

**AUSTRALIAN COMMISSION
ON SAFETY AND QUALITY IN HEALTH CARE**

DECISION
Regulation Impact Statement

**Review of the National Safety and Quality
Health Service Standards**

Version 1.9
September 2016

Version control

Date	Version	Amendments	Author
27 June	1.0 based on consultation RIS	Amend to reflect this is Decision RIS	MB
15/7/16	1.1	Drafting	MB
8/8/16	1.2	Incorporating feedback and analysis from RIS	LG
12/8/16	1.3	Review	MB
15/8/16	1.4	Edit	TO" M, LG
29/8/16	1.5	OBPR comments incorporated	MB
1/9/16	1.6	Cost calculations revised	MB
5/9/16	1.7	Amend cost calculations to include public sector	MB
7/9/16	1.8	OBPR comments accepted Appendix 5 added	MB
9/9/13	1.9	Editing – including comments from Accreditation team, Adam Cresswell, Mike Wallace and Catherine Katz	MB

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Executive summary

This Decision 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.

Background

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 national framework for safety and quality activities
- 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) reduced 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
- yearly red blood cell issues noted by the National Blood Authority fell from mid-2010 to mid-2015, from approximately 800 000 units to 667 000 units
- a continued reduction in Queensland hospital-acquired and a maintenance of previous improvements in pressure injuries in Western Australia
- declining in-hospital cardiac arrest rates in Victoria and New South Wales, and reduced admissions to intensive care units admissions data (Australian and New Zealand Intensive Care Society national data)
- a reduction in extreme harm incidents involving falls in South Australia, where clinicians are supported to report serious incidents, with the proportion of extreme harm (SAC1) incidents involving falls declining 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)
- the NSQHS Standards becoming a lever and impetus for other safety and quality initiatives.

A review of the NSQHS Standards was required to ensure that they remain current and consistent with best practice. The NSQHS Standards provide a framework for safety and quality improvements. The review has:

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

Consultation RIS

In July 2016, the Commission released a Consultation RIS, together with the draft version 2 of the NSQHS Standards (July 2016). The Consultation RIS sought feedback from consumers and the health sector on the costs and benefits of the three options.

Stakeholders were directed to the Commission's website to access the Consultation RIS and the draft version 2 of the NSQHS Standards. There were 3419 visits to the site to review the documents; 1 046 copies of the Standards and 836 copies of the Consultation RIS were downloaded during the consultation period.

The options outlined in the Consultation RIS included:

- option 1** – retain version 1 of the NSQHS Standards for an additional three years
- option 2** – transition to version 2 of the NSQHS Standards from January 2019
- option 3** – release of a sub-set of Standards from version 2 from January 2019

Decision RIS

Responses to the Consultation RIS are analysed in this Decision RIS. The key findings from this analysis are:

- eighty-three submissions were received: 53 submissions addressed the RIS; 17 addressed the NSQHS Standards; and 13 provided comment on both the RIS and Standards.
- Eighty-two per cent of the 66 respondents who noted a preferred option supported option 2
- the Consultation RIS underestimated the costs of implementing version 2
- respondents agreed that calculating an accurate cost of implementing version 2 is difficult
- the majority of respondents supported the inclusion of new areas in version 2, including mental health, cognitive impairment, end-of-life care, health literacy and Aboriginal and Torres Strait Islander health care
- respondents generally agreed version 2 had reduced the duplication, reduced the audit burden, the language and intent were clearer and there was a greater focus on quality improvement, which was welcomed
- respondents considered version 2 would improve the safety and quality of patient care.

Calculating an accurate cost of implementing version 2 is difficult, and estimates varied widely. The Commission has used the Commonwealth Regulatory Burden Measure to calculate the average cost of implementing version 2 for hospital and day procedure services to be \$33 000 per organisation.

Recommendation

The Commission, along with 82 per cent of RIS respondents, recommends the introduction of version 2 of the NSQHS Standards from January 2019, as proposed in option 2.

Introduction

This Decision Regulation Impact Statement (RIS) is the final report to health ministers following 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 Decision RIS analyses the costs and benefits of introducing a revised set of NSQHS Standards.

The NSQHS Standards were designed to protect the public from harm and to improve the quality of health care for consumers. Version 1 was endorsed by Australian health ministers in 2011 and has been implemented by health service organisations since January 2013.

Version 1 of the NSQHS Standards

The implementing of version 1 of the NSQHS Standards produced promising results, and generated widespread engagement and support among health service organisations. Preliminary evaluation shows a number of high-level impacts, including:

- a focused national framework for safety and quality activities
- 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.
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- the NSQHS Standards becoming a lever and impetus for other safety and quality initiatives.

In implementing the NSQHS Standards, health service organisations put in place safety and quality systems to ensure the described standards of care were met. State and territory health departments 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 accordance 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.

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

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

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

- reducing duplication
- incorporating content relating to new and emerging safety and quality issues
- updating the evidence base
- removing Standard 5: Patient Identification and Procedure Matching and incorporating a small number key actions into the new Communicating for Safety Standard
- removing Standard 8: Preventing and Managing Pressure Injuries and Standard 10: Preventing Falls and harm from Fall and incorporating key actions into the Comprehensive Care Standard
- 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 formatting of the NSQHS Standards to aid navigation of the document
- addressing the implementation issues associated with version 1 of the Standards.

Regulatory Impact Assessment Process

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, any 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.

The second stage of this involves the preparation of this recommendation report, or Decision RIS.

Section 1 Statement of the problem

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

- **Duplication of the Standards** that adds to the cost and time required to meet the requirements.
- There has been confusion about which parts of the **clinical workforce** are covered in the NSQHS Standards, because the definition was unclear and open to interpretation
- The Standards require significant investment in **clinical audit**, which has been criticised as burdensome
- Some of the **evidence base** for the Standards needed to be updated
- The move by jurisdictions to introduce **integrated screening** of patient risk is not reflected in the NSQHS 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 NSQHS 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 each of the actions. 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 are prescriptive and did not always focus on the areas of greatest risk. As a consequence, they divert resources from safety and quality issues that are 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 NSQHS Standards.

1.2 Coverage of the clinical workforce

Version 1 of the NSQHS Standards defines three workforce groups: clinicians, non-clinical workforce and workforce. These definitions have proven to be problematic, because the inclusion of credentialed practitioners is unclear. In some private sector organisations, credentialed practitioners are included for some actions and not in others. The Commission expects that all credentialed practitioners are included in implementation of the requirements of the clinical NSQHS 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 ten NSQHS Standards include items with three to five 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 NSQHS 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 NSQHS Standard that addresses priority safety and quality issues relevant to that organisation.

1.4 Outdated evidence base

The NSQHS 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 need to ensure 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 has changed since this time. The strategies and requirements in version 2 of the NSQHS 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. The National Standards for Mental Health Services do not apply in all settings 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 sector.

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 non-fatal 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 outcomes 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 NSQHS 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) and 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 (the 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 service organisations. 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 being treated 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 are covered in version 1 of the NSQHS Standards.

Recognition of cognitive impairment as the underlying cause allows health services to act to further reduce harm to these patients.

What are the risks associated with this area?

People who experience cognitive impairment while 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.

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 outcomes 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 for patients following an episode of delirium is reported to be 2.6 times higher 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 times 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 is 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 vary 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 (Australian Commission on Safety and Quality in Health Care)
- Delirium Clinical Care Standard (Australian Commission on Safety and Quality in Health Care)

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 the condition is identified, can reduce the rate of preventable delirium, and reduce 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 and emotional 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, persistent gaps remain in the quality and safety of end-of-life care.¹⁰

End-of-life care is not currently specifically addressed in version 1 of 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 and preferences.

