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Submission to the First consultation on NSQHS Standards (third edition)

Prepared by:

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> Dr Mary Dahm is a Senior Lecturer in Health Ethics and Professionalism in the School of Medicine at Deakin University. She currently holds an Australian Research Council (ARC) DECRA fellowship investigating the critical role and impact of communication on the diagnostic process in health settings. Her program of research is fundamentally interdisciplinary and innovative in breaking down traditional discipline barriers to address the critical issue of diagnostic safety from complementary perspectives and to enhance patient safety and improve professional practice. She is a leader in the field of interpersonal diagnostic communication.

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> Laura Chien is a PhD Candidate at the Australian National University Institute for Communication in Health Care and Institute for Healthcare Improvement (IHI) Fellow 2024-25. Her research investigates diagnosis and the communication of uncertainty from the perspective of patients and caregivers experiencing real-world diagnostic uncertainty, with the goal of enhancing diagnostic excellence in emergency care.

Endorsed by:

Mark Graber, Founder, Community Improving Diagnosis in Medicine (Attachment A, p.8)

Jen Morris, Patient Safety Advocate and Victorian Honour Roll of Women Inductee for service to patient safety (Attachment B, p. 9)

Stephanie Newell, Founding member - WHO Patients for Patient Safety programme, Convener - Australian Patient Safety Network, (Attachment C, p. 12)

Luke Slawomirski, Health Economist, Consultant OECD, WHO (Attachment D, p. 13)

Health Care Consumers Association ACT (endorsement in HCCA consultation submission)

Institute for Communication in Health Care Consumer Reference Group, Australian National University (endorsed by Co-Chairs Dr Ann Lawless and Dr Janney Wale, and members Linda Beaver, Margaret Fagan, Laila Hallam, Brian Osborne, Sandy Thomson)

What existing and emerging safety and quality risks should the Commission be considering in the third edition?

We strongly recommend the NSQHS Standards (third edition) **include *diagnostic safety* as a standalone standard addressing diagnostic safety (Option 1),** which represents our preferred approach.

An alternative approach would be to **integrate specific diagnostic safety criteria and actions across existing standards (Option 2)**, though this would provide less visibility and awareness for diagnostic safety as a distinct patient safety priority.

Key issue - Diagnostic safety is notably absent from the NSQHS Standards

- **Diagnostic safety is prevalent, harmful and costly, but notably absent from the NSQHS Standards 2nd edition.** While the standards address other safety priorities comprehensively (e.g. medication safety, infection control, clinical deterioration), diagnostic processes are only minimally, indirectly referenced.
- The field of diagnostic safety has become an internationally recognised priority for patient safety aiming to address **diagnostic errors as a major source of largely preventable patient harm globally.** [1] With 140,000 people affected annually in Australia, including estimations of **serious harm for 21,000 people and 4,000 deaths**, [2,3] diagnostic errors cause more harm and death than road tolls. [4]
- Diagnostic errors costs health systems an estimated 17.5% of healthcare expenditure, [5] **equating to $44.2 billion annually in Australia**[6] (almost as much as the entire budget for National Disability Insurance Scheme). [7]
- **National data on the scale and impact of diagnostic error in Australia is lacking.** [3] The lack of national data on diagnostic errors is becoming more critical in light of the World Health Organization's (WHO) *Global patient safety action plan 2021–2030* calling on governments, health care facilities and services to assure the safety of every clinical process, including measuring incidence and reductions in missed or delayed diagnosis. [8] **Australia currently does not measure or report on diagnostic error incidence.**
- **Diagnostic safety is rarely mentioned in Australian healthcare policies**, [9] despite diagnostic error experts calling for healthcare organisations to establish diagnostic safety programs. [10]

- **Diagnostic safety cannot remain an overlooked component of patient safety in Australia**. The NSQHS Standards must evolve to address diagnostic safety, which deserves at least equal priority with established domains of patient safety in the current standards.
- Progress in **addressing diagnostic safety in Australia will remain slow, ad hoc and inadequately resourced**, unless national standards prioritising diagnostic safety[11,12] require healthcare organisations to improve diagnostic safety[13,14] and incentivise implementation of diagnostic safety programs. [15]
- The current consultation represents **a critical once in a decade opportunity to establish comprehensive requirements for diagnostic safety**, positioning Australia as a world leading pioneer in this field and addressing a major source of preventable patient harm.

Recommendation - Implement diagnostic safety in the NSQHS Standards (third edition)

Option 1. Introduce a new standalone Diagnostic Safety Standard

- We strongly recommend the NSQHS Standards (third edition) include a standalone diagnostic safety standard. This is our preferred and most comprehensive option, recognising the maturity of the diagnostic safety field and giving diagnostic safety equal priority to other patient safety domains addressed in the existing standards.

