AUSTRALIAN COMMISSION
ON SAFETY AND QUALITY IN HEALTH CARE

Consultation Regulation Impact Statement

Review of the National Safety and Quality Health Service Standards

July 2016

NSQHS STANDARDS
A better way to care

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Executive summary

This consultation Regulation Impact Statement (RIS) is the final stage of a consultation process undertaken by the Australian Commission on Safety and Quality in Health Care (the Commission) to review the National Safety and Quality Health Service (NSQHS) Standards.

The Commission has legislative responsibility to develop and maintain the NSQHS Standards.

The NSQHS Standards were designed to protect the public from harm and to improve the quality of health care for consumers. They are applicable to all health service organisations, and have been used to assess all hospitals and day procedure services since January 2013.

The introduction of version 1 of the NSQHS Standards was successful. Preliminary evaluation shows a number of high-level impacts, including:

- a focused framework for safety and quality activities nationally
- a proactive rather than reactive approach to safety and quality
- better management of safety and quality risks by hospital Boards, nationally
- increased integration of governance and quality improvement systems, nationally
- decreased rates of several healthcare-associated infections, nationally, including
    - The *Staphylococcus aureus* bacteraemia (SAB) rate per 10,000 patient days under surveillance decreased from 1.1 to 0.87 cases. The yearly number of methicillin-resistant *Staphylococcus aureus* (MRSA) bacteraemia cases decreased from 505 to 389 over this period.
    - The national rate of central-line associated bloodstream infections (CLABSI) almost halved from 1.02 to 0.64 per 1000 line days from 2012-13 to 2013-14.
- greater prioritisation of antimicrobial stewardship activities in hospitals, nationally
- better documentation of adverse drug reactions and medication history, nationally
- reduction in red blood cell issues and discards, nationally
- yearly red blood cell issues by the National Blood Authority fell from mid-2010 to mid-2015, from approximately 800,000 units to 667,000 units
- hospital-acquired pressure injuries have continued to decline in Qld, while in WA, previous improvements appear to have been at least maintained
- declining in-hospital cardiac arrest rates in Victoria and NSW, and in ICU admissions data (ANZICS national data)
- reduction in extreme harm incidents involving falls, in South Australia, where reporting of serious incidents is relatively reliable, the proportion of extreme harm

(SAC1) incidents involving falls has decreased by more than 50 per cent since 2011 (from 0.31 per 10,000 occupied bed days in 2011-12 to 0.11 per 10,000 occupied bed days in 2014-15)

- a lever and impetus for other safety and quality initiatives.

A review of the NSQHS Standards is required to ensure that they remain current and consistent with best practice. While the NSQHS Standards provide a framework for safety and quality improvements, the review will:

- address implementation issues resulting from the introduction of version 1 of the NSQHS Standards.
- address safety and quality gaps in version 1 of the NSQHS Standards
- update the evidence base used.

The options to ensure the NSQHS Standards remain current and relevant are:

- **option 1** – retain version 1 of the NSQHS Standards for an additional three years
- **option 2** – transition to version 2 of the NSQHS Standards by 2018–19
- **option 3** – introduce a sub-set of NSQHS Standards from version 2 by 2018-19

This paper presents a preliminary analysis of costs and benefits for stakeholders of each option, and invites comment from stakeholders.

The Commission is recommending option 2, given its potential for the greatest net benefit to consumers. The current safety and quality framework, and the process for reporting of accreditation outcomes were created by implementing version 1 of the NSQHS Standards. Option 2 builds on the already established processes.

The Commission is seeking feedback from stakeholders on the impacts of these options and will consider this feedback before making final recommendations to Australian health ministers.

Introduction

This consultation Regulation Impact Statement (RIS) is the final stage of an extensive consultation process undertaken by the Australian Commission on Safety and Quality in Health Care (the Commission) to review the National Safety and Quality Health Service (NSQHS) Standards.[1]

The NSQHS Standards were designed to protect the public from harm and to improve the quality of health care for consumers. They were endorsed by Australian health ministers in 2011 and implemented in health service organisations.

The NSQHS Standards are applicable to all health service organisations. Australian, state and territory governments expect all hospitals and day procedure services to comply with the requirements of the NSQHS Standards. Therefore, major changes to the NSQHS Standards must be made in accordance with the RIS requirements of the Council of Australian Governments (COAG).

The COAG process for preparing and submitting a RIS comprises two stages. The first stage involves consultation on the costs and benefits of the proposed changes; this is known as a consultation RIS. The second stage involves preparation of a recommendation report, or decision RIS, that includes an analysis of comments from the consultation RIS, as well as evidence on the costs and benefits of the proposed changes. The decision RIS, along with the final draft version 2 of the NSQHS Standards, will be submitted to health ministers for their consideration.

Information in this report is based on the specifications of the Office of Best Practice Regulation.

Version 1 of the NSQHS Standards

Implementation of version 1 of the NSQHS Standards has produced promising results, and generated widespread engagement and support among health service organisations. In implementing the NSQHS Standards, health service organisations have put in place safety and quality systems to ensure that the described standards of care are met.

State and territory health departments have contributed significant resources to support health service organisations in implementing the NSQHS Standards, by developing policy updates; and aligning data collections, reports and performance agreements in keeping with the requirements of the NSQHS Standards.

Version 1 of the NSQHS Standards was drafted between 2008 and 2010. Since then, the evidence base and practice models of care have developed further. In addition, research conducted by the Commission and others has identified a number of emerging safety and quality issues that are not addressed in version 1 of the NSQHS Standards.

To continue to drive improvements in the safety and quality of health care, the Commission began a review of the NSQHS Standards in 2015. As part of this review, and following national consultation, the Commission developed a draft

version 2 of the NSQHS Standards. The draft version 2 (July 2016) was refined following piloting and extensive industry-wide consultation, and is the subject of this RIS process.

In version 2, the overall number of Standards has been reduced from 10 to 8, and the number of actions within the Standards has been reduced from 256 to 148.

The draft version 2 of the NSQHS Standards (July 2016) has been improved by:

- reducing duplication in version 1 of the Standards
- incorporating content relating to new and emerging safety and quality issues
- updating the evidence base
- adapting and clarifying the language to improve the applicability of the Standards to a broader range of health service organisations
- identifying who has primary responsibility for implementing each of the actions in the Standards
- improving navigation of the NSQHS Standards document by changing the format of items to subheadings
- addressing the implementation issues associated with version 1 of the Standards.

Element 1 Statement of the problem

Since the introduction of version 1 of the NSQHS Standards, a number of issues have been identified, including the following:

- **Duplication** in version 1 of the Standards adds to the cost and time required to meet the requirements of the Standards.
- There has been confusion about the **coverage of the clinical workforce** in the Standards, because the definition was unclear and open to interpretation.
- The Standards require significant investment in **clinical audit**, which has been criticised as unnecessary.
- Some of the **evidence base** for the Standards has been updated.
- The move by jurisdictions to introduce **integrated screening** of patient risk is not reflected in the Standards, which have separate screening processes for falls and pressure injuries, and do not address comprehensive care.
- **Patient identification and procedure matching** requirements are detailed and overlapping, placing an unnecessary burden on health service organisations implementing this Standard.
- **Gaps in coverage** of safety and quality issues in the Standards have been identified in areas that have a significant safety and quality burden, including mental health, cognitive impairment, end-of-life care, health literacy and Aboriginal and Torres Strait Islander health.

These issues are described in further detail in the following sections.

1.1 Duplication

Version 1 of the NSQHS Standards required organisations to undertake quality improvement activities for actions within each Standard. A majority of the 482 representatives of health service organisations involved in focus groups during May and June 2015 reported that, in some instances, these requirements were prescriptive and did not always focus on the areas of greatest risk. As a consequence they diverted resources from safety and quality issues that were of higher priority in their organisations. It was estimated that more than 30 per cent of the actions could be combined to reduce the duplication in the Standards.