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

What is the outcomes evidence in this area?

Some health service organisations do not see that providing end-of-life care is their responsibility, and care is outsourced to medical emergency teams, palliative care teams and intensive care teams. For patients, this may mean that the care they receive is provided because they begin to deteriorate acutely. It may also mean that the care is provided by strangers, and is often provided after hours and in urgent circumstances.

Acute treatment is often continued long after it becomes apparent that a person is at the end of life. A conversation with the patient, their family and carers may prevent the need for further treatment that is likely to be ineffective and provide a better experience of death for all concerned.

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 from 2003–04 to 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 (Australian Commission on Safety and Quality in Health Care)
- National Palliative Care Strategy 2010: supporting Australians to live well at the end of life. (Palliative Care Australia)

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 service organisations.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 service organisations.

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 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 outcomes 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 the adult population of Australia 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 low individual health literacy to the person, healthcare organisations or the health 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 due to poor health literacy corresponded to approximately 3–5 per cent of total healthcare spending.⁹ If this proportion 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 between \$4.2 billion and \$7 billion.

At an individual level, people with lower health literacy spend 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 (Australian Commission on Safety and Quality in Health Care)
- NSW health literacy program (Australian Commission on Safety and Quality in Health Care)

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 who seek care from mainstream health service organisations. Improvement strategies for health care of 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 service organisations.

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 outcomes 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 times higher)
- diabetes (3.3 times higher)
- hospitalisations for respiratory conditions (3 times higher)
- obesity (1.5 times higher)
- death from cancer (1.5 times higher)
- youth suicide for females (5.9 times higher) and for males (4.4 times higher)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

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

Aboriginal and Torres Strait Islander people do not always seek the treatment they need in mainstream health service organisations, because organisations are 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 contribute to poor health outcomes for Aboriginal and Torres Strait Islander people.

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

Section 2 Objectives of the NSQHS Standards

The objectives of the NSQHS Standards are to:

- protect patients from harm and improve the quality of health care that is delivered
- provide evidence-based 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 objectives of the review of the NSQHS Standards are to:

- reduce the duplication of actions across the NSQHS Standards
- address the issues of coverage of the clinical workforce
- redirect effort and resources associated with clinical audit to those areas of greatest risk and potential for improvement
- ensure the evidence base that underpins the NSQHS Standards is current
- support the introduction of integrated screening for patients at risk
- address safety and quality gaps in version 1 of the NSQHS Standards.

The introduction of the Australian Health Service Safety and Quality Accreditation (AHSSQA) Scheme means jurisdictions 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 health service 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 organisation 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.

Section 3 Statement of options

The Consultation RIS describes three options. Option 1 maintains the status quo, and option 2 introduces a revised set of Standards. In line with COAG requirements, a third option was included, and comment sought from stakeholders on its feasibility to introduce a subset of Standards from version 2.

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

Option 1 proposes health service organisations continue 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 would remain unchanged.

Health service organisations are familiar with the current NSQHS Standards, the resources supporting their implementation and the processes for assessing implementation through accreditation. There is likely to be ongoing improvement in systems and outcomes in areas covered by the NSQHS 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.

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

This option proposes health service organisations implement version 2 of the NSQHS Standards from January 2019 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 expected level of care to be provided by health service organisations. Many health service organisations across Australia already provide care that exceeds acceptable requirements in most, if not all, of the requirements of the NSQHS Standards. This is known to be the case because 86 per cent of health service organisations 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 organisations will continue to have the necessary systems in place for safe and good-quality care in these areas and complying with these actions will be a straightforward process.

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 and the assessor workforce
- supporting health service organisations through an advice centre and a mediation service
- reviewing the AHSSQA Scheme to increase its efficiency and effectiveness.

3.3 Option 3 – release of a subset of NSQHS Standards from version 2 from January 2019

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 six of the eight standards from version 2 of the NSQHS Standards are released.

The option proposed in the Consultation RIS was for the introduction of version 2 of the NSQHS Standards, with the introduction of two Standards, namely the Blood Management and Recognising and Responding to Acute Deterioration Standards, be delayed or omitted.

The Commission did not consider this option to be feasible. However, stakeholders were invited to provide comment on this option as part of the RIS consultation.

Section 4 RIS consultation

4.1 Consultation process

The Office of Best Practice Regulation approved a Consultation RIS for release in May 2016. This document was endorsed by the Commission's Inter-Jurisdictional, Private Hospital Sector and Primary Care Committees prior to being approved for release by the Chairman on behalf of the Commission's Board.

The national consultation process was conducted between 7 July and 5 August 2016. Stakeholders were invited to indicate which of the three options they preferred and were then asked to provide feedback on the costs and benefits of option 2.

Stakeholders were notified of the consultation RIS process by direct email, through presentations at various committee meetings and presentations during the preceding months, or from information provided on the Commission's website. The Commission wrote directly to each health department seeking comment on the consultation RIS. A list of key stakeholders contacted directly is at Appendix 1. Stakeholders were invited to forward the invitation to comment on the consultation RIS to their networks, so the final distribution list is unknown.

Information provided to stakeholders included a copy of the consultation RIS and the draft version 2 of the NSQHS Standards (July 2016).

4.2 Consultation questions

The consultation RIS sought responses to the following questions, but accepted submissions that addressed any matter related to the RIS, the draft NSQHS Standards or the assessment processes. The questions included in the consultation RIS are listed below:

Text Box 1: Extract of questions from the consultation RIS

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 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
<ul style="list-style-type: none"> • Mental health • Cognitive impairment • Mental health • Health literacy • End-of-life care 	<ul style="list-style-type: none"> • 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?

4.3 Results of consultation RIS process

The Consultation RIS was released in conjunction with the draft version 2 of the NSQHS Standards. Both documents were available to download from the Commission's web site in PDF or Word format.

Between 7 July and 5 August 2016, there were:

- 3 419 page views (of which 2 476 were unique) of the NSQHS Standards consultation landing page on the Commission's website
- 836 downloads of the consultation RIS
- 1 046 downloads of the draft version 2 of the NSQHS Standards.

A total of 83 organisations and individuals provided written or verbal submissions in response to the consultation RIS. Table 1 summarises respondents by sector. A list of respondents who provide comment on the RIS is at Appendix 3.

Table 1: Responses by sector type

Sector category	Number of submissions
Health department or government agency	18
Industry or member organisation	17
Local health network	13
Public health service organisation	10
Individual clinician	8
Private health service organisation	6
Accrediting agency	5
Consumer	4
Education or research organisation	2
Total	83

Table 2: Number of responses by jurisdiction and type of response

Jurisdiction	RIS only	Version 2 only	RIS and V2	Total
ACT	0	0	0	0
NSW	8	5	1	14
NT	1	0	0	1
QLD	2	1	1	4
SA	2	0	1	3
TAS	1	0	0	1
Victoria	11	1	2	14
WA	6	3	0	9
Commonwealth	7	0	0	7
National	12	4	7	23
Unknown	3	3	1	7
Total	53	17	13	83

Not all submissions addressed the Consultation RIS. Of the 83 responses received:

- 53 submissions provided feedback on the Consultation RIS only
- 17 submissions provided feedback on version 2 of the NSQHS Standards only
- 13 submissions provided feedback on both the Consultation RIS and version 2 of the NSQHS Standards.

Table 3 outlines the preferences of the 66 submissions that commented on the Consultation RIS.