The structure of a diagnostic safety standard could mirror that of existing NSQHS standards and address the criteria below*:*

Clinical governance and quality improvement to support diagnostic safety

Organisation-wide systems and leadership are used to promote and support diagnostic safety. This includes establishing a dedicated diagnostic safety committee and providing oversight for the implementation of diagnostic quality improvement initiatives. The organisation fosters a safety culture that prioritises diagnostic excellence, with an emphasis on continuous education and training for clinicians.

Monitoring and improvement systems

Measurement and learning: systems are in place to identify, measure, and learn from diagnostic errors and near-misses. This includes robust reporting systems and mechanisms to monitor for variation and discrepancy. The organisation actively incorporates feedback loops for clinician and consumer to identify system breakdowns and opportunities for improvement in diagnostic processes.

Safe diagnostic processes

Clear and safe systems are established for communicating critical diagnostic results and ensuring timely follow-up. A formal process ensures that diagnostic tests and referrals are followed up on to prevent delays in diagnosis. Clinicians have access to tools and resources that support clinical reasoning, such as decision support systems, AI tools, and timely access to specialist consultations.

Communication and documentation of (working) diagnosis and uncertainty

Clinicians are supported in explicitly communicating and clearly documenting differential diagnoses considered and diagnostic uncertainty to both colleagues and consumers, including during care transitions.

Partnering with Consumers

Consumers and their families are a part of the diagnostic team and actively involved in the diagnostic process, information sharing and decision-making. Patients are empowered to ask questions, seek second opinions, and voice their concerns to ensure they are full partners in their own care.

Option 2. Integrate diagnostic safety into existing standards

- While we strongly advocate that diagnostic safety would be best recognised with a standalone standard, should the Commission determine that working within the existing eight standard framework is preferred, an alternative option would be to integrate diagnostic safety into existing standards.
- This approach recognises that diagnostic safety cuts across elements of care and would strengthen the clinical governance and partnering with consumers standards.

Diagnostic safety could be integrating into existing standards as in the examples below:

Clinical governance standard

Organisational leadership and governance would be responsible for diagnostic safety oversight. This includes implementing measurement and reporting systems and regularly reviewing diagnostic performance and variation to drive continuous improvement.

Partnering with consumers standard

This standard would ensure that consumers are active participants in the diagnostic process and decision-making, can understand diagnostic uncertainty, and have mechanisms for providing feedback to the healthcare system.

Comprehensive care standard

Diagnostic safety should be integrated into comprehensive patient care. This includes a clear expectation for clinicians to document differential diagnosis, diagnostic uncertainty and to reassess patients when there is ongoing diagnostic uncertainty.

Communicating for safety standard

The standard would outline communication and documentation requirements about sharing differential diagnosis, diagnostic uncertainty with colleagues and patients, including during care transitions. It would also ensure clear communication of (critical) test results, their interpretation, and highlight support need for patients with ongoing diagnostic uncertainty following investigation.

Recognising and responding to acute deterioration standard

This standard would require a diagnostic review as part of the response to a deteriorating patient and would outline clear patient/carer and clinician-initiated escalation pathways for those with signs of clinical or carer-recognised decline and ongoing diagnostic uncertainty or who decline despite diagnosis-consistent treatment.

Background

What is diagnostic safety?

Diagnostic safety, a domain of patient safety, is concerned with ensuring safe and high-quality care during the diagnostic process.[9,16] The diagnostic process encompasses a patient accessing the health system, and collaborating with a diagnostic team of clinicians who gather, interpret and integrate information (via clinical history, physical examination, diagnostic investigations, specialist referrals and consults) to form a (working) diagnosis and communicate that diagnosis to the patient to commence treatment.[16]

Diagnostic safety is focussed on the prevention of diagnostic errors including delayed, missed, and/or wrong diagnosis.[16] Diagnostic error is the failure to provide an accurate and timely diagnosis, or failure to communicate the diagnosis and/or diagnostic uncertainty to the patient.[16,17]