1.2 Coverage of the clinical workforce

The NSQHS Standards currently define three workforce groups: clinicians, nonclinical workforce and workforce. These definitions have proven to be problematic, because the inclusion of credentialed practitioners is unclear. Health service organisations are keen to ensure that credentialed practitioners are included in implementation of the requirements of the clinical Standards. However, there are difficulties associated with documenting and/or providing access to training for credentialed practitioners.

1.3 Clinical audit

In version 1 of the NSQHS Standards, each of the 10 Standards includes items with 3–5 actions that require health service organisations to implement changes to processes, monitor or audit the changes, and evaluate and improve the processes. Thirty-seven actions specifically require audits or monitoring, and jurisdictions have suggested that as many as 143 audits are required to fully meet the requirements of the Standards.

Health service organisations have stated that, in some instances, these requirements for clinical auditing are prescriptive and unduly burdensome, and do not allow organisations to consistently focus on areas of greatest risk for their organisation. Stakeholders suggested that future Standards should consolidate the auditing requirements and replace them with a single action. This action would require organisations to have a quality improvement program for each Standard that addresses priority safety and quality issues relevant to that organisation.

1.4 Outdated evidence base

The Standards address areas in which there are:

- a large number of patients involved
- known gaps between the current care delivery and best-practice outcomes
- existing improvement strategies that are evidence based and achievable.

The evidence base for determining which actions are included in the NSQHS Standards comes from a range of sources, including scientific journal articles, project reports, internal research, and feedback from committees, technical advisory groups, clinicians and consumer focus groups.

The credibility of the NSQHS Standards requires that they are based on a strong and current evidence base. The NSQHS Standards were developed in 2009–10, and the evidence base predates this time. The strategies and requirements in version 2 of the Standards have been appraised either through a review of the literature with technical experts or in collaboration with expert clinicians to agree and describe best practice, based on current evidence.

1.5 Integrated screening and comprehensive care

Currently, the NSQHS Standards have separate screening and assessment processes for falls and pressure injuries. If cognitive impairment, mental health and end-of-life care are introduced in version 2 of the Standards, clinicians would need to conduct multiple screening processes on patients at presentation. Jurisdictions have indicated that they are moving to integrate screening processes to ensure that all of an individual’s risks are identified so that comprehensive care plans can be developed to meet these needs. To support these initiatives, the NSQHS Standards could consolidate the screening requirements in the Standards, and link them to a patient-centred comprehensive approach to screening and care.

1.6 Patient identification and procedure matching requirement

Patient identification mechanisms are used in health service organisations to ensure that the correct person is matched with the correct procedure whenever care is provided. Misidentification and the wrong procedure are serious adverse events, occasionally leading to serious harm. Stakeholders have recommended that this Standard be streamlined and simplified, and strongly support combining it with an increased focus on effective and safe clinical communication.

1.7 Gaps in coverage

The Commission facilitated 31 focus groups nationally – with more than 470 representatives from health service organisations, consumers, peak bodies and interest groups – to discuss the content and implementation of version 1 of the NSQHS Standards. Participants agreed that there were gaps in the Standards, including in the areas of:

- mental health
- cognitive impairment
- end-of-life care
- health literacy
- Aboriginal and Torres Strait Islander health.

These areas are described in further detail below.

Mental health

Why is it a problem?

Two set of standards are applicable to mental health services: the National Standards for Mental Health Services and the NSQHS Standards. Although there are some areas of duplication, there are still gaps in the coverage of safety and quality across health service organisations. The National Standards for Mental Health Services do not apply in all settings of care where patients receive care for their mental illness (e.g. emergency departments), and the NSQHS Standards are not directly applicable in the large and growing community-managed organisations.

There is also large variation in the dispensing of prescriptions commonly used to treat mental health disorders, including psychotropic medicines, antidepressants, and anxiolytic and antipsychotic medications, indicating the potential for inappropriate use or overuse by some patients.[2]

What are the risks associated with this area?

Mental and behavioural disorders are the second largest contributor to the nonfatal burden of disease and account for 13 per cent of the total burden of disease in Australia.[3]

Identified gaps in safety and quality systems have the potential to affect the quality of care provided to people who have lived experience of mental health disorders – in

terms of both receiving care in an environment where they feel safe and receiving care that is consistent with best practice.

These safety and quality risks may lead to poorer health outcomes for patients, which in turn may increase costs of care.

The impact of mental health disorders is significant for patients, families and other support people, and communities more broadly.[3]

What is the evidence in this area?

The Commission has conducted research to identify issues associated with safe and high-quality care for people with experience of mental health disorders.

The specific safety and quality issues identified include:

- seclusion and restraint
- sexual safety
- psychological deterioration and recovery principles
- delivery of care in community settings.

More than 40 per cent of survey respondents and many focus group participants agreed that the implementation of standards improved direct service delivery. Service providers particularly noted the increased prominence of recovery principles, and stated that the standards provide an impetus to focus on good-quality clinical care for each person. Respondents also noted that these improvements were driven by collaboration with service users.

What is the magnitude of risk?

It is estimated that 2–3 per cent of Australians (600 000 people) have severe mental health disorders, as judged by diagnosis, intensity and duration of illness. Another 4–6 per cent (1 million people) have a moderate disorder, and 9–12 per cent have a mild disorder.

Twenty per cent of adults (3.2 million people) have experienced a mental disorder in the previous 12 months.[4]

This is associated with the following costs:

- More than $8 billion, or $344 per person, was estimated to be spent on mental health–related services in Australia during 2013–14, an increase from $321 per person (adjusted for inflation) in 2009–10.
- A total of $4.9 billion was spent on state and territory specialised mental health services in 2013–14; there was an average annual increase of 5.8 per cent between 2009–10 and 2013–14. Of the expenditure in 2013–14, most was spent on public hospital services for admitted patients ($2.1 billion), followed by community mental health care services ($1.9 billion).
- Expenditure on specialised mental health services in private hospitals was $335 million in 2013–14.

- The Australian Government spent $753 million, or $32 per person, on subsidised prescriptions under the Pharmaceutical Benefits Scheme (PBS)/Repatriation Pharmaceutical Benefits Scheme (RPBS) during 2013–14, equating to 8.1 per cent of all PBS/RPBS subsidies.[5]

What other priorities are linked to this issue?

- National Mental Health Strategy – National Standards for Mental Health Services (Mental Health Standing Committee).
- *Recognising and responding to deterioration in mental state: a scoping review* (Commission).

How can the NSQHS Standards address this problem or reduce the risk?

The NSQHS Standards provide a standardised framework for addressing safety issues facing mental health patients in mainstream health services. If these requirements are included in mandatory standards, areas not currently implementing mental health standards will be required to comply.

The direct and indirect costs of mental ill health are estimated to be up to $28.6 billion per year.[3] The introduction of mandatory standards that improve care for people with lived experience of mental ill health, even with a small improvement, could save expenditure of hundreds of millions of dollars annually.

Cognitive impairment

Why is it a problem?

Cognitive impairment (such as delirium or dementia) is a common condition experienced by people in hospitals. It is often not detected, or is overlooked or misdiagnosed.

Harm can be minimised if cognitive impairment is identified early and risks are addressed.

Cognitive impairment is not specifically addressed in version 1 of the NSQHS Standards. However, the harm that is associated with cognitive impairment, such as pressure injuries and falls covered in version 1 of the NSQHS Standards. Recognition of cognitive impairment as the underlying cause could further reduce harm to these patients.

What are the risks associated with this area?

People with cognitive impairment in hospital are at significantly increased risk of adverse events and preventable complications such as falls, pressure injury, accelerated functional decline, longer lengths of stay, premature entry to residential care and increased mortality.

If this issue is not addressed, the condition will continue to be under-recognised. People with cognitive impairment are at risk of poorer health outcomes. It is known that there are ways to better prevent and manage these risks.

What is the evidence in this area?