Table 3: Preferred options

Preferred option	Number	Percentage
Option 1	9	14%
Option 2	54	82%
Option 3	0	0%
Other option - release version 2 with some modifications	1	1%
No preference declared	2	3%
Total	66	100%

Data limitations

While the response from the Australian Day Hospitals Association included responses from 26 of its members, the number of responses for some sectors was small. Caution is required when interpreting information these small samples as comments may not be representative of the sector.

Few respondents addressed all of the consultation questions. The majority of responses nominated a preferred option and providing a rationale for this choice. Detail on the number of responses for each consultation question is detailed at Appendix 4.

Estimating costs

Fifteen respondents provided estimates of the direct costs associated with implementation of version 2 of the NSQHS Standards, however, none provided detail of the components of these costs. Indeed, many said the costs could not be quantified and provided an estimate.

The Consultation RIS sought feedback on the costs and benefits of implementing option 2, and feedback was received from the stakeholder groups as outlined in Table 4.

Table 4: Number of responses by stakeholder category

Sector category	No. of submissions
Health service organisation	29
Health department	11
Accrediting agency	5
Consumer	4
Primary care service	5
Total	54

Section 5 Impact analysis

The impact analysis for the review of the NSQHS Standards was undertaken over a two-year period and has involved an extensive consultation process.

It began with the initial consultation and piloting processes that were undertaken during the review of the NSQHS Standards. During this time an extensive range of stakeholders were consulted. Over 980 people participated in various forums organised by the Commission, which included focus groups, piloting, surveys, written submissions and workshops. A summary of these activities and the feedback received is included at Appendix 2.

In addition the Commission attended conferences and meetings during this time reaching an estimated 2,700 people.

This section analyses the information from submissions to the Consultation RIS and includes analysis of the costs and benefits of each option.

5.1 Feedback on option 1

The consultation RIS provided an analysis of the costs and benefits for each stakeholder group, see Table 5. Respondents did not provide additional comments on this analysis.

Table 5: Analysis of costs and benefits of option 1

Consumers
Costs
<ul style="list-style-type: none"> 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:
<ul style="list-style-type: none"> 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
<ul style="list-style-type: none"> 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 service organisations.
Benefits include
<ul style="list-style-type: none"> 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 provides time for some organisations to fully embed version 1 of the NSQHS Standards.
Jurisdictions
Costs include:
<ul style="list-style-type: none"> individual health service organisations will need to develop and implement evidence-based programs to address safety and quality issues included in the new content of version 2, but not in version 1 negative patient health outcomes or opportunity costs for their populations. increased costs associated with unwarranted procedures and care.

Benefits

- continuous improvements in safety and quality as systems become more embedded across the areas covered by version 1

Accrediting agencies

Costs

- ongoing training of surveyors in the assessment of health service organisations using the NSQHS Standards
- maintaining assessment systems to comply with reporting requirements.

Benefits

- 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.

RIS feedback on the costs and benefits of option 1

While nine respondents (14 per cent) preferred option 1, some acknowledged version 2 of the NSQHS Standards contained positive changes that would improve patient safety and quality. Two respondents indicated they would support option 2 if the transition time was extended by 12 to 18 months.

Two respondents commented on costs for consumers, both indicating the safety and quality risks for patients would be reduced with the implementation of version 2 of the NSQHS Standards. One respondent indicated they supported option 1 because version 2 of the NSQHS Standards did not make a big enough change to warrant the transition.

The most common reason for supporting option 1 by this group of respondents was that they had only completed one full cycle of assessment to version 1 of the NSQHS Standards and they had not had long enough to fully embed the NSQHS Standards into routine practice.

Respondent justified their preference for option 1 by raising their concerns with option 2, including:

- the costs of transition arrangements from version 1 to version 2 of the NSQHS Standards, which are currently unclear
- the audit burden in version 2 remaining high and some respondents considered this was still the same as in version 1
- the need to adapt version 2 to make the requirements more relevant to primary care settings

Further, respondents were unable to determine costs of introducing version 2 because:

- the resources to support implementation of version 2 of the NSQHS Standards are not yet available
- some of the requirements for implementation are set by health departments, for example the My Health Records and facility design, and these requirements are not yet known.

In response to these issues, the Commission notes:

- work with jurisdictions, health service organisation and accrediting agencies is underway to determine transition arrangements
- a comprehensive suite of resources are being developed to support the implementation of version 2
- the audit requirements are determined by individual health service organisations, not the NSQHS Standards, and version 2 had specifically reduced the nominated audit requirements

- work is underway to adapt the NSQHS Standards to the primary care sector and this should be available during 2017
- requirements set by health departments are outside of the scope of this review.

Recommendation

The Commission does not recommend option 1.

5.2 Impact of option 2

Responses to the Consultation RIS have been analysed and the costs and benefits for stakeholder groups from option 2 identified in the following tables.

The costs and benefits of option 2 are considered against option 1, which is the status quo have been identified for each of the stakeholder groups.

Table 6: Analysis of costs and benefits of option 2 for Consumers

Consumers

Costs

- No direct costs for consumers from the revised standards
- Part of the perceived additional costs for private health service organisations complying with the new standards could eventually be passed on to consumers through higher private hospital and day surgery fees.

Benefits

- Likely incremental improvements in patient safety and quality of care from:
 - organisations establishing systems and increasing their focus on:
 - clinical governance systems and leadership that will improve care by promoting a culture and framework for driving safety and quality improvements.
 - comprehensive care strategies that address cross-cutting issues that are often present in patients with acute care needs or those with chronic illness
 - better management of adverse events and safer clinical communication
 - focusing blood management on the conservation of the patient's own blood
 - improved recognition of acute deterioration and better processes for managing critical clinical communication
 - the application of current, evidence-based strategies that are critical to identifying safety and quality gaps and for improving the safety and quality of care for patients
 - the workforce using safety and quality systems to promote learning and identify ways to provide better care for patients
 - the increased availability of tools and resources, such as integrated screening tools, to assist clinicians in providing better care for consumers
- Likely reduction of inappropriate care for patients receiving care at the end-of-life
- Likely improvements in health outcomes for:
 - patients with low levels of health literacy through organisations providing information that is appropriate for the need of consumers and supporting effective partnerships between patients and healthcare providers
 - patients with mental health disorders from the coordinated use of screening and assessment tools, recognition and response to deterioration in mental state, use of advance care directives as a tool in planning treatment and reducing restraints and seclusion for patients with mental ill-health
 - patients with cognitive impairment due to coordinated use of screening and assessment tools detecting delirium earlier so treatment can be commenced, recognition and response to deterioration in cognitive state, and use of evidence based strategies for providing quality care
 - Aboriginal and Torres Strait Islander patients from the introduction of targeted, systemic strategies to make health service organisations more culturally aware and culturally competent.

The size of the benefits for consumers is difficult to quantify, but are associated with: reaching optimum health sooner; patients returning to normal daily activities sooner; reducing payments of extended care from errors; adverse events; unsafe or poor quality care; and better health outcomes.

Health Service Organisations (includes both private and publicly owned)

Costs

- Initial costs of updating or establishing compliance systems:
 - to align existing policies, processes and reporting requirements to the revised numbering for existing NSQHS Standards content
 - to create policies, procedures and reporting systems for new content in the revised NSQHS Standards
 - make structural changes to committees and individual roles and responsibilities to align to the Standards
- Initial cost of updating or establishing training systems:
 - to address requirements in existing NSQHS Standards content
 - to address new content in the NSQHS Standards

These one-off costs are estimated to be of the order of:

- \$2 842 for small public hospitals less than 50 beds
- \$6 088 for day procedure services
- \$84 960 for public hospitals with more than 50 beds
- \$85 263 for private hospitals

Ongoing compliance/regulatory costs are expected to be similar to Option 1, the status quo.

