risk services, modifications to accreditation processes were proposed. These included self assessment and compliance with continuing professional development requirements of professional associations, together with random audit of conformity with the former proposals. Higher risk services accreditation could mean a requirement to provide regular data submission and participate in structured surveys and random visits.

Concerns were raised by stakeholders that the costs of this expanded accreditation would be significant. Some services are looking for incentive payments [as are available to General Practitioners] to implement these changes. Others suggested health services should meet the costs of the implementation. In progressing this work, there will be a need to identify these costs and identify funding source(s). It was noted that the implementation of this reform proposal is an essential component of the introduction of changes to the private health legislation and system reforms such as national registration and accreditation of education and training currently underway.

2.4 National minimum safety standards

This issue generated the most comment of the seven reform proposals with forty-one (41) written submissions addressing the issue and detailed discussion at all eleven (11) stakeholder forums.

There was general support for the establishment of some national standards, but it was noted these would need to be appropriate to the setting of care and not onerous to implement or measure. Respondents did not generally support standards merely to ensure ‘minimum safety’ but suggested standards should cover the spectrum of both safety and quality and be set at a level that is considered relevant and acceptable, not minimal. It was noted definitional issues would need to be addressed in the early stages of implementation to agree on the format, definition and purpose of a standard and the criteria and evidence used to assess the standard.

While there was no support for a pass/fail system, there was broad acceptance of the need for escalating sanctions for failing to meet such standards. A limited number of respondents suggested that registration boards should be responsible for implementation of sanctions and penalties. Suggestions for incentives and sanctions included funding, reimbursement, licensing conditions and scope of clinical privileges.

Participants suggested that the national standards could be incorporated into existing sets of standards, for example ACHS mandatory standards. As an extension to this approach, some participants suggested that there could be principles to identify the

areas for national standards. These could then be incorporated into existing standards and reviewed by a national entity. Other participants were supportive of an approach that enabled the national entity to endorse existing standards as compliant with the requirements for national standards.

A number of respondents provided suggestions for the clinical domains to be covered by the national standards, including:

- adverse events and serious near misses
- clinical handover and communication
- consumer participation
- credentialing (this was both supported and specifically excluded by other respondents)
- falls
- high risk / high volume conditions
- infection control / hygiene / health service acquired infections
- informed consent, including informed financial consent
- medication safety, for example 'warfarin'
- standards that consider mortality rates
- open disclosure
- patient experience
- patient identification including correct patient, site, procedure
- record keeping
- waiting times

It was noted the implementation of standards would be complex and that a suite of standards under each standard domain would be necessary to ensure their applicability across all settings of care. However, health services would only be required to comply with those national standards that are relevant to the service being assessed. Respondents have also recommended that the priority for standards development should be determined based on the risk of harm to patients.

There was strong interest by respondents in a participatory approach to standards development. Some respondents wanted to ensure input from practicing clinicians, while others wanted to ensure that standard setting was not dominated by any one professional group. There was a call for strong consumer involvement in both setting the criteria for the development of standards and for the actual development of standards. Other respondents suggested broad consultation and participation in standards development, including by relevant government agencies, health funds and indemnity insurers in an attempt to gain universal acceptance of the standards and reduce the overall burden of compliance and duplication of effort.

There was concern expressed that the standards should not be acute sector specific, and that they take account of high risk safety and quality issues that affect primary and community care. Further, it was suggested that national standards should be subject to external review by an organisation such as ISQua. It was suggested in a number of submissions that mapping of existing standards as part of the development of national standards would be beneficial.

Most respondents supported the proposal to collect and analyse data from the national standards and respondents saw this as a key role of the national entity. However, they expressed concern about the extent and frequency of reporting and stressed this

should not become time consuming, costly or a burden on clinicians. Generally, stakeholders wanted to access the information collected, although health services raised concerns about information being made public and misused or misinterpreted. Health insurers however saw access to 'real-time' performance indicator data on health services achievement against national standards as key to their support of the national standards.