Diagnostic errors - prevalence and impact

- "**Most people will experience at least one diagnostic error in their lifetime**, sometimes with devastating consequences" according to the US National Academies of Sciences, Engineering, and Medicine (NASEM).[16]
- The incidence rate for diagnostic errors is between 5-15%.[16,18]
    - In Australia, every year an estimated 140,000 patients experience a diagnostic errors, causing **serious harm for an estimated 21,000 patients and death for up to 4,000 patients**.[2,3] In contrast, 1,185 people died on Australian roads in 2022.[4]
- **Diagnostic errors cost health systems an estimated 17.5% of healthcare expenditure**.[5]
    - In Australia, costs to the health system from diagnostic errors would equate to **an estimated $44.2 billion** (based on the latest Australian health expenditure of $252.5 billions in 2022–23);[6] close to the entire 2025-26 budget ($46.2 billion) for the National Disability Insurance Scheme.[7] The human impact on patient and clinicians involved in diagnostic errors cannot be easily quantified.
- **Diagnostic errors are a major driver of medical malpractice claims**, described as the most common, catastrophic and costly of all medical errors.[19]
    - In Australia, 17-45% of malpractice claims are linked to diagnostic errors.[20,21]
- The staggering personal and economic burden of diagnostic error is unnecessary as **around 80% of patient harm from diagnostic error is preventable**.[5]

International recognition of diagnostic safety as a patient safety priority

- Focus on **diagnostic safety as a patient safety priority requiring urgent attention** is growing among the global healthcare community.[1]
- **The WHO has recognised diagnostic error as a global public health priority** and choose this safety issue as its theme for World Patient Safety Day 2024.[13] The WHO has urged countries to improve patient safety through policies and practices to reduce diagnostic error.[8,22]

- The 2015 US NASEM landmark report *Improving Diagnosis in Health Care* outlined the nature and scale of diagnostic error, **calling improving diagnosis "a moral, professional, and public health imperative".** [16]
- Diagnostic error topped the US ECRI's (formerly Emergency Care Research Institute) list of top-10 **most pressing patient safety concerns** in 2018. [23] Diagnosis-related safety concerns were still prominent in the 2025 list with 'Risk of dismissing patient, family, and caregiver concerns' at #1 and 'Diagnostic error: The big three—cancers, major vascular events and infections' at #7. [24]
- The Agency for Healthcare Research and Quality (AHRQ), the lead US agency for patient safety research, recognises diagnostic safety as an integral component of patient safety and has been investing in diagnostic safety research for almost 20 years. [25] AHRQ has developed comprehensive resources and practical tools to address diagnostic safety. [26,27]
- Australian diagnostic error experts, Drs Carmel Crock and Ian Scott, have called for healthcare organisations to establish diagnostic safety programs, noting "**health service standards will likely come to include specific diagnostic safety standards**". [10]
- However, recent research by diagnostic error expert Dr Mary Dahm and colleagues identified a significant diagnostic safety policy vacuum in Australia/NZ compared to the US, where approaches to diagnostic safety are better embedded in policy. [9]

Attachment A: Mark Graber letter of endorsement

To: The Australian Commission on Safety and Quality in Health Care
Re: Proposed standards for the NSQHS 3rd Edition

Dear Commissioners:

As you develop the 3rd edition of the NSQHS, I sincerely hope you will incorporate elements to improve diagnostic safety. The proposal submitted by Dr Mary Dahm and Laura Chien is excellent and has my strongest endorsement.

I'm considered 'the father' of the modern movement to recognize and address diagnostic error and the harm it causes. I started Patient Safety Awareness Week in the US, I founded the non-profit Society to Improve Diagnosis (SIDM) in the US, and more recently, the Community Improving Diagnosis in Medicine (CIDM). I founded the Diagnostic Error in Medicine conference series; this year will mark our 15th annual conference in the US, Australia has now hosted 3 partner conferences, and others have been held in Japan and the EU. I was also responsible (with others from SIDM) for the US Institute of Medicine developing its landmark report on Improving Diagnosis in Health Care, which has clearly identified the problem of diagnostic error and the need to address it.

We now know that diagnostic error is a top-10 cause of death in developed countries, and the associated harm is comparable to that related to diabetes, heart disease, and cancer. Diagnostic errors are happening every day in every setting, and every patient is at risk. We also have an excellent idea of how to start preventing these errors and finding them before there is harm. Many of these ideas are outlined in the Dahm/Chien proposal, and these measures will save harm and lives.

Healthcare providers and healthcare organizations can and should help in efforts to improve diagnostic safety, and embedding these expectations in the NSQHS standards is the place to start. With the many individuals and groups in Australia now engaged in diagnostic safety work, Australia can and should become the international leader in setting national health care standards in this area.

