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Measuring value in new health technology assessments: a focus on robotic surgery in public hospitals

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Key messages

- The current processes for assessing the merits of implementing new health technology in public hospitals differ vastly across states, territories and public and private health systems. This makes it difficult to measure value as part of the assessment.
- There needs to be a clear and consistent approach across governments, health services and clinicians to ensure that evidence to support the value of new technologies such as robotic surgery can be demonstrated in terms of both costs and patient outcomes.
- To determine the value of new technologies we need to ensure that patient outcomes and experiences are measured and included in datasets through standardised systems or collections.
- Data and evaluation need to be more coordinated with an open approach to collection and sharing. Current arrangements around registries are not consistent and it is not always clear who decides who has access to certain data or who decides what to collect.
- Funding models need to be re-considered and adapted accordingly to enable providers to focus on outcomes that matter to patients as well as cost efficiencies.
- Strategies need to be undertaken to ensure that clinicians are more engaged with overall hospital objectives to identify innovative new technologies and enable access through the public hospital system.
- To demonstrate value, health technology assessments must also include consideration of equity. Are the right patients receiving the right treatment? Value is only achieved across the whole health system if everyone that needs it can access it.

Executive summary

A value-based approach to health care that puts patient outcomes and experience at the centre of a cost-effective universal healthcare system is generally supported by all Australian governments. This is demonstrated in their commitment to the Addendum to the National Health Reform Act 2020-2025 (the Addendum).

The Addendum also foreshadows the development of a national framework that would provide a more consistent and transparent approach to assessing how new technologies are implemented in public hospitals and how funding mechanisms are applied to these processes to ensure that value is achieved.

The paper considers the concept of value in health technology assessments conducted in the public hospital sector, with a specific focus on robotic surgery for hip and knee replacements. This includes what constitutes value in arthroplasty care, issues around evidence and data flows, the effectiveness of local and international bodies and committees, measurement of patient outcomes and experience, appropriate funding mechanisms, encompassing an innovative culture with strong clinician leadership and ensuring equity of access.

The creation of a robotic surgery program at Metro North Hospital and Health Service in Queensland is used as an example of how robotic surgery, specifically the Mako robot for hip and knee replacements, was assessed and implemented in a major metropolitan public hospital. The case study is used to highlight key success factors as well as limitations in identifying and implementing a new technology in the public hospital system and whether the value of the technology can be demonstrated.

Recommendations are provided for incorporation into health technology assessments to ensure that patient outcomes are considered as well as cost in order to demonstrate the value of the new technology to the whole public health system.

1 Introduction

Currently in Australia, processes differ across jurisdictions and public hospitals in relation to how new technologies are assessed and implemented, making it difficult to know if the technology leads to better patient outcomes at an efficient cost.

As noted in the Addendum to the National Health Reform Agreement 2020-2025 (the Addendum), the current approach to health technology assessment to inform investment and disinvestment decisions in Australia is fragmented and does not facilitate coordinated and timely responses to rapidly changing technologies (Appendix). Separate processes exist across all levels of the health system, which has the potential to duplicate effort, create inefficiencies and inconsistent advice, and delay access to innovative and emerging technologies.

From a funding perspective, while fee-for-service or activity-based funding models have provided greater transparency in terms of variation of costs in the public hospital system, many commentators are seeing a 'value' based approach as better suited to drive overall improvements in patient outcomes as well as cost efficiency.

The discussion around value-based health care to date has largely been around organisational transformation and system design, with limited consideration of the impact of new technologies. Ultimately, new technologies are only useful if they provide better patient outcomes at an efficient cost, and this may not be easy to demonstrate in the short term.

It is difficult to balance the type of data and evidence required for current health technology assessments, which are largely based on clinical outcomes, with patient outcomes or experiences which are an important part of the 'value' assessment. This is perhaps due to difficulties in assessing the cost, which could be a substantial capital outlay versus value to the patient, as clinical evidence can take many years to become accepted as clinically reliable. In addition, data limitations exist such as inconsistencies in measuring patient reported outcome or experience and the interplay with technology issues, patient complexity and the fact that what matters to patients might be different to clinical outcomes.

The Addendum signed by all Australian governments provides a framework to build on existing initiatives around value-based health care, such as paying for volume and outcomes. The Addendum also provides a commitment to develop a national framework for health technology assessment (HTA) noting that HTA is an important means of delivering value to patients and the broader health system (Appendix). There is broad acknowledgement amongst jurisdictions that patient reported measures are a vital component of a value-based approach to HTA; however work is still required to incorporate these measures, and value-based health care principles more broadly, into HTA in a timely manner.