The alternative model proposed that compliance with national standards would be mandatory. Some respondents did not support this proposal, stating it would be difficult to develop a suitable regulatory mechanism to implement and enforce mandatory standards.

The August 2007 Consultation Paper did not quantify the costs of implementing the reform proposals. It did however recognise that there were likely to be cost implications and sought comment from stakeholders. Respondents called for cost data to be collected, and many stakeholders called for government funding of these initiatives.

2.5 Assessment of non-clinical and technical compliance

This issue was not discussed in all focus groups and was addressed by only twenty-seven (27) of the written submissions. There was majority support for the concept of mutual recognition, where assessment certification awarded by one accreditation body is accepted by other accreditation bodies and the assessment is only carried out once. Commentators were keen to ensure that non-clinical and specialised technical areas only require assessment once. However, for a number of respondents the separate treatment of non-clinical and technical compliance was considered confusing and implied that these areas would always be assessed separately. They noted this would be inefficient and could disregard areas where mutual recognition already exists, such as Workplace Health and Safety in Queensland and ACHS recognition of RACP/NATA accreditation. Accrediting bodies emphasised the complexity of introducing mutual recognition processes, noting that the timing, content and standard of assessment are all factors to be considered in recognizing the accreditation results of another accreditation process.

There was concern expressed about the use of the term 'technical' to describe accreditation processes such as those used for pathology. It was highlighted that much of pathology can be described as clinical practice, although its application may be highly technical.

Some respondents found this reform proposal confusing and were unclear if cost benefits or efficiencies could be achieved. They suggested that non-clinical functions were integral to good patient care and therefore should be included in an overarching safety and quality improvement framework.

The alternative model is not aiming to achieve consistency across jurisdictional regulation in areas such as fire safety. Regulatory variations are a result of different legislation and approaches. However, respondents suggest that the role for the National Entity could include reaching cross jurisdictional consistency in health-

related areas, particularly where there are national standards such as relevant Australian Standards.

2.6 National framework for quality improvement

Thirty four (34) written submissions commented on this reform proposal and it was discussed in a number of stakeholder forums. The majority of submissions supported the proposal to establish a national framework for quality improvement.

Participants in forums that discussed the quality framework agreed that quality improvement activities by health services needed to continue and in some cases needed to be enhanced. Some participants welcomed the proposal that the framework would provide more flexibility for services to tailor quality improvement activities to their needs. Others considered that there should be some specificity in the framework such as standards or principles to achieve better quality outcomes, uptake of evidence based practice or means to enable quality to be measured.

The scope proposed for the framework varied widely and included:

- Mapping the full range of quality improvement activities (including accreditation) undertaken by health services, identifying the role and the expected outcome of each of these activities and presenting a plan for maximising the effectiveness of a national accreditation system.
- Identifying how accreditation should be developed over the next decade, including proposed structures and processes to achieve this.
- Developing a framework consisting of guiding principles only.
- Encouraging and supporting health services to achieve best practice.
- Ensuring public reporting of quality improvement activity.
- Covering the following domains of safety and quality:
 - access to care
 - clinical support processes
 - collaboration with patients
 - content of patient health records
 - continuity of care
 - coordination of care
 - diagnosis and management of specific health problems
 - education and training
 - equipment for comprehensive care
 - facilities and access
 - health promotion and prevention of disease
 - information about the practice
 - management of health information
 - practice systems.

Stakeholders were concerned that the quality framework should not be so general that it became ambiguous. It would therefore need to be tailored to service settings or professional groups to be implementable. Many of the respondents highlighted the availability of multiple, existing quality frameworks that could either be adapted or

endorsed, rather than investing in the development of a ‘new’ framework. There was not consensus about the level of detail or areas to be covered by a National Quality Improvement Framework.

2.7 National body to coordinate reform

Thirty seven (37) written responses and all of the stakeholder forums raised the proposal that a national entity be established to lead and coordinate the reform process.