Benefits

- Potential reduction in costs associated with compensation, insurance and legal action due to fewer adverse events and safer and better quality of care
- Potential for reduction of costs through:
 - reduction in length of stay and less follow-up care from the use of evidence-based care
 - decreasing the length of stay of patients through improvements in the assessment and coordination of an individual's care and discharge planning at the commencement of care
 - early identification and management of safety and quality risks, accurate identification and prioritisation of areas for improvement and closer monitoring and evaluation of performance from improved oversight of clinical governance by the governing body, executive and clinical leaders
 - focusing resources on high-priority safety and quality issues that affect large numbers of patients and have a high impact on costs, and where small improvements can increase the capacity to manage demand and reduce costs
 - reducing time spent finding and managing clinical records, through the use of electronic health records systems
 - reducing the number of repeated tests, hospitalisations and readmissions through access to electronic health records
 - greater engagement of consumers in governance and their own care reducing follow-up care and cost of providing more complex services to patients who don't follow treatment plans
 - providing a greater choice for people at the end of life, reducing length of stay and the cost of unnecessary procedures.

The size of these cost savings cannot be reliably quantified, but across the sector the existing costs are of the order of hundreds of millions of dollars annually, by reducing complications and length of stay from undetected delirium through early detection. Delirium can be prevented in 30–40 per cent of cases, and if undetected increases the length of stay by 7.32 days in the intensive care unit and by 6.53 days in hospital.

Government (exclusive of direct impacts for publicly-owned health service organisations)

Costs

- Initial cost of establishing or updating jurisdictional regulation, policies, education modules, tools and resources
- Initial cost of updating data collection and reporting system in line with the revised NSQHS Standards
- Initial cost of promulgating new standards among the workforce in health service organisations
- No ongoing costs anticipated

Benefits

Government benefits are from decreased costs associated with providing safe care and from improvements in population health and a more productive population.

Specifically benefits are derived from:

- national consistency of safety and quality requirements leading to safer health service organisations and allowing clinicians to more seamlessly transition between health service organisations
- focusing activity in health service organisations on high priority safety and quality issues that affect large numbers of patients and have a high impact, and where small improvements can result in significant cost savings to State and Territory health budgets
- increased efficiency of the overall health system from
 - fewer resources being used to rectify avoidable patient harm
 - timely care that reduces the need for future complex secondary or tertiary care
- likely reduction in readmissions within the public health system
- reduction in the number of patients that require remedial treatment in the public health system as a result of poor quality care in the private sector

The size of these cost savings cannot be reliably quantified. Government costs are currently in the order of \$28.6 billion per year. Even a small improvement in care can lead to significant reductions in cost.

Similarly, providing appropriate health care and as a result improving health outcomes for Aboriginal and Torres Strait Islander people Average annual health expenditure for Aboriginal and Torres Strait Islander people is \$7 995 per person, compared with \$5 437 for non-Indigenous Australians.

Accrediting agencies

Costs

- Initial cost of updating reporting templates
- Initial costs of developing or adapting assessment tools and processes, and information technology systems for NSQHS Standards
- Rearranging accreditation assessments to allow assessors to attend training provided by the Commission on the NSQHS Standards

Benefits

- Not significant

Section 1 identifies the policy problems that exist with the current requirements. An analysis of the extent to which these problems are addressed by options 1 and 2 is summarised in Table 10.

Table 10: Analysis of policy problems being address

Policy problems	What is the cost / benefit?	Will this policy problem be addressed by implementing?	
		Option 1	Option 2
Duplication	<p>All RIS respondents identified this as an issue with the current NSQHS Standards. There was concern that some duplication remained in version 2.</p> <p>There are costs associated with producing evidence to meet the requirements of accreditation.</p>	No	Yes
Coverage of the clinical workforce	<p>The definitions remain unchanged in option 1 but have been addressed in option 2.</p> <p>There are no cost implications associated with this item.</p>	No	Yes
Clinical audit	<p>RIS respondents identified this as an issue and clinical audit was commonly given as the reason for respondents supporting version 2.</p> <p>The extent of the clinical audits required is not specified in the NSQHS Standards.</p> <p>In option 1 the areas to be audited are specified. In version 2 the organisation is required to have a quality improvement program for each of the NSQHS Standards, and auditing is in the areas of greatest risk.</p> <p>The costs of auditing will be organisation specific.</p>	Partially	Yes
Evidence base	<p>Without revising the NSQHS Standards, the evidence base cannot be updated. This issue was not raised by RIS respondents.</p> <p>The costs associated with this relate to the opportunity costs from improved care based on current evidence and wasted effort continuing to implement actions that are now known to be less effective.</p>	No	Yes
Integrated screening	<p>Jurisdictions and health service organisations are developing integrated screening tools. The application of these will, however, be uncoordinated without a mechanism to drive consistency and</p>	Partial – high performing organisations with the resources to develop these	Yes

Policy problems	What is the cost / benefit?	Will this policy problem be addressed by implementing?	
		Option 1	Option 2
	<p>implementation. This issue was not raised by RIS respondents.</p> <p>The development of these tools has been complex and difficult. The cost implications of this policy problem are related to this process being repeated by individual organisations and achieving variable results.</p>	tools will achieve effective integrated screening, other organisations will not.	
Patient identification and procedure matching	<p>There are a large number of duplicated and detailed actions in the Patient Identification and Procedure Matching Standard that are unnecessary, and there is widespread compliance with this Standard. RIS respondents supported the key actions from this Standard being included in the Communication for Safety Standard.</p> <p>The costs are associated with producing evidence to meet the requirements of accreditation.</p>	No	Yes
Gaps in mental health	<p>Mental health is a national priority area that is not addressed in version 1 of the NSQHS Standards. The National Standards for Mental Health Services are not mandatory nationally and are not used in many sectors where mental health care is provided, such as emergency departments. There was strong support for the inclusion of the mental health actions in version 2.</p> <p>The costs associated with this policy gap relate to the opportunity costs from failing to improve care for patients with mental health.</p>	No	Yes
Gaps in cognitive impairment	<p>Cognitive impairment is a significant and growing issue for health service organisations. Even with small improvements, there are significant cost savings. RIS respondents supported the inclusion of cognitive impairment in the NSQHS Standards.</p> <p>The costs associated with this policy gap relate to the opportunity costs of prevention, better diagnosis and improved care for patients with cognitive impairment.</p>	Partial – there are no specific actions dealing with this issue, but a general requirement for organisations to identify patients at risk.	Yes
Gaps in end-of-life care	RIS respondents supported the inclusion of end-of-life care in version 2.	Partial – there are no specific actions dealing	Yes

Policy problems	What is the cost / benefit?	Will this policy problem be addressed by implementing?	
		Option 1	Option 2
	The costs associated with this policy gap relate to the provision of unnecessary and ineffective treatment when a person is nearing the end of their life.		
		with this issue, but a general requirement for organisations to identify patients at risk.	
Gaps in health literacy	<p>This is a significant problem as more than 60 per cent of Australian adults have poor levels of health literacy. It affects their capacity to understand treatment options, participate in shared decision making and comply with treatment plans. RIS respondents supported the inclusion of this policy gap in version 2.</p> <p>The costs associated with this policy problem area result from the adaption of tools and development of resources to support shared decision making.</p>	No	Yes
Gaps in Aboriginal and Torres Strait Islander people	<p>This is a national priority area for all areas of government. RIS respondents supported the inclusion of this policy gap in version 2, although there was also concern that other vulnerable groups were not identified.</p> <p>The costs associated with this policy gap relate to the opportunity costs from failing to improve care for Aboriginal and Torres Strait Islander patients.</p>	Partial – there are no specific actions dealing with this issue, but a general requirement for organisations to identify patients at risk.	Yes

RIS feedback on the costs and benefits of option 2

Option 2 was preferred by 54 respondents (82 per cent). Across all stakeholder groups, there was strong support for the new content in version 2. The majority of respondents agreed that version 2 would reduce the duplication of requirements found in version 1, reduce the auditing requirements, enable health service organisations to focus on the specific risks facing their health service organisation and potentially reduce compliance costs because of the smaller number of actions.