Mark L Graber, MD FACP
Founder, CIDM
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Attachment B: Jen Morris letter of endorsement

Attention: Australian Commission on Safety and Quality in Health Care

Subject: Endorsement of Dahm-Chien submission to NSQHS Standards (third edition) public consultation one

I write to emphatically endorse the submission authored by Dr Mary Dahm and Laura Chien, calling for diagnostic safety to be included in the third edition of the NSQHS Standards (the Standards). In particular, I believe including diagnostic safety as a standalone standard would be demonstrably proportional to the degree of harm caused by diagnostic error in Australia, and in fitting with the ability and responsibility of health services to reduce this harm at a system level.

The Commission has a once-in-a-decade opportunity to lead innovation and improvement in diagnostic safety in Australia, and in doing so, to save lives and prevent much needless patient harm. More than anything else, the healthcare sector needs an authoritative signal that addressing diagnostic safety is everybody's responsibility, and that the public rightly expects health services to act to curb this scourge upon public health. Given the prominence and ubiquity of the Standards, the Commission is in the privileged position to be that authority, and to drive transformational change in patient safety.

I live and breathe the reality of diagnostic safety and harm in Australia, from the patient perspective. I have been a patient safety advocate for 15 years. In 2024 I was inducted by the Victorian government into the Victorian Honour Roll of Women for outstanding service to patient safety.

I have worked with over 120 organisations across the full spectrum of the health sector to improve patient safety, including as a patient safety investigator conducting clinical governance and safety systems reviews of health services. I have therefore seen the Standards in operation as they relate to patient safety, as well as how health services interpret them. I have also advised and advocated for countless individual patients who have contacted me in distress, while experiencing inequity, risk and harm in the healthcare system. Diagnostic errors are the second most common reasons patients contact me for help (second only to being unlawfully denied access to their health records).

This is a problem so ubiquitous that it touches absolutely everybody, directly, or indirectly through somebody important to them. It is a source of national trauma, disability and death on a devastating scale. Based on the empirical data and my wealth of experience, I am without doubt that in Australia, diagnostic error is the most under-served of all major categories of patient harm, by a large margin that is hard to understand, and impossible to justify. Diagnostic safety is a necessary national priority whose time has well and truly come.

Like the majority of Australians, I have experienced diagnostic errors, as have my loved ones. One of my loved ones died from a readily preventable diagnostic error aged just 25. I am also a survivor of three separate, near fatal diagnostic errors, and two protracted misdiagnoses (each lasting decades). The impact on my life has been devastating. [redacted]. And that's not to

mention the enormous financial impact – arising from both the costs of healthcare I wouldn't otherwise have needed, and lost income. For the rest of my life I will literally pay the price for harm visited upon me, for which I hold no responsibility, but bear all of the consequences. That this situation is replicated many thousands of times every year is a national tragedy, and it is time for change.

One of the hardest things to live with is the knowledge that what happened to me is no less likely to happen to somebody else tomorrow, either at the same health service, or any other health service. Because the necessary attitudes, expectations and systems are simply not in place for health services to meaningfully learn from diagnostic errors, and use these lessons to improve care and keep patients safe within their own services, much less share those lessons more broadly. In all three of my near-fatal incidents, the health services refused to acknowledge these events as learning opportunities, and refused to attempt to learn from them, or use them to drive improvement. In two out of three cases the health services refused to even meet with me to discuss what happened. Because they viewed these preventable, life-altering harm events as just 'one of those things that happens'.

Every day, I see everyday people suffer harrowingly and needlessly from the impacts of diagnostic errors. They experience months, years and even decades of preventable, untreated suffering from undiagnosed or incorrectly diagnosed conditions. Their relationships break down. They experience harrowing psychological trauma. They endure social isolation. They are left financial ruined. Their physical illnesses are incorrectly dismissed as psychiatric, with some wrongly compelled into psychiatric treatment. Their lives are hollowed out by preventable disability, as they are lost to community, leisure, family, friends, work, social participation and the things that make life worth living. Their suffering, and their deaths, are of course first and foremost an enormous loss to them and their loved ones. However, multiplied by the immense incidence of diagnostic error, they are also an incalculable loss to our society.

My personal experiences are consistent with what I have observed over 15 years as a patient safety advocate. There is a pervasive yet erroneous view among health services that improving diagnostic safety is not their responsibility. The reasons for this are two-fold.

First, health services operate under the mistaken belief, born of outdated individual blame models of safety thinking, that diagnostic error is an individual issue (an isolated moment of clinician's personal reasoning failure), rather than a system safety issue. This is simply not the case. Diagnostic safety is a system issue. A wealth of research has shown diagnostic error can (and indeed must) be successfully addressed at a systems level, including by health services.