A number of forum participants considered that the role of the national entity will be critical to the effective implementation of the alternative accreditation model and suggested its exact role would become clearer once the alternative model was more fully described. Stakeholders suggested the national entity could take on a range of roles, including:

- Agreeing on appropriate quality indicators
- Endorsing existing standards and processes
- Ensuring competency of health professionals
- Establishing a process for standards development
- Focusing on reducing duplication of effort around accreditation
- Identifying the need for standards
- Implementing assessment, monitoring and reporting
- Maintaining a register of accreditation status, with access by funders to this information
- Mapping, developing and setting of standards
- Negotiating, consulting and formulating national policy and guidelines on accreditation
- Providing resources and support for health services to achieve accreditation
- Registering/endorsing accreditation bodies and surveyors to accredit against national standards and/or quality standards
- Providing accountability for its decisions through review and appeals mechanisms.

Other stakeholders saw a more limited role and suggested the National Entity:

- Monitor health services to ensure quality activities are undertaken.
- Be independent of standards setting and accreditation assessment providers.

Participants suggested the need for clarification of the regulatory or other powers of this body. Some suggested the national entity be established as a statutory authority, or hold authority under Commonwealth and corporations legislation. Some stakeholders recommended the national entity report to Minister(s), the Australian Health Ministers Conference or parliament while others suggested it should be independent of government and/or report to the professions.

A number of stakeholders discussed the membership of the national entity. These respondents were unanimous in their request for their professional or interest group to be represented on the national entity. It was noted however that a board that was representative of all stakeholders would be very large and cumbersome.

Opponents to this reform proposal noted that a national entity represented a bureaucratic response to coordination and was not supported on the basis of potential cost and administrative burden.

2.8 Review of surveyor training

There was general support for a review of surveyor participation from the stakeholder forums and among the thirty-three (33) respondents who made submissions. However, there was no agreement on whether this is a high priority or low priority issue.

Respondents were divided on the purpose of the review and whether it should seek to:

- Review all existing arrangements with intention of creating a national model, although it is suggested this may be time consuming and costly.
- Examine existing arrangements and determine the acceptable elements of a surveyor training and performance management program. It is suggested this option would be quick and low cost.
- Develop criteria that organisations must meet for training and managing surveyor performance. This option could be completed over a short timeframe and at reasonably low cost, as it could utilise existing resources such as those developed by ISO and ISQua.

There was agreement that the scope of the review should be greater than just surveyor training. It was suggested it include performance management, surveyor competence and workforce availability and sustainability also.

Professional groups and consumers supported the continuation of peer led onsite assessment of services and consumers also called for a greater participation of consumer surveyors and support to allow this to happen. Stakeholders highlighted the potential for increased training and assessment requirements to have substantial costs. It was suggested this could lead to a reduction in the availability of surveyors who maybe unable or unwilling to meet additional competency requirements.

2.9 Associated reforms

Thirty-three (33) written submissions addressed these proposals, however the forums did not identify associated reforms as key issues and therefore spent little time discussing them.

Some forum participants sought reassurance that the associated reforms were still being considered as part of the alternative model. The proposal to pilot unannounced surveys was the reform option that received greatest discussion. This was viewed as having the greatest potential to ensure safety and quality were embedded in day-to-day operations of health services, but it also had the potential to disrupt services, particularly in small practice settings.

Mutual recognition was considered to be highly desirable and a priority for some respondents, while it was rated as a second order issue for others. It was also

considered complex, difficult to achieve harmonised regulation and technical standards and requiring extensive consultation to implement.

Participants were generally supportive about piloting patient journey methodologies (tracer) to obtain better information about how these approaches might work in the Australian context. However, as in previous consultations respondents suggested that assessment of a patient journey should follow a narrow and defined scope.

2.10 Other issues

A range of other issues were addressed in the forums and written submission. These are discussed in the following section.