The overall benefits they identified came from:

- improvements in patient-care and consumer engagement
- improvements in the workforce safety and quality culture
- care focused on Aboriginal and Torres Strait Islander health needs

- reduction in adverse events
- use of electronic health records to improve the effectiveness and efficiency of care for consumers
- use of integrated screening tools that identify risks of harm for patients earlier in the care process and for the patient as a whole
- reduction in prolonged inappropriate treatment at the end of life that can reduce pain and distress
- decreased length of stay due to safer care, and the associated benefits of reduced risks of infection or harm from other treatment related causes
- reduction in the use of blood products and associated cost savings
- reduction in antimicrobial resistance and the associated cost savings.

Feedback from these respondents indicates:

- Two **consumers** commented on the Consultation RIS. Both supported Option 2, noting it had the greatest potential to improve health outcomes for consumers. No consumers provided information in relation to the costs of Option 2
- Consumer respondents noted option 2 provides coordination of some existing processes, such as streamlining reporting requirements and also has the potential for improved care from the introduction of the Comprehensive Care Standard. Consumers also reported that option 2 provided greater opportunity for engagement of consumers and their carers in the organisation and in care
- Eight **jurisdictions** preferred Option 2, noting:
 - version 2 of the NSQHS Standards was applicable across a broader range of settings and had a stronger quality improvement focus. Version 2 focuses on areas and populations at greatest risk of harm in the new elements added
 - option 2 builds on previous work undertaken when implementing version 1 of the NSQHS Standards, and facilitates evidence-informed improvement, by focusing action on areas of greatest risk
 - some respondents, while supporting option 2, felt that health service organisations should complete two cycles of accreditation to version 1 before transitioning to version 2
 - the greatest cost for jurisdictions would be in mapping the current policy and legislative frameworks to version 2, and the development of resources to support version 2. It was suggested the cost of implementing version 2 of the NSQHS Standards would be significantly smaller than the cost of implementing version 1.
- Twenty **health service organisations** supported option 2 and noted the benefits of this option were:
 - the inclusion of new content in version 2 of the NSQHS Standards, which provided the greatest potential net benefit for consumers
 - potential cost savings from improvements in safety and quality of care, health outcomes and health service delivery.
- **Health service organisations** also noted the costs of option 2 were associated with:
 - informing and training staff
 - updating documentation and resources
 - the application of clinical care standards in some services
 - developing tools and processes for auditing, monitoring and reporting
 - increased staffing levels

- redeveloping facilities and buildings
- developing and using auditing tools for new content areas
- updating information technology infrastructure, including introducing My Health Records
- implementing strategies to comply with the new content
- increasing/new auditing requirements because of the new content in version 2
- assessment costs to undertake a gap analysis of current compliance with version 2 requirements.

An estimate of the quantum of the costs varied widely however, respondents largely agreed the benefits outweighed the costs. They also agreed the Commission had underestimated the costs of implementing version 2 of the NSQHS Standards in the Consultation RIS.

Detail was provided on the factors that would need to be considered when costing training. They included developing education material, staff salaries to attend training, and online hosting costs for training.

- Three **accrediting agencies** preferred Option 2, and noted the following benefits of this option:
 - version 2 is more broadly applicable in community health, primary care and other health service organisations
 - there is the potential to reduce assessment costs as the NSQHS Standards are more applicable across settings and do not require administrative processes associated with version 1 such as reviewing non-applicable actions.
- **Accrediting agencies** also noted the costs of this option were:
 - increased assessment time and assessment costs
 - training of assessors
 - developing education materials
 - one agency noted that the content in version 2 of the NSQHS Standards overlaps with content in a standards product they have developed and offer to health service organisation, and removing the overlap from their standards will impact on their revenue
- Respondents noted that most of the costs of this option related to one-off, initial costs and that once implemented the ongoing costs of this option were likely to be less than option 1, because of the reduction in duplication and auditing requirements
- One respondent from the primary care sector supported option 2. They considered the benefits of this option to come from the introduction of the new content
- This primary care respondent considered the costs were primarily associated with assessment costs that are proportionately high for small services
- Other concerns that may have cost implications were raised, including
 - the need for additional time before transitioning to version 2 for small primary care services
 - the availability of support, tools and resources to implement version 2
 - the skills and experience of assessors testing compliance with the NSQHS Standards
 - the application of some standards in primary care settings.

In response to these issues, the Commission notes:

- version 1 of the NSQHS Standards states the areas where audits are required, but did not specify the frequency, format, focus or length of audits that were required. As a result, health service organisations have significantly increased the scope and frequency of auditing, sometimes in areas that did not involve a high risk of harm. Version 2 links audit to quality improvement and requires health service organisations to use a risk management approach so effort is concentrated in areas where the greatest harm occurs
- similarly regarding training health service organisations are required to provide, the NSQHS Standards specify a small number of areas where training is required but not the frequency or content of that training. Organisations need to adopt a risk management approach to setting priorities and implementing training to reduce harm
- 65 per cent of version 2 is consistent with version 1, which is familiar to health service organisations
- the Commission has in place or is developing a range of tools, resources and support processes to assist health service organisations to implement version 2
- a suite of resources is being developed in paper-based and electronic formats to support groups of health professionals and different health service sectors to implement version 2
- training and education packages are being developed for assessors and health service organisations to train the workforce on version 2 of the NSQHS Standards
- work has commenced with the education sector to better prepare health practitioners to implement the NSQHS Standards
- the processes of assessment are being reviewed with the aim of making them more robust, efficient and effective
- work is underway to adapt version 2 to different sectors, including primary care
- the cost burden regulation measure has been updated to address comments that the estimates of costs in the Consultation RIS were too low.

Recommendation

That health ministers endorse option 2, for version 2 of the NSQHS Standards to be implemented in health service organisations from January 2019.

5.3 Feedback on option 3

Option 3 represents an intermediate option that offers some change but not as great as option two. None of the respondents selected this option and three respondents said this option was confusing. Twenty-three respondents stated this option was not feasible.

Twenty respondents provided reasons for not supporting this option 3, including:

- removing two standards (Blood Management and Recognising and Responding to Acute Deterioration Standards) ignored evidence from the evaluation of version 1 that demonstrated the improvement to patient outcomes and reduction in costs from a reduction in cardiac arrests in wards and reductions in ICU admissions
- substitute resources would need to be developed by individual health service organisations for the recognising and responding and blood standards to address these issues locally.

DECISION Regulation Impact Statement

- a consumer organisation noted that implementing option 3 would mean that potential benefits from option 2 would not be realised and that this approach would greatly compromise the quality and safety of care.

Recommendation

There was no support from the system for this option. This option is not recommended.