Patients with dementia are almost twice as likely to die in hospital as patients without dementia.[8]

Mortality rates for hospitalised patients with delirium are high, ranging from 22 per cent to 76 per cent.[8] The chance of dying in hospital following an episode of delirium is reported to be 2.6 times higher for patients with delirium than for patients without delirium.[8]

Patients who have a stroke are 4.7 times more likely to die and 4.9 times more likely to have an increased burden of disease if they also have delirium.[8]

Delirium is 8.3 per cent more common in older patients in the emergency department, although in 86 per cent of cases it is not detected. The non-detection of delirium in the emergency department may be associated with increased mortality within six months following discharge.[8]

Between 3 per cent and 29 per cent of older patients (65 years and older) develop delirium during a hospital stay, although rates as high as 47–53 per cent in older surgical patients have been reported.[8]

Studies suggest that critical illness and intensive care treatment are associated with long-term cognitive impairment in older patients (65 years and older), although the magnitude of the problem is unclear.[8]

What is the magnitude of risk?

One in 10 Australians aged over 65 years and 3 in 10 aged over 85 years have dementia.

There were 332 000 people living with dementia in Australia in 2014. The number is anticipated to reach 400 000 by 2020, and 900 000 by 2050. This could change if there are changes in dementia risk, and in the prevention, management and treatment of the condition.[4]

The development of delirium in hospital has been shown to increase the length of stay by 7.32 days in the intensive care unit and by 6.53 days in hospital.[8]

What other priorities are linked to this issue?

- Caring for Cognitive Impairment Campaign to improve knowledge and care practices, providing better outcomes for patients with cognitive impairment, hospitals, staff and loved ones, and reducing the risk of harm in hospitals.

How can the NSQHS Standards address this problem or reduce the risk?

Better detection of people with delirium through routine screening and better management when identified, can reduce the rate of preventable delirium, and the complications and cost of delirium.

It is estimated that 30–40 per cent of delirium cases can be prevented with the right care. The introduction of mandatory actions to screen for delirium can result in early detection, reduce length of stay and reduce complications from undetected delirium.

Even a small improvement in detection rates, can reduce the costs of care by many millions of dollars annually.

End-of-life care

Why is it a problem?

Acute hospitals provide end-of-life care to the majority of people who die in Australia. The population is ageing, and, as the proportion of older Australians grows, it is likely that the numbers of people requiring end-of-life care in this setting will rise.

The quality and safety of end-of-life care have important implications not only for the individual patient but also for their family, the people involved in providing care and society as a whole. Potentially preventable physical, emotional and spiritual distress can occur if care is less than optimal, and there are significant cost implications for society if unwanted or inappropriate medical treatments are continued.

Even with the considerable investment in palliative care services that already exists, and the implementation of initiatives such as palliative care guidelines, education programs, care pathways and advance care planning programs, it appears that persistent gaps remain in the quality and safety of end-of-life care.[10]

End-of-life care is not currently specifically addressed in the NSQHS Standards. Indeed, until recently, there was no consensus on what was required to provide high-quality end-of-life care.

What are the risks associated with this area?

Care provided may be inappropriate and unnecessary when more conservative treatment may better reflect the patient's health status.

Resources may not be allocated effectively or in accordance with the patient's wishes or needs.

What is the evidence in this area?

End-of-life care is not always usual business, and care is outsourced to medical emergency teams, palliative care teams and intensive care teams. For patients, this means that the only care provided results from acute deterioration, by strangers, after hours and in urgent circumstances.

Treatment is often continued long after it becomes apparent that a person is at the end of life. A conversation with them and their family and carers may prevent the need for further treatment that is likely to be ineffective.

What is the magnitude of risk?

In 2012–13, 61 596 palliative care–related hospitalisations were reported from public and private hospitals in Australia.

People aged 75 years and over accounted for just over half (51 per cent) of all palliative care–related hospitalisations.

There was a 52 per cent increase in palliative care–related hospitalisations between 2003–04 and 2012–13.

In just over 2 in 5 (42 per cent) of hospitalisations where the patient died as an admitted patient, the patient had received palliative care.

In 2011–12, palliative care–related separations accounted for nearly 646 000 patient days, with an average length of stay of 11.2 days – nearly four times as long as the average length of stay of 3.0 days for all separations.[11]

What other priorities are linked to this issue?

- Introduction of the National Consensus Statement on end-of-life care in 2015 by the Commission.
- *National Palliative Care Strategy 2010: supporting Australians to live well at the end of life*.

How can the NSQHS Standards address this problem or reduce the risk?

The introduction of mandatory standards that provide greater choice for people at the end of life, even with a small improvement, could reduce length of stay and the cost of unnecessary procedures, which has the potential to save millions of dollars annually.

Health literacy

Why is it a problem?

Individual health literacy can influence how people undertake a range of tasks, including:

- reading, understanding and acting on preventive health messages, healthcare plans, medication instructions and other health information
- completing health and healthcare forms such as consent forms, insurance forms, Medicare claim forms and diagnostic survey tools
- finding a healthcare provider or service and making an appointment
- making informed decisions about health and health care
- navigating healthcare systems and services
- understanding signage and way-finding within and between health services.[9]

Health literacy is linked to health outcomes and can influence:

- how people access and use healthcare services
- interactions between consumers and healthcare providers
- how people manage their own health
- how people exert control over the factors that shape their health.[9]

Health literacy is linked to a number of health and healthcare concepts, including:

- patient-centred approaches to care
- patient motivation or activation
- cultural competence
- human rights–based approaches to health care
- shared decision making
- informed consent.[9]

Health literacy is not specifically addressed in the current NSQHS Standards, and this is a new area of improvement for many Australian health services.

What are the risks associated with this area?

Low individual health literacy has been found to be associated with:

- increased rates of hospitalisation and greater use of emergency care
- lower use of mammography and lower uptake of the influenza vaccine
- poorer ability to demonstrate taking medications appropriately
- poorer ability to interpret labels and health messages
- poorer knowledge among consumers about their own disease or condition
- poorer overall health status among older people
- higher risk of death among older people.[9]

What is the evidence in this area?

Low individual health literacy has been found to be significantly associated with a poorer understanding of medications and medication instructions, and poorer adherence to treatment regimens.

Studies have estimated that nearly half of adults misunderstand common dosing schedules (e.g. take two tablets by mouth twice daily), and warnings that detail important information to support safe and effective use (e.g. do not chew or crush, swallow whole; for external use only).

Research about the readability of written information for consumers has often found that documents contain language and complex concepts that would be difficult for the average person to comprehend. Other studies that have looked at the information provided to patients about their condition and treatment, particularly for specific conditions such as cancer, have suggested that healthcare providers may need to pay more attention to providing patient-centred information.

Consumers report that their needs regarding information are not always met. People who are provided with appropriate information (based on satisfaction with received information, fulfilled information needs, and high-quality and clear information) report better health-related quality of life, and lower levels of anxiety and depression.[9]

What is the magnitude of risk?

Sixty per cent of adult Australians have low health literacy.

It is difficult to accurately determine the cost of lower individual health literacy to the person, healthcare organisations and the system as a whole. This is partly due to the difficulty in separating the effects of individual health literacy from other related concepts that influence behaviour.

One systematic review in the United States that examined the costs associated with lower individual health literacy found that, at a system level, additional costs corresponded to approximately 3–5 per cent of total healthcare spending.[9] If this percentage were applied to Australian healthcare data, where the total healthcare expenditure for 2011–12 was $140 billion,[4] the costs associated with lower individual health literacy would be $4.2–7 billion.

At an individual level, people with lower health literacy cost between US$143 and US$7798 more per person per year on health care than people with higher individual health literacy. However, a later systematic review found that the results of cost-impact studies were mixed, and further research was needed to accurately estimate the cost of health literacy and the benefits of applying health literacy strategies.[9]

What other priorities are linked to this issue?

- *Health literacy: taking action to improve safety and quality* (Commission).
- NSW health literacy program.

How can the NSQHS Standards address this problem or reduce the risk?

The introduction of mandatory standards can support people with poor levels of health literacy to achieve better health outcomes. Even with a small improvement in this area, there can be savings of millions of dollars in costs annually.

Aboriginal and Torres Strait Islander health

Why is it a problem?

Despite some improvements, Aboriginal and Torres Strait Islander people still have poorer health outcomes than non-Indigenous Australians. They are more likely to die at younger ages, experience disability and report their health as fair or poor.[4]

Research by the Commission has identified the need for targeted strategies that better meet the health needs of Aboriginal and Torres Strait Islander people who access care in mainstream health service organisations.