Principles

Stakeholders recommended guiding principles as the basis for implementation of reforms. Examples were of two types. One type provided guidance around processes for implementation, for example:

- The nature and purpose of safety assurance and quality accreditation should be clear.
- The roles of parties involved in safety assurance and quality accreditation should be clear and unambiguously delineated.
- Systems for ensuring minimum safety levels for health services and encouraging quality improvement should be:
 - cost effective
 - coherent and comprehensive across the health system
 - oriented towards enhancing health outcomes, national priorities and consumers' experience of the health system.
- Existing organisations, processes and structures that are effective should be used in preference to establishing new ones.
- Standards development processes should conform to the international Code of Good Practice for the Preparation, Adoption and Application of Standards.⁵

Others recommended that principles could be developed by the National Entity instead of standards or a quality framework. These stakeholders asserted that principles would provide the flexibility that will be required to implement the reforms across the multiple settings of care and service types.

Consumer focus

There was a general view that the alternative model of accreditation should focus on outcomes for consumers. Consumers considered that they should be fully integrated as equal partners into all aspects of the development and implementation of the alternative model and the new accreditation system. Some stakeholders have stated that the proposed reform is not sufficiently consumer focused, nor is the role of consumers apparent in the model.

⁵Available at http://www.standardsinfo.net/isoiec/docs_wto/tbt-a3.pdf

Evidence, Research and Evaluation

Reform opponents called for greater evidence to support the reform proposals. They acknowledged that extensive discussions had been held with stakeholders, but noted the model did not include evidence that patients had been harmed or were at risk.

Stakeholders have noted the limited evidence available in the literature on the effectiveness of accreditation. It has been recommended that reforms include support for research in this area and that the capacity for rigorous evaluation is built into each of the reform projects.

Duplication

Private sector respondents again called for broader reform of safety and quality compliance requirements. They note the growing compliance requirements from accreditation, licensing, health funds, indemnity insurers and statutory entities and adding to the complexity the variation that occurs between state regulatory requirements.

All stakeholders called for a reduction in duplication and suggested national standards may provide a mechanism for achieving this.

Data collection and reporting information

Participants agreed that it was important to collect data about key clinical indicators to measure trends in safety and/or quality in terms of patient outcomes. Generally participants supported the publication of national performance information. They saw it as important to the success of the reforms, but suggested the diversity of services providing data will make collection and analysis difficult. Use of the existing ACHS performance indicators was suggested as an option.

Some participants supported the publication of institutional performance information to enable informed consumer choice. Funders, governments and consumers strongly supported the availability of accessible, consistent, national, public reporting of accreditation outcomes. There was recognition that data definitions are needed to support reporting and ensure valid comparisons. Participants generally accepted that current indicators might need to change. A number of participants wanted to avoid the imposition of any additional reporting requirements but were prepared to accept changes to current requirements if data items were replaced rather than added on.

It was noted that any new national data set must be adequately funded to allow accurate and appropriate data collection.

Regulatory mechanism

Respondents pointed out that the alternative model of accreditation proposes mandatory compliance with a legislative or regulatory base, but does not identify what this may be, where it would operate, or if it would be state and territory or Commonwealth based. Concerns were raised that jurisdictional specific regulation will continue to result in variation and fragmentation in safety and quality requirements. It was also suggested that regulation has the potential for down stream consequences that are not foreseeable and that the system already has multiple layers

of bureaucracy, regulation and guidelines. There was concern that the alternative model has the potential to add to this burden.

Implementation

Participants sought more detail about the timeframe, mechanism and resources for implementation. The need for rigorous evaluation of any changes was emphasised by a number of participants. Most participants wanted to understand how the alternative model would relate to other reform processes such as the COAG national registration and accreditation scheme for health professions and the Australian Government private health insurance reforms.

Respondents also made recommendations about implementation arrangements. As implementation across all registered health professionals is a large task, the following implementation options were suggested for services not currently accredited:

- High risk services should be addressed first.
- A registration period which would award 'provisional accreditation'.
- Self assessment to assist services in preparing for site assessment.
- Site assessment which leads to accreditation awards.

Communication strategy

Stakeholders highlighted the need for timeframes for change to be communicated well in advance to allow for organisational planning and investment. It was recommended that national standards be implemented in a gradual way as part of the normal cycles of accreditation.