5.4 Feedback on other options

A member-based industry organisation supported an alternative option that involved implementation of version 2 of the NSQHS Standards, with some modifications. This response noted version 2 of the NSQHS Standards was more refined in version 1 and comprehensively covered a wider range of safety issues present in clinical practice, they supported the new content areas and the streamlining of the NSQHS Standards, particularly blood management.

However, this respondent proposed an alternative option would be to implement two or three new clinical care standards every year instead of revising the NSQHS Standards. They claimed the bulk of improvements in safety and quality over the long term have arisen from an adequately resourced, highly trained and fully credentialed health and medical workforce and this should be the focus of the NSQHS Standards. If version 2 is to be introduced, they recommended a staged introduction commencing with actions for Aboriginal and Torres Strait Islander people, infection prevention and control, medication safety, comprehensive care, communicating for safety and blood management.

In response to these issues, the Commission notes:

- a well-trained and supported workforce is essential to the safety and quality of health service organisations, and it is not the remit of the Commission or the NSQHS Standards to provide guidance on workforce mix or levels
- as the NSQHS Standards are interrelated it would be difficult to separate the actions that relate specifically to Aboriginal and Torres Strait Islander health
- excluding comprehensive care would mean that the cross-cutting issues that are routinely identified in adverse events are not addressed through the introduction of version 2 of the NSQHS Standards
- there is strong evidence of the need to update the NSQHS Standards, outlined in the Consultation RIS and draft version 2 of the NSQHS Standards document
- work is underway on education, tools and resources to support the introduction of version 2
- implementation of the new areas in the NSQHS Standards is not currently consistent nationally and version 2 provides a consistent framework for improvement across all health service organisations
- a set of safety and quality measures is being identified that can be used to measure improvement. These measures will be released with version 2 in late 2017.

Recommendation

This option is not considered feasible and is not recommended.

5.5 Impact of individual Standards in version 2

The Consultation RIS provided an analysis of the costs and benefits of each of the eight Standards in the NSQHS Standards, see Appendix 5. Respondents did not provide any additional comments or challenge the content of this table.

RIS feedback on the costs and benefits of individual standards

Eleven respondents provided information on specific Standards. They identified the following benefits associated with the NSQHS Standards in version 2:

- Respondents supported the new content in version 2, specifically mental health; Aboriginal and Torres Strait Islander health; health literacy; communicating for safety; cognitive impairment; end-of-life care; and comprehensive care
- The National Mental Health Commission (NMHC) noted the new actions with specific reference to mental health in relation to Governance for Safety and Quality, Partnering with Consumers and Recognising and Responding to Acute Deterioration, will provide greater certainty for people with a mental illness and their families, in being able to receive the care they need and participate in shared decision making about their care
- The Australian Digital Health Agency noted that the Clinical Governance Standard supports the national introduction of My Health Record, by requiring health service organisations to work towards use of standard national terminologies and identifiers. The benefit of this initiative is wider use of patient-centred electronic clinical information systems for sharing information between health services providers that can drive improved quality, efficiency and effectiveness of care
- A member-based organisation stated changes in language, content and structure in the Medication Safety Standard would improve patient outcomes through reductions in medication errors
- Five respondents commented specifically on the Comprehensive Care Standard, noting:
 - the integrated screening and assessment requirements would benefit both patients and the workforce
 - the actions in this Standard align with NMHC work on a National Consensus Statement on improving the physical health of people living with a mental illness and will help build and improve a system that enables clinicians to identify a consumer's health care needs
 - this Standard addresses critical gaps from version 1 by addressing mental health, end-of-life care, health literacy and Aboriginal and Torres Strait Islander health, which have the potential for significant improvements in care.
- The Blood Management Standard provides an evidence-based approach to patient blood management, which can improve patient outcomes by ensuring that the focus of the patient's medical and surgical management is on optimising and conserving the patient's own blood. As a consequence of better management, patients usually require fewer transfusions of donated blood components, thus avoiding transfusion-associated complications
- The National Blood Authority (NBA) noted they had delivered a saving of \$355.8 million for governments in the three-year period from 2012 to 2015. They noted the introduction of the NSQHS Standard 7 contributed to this achievement.
- From 2012-13 to 2014-15, governments have seen a total reduction in red blood cell demand of 18 per cent, leading to significant improvements in patient outcomes and realising financial savings in excess of \$78 million. They note the cost to the health

system of the implementation of the current blood standard has been more than offset by the considerable cost saving for all governments.

The following costs were identified with specific Standards in version 2:

- in the Clinical Governance for Health Service Organisations Standard, the training costs specifically for health literacy were seen as being a major contributor to the cost of training, and the introduction of systems to support My Health Records were thought to be costly
- complying with national standards for reprocessing of reusable medical devices (AS/NZS4187:2014) required in the Preventing and Controlling Healthcare-Associated Infections Standard were thought to be considerable
- the meaningful engagement of the medical workforce in implementing the Comprehensive Care Standard was thought to require significant resources.

In response to these comments, the Commission notes:

- the Commission is developing a range of tools and supports to assist health service organisations address requirements for health literacy, including training tools
- work is underway to support the appropriate implementation of strategies to reprocess reusable medical devices (AS/NZS4187:2014).

5.6 Calculation of costs

Preliminary cost estimates were developed using the Office of Best Practice Regulation compliance costing tool. This tool provides an automated and standard process for quantifying regulatory costs on business, community organisations and individuals, using an activity-based costing methodology.

This method calculated an average annual regulatory cost to health service organisations of implementing option 2 at \$346 000 over 10 years. Many respondents indicated these costs were too low and the Commission had not fully justified the costs it used.

Respondents noted that the costs of implementing option 2 are difficult to calculate. However, 15 respondents stated that the Commission had underestimated the costs of implementing option 2 in the Consultation RIS. Respondents did not agree on the size of the underestimate.

Where respondents provided a dollar amount it varied widely, and included:

Table 7: Respondents' estimated costs of implementing option 2

Stakeholder group	Estimated cost	Activity
Health department	\$47/hour multiplied by workforce number	Covers the cost of presenter, but needs to be include all participants
Health department	\$150 000	Development of online tools and resources, but could be done in collaboration with the Commission
Local health network	\$4 000	Training of the workforce
	\$6 000	Resources to support implementation
Local health network	\$47/hour multiplied by a factor of 10	Cost of workforce participating on committees to update policies and procedures
Local health network	\$4 152	Implementation support
Hospital	\$47/hour multiplied by 140 hours	For one staff member to update policies and procedures
Day procedure service	\$12 000/year	Consulting costs to support implementation
Day procedure service	\$100 000 over 2 years	Implementation support
Day procedure service	\$200 000 over 3 years	Audit costs
Day procedure service	\$7 000	Implementation support
Day procedure service	\$15 000	Staff training and introduction of version 2
Accrediting agency	\$57 335	Training materials for assessors, internal staff, client liaison officers and decision makers

Note: None of the respondents provided a detailed breakdown of how these costs were reached.

These costs were recalculated, taking note of the additional costs associated with:

- Salary costs of staff participating in training as well as the cost of trainers
- Recognition of the difference between small and large health service organisations
- Administrative costs associated with updating documentation, committee structures, audit tools and reporting schedules
- Renumerating consumers for participation in engagement activities

These costs were calculated using the following parameters:

- 1 400 health service organisations are required to meet the NSQHS Standards. of these, 599 of these organisations are in the private sector, this includes: 306 day procedure services and 293 private hospitals. There are 801 public sector services: 578 small health services and 223 hospitals
- costs have been calculated using the Regulatory Burden Measure. This shows an average total cost for an organisation to be \$33 000
- costs to health service organisations relate to informing the workforce about the changes in the NSQHS Standards, and updating policies and procedures in line with the NSQHS Standards

For day procedure services and small public health service organisations these costs are made up of:

- informing the workforce of changes to the NSQHS Standards, calculated using an average two staff members per organisations, for eight hours at a cost of \$50.75 per hour in 306 day procedure services and 578 public small health service organisations.
- updating policies and procedures to align to version 2 Standards, calculated using an average of one staff member, for 35 hours at a cost of \$50.75 per hour in 306 day procedure services and 578 public small health service organisations.