There are currently no safety and quality health service standards that specifically address the needs of Aboriginal and Torres Strait Islander people that apply to mainstream health services. Improvement strategies for health care for Aboriginal and Torres Strait Islander people have typically focused on a location, service or disease. The NSQHS Standards provide a mechanism for implementing systemic change across all health services.

What are the risks associated with this area?

The burden of disease suffered by Aboriginal and Torres Strait Islander Australians is estimated to be 2.5 times greater than the burden of disease in the total Australian population.[6]

What is the evidence in this area?

Compared with non-Indigenous people, Aboriginal and Torres Strait Islander people experience higher incidence rates of:

- end-stage kidney diseases (×7)
- diabetes (×3.3)
- hospitalisations for respiratory conditions (×3)
- obesity (×1.5)
- death from cancer (×1.5)
- youth suicide for females (×5.9)
- youth suicide for males (×4.4).[4]

What is the magnitude of risk?

In 2010–11, 3.7 per cent of Australia's total health expenditure, or $4.6 billion, was spent on Aboriginal and Torres Strait Islander people, who make up 2.5 per cent of the Australian population.[7]

What other priorities are linked to this issue?

- National Partnership Agreement on Closing the Gap in Indigenous Health Outcomes and *National Aboriginal and Torres Strait Islander health plan 2013–2023*.
- State, territory and local initiatives that focus on Closing the Gap targets.

How can the NSQHS Standards address this problem or reduce the risk?

Indigenous people do not always seek the treatment they need in mainstream health services because the service is not set up to recognise or support their cultural beliefs and practices. They are more likely than non-Indigenous people to leave before treatment is conducted or completed. The opportunities to partner in their own care and share decision making are fewer for Aboriginal and Torres Strait Islander people because of language difficulties, and lack of cultural awareness within organisations and the by health workforce. These factors result in poor health outcomes for Aboriginal and Torres Strait Islander people.

The average annual health expenditure on Indigenous Australians is $7995 per person, compared with $5437 for non-Indigenous Australians.[7]

The introduction of mandatory standards that improve health outcomes for Aboriginal and Torres Strait Islander people, even with a small improvement of 1–2 per cent, has the potential to save many millions of dollars in expenditure annually.[7]

Element 2 Objectives of the NSQHS Standards

The objectives for implementing the NSQHS Standards are to:

- protect patients from harm and improve the quality of health care that is delivered
- provide evidence-based safety and quality standards that can maximise the safety and quality of health care for patients
- reduce the unnecessary use of healthcare resources by reducing preventable patient harm
- ensure that safety and quality change is introduced in the most efficient and effective way possible.

The introduction of the Australian Health Service Safety and Quality Accreditation (AHSSQA) Scheme has meant that jurisdictions now have an efficient regulatory approach to address safety and quality issues in health service organisations.

The processes for implementing the NSQHS Standards, assessing health service organisations and reporting assessment outcomes by accrediting agencies are well established. Jurisdictions use existing regulatory mechanisms to require health service organisations to implement the NSQHS Standards. These include issuing policy directives in the public sector; and applying state and territory private health services licensing legislation in the private sector.

Each jurisdiction has developed a responsive regulatory approach to manage organisations that do not meet the requirements of the NSQHS Standards. The regulatory response scale commences with confirming and assessing the impact of the safety and quality issues that are not met and may ultimately lead to the closure of a health service if there are serious safety and quality breaches that are unresolved.

The introduction of version 2 of the NSQHS Standards will have no impact on the operation of the AHSSQA Scheme. Continued use of the AHSSQA Scheme will retain national consistency, with a low regulatory impact and high net benefit for the community seeking safe and good-quality health care.

Element 3 Statement of options

The NSQHS Standards were developed by the Commission in consultation and collaboration with jurisdictions, technical experts and a wide range of stakeholders, including patients and health professionals. Health ministers endorsed the NSQHS Standards in 2011 and mandated their implementation in all hospitals and day procedure services across Australia. Since then, the Standards have been used in community and prison health services, retrieval and transport services, and primary care.

The primary aims of the NSQHS Standards are to protect the public from harm and improve the quality of health service provision.

The initial evaluation of version 1 of the NSQHS Standards indicated that the Standards are making a difference in health service organisations.[12] However, patient harm from health care still occurs, and the use of standards and routine assessment is one way in which health services can continue to improve the safety and quality of care.

International and national evidence shows that, without financial or regulatory levers, health service organisations may implement standards and accreditation, but do not maintain them beyond two or three cycles.[13] For this reason, governments around the world are becoming increasingly involved in regulation of safety and quality systems through the introduction of standards and accreditation systems.

This RIS requires consideration of all feasible options for regulatory change. Two options are considered feasible. Option 1 maintains the status quo, and option 2 introduces a revised set of Standards. In line with COAG requirements, a third option is included, and comments are sought from stakeholders on the feasibility of option 3.

3.1 Option 1: retain version 1 of the NSQHS Standards for an additional three years

Option 1 involves health service organisations continuing to use version 1 of the NSQHS Standards for a further three years, when a review of the Standards would again be conducted to determine the need for revision. The existing implementation resources would continue to be available to health service organisations, and the processes in place for assessment under the Standards would remain unchanged.

Health service organisations are familiar with the current Standards, the resources supporting their implementation and the processes for assessing implementation - accreditation. There is likely to be ongoing improvement in systems and outcomes in areas covered by the Standards. However, it is unlikely that there would be systematic improvements in the new areas addressed in version 2 of the NSQHS Standards from this option.

The actions that are currently developmental, however, may need to be reviewed and introduced as core actions. The Commission may need to develop new

resources to support new sectors, such as office-based services that introduce the NSQHS Standards into their health service organisations.

This option would require support from health ministers for the changes to the timeframe for the revision of the NSQHS Standards. There would be no regulatory changes.

3.2 Option 2: transition to version 2 of the NSQHS Standards by 2018–19

This option involves health service organisations implementing version 2 of the NSQHS Standards from 2018–19 by developing or adapting their safety and quality systems to address all of the actions covered in this version of the NSQHS Standards.

Version 2 of the Standards is a revision of version 1. It has 8 Standards and 148 actions, compared with version 1, which has 10 Standards and 256 actions. Approximately 65 per cent of the content is consistent with the requirements of version 1 of the Standards, and 35 per cent is new content.

The NSQHS Standards describe the acceptable level of care. Many health service organisations across Australia already provide care that exceeds acceptable requirements in most, if not all, of the requirements of the Standards. This is known to be the case because 81 per cent of health services currently achieve accreditation when assessed and have no remedial actions that need to be addressed. Since 65 per cent of version 2 is consistent with version 1, it is expected that these organisations will continue to have the necessary systems in place for safe and good-quality care. Complying with those specific actions in version 2 copied from version 1 will be a straightforward process. The benefits for these organisations are the implementation of nationally consistent and coordinated requirements across all the Standards, where resources, tools and learning can be shared; performance can be compared; and the overall implementation effort can be more efficient.

Even for these organisations, version 2 of the NSQHS Standards will address the implementation issues that have been identified with version 1 of the NSQHS Standards, and provide a systematic way of addressing gaps in coverage.

It is expected that health service organisations providing services to patients at risk of harm – such as people with lived experience of mental health disorders, with cognitive impairment, or with an Aboriginal or Torres Strait Islander background – will already have strategies in place, and implementing version 2 of the NSQHS Standards will provide a framework to implement existing strategies rather than introduce new areas of work.

The Commission will support the implementation of this option by:

- developing a suite of resources to support the application of version 2 of the NSQHS Standards and accreditation to these Standards
- providing training for accrediting agencies
- supporting health service organisations through an advice centre and a mediation service.

3.3 Option 3 – release of a subset of Standards from version 2

COAG requires that more than two options be considered as part of a regulatory impact assessment process.

This option is a modification of option 2, where a limited number of standards from version 2 of the NSQHS Standards are released.