Specifically there was a call for a community campaign to educate and explain the reforms and provide consumers with the tools to recognise and understand the implications of a health services' accreditation status.

3 Issues of Importance to Consumers

3.1 Process issues

The Commission considers that the purpose of accreditation should be to provide safer and better care for consumers. To achieve that, it is important that the model takes account of consumer concerns about the accreditation system. Consumers see it as essential that they be involved in the development and implementation of reform to the system. The consultation paper was criticised for not clearly defining a consumer, for not clarifying what an accreditation system is and because the alternative model of accreditation lacked a sufficient consumer perspective.

Consumer advocates have been actively engaged in the consultation process, however it is not possible for the countless number of consumer experiences to be described and therefore the process may not have captured the full range of views consumers hold. Those consumers who have been involved, do not consider the consumer voice to have been adequate in the process so far. The vast number of groups that have a legitimate interest in accreditation has meant this criticism has also been made by other stakeholder groups.

3.2 Issues with the reform proposals

Consumer representatives at the September 2007 forum and those that provided written comment on the Consultation Paper reported that while there was a logical argument connecting the issues identified in the November 2006 discussion paper and the reform proposals, not all of the issues of concern to consumers were discussed in that 2006 discussion paper or reflected in the reform proposals. The issues that were of most concern included the following areas of activity:

Continuity and integration of processes

Consumers noted they are the one stakeholder group that crosses all the health service interfaces, therefore consumers' were looking for enhanced support systems and process that can reduce fragmentation. Consumers suggested that limiting the proposed accreditation model to health perpetuates systems fragmentation. They are seeking reforms that operate nationally and consistently across different service locations and types, including community, home support services and aged care.

Safety and Quality Information

Consumers reported looking for information that explained what a health services' accreditation status meant for their care. They also wanted information about the safety and quality measures implemented by health services and their effectiveness. Consumer respondents recommend public reporting of qualitative data, such as data collected from reviewing the patient journey (tracer methodology) and unannounced surveys. They acknowledge the difficulties in collecting this information but believe that it is a valid source of data providing meaningful information about a consumer's experience. They also strongly support information being provided back to health services and individual clinicians as a means of influencing changes to improve safety and quality.

Mandatory requirements

Consumers have argued that failures of the current accreditation system are in part due to the system being voluntary and that trends in safety and quality are difficult to interpret because performance indicator data reporting through ACHS is currently optional. They do however note the need for caution when implementing a mandatory model of accreditation as there is the potential to limit innovation by health services.

Access to services

Consumers are concerned to ensure that reforms do not lead to reduced access to health services. They see that proposals such as pass / fail requirements for national standards could impact on access to care, with failed services unable to provide services. Further, they have concerns that any focus in the reforms on 'efficiency gains' could have an impact on the equity, fairness and appropriateness of services for consumers.

Safety and quality systems

Consumers raised the issue of stakeholders with economic and other vested interests in gaining accreditation for a service seeking a greater say in how the current and future accreditation systems and organisations operate, thus limiting opportunities for the consumer voice to influence outcomes. Consumers are also keen for strong links to be established between the accreditation reforms and other national initiatives, such as national registration and accreditation of education and training, which in their view will strengthen safety and quality in health services and improve patient outcomes.

Health services

While consumers are seeing some improvements in safety and quality at a local level, there is concern that quality is not always well resourced and that the factors that impact on safety, such as workload and staffing numbers cannot be addressed through this reform process. There is a call by consumers for a gradual introduction of accreditation and support for health services not currently accredited to become accredited so that there is minimal disruption to service delivery.

Barriers to consumer participation

Consumers advocated vigorously for greater participation in all decision making processes associated with accreditation. They highlighted that consumers had campaigned for a voice in these processes over many years. They are seeking equal partnership in processes and the necessary systems changes to support and resource this happening. Further, consumers believe that if the alternative model explicitly recognises the 'value add' of consumer contribution, this will facilitate a broader recognition of the benefits consumers bring to such processes. Consumers reported artificial barriers still existed to their meaningful participation. Some consumers suggested that evidence based practice and its methodology can lack a robust consumer perspective.