For private hospitals and large public health service organisations these costs are made up of:

- informing the workforce of changes to the NSQHS Standards, calculated using an average two staff members per organisation, for 40 hours at a cost of \$50.75 per hour in 293 private and 223 public health service organisations
- updating policies and procedures to align to version 2 of the NSQHS Standards, calculated using an average of 10 staff members, for 80 hours at a cost of \$50.75 per hour in 293 private and 223 public health service organisations
- cost to update administrative processes such as committee structures, reporting schedules, auditing tools using an average of two staff for 70 hours at a cost of \$50.75 per hour in 293 private and 223 public health service organisations

Accrediting agencies costs are associated with updating reporting, business processes and templates to align these with version 2 of the NSQHS Standards. These costs are made up of:

- aligning reporting requirements to version 2 of the NSQHS Standards, calculated using an average of one staff member, for 16 hours at \$59.45 per hour in nine accrediting agencies
- updating assessment tools and process, calculated using an average of one staff member, for 16 hours, at \$59.45 per hour in nine accrediting agencies
- informing staff of changes to the NSQHS Standards, calculated using an average of two staff members per organisation, for 16 hours at a cost of \$50.75 per hour in nine accrediting agencies.

These calculations result in costs of approximately \$33 000 per organisation associated with implementing version 2 of the NSQHS Standards or \$4.78 million per year for 10 years across the health care system.

These costs do not take into account the savings that can be achieved from safer care, a reduction in adverse events and better patient outcomes. Even minor improvements in the new areas in version 2, through the implementation of a mandatory set of NSQHS Standards, have the potential to save hundreds of millions of dollars annually, by:

- reducing the direct and indirect costs of mental ill health, which are estimated to be up to \$28.6 billion per year
- reducing complications and length of stay from undetected delirium through early detection. Delirium can be prevented in 30–40 per cent of cases, and if undetected can increase the length of stay by an average of 7.32 days in the intensive care unit and by 6.53 days in hospital
- providing a greater choice for people at the end of life, reducing length of stay and the cost of unnecessary procedures
- providing appropriate health care and as a result improving health outcomes for Aboriginal and Torres Strait Islander people. Average annual health expenditure for Aboriginal and Torres Strait Islander people is \$7 995 per person, compared with \$5 437 for non-Indigenous Australians.

The costs associated with the workforce reading and being informed about the revised Standards is not included in these costs. The workforce are informed of the changes in Standards through routine processes such as policy, procedure and protocol updates, safety and quality training, team meetings and routine feedback to the workforce. It is not possible to separate the day-to-day costs of providing safe and good-quality care from the incremental costs associated with the NSQHS Standards.

Section 6 Implementation

Section 9 of the *National Health Reform Act 2011* states the Commission has responsibility for developing and coordinating national models of accreditation.

The implementation of the NSQHS Standards is managed through the Australian Health Service Safety and Quality Accreditation (AHSSQA) Scheme. The Scheme describes the roles and responsibilities of the organisations involved with the NSQHS Standards, including: health ministers who endorse the NSQHS Standards; health departments as regulators of the use of the NSQHS Standards; health service organisations that implement the NSQHS Standards; accrediting agencies that assess to the NSQHS Standards and the Commission that develops and maintains the NSQHS Standards and supports and monitors their use.

The Commission will commence a review of the Scheme in September 2016, which will involve extensive consultation with stakeholders. This process will clarify the transition format, timelines and any issues for health service organisations such as the rating scale, notifying regulators of a significant risk if one is identified and the assessment format.

Section 7 Conclusion

The Commission submitted three options for consideration in the Consultation RIS.

The first option was to retain version 1 of the NSQHS Standards for an additional three years. This would allow health service organisations to fully embed the requirements of the NSQHS Standards into day-to-day operations. This options requires little if any new expenditure for health service organisations, but is likely to provide the least overall improvement in safety and quality for consumers. Only 14 per cent of respondents supported this option. A majority of these respondents recognised the potential benefits to patients of version 2 but wanted to delay its introduction until they had fully implemented version 1.

The costs of Option 1 for health service organisations related to:

- increased risk associated with safety and quality gaps
- missed opportunity costs associated with reduced safety and quality risks.

There is likely to be a significant cost to consumers who will not benefit from improved health outcomes associated with improvements resulting from:

- updating the evidence base
- addressing safety and quality gaps.

The direct costs of implementation this option are smaller than other options, but are unlikely to reduce preventable patient harm. Therefore, the overall benefit of this option is less..

The second option recommended the introduction of version 2 of the NSQHS Standards from 2019. This option presented the greatest likelihood of improving safety and quality and reducing costs of care for health service organisations and consumers who will benefit from improved health outcomes associated with:

- addressing safety and quality gaps
- updating the evidence base.

Health service organisations will also be able to realise cost savings through:

- addressing the risks associated with safety and quality gaps
- opportunity costs associated with reduced safety and quality risk.

Although it is not possible to quantify costs savings that are directly attributable to implementing version 2 of the of the NSQHS Standards, the estimated costs of these safety and quality gaps are of a such a magnitude that even small improvements are likely to have significant monetary impacts.

Feedback from the consultation processes conducted by the Commission indicates widespread support across the healthcare sector for version 2 of the NSQHS Standards, with 82 per cent of respondents supporting this option.

There are additional costs associated with Option 2 for health service organisations related to:

- aligning systems to version 2 of the NSQHS Standards
- training of the clinical workforce.

There was no support for option 3, so no costs or benefits were identified. One respondent proposed an alternative option be explored. However, the submission contained no detail about the proposal, so it was not possible to calculate the potential reductions in harm, or the savings from this option.

Recommendation

To generate the greatest reduction in harm for patients, and community and health service organisations, the Commission is recommending option 2: that version 2 of the NSQHS Standards be implemented from January 2019, 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 assessment.

This option:

- resolves the implementation issues that all health service organisations currently encounter in implementing version 1 of the NSQHS Standards, reducing the resource burden associated with duplication in the NSQHS Standards
- clarifies which members of the workforce are covered by version 2
- focuses clinical auditing and monitoring of performance on areas of greatest risk within an organisation, rather than in areas prescribed by version 1, where the risks may be minimal
- ensures that the evidence base on which the NSQHS 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 five major safety and quality 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 extent of 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.

Appendix 1 Stakeholder distribution list

Table 8:

Organisation category	No of unique addresses
Aboriginal and Torres Strait Islander Working Group	7
Accrediting Agencies Working Group	17
Allied Health Professionals Association	1
Ambulance services nationally	10
Australian College of Health Informatics	1
Australian Day Hospital Association	1
Australian Dental Association	3
Australian Private Hospitals Association	1
Catholic Health Australia	1
Consumer organisations	8
CRANAPlus	2
Department of Veterans Affairs	3
Falls working group	17
Multipurpose Services Project Advisory Committee	14
National Blood Authority	1
National Centre for Cultural Competency	1
National Aboriginal and Torres Strait Islander Health Standing Committee secretariat	1
NSQHS Standards Steering Committee	17
NSQHS Standards pilot sites	150
Pressure injuries working group	22
Regulators Working Group	22
Royal Flying Doctor Service	1
South Australian Health and Medical Research Institute	1
Women's & Children's Healthcare Australasia	1
Secretariat for program and technical committee convened by the Commission	12
Commission Standing Committees	36
Secretaries of health departments	9
Commission contact stakeholder list	5079
Coroners offices nationally	5
Health care complaints commissioners nationally	8
TOTAL	5 452

Appendix 2 Development of Version 2 of the NSQHS Standards

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

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 NSQHS Standards and accreditation processes
- national focus groups of health service providers and special interest groups
- technical and expert committees from clinical areas in the NSQHS 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 NSQHS 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 NSQHS 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.