Version 2 Standards are interrelated and interdependent. By not introducing some Standards there will be an impact on the implementation of other Standards. The Commission does not consider this option to be feasible. However, feedback from stakeholders is being sought in relation to the feasibility and associated costs of option 3.

To enable comment from stakeholders this option proposes six of the eight Standards be released. These set of Standards would include:

- Clinical Governance for Health Service Organisations and Partnering with Consumers Standards as these are overarching.
- Comprehensive Care and Communicating for Safety Standards as these establish the systems for effective clinical management of care
- Preventing and Controlling Healthcare-associated Infections and Medication Safety address areas where there is a high rate of error and/or serious harm when errors occur. Antimicrobial stewardship (part of the Preventing and Controlling Healthcare-associated Infections) is a national priority across multiple sectors including agriculture, veterinary and health.

Governments, through the National Blood Authority, spend over $1 billion per annum funding the supply of blood and blood products. This Standard supports the efficient and appropriate use of blood, however could be excluded from version 2 of the NSQHS Standards.

The evaluation of version 1 of the NSQHS Standards, found that Standard 9: Recognising and Responding to Clinical Deterioration in Acute Settings was responsible for declining in-hospital cardiac arrest rates in two jurisdictions and a reduction in ICU admissions post cardiac arrest nationally. Version 2 NSQHS Standards broadens the requirements of version 1 to include acute deterioration in mental and cognitive state and reinforces the requirements for physical deterioration. Actions from the version 2 of the Standard relating to mental health and cognitive impairment are linked to actions in the Comprehensive Care Standard and provide the mechanism for monitoring and preventing deterioration. However, this Standard could also be excluded from version 2.

The Commission does not consider this option to be feasible. However, stakeholders are invited to provide comment on this option as part of the consultation. Please see consultation questions on page 38.

3.4 Other considerations

One additional option could be to remove the regulatory requirement for the implementation of the NSQHS Standards. Based on international evidence that safety and quality failures continue to occur in health service organisations, and jurisdictions' preference for mandatory accreditation, health departments are not considering a return to a self-regulation, co-regulation or non-regulatory model. The Commission does not consider this option to be feasible and it is not analysed further in this RIS.

Another option is the release of version 2 and maintenance of version 1, allowing health service organisations to choose which version of the NSQHS Standards they implement.

Before the mandatory introduction of the NSQHS Standards, the requirements for the implementation of clinical risk management strategies for major adverse events varied. The NSQHS Standards require the implementation of an organisational clinical governance framework and clinical risk mitigation strategies for high prevalence adverse events; healthcare associated infections, medication safety, patient identification and procedure matching', clinical handover, prevention and managing pressure injuries, recognising and responding to clinical deterioration and preventing falls.

The introduction of the NSQHS Standards provided national consistency across different types of services and between sectors – this was one of the reasons for their introduction.

Therefore this option is not thought to be feasible because it reduces national consistency, and significant resources would be required to maintain and support implementation of both sets of Standards. This option is therefore not considered further in the RIS.

The Commission welcomes comment as part of this consultation process on any of these options, or other options for the introduction of Standards that respondents consider feasible.

Element 4 Impact analysis (cost and benefits)

The RIS process requires the Commission to undertake an analysis of costs and benefits for stakeholders affected by the changes.

4.1 Stakeholders

The groups that will be most affected by changes to the NSQHS Standards include the following.

Consumers

Patients are recipients of care, and therefore the beneficiaries of safe and good-quality care. They are the most affected when harm occurs during the delivery of health care.

Health service organisations

Health service organisations provide care, and operate the safety and quality systems required by the NSQHS Standards.

Table 1 shows the health service organisations affected.

Table 1 Numbers of health service organisations affected by changes to NSQHS Standards

Type of organisation	Public	Private	Total
Hospitals	764	298	1062
Day procedure services	0	315	315
Others	63	0	63
Total	**827**	**613**	**1440**

Regulators

Health departments are responsible for regulating, setting the policy direction, and monitoring the performance of health service organisations implementing the NSQHS Standards. All states and territories actively regulate safety and quality accreditation for their jurisdictions.

Accrediting agencies

Accrediting agencies recruit, train and support a team of surveyors who assess health service organisations to the NSQHS Standards, and manage the assessment processes. Nine agencies are approved by the Commission to assess compliance with the NSQHS Standards.

Other groups may choose to be involved in the implementation of the NSQHS Standards. However, the costs and benefits for these groups will vary widely and have not been included in this analysis. These groups include:

- the education sector, when the NSQHS Standards are included in curriculum content

- complaints commissioners, who may use the NSQHS Standards as the basis for a nationally consistent level of expected care
- coroners, who may use the NSQHS Standards and the AHSSQA Scheme as a mechanism for driving change in health service organisations following investigations
- private health insurers and the Australian Government Department of Veterans' Affairs, who use accreditation to the NSQHS Standards as a condition to access private health insurance funding or contracts.

4.2 Impact of option 1 on stakeholders

Option 1 retains version 1 of the NSQHS Standards and allows health service organisations to continue to embed the requirements of these Standards into day-to-day operations. The costs and benefits vary across stakeholders. A preliminary analysis of the costs and benefits for each stakeholder group is shown in Table 2.

Table 2 Costs and benefits of option 1

Costs	Benefits
Consumers	
Costs include: • new areas covered in version 2 of the NSQHS Standards not being addressed in a systematic way, and care being provided that does not meet their needs.	Benefits include: • further reduction in the risk of harm in the areas covered by version 1 • access to comparable information on accredited health service organisations driving improvement strategies at all levels.
Health service organisations	
Costs include: • potential continuing or increasing costs from uncoordinated management of areas that are not covered by the NSQHS Standards, but for which there is evidence that safety and quality gaps exist • ongoing cost of complying with Standards that are known to have unnecessary duplication and high audit requirements • implementation issues remaining unresolved and burdensome for health services.	Benefits include: • systems to meet version 1 are already in place and would continue to apply, with no additional requirements for health service organisations to establish further safety and quality systems.
Jurisdictions	
Costs include: • negative health outcomes for their populations • increased costs associated with unwarranted procedures and care.	Benefits include: • continuous improvements in safety and quality as systems become more embedded across the areas covered by version 1.

Costs	Benefits
Accrediting agencies	
Costs include: • ongoing training of surveyors in the assessment of health service organisations using the NSQHS Standards • maintaining assessment systems to comply with reporting requirements.	Benefits include: • an increase in the client base of health service organisations that voluntarily seek assessment to version 1 because they address their safety and quality issues.

There are no changes in regulation as a result of option 1, so no regulatory burden measures have been generated for this option.

4.3 Impact of option 2 on stakeholders

Option 2 represents the greatest change of the three options. Health service organisations would transition to new national Standards, and accrediting agencies would need to adapt their processes and train their surveyors in assessment to the Standards. A preliminary analysis of the costs and benefits for each stakeholder group is shown in Table 3.

Table 3 Costs and benefits of option 2

Costs	Benefits
Consumers	
• No additional healthcare costs for consumers.	Benefits include: • reduced risks and safer care • improved health outcomes associated with – greater focus on health outcomes in the areas of mental health, cognitive impairment, end-of-life care, health literacy and Aboriginal and Torres Strait Islander health, – greater focus on patients participating in making decisions about their own care – coordinated clinical communication – wider use of patient-centred electronic clinical information systems for sharing information between health service providers.
Health service organisations	
Costs include: • updating or establishing systems and processes to comply with the revised NSQHS Standards – in particular, for the new content. The costs associated with participation in accreditation processes are unlikely to change • training key quality and safety personnel to inform them about the requirements of version 2 so that they can inform the workforce of the changes.	Benefits include: • a framework for improving safety and quality areas not currently covered by version 1 • reduced costs by providing safer and better quality care – for example, reduced compensation, insurance and legal costs from fewer adverse events to patients • a contemporary evidence base • increased engagement of the governing body, executive and clinical leaders in safety and quality

Costs	Benefits
	• reduced duplication and clearer requirements, to make implementation more efficient • improved health outcomes in the areas of Aboriginal and Torres Strait Islander health, mental health, cognitive impairment and end-of-life care • increased effectiveness of local programs in the new areas covered in version 2.
Jurisdictions	
Costs include: • establishing or updating jurisdictional regulation, policy positions, training, data and reporting requirements aligned to the new and revised actions in version 2.	Benefits include: • a nationally consistent set of Standards so that jurisdictions do not need to undertake the development and maintenance of standards individually • a consistent evidence base that is contemporary and relevant • addressing of gaps in the NSQHS Standards • improved effectiveness of jurisdictional programs in the new areas covered in version 2 • access to information, tools and resources that are developed nationally to implement and measure the new content of version 2 • savings to the system from improved quality of care.
Accrediting agencies	
Costs include: • updating reporting templates • developing or adapting assessment tools and processes, and updating information technology systems for version 2 • rescheduling of accreditation assessments for surveyors to attend training provided by the Commission on version	Benefits include: • increased client base of health service organisations that are required to be assessed or are voluntarily being assessed to version 2 because they better address their safety and quality issues.