3.3 The way forward

The Commission has aimed to respond to consumer perspectives in revising the alternative model. In addition, to facilitate consumer input and participation, a community participation strategy will be developed that includes mechanisms to ensure consumers are:

- informed about accreditation developments and outcomes of the change process as well as individual service accreditation outcomes and
- involved in decision making processes.

In addition, mechanisms need to be identified to ensure that the diverse range of consumer perspectives are captured in the accreditation process.

4 Issues of Importance to Clinicians

4.1 Issue

While the purpose of accreditation is to provide safer levels of care for consumers, in doing so it should also produce systems that support clinicians to improve the safety and effectiveness of care. Clinicians are vital to the implementation of and compliance with, safety and quality standards. Therefore, understanding the views that clinicians have about current accreditation processes and the alternative accreditation model are crucial to the successful implementation of any reform proposals. Clinicians have identified the following issues:

Health system issues

Pressures exist in the current health system that cannot be addressed by accreditation but have a significant impact on the safety and quality of service delivery. These pressures include:

- workforce shortages associated with inadequate supply and mal-distribution of clinical staff, and
- increased demand for services.

Clinicians are emphatic that any increase in workload and administrative burden must deliver efficiencies and information that can improve patient care. Clinicians recognise that safe and good quality care, provided the right way the first time, results in service efficiencies.

Events management of accreditation surveys

The current accreditation system can deliver change for health services in part because of the internal and external review cycles of assessing performance, acting, evaluating and reassessing. It also provides an opportunity to demonstrate to external surveyors system changes that have worked well. However, the accreditation process can also present perverse incentives for clinicians, which discourage exploration of failure or system breakdowns. Numerous clinicians reported 'event management' of external accreditation visits to ensure the health service achieved accreditation, without necessarily identifying issues in the delivery of care that concern clinicians.

Costs

Clinicians associate accreditation with administrative processes and tasks, which often seem to have a limited relevance to patient care. They expressed concerns that an increase in administrative burdens associated with accreditation reforms may divert funding and effort away from patient care.

Standards

There has been significant clinician engagement in the development of accreditation standards, both through organisations such as ACHS, medical colleges, QIC and others, and through professional associations. The alternative model proposes

Ministerial endorsement of Australian Health Standards and standard setting processes. Clinicians are concerned that standards could be developed without the adequate collaboration of clinical practitioners, which could result in practitioners having to comply with standards that are not meaningful or relevant to the delivery of safe and good quality care to patients. Clinicians are keen to participate in the development of standards to ensure they remain relevant to patient care and address recognised safety and quality improvement needs.

Impact of public systems failures

High profile safety and quality systems failures in accredited hospitals, in the recent decade, have impacted negatively on numerous clinicians. These failures have led to a drop in public confidence and lower morale among some clinicians. Implementing change in this environment is both important and difficult.

Data collection

Clinicians are concerned about the impost of possible additional data collections. They do however realise the value of data in supporting care management decisions. Clinicians have called for access to timely, accurate clinical data that can generate clinically meaningful information.

Some respondents have recommended that detailed data collections on specific topics of concern be undertaken and made available once over a five or ten year cycle. While this would require significant effort over a short period, the information generated could be used to inform policy and practice at all levels and would not result in an ongoing burden.

Risk

Clinicians have raised concerns that options for expanding the accreditation system to registered health professionals ignores non-registered professionals providing high risk services. They recommend phased implementation based on a risk management approach.

4.2 The way forward

To address the concerns of clinicians and ensure their participation in the implementation of a fully inclusive model of accreditation, it is proposed that they:

- Are involved in decision making processes.
- Are given access to information, training and/or education relevant to the reforms prior to its introduction.

In addition, mechanisms need to be identified to ensure the diverse range of clinician perspectives are incorporated into the further development of the alternative model and its implementation.

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