Phase 4

- Consultation RIS

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

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 9.

Table 9: 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 of total participants), 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 six 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.

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 10 provides a summary of the responses.

Table 10: 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 NSQHS 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 NSQHS 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 service organisations 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 11 summarises the responses.

Table 11: Survey responses relating to change needed in organisations to implement version 2

Standard	Percentage					Number of responses
	No change	Small changes	Moderate changes	Substantial changes	Not sure	
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
Communicating for Safety	9	53	29	7	2	103
Blood Management	10	62	23	2	2	99
Recognising and Responding to Acute Deterioration	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.

Appendix 3 RIS Respondents

Table 12: Respondents and their preferred options

Organisation	Preferred option
Individual clinician	Option 2
Albury Day Surgery	Option 1
Australian Physiotherapy Association	Option 2
Individual clinician	Option 2
Peel Health Campus	Option 1
Latrobe Regional Hospital	Option 2
Office of the Chief Psychiatrist, Western Australia	Option 2
Murrumbidgee Local Health District	Option 1
Rural Northwest Health	Option 2
St John of God Murdoch Hospital	Option 2
National Mental Health Commission	Option 2
Children's Health Queensland	Option 2
St Vincent's Health Australia	Option 2
North Sydney Local Health District	Option 2
Australian Day Hospital Association	Option 2
Alfred Hospital	Option 2
Orbost Regional Health	Option 2
Alpine Health	Option 2
St Vincent's Health Australia	Option 2
Individual consumer	Option 2
Hunter New England Local Health District	Option 1
Alzheimer's Australia	Option 2
St Vincent's Melbourne	Option 2
South Australian Department of Health	Option 2
Individual consumer	Option 2
Justice Health and Forensic Mental Health Network, NSW	Option 1
Monash Health	Option 2
BSI Group	Option 2
Hunter New England Local Health District	Option 1
Victorian Department of Health and Human Services	Option 2
The Society of Hospital Pharmacists of Australia	Option 2
AGPAL and QIP	Option 2
Australian Government Department of Health	Option 2
Australian Medical Association	Other Option
Northern NSW Local Health District	Option 1
National Blood Authority	Option 2
South Metropolitan Health Service, Western Australia	Option 2
Royal Australian and New Zealand College of Radiologists	Option 2
National Pathology Accreditation Advisory Council	Option 2
South Australian Ambulance Service	Option 1
Northern Health, Victoria	Option 2

Organisation	Preferred option
Congress of Aboriginal and Torres Strait Islander Nurses and Midwives	Option 2
Australian Psychological Society	Option 2
National Mental Health Consumer and Carer Forum	Option 2
Metro South Health, Queensland	Option 1
Individual clinician	Option 2
Australia Council on Healthcare Standards	Option 2
National Blood Authority	Option 2
Australian Digital Health Agency	Option 2
Adelaide Primary Health Network	Option 2
Child and Adolescent Health Services and Perth Children's Hospital Commissioning	Option 2
Clinical Excellence Commission, NSW	Option 2
Dieticians Association of Australia	Option 2
Cardinal Services Corporate	Option 2
Southern NSW Local Health District	Option 2
Australasian college of Emergency Medicine	Option 2
Australian Government Department of health	Option 2
Western Australian Department of Health	Option 2
Tasmanian Department of health	Option 2
Melbourne Health	Option 2
Royal Australian and New Zealand College of Psychiatrists	Option 2
Queensland Department of Health	Option 2
Northern Territory Department of Health	Option 2
Speech Pathology Australia	Option 2

Note: Responses from individual clinicians and consumers have been de-identified in this table

Appendix 4 Responses to consultation questions

Table 13:

Question	Total
Which options do you believe would be the most effective at improving safety and quality for patients?	62
What do you believe are the costs, benefits and other impacts of your preferred option for your organisation; consumers; the health system?	34
Comment on the costs and benefits of option 3.	22
Are the estimates and assumptions by the Commission for option 2 reasonable? What additional costs or benefits should be considered?	20
What direct costs, either one-off or recurrent, do you anticipate from implementing version 2 or specific Standards from version 2?	15
What indirect costs or other impacts do you anticipate from implementing version 2 or specific Standards from version 2?	16
What benefits – financial, improved safety and quality, or other benefits – do you anticipate from implementing version 2 or specific Standards from version 2?	15
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?	10
To what extent do you believe that your organisation is currently meeting the requirements of version 2 of the NSQHS Standards?	9
Are there changes to option 2 that you believe are necessary for implementation to be more effective?	10

Appendix 5 Costs and benefits by Standard

Table 14: Costs and benefits of introducing version 2 of the NSQHS Standards, by Standard

Costs	Benefits
Clinical Governance for Health Service Organisations	
<p>Costs may include:</p> <ul style="list-style-type: none"> • establishing or adapting systems to implement and monitor new content in this Standard <ul style="list-style-type: none"> - 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. 	<p>Benefits may include:</p> <ul style="list-style-type: none"> • 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	
<p>Costs may include:</p> <ul style="list-style-type: none"> • establishing or adapting systems to implement and monitor the new content in this Standard <ul style="list-style-type: none"> - 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. 	<p>Benefits may include:</p> <ul style="list-style-type: none"> • 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	
<p>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.</p>	<p>Benefits may include:</p> <ul style="list-style-type: none"> • increasing the focus on antimicrobial stewardship and management of antimicrobial resistance • establishing a link with the Antimicrobial Stewardship Clinical Care Standard¹⁴ • 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	
<p>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.</p>	<p>Benefits may include:</p> <ul style="list-style-type: none"> • 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	
<p>Costs may include:</p> <ul style="list-style-type: none"> • establishing or adapting systems to implement and monitor the new content in this standard, including <ul style="list-style-type: none"> - 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 	<p>Benefits may include:</p> <ul style="list-style-type: none"> • integrating screening, assessment and risk identification processes to develop an individualised care plan • improving systems for clinicians to identify consumers' 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
<ul style="list-style-type: none"> 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. 	<ul style="list-style-type: none"> • 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.

Costs	Benefits
Recognising and Responding to Acute Deterioration	
<p>Costs may include:</p> <ul style="list-style-type: none"> • establishing or adapting systems to implement and monitor the new content in this Standard <ul style="list-style-type: none"> - recognising and responding to acute deterioration in cognitive state and mental state - escalating care for patients with acute deterioration in physical, cognitive or mental state • training the workforce in the new actions for recognising and responding to deterioration. 	<p>Benefits may include:</p> <ul style="list-style-type: none"> • 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 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.

Appendix 6 Regulatory burden estimate

Table 15: Regulatory burden estimate for the private sector

Average annual regulatory cost				
Change in costs (\$ million)	Business	Community organisations	Individuals	Total change in costs
Private health sector	\$2.68 million	-	-	\$2.68 million
Accrediting agencies	\$0.04 million	-	-	\$0.04 million

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