4.4 Impact of option 3 on stakeholders

Option 3 represents an intermediate option that offers some change but not as great as option two. Health service organisations would transition to some, but not all, version 2 Standards, and accrediting agencies would need to adapt their processes and train their surveyors in assessment to a reduced number of new Standards. A preliminary analysis of the costs suggested there would be a marginal reduction in costs. The benefits associated with the Blood and Blood Products and Recognising and Responding to Acute Deterioration would not be realised and the some of the benefits from the Comprehensive Care would not be realised as the mechanism for recognising and responding have been removed.

The impact of this option has not been calculated separately.

4.5 Impact of individual Standards in version 2

Table 4 provides a preliminary analysis of the costs and benefits of introducing version 2 of the NSQHS Standards, organised by Standard. It should be noted that effective governance is an essential feature of safe organisations, and all health service organisations are required to have governance arrangements in place.

The majority of health services will already meet most of the requirements of version 2 of the NSQHS Standards. This is borne out by the accreditation results, which show that the most highly rated Standard (i.e. the most met with merits awarded) was governance in both the public and private sectors.

In version 1, the Partnering with Consumers Standard has 15 actions, but organisations are required to comply with only four of these actions to achieve accreditation. Even with only four mandatory actions, this Standard was the area that health service organisations found most difficult to implement. In version 2, the critiera on engaging consumers in the governance of an organisation have been amended to better target and focus effort.

The changes to the Standards on healthcare-associated infection and medication safety are limited to one action in each Standard. The overall regulatory changes are therefore negligible.

All health service organisations currently assess the healthcare needs of their patients and develop care plans or pathways. The Comprehensive Care Standard seeks to ensure that care is coordinated and streamlined to deliver all of the care that is required or requested by the patient. Similarly, the requirements in the Communicating for Safety Standard are core business for health service organisations. The degree of change required by organisations to implement this is not yet known and will be assessed as part of the consultation process.

The requirements in the Blood Management Standard have been reduced from 23 to 10 actions, and aligned to the requirements of the National Blood Authority. This should streamline and simplify requirements for this Standard.

The Recognising and Responding to Acute Deterioration Standard now incorporates requirements for mental health and cognitive impairment. The degree of change

required by organisations to implement this Standard is not yet known and will be assessed as part of the consultation process.

These costs and benefits are additional to those associated with retaining version 1.

Table 4 Costs and benefits of introducing version 2 of the NSQHS Standards, by Standard

Costs	Benefits
Clinical Governance for Health Service Organisations	
Costs may include: • establishing or adapting systems to implement and monitor new content in this Standard – leadership – measuring and acting on unwarranted variance in clinical practice – providing a safe environment • training the workforce in their roles, responsibilities and accountabilities for safety and quality.	Benefits may include: • providing clarity on components of an effective and robust clinical governance system for health service organisations • focusing on the engagement of the governing body in clinical governance, and safety and quality performance • better outcomes arising from strategies that specifically target Aboriginal and Torres Strait Islander people • establishing a link to Clinical Care Standards and other evidence-based guidelines to drive improvements in clinical practice • increasing safety, with associated improvements in reputation and savings from reduced harm • improving governance of the nation's health systems.
Partnering with Consumers	
Costs may include: • establishing or adapting systems to implement and monitor the new content in this Standard – health literacy – establishing partnerships with Aboriginal and Torres Islander communities • developing or adapting tools to support shared decision making with patients • training the workforce in the new actions for health literacy and consumer participation in their own care.	Benefits may include: • increasing patient safety • increasing effectiveness of health service organisations through greater consumer participation • reducing duplication of actions and clarifying requirements for actions that are carried forward from version 1 • introducing strategies for shared decision making and support for people with poor health literacy to participate in their care • providing a clearer focus on partnering with consumers in their own care, which has the potential to lead to a better experience of care, and higher levels of adherence to recommended prevention and treatment plans • driving a better understanding by health service organisations of the diversity of the consumers using services and the implementation of targeted strategies for their most vulnerable consumers.

Costs	Benefits
Preventing and Controlling Healthcare-associated Infection	
Costs associated with this Standard are likely to be consistent with the costs of implementing, monitoring and improving healthcare-associated infections in version 1 of the NSQHS Standards because the intent of this Standard remains unchanged.	Benefits may include: • increasing the focus on antimicrobial stewardship and management of antimicrobial resistance • establishing a link with the Antimicrobial Stewardship Clinical Care Standard[14] • focusing on risk management and implementation of actions to address healthcare-associated infection risks for the organisation and consumers • decreasing the use of antibiotics, with associated savings to the system • improving health by reducing the severity of infections.
Medication Safety	
Costs associated with this Standard are likely to be consistent with the costs of implementing, monitoring and improving medication safety in version 1 of the NSQHS Standards because the intent of this Standard remains unchanged.	Benefits may include: • more closely linking the actions in this Standard with systems required in the Clinical Governance and Partnering with Consumers Standards, increasing the potential for coordinated and integrated systems • reducing medication errors, with a resulting reduction in costs, including Pharmaceutical Benefits Scheme costs • improving patient health where polypharmacy contributes to other health conditions, and safety and quality risks • improving processes for assessing a person's ongoing medication management, in line with the Australian Pharmaceutical Advisory Council's *Guiding principles to achieve continuity in medication management*.[15]
Comprehensive Care	
Costs may include: • establishing or adapting systems to implement and monitor the new content in this standard, including – structured systems for the delivery of comprehensive care – improving collaboration and teamwork – integrated screening and assessment processes – development and use of comprehensive care plans – improving care for patients at the end of life – risk management of patients at risk from	Benefits may include: • integrating screening, assessment and risk identification processes to develop an individualised care plan • improving systems for clinicians to identify a consumer's healthcare needs, and work with them to identify shared goals and develop a comprehensive care plan • reducing the length of stay and therefore costs of care • reducing the duplicative processes of the NSQHS Standards and the National Standards for Mental Health Services (NSMHS) to provide better care for patients with mental illness

Costs	Benefits
poor nutrition and hydration – managing risks of harm from cognitive impairment – reducing the risk of harm related to unpredictable behaviour of patients – minimising the use of restrictive practices on patients • training the workforce in the requirements of this Standard • procuring equipment to prevent and manage identified health conditions.	• applying this Standard in health service organisations where people present with mental illness, but the organisation is not required to comply with the NSMHS • focusing on end-of-life care that has the potential to reduce inappropriate and costly care for patients who are dying • focusing on safety and improved quality of care for people living with mental illness or cognitive impairment, or those who are at the end of life • reducing errors and associated legal costs.
Communicating for Safety	
Costs may include: • establishing or adapting systems to implement and monitor the new content in this standard – establishing effective communication systems – establishing mechanisms for communicating critical information • training the workforce in the new actions for communication.	Benefits may include: • standardising and structuring systems applied consistently across health service organisations that have the potential to reduce the risk of patient harm from communication errors • simplifying the requirements for patient identification for streamlined compliance with these actions • focusing on critical information that includes patient goals and preferences, and the involvement of carers and all relevant clinicians, to improve the effectiveness of communication • reducing legal action by providing better communication and fewer communications-based errors.
Blood management	
Costs may include: • establishing or adapting systems to implement and monitor the new content in this Standard – prescribing and administering blood and blood products • training the workforce in the new actions for blood and blood products.	Benefits may include: • optimising and conserving a patient's own blood, providing better management of an expensive and scarce resource • simplifying the requirements of the Standard by reducing duplication • generating improved compliance with national policy by aligning these requirements with actions in the Standard • reducing costs associated with inappropriate use of blood.
Recognising and Responding to Acute Deterioration	
Costs may include: • establishing or adapting systems to implement and monitor the new content in this Standard – recognising and responding to acute deterioration in cognitive state and mental state – escalating care for patients with acute	Benefits may include: • extending the focus from solely acute physical deterioration to include physical, cognitive and mental deterioration in any setting of care • simplifying and clarifying actions from version 1 of the NSQHS Standards that were inappropriate in a range of health