Second, within health services, diagnostic error has been tragically normalised, such that it is perceived as an unavoidable and inevitable feature of healthcare. This is not the case and, as a society, we must never accept this. As outlined in the submission, research clearly shows the vast majority of diagnostic errors are preventable. We must never resign ourselves to the idea that patient harm, in whatever form, is just part and parcel of healthcare.

Including diagnostic safety in the Standards will address these unfortunate misconceptions, and help to shift healthcare culture. It will be a clear, constructive, positive signal to health services that diagnostic error is not inevitable, is preventable, and is within their remit to address and improve. Including diagnostic safety in the Standards will change attitudes towards diagnostic safety, and drive practical action. Bringing it out of the old-fashioned individual 'name, shame and blame' approach that serve nobody's interests, towards a comprehensive, systems-based and evidence-based approach – saving lives, preventing suffering, reducing costs, and creating a better healthcare system for everybody.

I commend to you Dr Dahm's and Ms Chien's submission, and call for diagnostic safety to be explicitly and comprehensively included in the third edition of the Standards.

Regards,

J. Morris

Jennifer (Jen Morris)

Patient Safety Advocate

Victorian Honour Roll of Women Inductee

BA, BSc, GDipSciCom, GCHealthServMgt(Safe&Qual), GCtConsCommEngage, GAICD

Attachment C: Stephanie Newell letter of endorsement

Dear Professor Duggan,

I strongly endorse the submission by Dr Mary Dahm and Ms Laura Chien recommending diagnostic safety for inclusion in the NSQHS Standards for Accreditation (3rd edition).

As you know, I have considerable experience in patient safety, governance and improvement that ensures that the health consumer is a partner.

I have contributed to the development of 1st and 2nd editions of the NSQHS Standards, in particular, the Partnering with Consumers Standard and the Clinical Governance standard as part of the ACSQHC committees. For over 7 years, I developed and facilitated education and training to health service boards, executives, clinical staff and consumers on the Partnering with Consumers and Clinical Governance Standard, both as an educator with the Australian Council on Healthcare Standards and as an independent facilitator. I have also been an Accreditation Assessor of the NSQHS Standards during the implementation of the 1st edition of the NSQHS Standards.

I believe that diagnostic safety should be included within and throughout all NSQHS Standards of the 3rd edition, as there is significant evidence of the extent, impact and cost of diagnostic error. Harm caused to patients due to diagnostic error is high and equally, is highly preventable. The number one risk to safe patient care is the dismissal of patient, family and caregiver input and concerns. The experience of not being listened to is a consistent factor across all adverse events caused to patients. Extensive research in the areas of diagnostic error and patient-centred communication is now supporting what patients and health consumer advocates have long been experiencing, identifying and vocalising of their input not being heard and listened to. With diagnostic error being experienced by most patients, at least once in their lifetime, the opportunity to increase patient safety and quality of health care and reduce patient harm by the inclusion of diagnostic safety within the 3rd edition of the NSQHS Standards is paramount.

Kind regards

Stephanie Newell, Patient Safety Advocate

Founding member - WHO Patients for Patient Safety programme,

Convener - Australian Patient Safety Network,

Contributor - ·development and implementation of the WHO Global Patient Safety action plan 2021-2030: towards eliminating avoidable harm in health care,

Invited expert to the 2025 WHO Global Ministerial Summit on Patient Safety.

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Attachment D: Luke Slawomirski letter of endorsement

Conjoint Prof Anne Duggan

Chief Executive Officer

Australian Commission on Safety and Quality in Health Care

Sydney

Re: Diagnostic safety in the NSQHS Standards (3rd edition)

Dear Anne

I strongly endorse the submission by Dr Mary Dahm and Ms Laura Chien recommending diagnostic safety for inclusion in the NSQHS Standards (3rd edition).

As you know I have considerable experience in patient safety measurement, governance and improvement, and recently led a comprehensive OECD report on diagnostic safety.

I firmly believe that diagnostic safety should be a key component of clinical governance. The evidence is clear. Harm from diagnostic error is not only more burdensome than other harms it is also among the most preventable. Combined with the high costs, the potential return from investing in diagnostic safety is high.

A key reason why diagnostic safety has not received the attention it deserves is that it is harder to measure than other safety events. However, new innovations that take advantage of the digitalisation in health data systems have made measurement achievable. I believe that building an information infrastructure should be a key focus of a new 'Diagnostic Excellence' standard.

In addition, including diagnostic safety in the Standards would demonstrate leadership, and send an important message here and abroad.

Kind regards

Luke Slawomirski

Health Economist

Consultant OECD, WHO

Visiting Lecturer Imperial College London

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