Costs	Benefits
deterioration in physical, cognitive or mental state • training the workforce in the new actions for recognising and responding to deterioration.	settings • incorporating acute suffering as an aspect of acute deterioration and minimising the risk of poor-quality care where acute suffering is not addressed • simplifying the requirements of the Standard by reducing duplication • clarifying requirements for training of the workforce that posed an unnecessary additional burden on health service organisations.

4.6 Preliminary calculation of costs

The Office of Best Practice Regulation provides access to a compliance costing tool that measures regulatory burden. It provides an automated and standard process for quantifying regulatory costs on business, community organisations and individuals, using an activity-based costing methodology. Using this instrument, average annual regulatory costs to businesses of implementing option 2 are summarised in Table 5.

Table 5 Estimated average annual regulatory costs of implementing option 2 compared with business as usual, by sector

Sector	Business	Total change in costs
Change in costs	$0.346 million	$0.346 million

The compliance costing tool estimates one-off costs to be $346 000 over 10 years.

Costs include:

1. costs to health services in informing the workforce about the changes in the NSQHS Standards, and updating policies and procedures in line with the Standards. These costs are made up of:
    - Informing the workforce of changes to the Standards, calculated using an average 2 staff members per organisations, for 8 hours at a cost of $47 per hour in 1440 organisations.
    - Updating policies and procedures to align to version 2 Standards, calculated using an average of1 staff member, for 35 hours at a cost of $47 per hour in 1440 organisations
2. costs to accrediting agencies in amending reporting, business processes and templates to align with the changes in the NSQHS Standards. These costs are made up of:
    - Aligning reporting requirements to version 2 of the NSQHS Standards, calculated using an average of 1 staff member, for 16 hours at $54.4 per hour in 9 accrediting agencies.
    - Updating assessment tools and process, calculated using an average of 1 staff member, for 16 hours, at $54.5 per hour in 9 accrediting agencies.

Ongoing costs not included in this RIS calculation include accreditation assessment costs as there is no change to current compliance cost; and the cost of safety and quality training for the workforce, implementing improvement strategies and monitoring performance which are routine activities that a health service organisation is required to undertake to provide safe and good-quality care.

Cost savings associated with changes to the Standards that reduce duplication and clarify the requirements are likely to be insignificant and difficult to identify because resources and effort will be redirected to improvements in other areas.

Accrediting agencies have an ongoing obligation to ensure that the skills of their workforce are current. The one-off costs of training this workforce when version 2 of the NSQHS Standards is introduced will largely be met by the Commission.

There would be a marginal reduction in these costs if option 3 was introduced.

4.7 Recommended option

To generate the greatest net benefit for patients, the community and health service organisations, the Commission is recommending option 2 – that health ministers require the adoption of version 2 of the NSQHS Standards – where:

- version 2 of the NSQHS Standards is endorsed by health ministers
- version 2 of the NSQHS Standards is used as a framework for safety and quality improvement activities, and for the purposes of accreditation.

This option:

- resolves the implementation issues that all health services currently encounter in implementing version 1 of the NSQHS Standards, reducing the resource burden associated with duplication in the Standards
- clarifies which members of the workforce are covered by the Standards
- focuses clinical auditing and monitoring of performance on areas of greatest risk within an organisation, rather than in areas prescribed by the Standards, where the risks may be minimal
- ensures that the evidence base on which the Standards rely is current and focuses effort in areas that will provide the greatest improvements in care
- ensures that action is taken nationally to address the five new content areas in a systematic way in organisations where improvement efforts in these areas have not commenced; for health service organisations where strategies for these areas are in place, it can drive national consistency and coordination of effort.

The cost of poor care is such that even small improvements in safety and quality have the potential for significant benefits, including reduced costs of services, reduced lost productivity for the community and reduced harm to patients.

Element 5 Version 2 of the NSQHS Standards

The development of version 2 of the NSQHS Standards has involved extensive consultation.

5.1 Consultation process

The following consultation processes were undertaken.

Phase 1

- Analysis of data collected on accreditation assessments, and enquiries to the Commission on implementation of the Standards and accreditation processes.
- National focus groups of health service providers and special interest groups.
- Technical and expert committees from clinical areas in the Standards.
- Research into specific gaps in version 1, including mental health, end-of-life care, health literacy, cognitive impairment, and health care for Aboriginal and Torres Strait Islander people.
- Research into actions and implementation issues for version 1, including partnering with consumers, patient identification bands and training for clinicians in basic life support.

Phase 2

- National focus groups on the content of version 2 of the NSQHS Standards.
- Call for written submissions on version 2.
- Survey of representatives of health service organisations on the content and implementation of version 2.
- Survey of consumers on the content and engagement of consumers in version 2.
- Piloting version 2 with health service organisations, which involved health service organisations from all jurisdictions, the public and private sectors, different service types and different locations.
- Piloting version 2 with accrediting agencies to assess the measurability of the Standards.

Phase 3

- Analysis of feedback received from each of the consultation processes.
- Redrafting version 2 of the NSQHS Standards in collaboration with technical and expert committees.
- Review of the amended Standards by an industry steering committee.
- Consultation with critical friends groups and special interest groups to test the intent and scope of specific requirements in the Standards.
- Review of the amended Standards by the Commission's public, private and primary care standing committees to obtain endorsement from these sectors.

- Submission of the amended Standards to the Commission Board for endorsement.

With each consultation process, the Standards were amended and refined to incorporate the feedback that was received.

5.2 Summary of participation

Focus groups

In May–July 2015, the Commission facilitated 37 focus groups with approximately 480 clinicians in all Australian capital cities and a select number of regional centres. These focus groups discussed the applicability, challenges and strengths of version 1 of the NSQHS Standards. The broad concepts of version 2 were also discussed during these sessions.

Consultation and piloting processes

The piloting and public consultation processes for the draft version 2 of the NSQHS Standards ran from 27 August to 30 October 2015. These processes included surveys, written responses, self-assessments and gap analyses.

As at 10 March 2016, 162 written responses had been received: 43 per cent (70) from the public sector, 42 per cent (68) from the private sector and 15 per cent (24) from others. Responses by jurisdiction are shown in Table 6.

Table 6 Written submissions received, by jurisdiction

Sector	ACT	NSW	Qld	SA	Tas	Vic	WA	National	Unknown	Total
Public	3	23	10	6	1	12	7	8	0	70
Private	1	4	8	3	0	13	1	33	5	68
Other	0	2	2	0	0	5	1	10	4	24
Total	4	29	20	9	1	30	9	51	9	162

Participation in national focus groups was broadly representative of the health system, with 171 nurses (37 per cent), 79 consumers (17 per cent), 59 allied health professionals (13 per cent), 29 doctors (6 per cent) and 129 other staff (28 per cent) taking part in sessions, for a total of 467 participants.

The Commission received 206 responses to the health service organisation survey, 71 to the consumer survey and 6 to the accrediting agency survey.

For the health service organisation survey, 53 per cent of responses were from individuals and 47 per cent were on behalf of organisations. Clinicians made up approximately 40 per cent of all respondents to this survey, and a further 24 per cent of responses were from safety and quality managers. Fifty per cent of respondents work in public hospitals.

The piloting process resulted in 132 of 159 sites submitting returns in the form of 132 surveys, 74 self-assessment tools and 10 gap analyses – a participation rate of 86 per cent.

Feedback provided has been collated in a single database that allows analysis by theme, and by standard and action. Preliminary results of the analysis were discussed with key stakeholders, and feedback was incorporated into version 2 of the NSQHS Standards.

5.3 Consultation feedback

A summary of relevant feedback from the consultation processes follows.

Duplication and clinical audit

Of the 206 survey responses received from health service organisations piloting version 2, 95 per cent reported that their major concern was duplication of actions in version 1, and 59 per cent indicated that audit was a major concern. Eighty-eight per cent of respondents also indicated that all or most of their major concerns had been addressed in version 2.

New content areas

Pilot sites and survey participants were asked about the inclusion of new content areas in the NSQHS Standards. Table 7 provides a summary of the responses.

Table 7 Survey responses relating to new content areas

New content area	Are the following issues important for safety and quality in your health service organisations and so should be included in version 2 of the NSQHS Standards? (n = 206)			Do the actions in version 2 of the NSQHS Standards place the right amount of importance on these new actions? (n = 206)			Are the issues adequately addressed in version 2 of the NSQHS Standards? (n = 135)		
	Agree and strongly agree (%)	Disagree and strongly disagree (%)	Undecided (%)	Too little (%)	Appropriate (%)	Too much (%)	Agree and strongly agree (%)	Disagree and strongly disagree (%)	Undecided (%)
Mental health	89	9	2	6	88	6	70	25	5
Aboriginal health	84	10	6	5	82	13	83	16	1
Cognitive impairment	90	5	5	4	93	3	89	9	2
Health literacy	94	1	5	6	89	5	84	14	2
End-of-life care	89	4	7	4	92	4	91	7	2

Integrated screening

Pilot sites were asked if the action requiring integrated screening should be considered a core (mandatory) action, and 99 per cent of the 132 respondents agreed. Of the respondents, 93 per cent said that the action should be retained as it is, and 7 per cent provided recommendations on how it could be amended. None of the respondents suggested that the action be removed or that it was not applicable.

Survey respondents were asked if changes to version 2 of the Standards would affect the implementation of strategies for preventing and managing pressure injuries; 49 per cent said the impact would be positive, 41 per cent said there would be no impact, and 10 per cent said the impact would be negative. Amendments to the actions have been made following a review of the comments from respondents

who provided negative views. When the same question was asked about strategies for reducing falls and harm from falls, 49 per cent said the impact would be positive, 40 per cent said there would be no impact, and 11 per cent said the impact would be negative. Again, these comments were analysed and changes were made to the draft Standards.

Patient identification

The Standard on patient identification and procedure matching in version 2 has been incorporated into the Communicating for Safety Standard. Survey respondents were asked to rate the impact on their health services of these changes. Of the 206 respondents, 47 per cent said there would be a positive impact, 42 per cent said the change would have no impact, and 11 per cent said the impact would be negative.

Feedback on draft version 2 of the NSQHS Standards

As part of the consultation on version 2 of the NSQHS Standards, pilot sites were asked about the degree of change needed in their health service organisations to implement the 'consultation draft version 2' of the Standards. Table 8 summarises the responses.

Table 8 Survey responses relating to change needed in organisations to implement version 2

	Percentage					
Standard	No change	Small changes	Moderate changes	Substantial changes	Not sure	Number of responses
Clinical Governance for Health Service Organisations	8	74	25	3	0	113
Partnering with Consumers	8	46	37	8	1	107
Preventing and Controlling Healthcare-associated Infections	28	60	9	1	2	101
Medication Safety	21	59	18	1	1	100
Comprehensive Care and Reducing Harm[a]	6	32	40	16	6	100
	9	53	29	7	2	103
Communicating for Safety	10	62	23	2	2	99
Blood Management	40	50	5	3	2	100
Recognising and Responding to Acute Deterioration	20	59	19	1	1	100

a Comprehensive Care and Reducing Harm were separate Standards during the pilot phase, which have been combined following feedback from stakeholders.

The information in this table provides a guide to the systems changes needed on the first draft document. The current draft of version 2 has incorporated feedback from the consultation processes, and the degree of change organisations may now need to make to implement version 2 of the Standards will differ as a result of these amendments.

These impacts were considered in the redrafting of version 2 of the NSQHS Standards and in the development of supporting resources, and will be explored as part of this RIS process.

Element 6 Consultation on this Regulation Impact Statement

The Commission is seeking comment on the three options. Stakeholders are invited to comment on the potential costs and benefits of these options, including:

- What are costs and benefits of each option?
- Who meets the costs and who obtains the benefits?

The following questions provide a guide for responses. Comments provided by stakeholders will be incorporated into the decision RIS, along with the Commission's recommendations for the revision of the NSQHS Standards. The decision RIS will be approved by the Office of Best Practice Regulation before it is submitted to health ministers.

6.1 Consultation questions

1. Element 3 outlines three options. Which of these options do you believe would be the most effective way of improving safety and quality for patients?

2. What do you believe are the costs, benefits and other impacts of your preferred option for:

   a) your organisation?

   b) consumers?

   c) the health system?

   Please include in your feedback evidence of costs or analysis that has been conducted to quantify and support your position.

3. Option 3, the release of a limited number of Standards from version 2 is not considered feasible by the Commission. You are invited to comment on the costs and benefits of this option.

The Commission is recommending option 2: release of version 2 of the NSQHS Standards.

You are invited to provide comment for individual Standards or all of version 2 of the NSQHS Standards on the following questions.

4. Element 4.6 (see page 31) outlines direct costs for implementing option 2? Are the estimates and assumptions reasonable? What additional costs or benefits should be considered?

5. What direct costs, either one-off or recurrent, do you anticipate from implementing version 2 or specific Standards from version 2?

6. What indirect costs or other impacts do you anticipate from implementing version 2 or specific Standards from version 2?

7. What benefits – financial, improved safety and quality, or other benefits – do you anticipate from implementing version 2 or specific Standards from version 2?

8. What increase or savings in costs do you anticipate from the reduction in duplication and clearer statement of requirements in version 2 of the NSQHS Standards?

9. To what extent do you believe that your organisation is currently meeting the requirements of version 2 of the NSQHS Standards, with respect to:

Safety and quality gaps	Standards	
• Mental health • Cognitive impairment • End-of-life care • Health literacy • Aboriginal and Torres Strait Islander health	• Clinical Governance for Health Service Organisations • Partnering with Consumers • Preventing and Controlling Healthcare-associated Infections	• Medication Safety • Comprehensive Care • Communicating for Safety • Blood Management • Recognising and Responding to Acute Deterioration

10. Are there changes to this option that you believe are necessary for implementation to be more effective?

11. Do you have any general comments in relation to the options proposed?

A copy of the draft version 2 of the NSQHS Standards (July 2016) is available on the Commission's website: http://www.safetyandquality.gov.au/our-work/accreditation-and-the-nsqhs-standards/current-consultations/.

All submissions received will be published on the Commission's website, including names of individuals and organisations making the submission. The Commission will consider requests to withhold part or all of the contents of any submission made. Any submission that includes personal information identifying specific individuals without their express permission may be withheld from publication or de-identified before submissions are published.

The Commission's privacy policy is available on the Commission's website at: www.safetyandquality.gov.au/about-us/governance/privacy-policy.

6.2 Submissions

Submissions can be sent by post or email. All written submissions should be received by close of business on **5 August 2016** to be considered in the consultation process.

Written submissions marked 'NSQHS Standards Consultation RIS' can be sent to:

NSQHS Standards Consultation RIS
Australian Commission on Safety and Quality in Health Care
GPO Box 5480
SYDNEY NSW 2001

Or via email to: NSQHSStandards@safetyandquality.gov.au

Stakeholders may also seek to directly discuss the options with representatives of the Commission. This should be arranged by calling 1800 304 056 or emailing NSQHSStandards@safetyandquality.gov.au before **5 August 2016**

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