This paper draws on the experience of Metro North Hospital and Health Service (MNHHS) in Queensland and the processes it undertook to purchase the Mako robotic system for hip and knee replacements and how it was implemented into a major public hospital. This case study provides some insights that can potentially be adapted to a national framework that considers value as part of health technology assessment process.

2 Health technology assessment in Australian public hospitals

There is currently no uniform approach internationally, nationally or locally as to how new technology is assessed and implemented into public hospitals which is perhaps why some public hospitals and their associated governing systems, have chosen to navigate the journey according to their own strategic priorities.

As the Addendum states, Australia requires a strategic, systematic, cohesive, efficient and responsive national framework for health technology assessments, noting that 'the current approach to the use of Health Technology Assessment to inform investment and disinvestment decisions in Australia is fragmented and does not facilitate coordinated and timely responses to rapidly changing technologies' (Appendix).

There are several bodies that exist nationally to perform assessments of medical technologies including the Medical Services Advisory Committee (MSAC). The principal role of MSAC is to advise the Australian Minister for Health on evidence relating to the safety, effectiveness and cost-effectiveness of new medical technologies and procedures. This advice informs Australian Government decisions about public funding for new, and in some cases existing, medical procedures. MSAC also advises the Australian Health Ministers' Advisory Council (AHMAC) on health technology. This is a rigid framework and process with set meetings meaning that consideration of technologies can be lengthy.

In their assessment of innovation in public hospitals from the Queensland perspective, Mundy et al., (2019) list some national and state level bodies that have attempted to provide guidance in the adoption of new health technologies. The Health Technology Reference Group (formerly HealthPACT) has responsibility for national coordination of HTA and provides advance notice to jurisdictional policy makers on the potential effect of adopting significant new technologies, primarily into public hospitals. This has been re-created at a jurisdictional level in Victoria (VPACT), Western Australian (WAPACT) and South Australia (SAPACT). However, funding for these organisations has been small and they are limited in the scope of their work. Queensland's (QPACT) and the NTEP (Northern Territory Evaluation Program) have a little more power and specific scope to assess innovative new health technologies noting that the Hospital and Health Services in Queensland are encouraged to apply for grants through the New Technology Funding Evaluation Process (NTFEP) (Mundy et al., 2019).

Queensland's NTFEP was put forward as a solution to 'provide an opportunity to collect real-world data outside of formal clinical trials that can be used to inform clinical, purchasing and decision making within the public health system'. It gives patients access to innovative and potentially beneficial technologies, but also acts as a gatekeeper, protecting them from technologies that may be detrimental or harmful. This allows the Queensland Department of Health to gauge whether promising results from the literature can be replicated in the real-work setting of clinical practice before state-wide adoption of technologies in the state (Mundy et al., 2019).

In addition to the time for approval of new health technology, current funding arrangements do not adapt well to the deployment of new technologies. Commonwealth funding is not provided for the capital outlay, such as for a robotic arm or for associated consumables, which can be quite costly.

Activity Based Funding (ABF) is not designed to support capital investment, only the 'activity' or the procedure provided in public hospitals.

Any process to obtain funding for new technologies through Commonwealth, state or territory systems can be prohibitive in terms of timeframes. The Independent Hospital Pricing Authority (IHPA) uses MSAC recommendations on new technologies to consider procedures that need to be updated or added into the acute care classification system under its *Impact of New Health Technology Framework (2019a)*. This can be a lengthy process as it is dependent on the revision cycle for the classification at any given time and can potentially mean a wait of up to seven years before a new procedure is incorporated into the classification. IHPA is reviewing this process and looking at options for interim codes to assist with more rapidly incorporating new technologies and other innovations into the classification system.

Linking funding to statutory health technology assessments is problematic as although it provides the option for public hospitals to apply for grants to acquire new and expensive technology through processes such as the QPACT and the NTFEP, if the hospital already has funds available there is no need to participate in a statutory health technology assessment process. A more standardised requirement for health technology assessments that is separate to the funding may be of more value to the public health system as a whole.

A more systematic approach to funding including close monitoring of evidence-based data to assess the costs of ongoing operation would ensure that both value and equity of access are given due consideration.

The Addendum provides a way forward for governments and public hospitals in some of these issues providing a commitment to long term health reform principles, specifically 'delivering safe, high-quality care in the right place at the right time; through a nationally cohesive HTA, paying for value and outcomes and joint planning and funding at a local level' (Appendix).

3 Assessing the value of robotic surgery in public hospitals

3.1 What constitutes value?

Value-based health care is increasingly being discussed by governments and health services in Australia as they seek to improve patient outcomes and experiences while reducing wastage and cost. Rising health care costs mean that efficiency, doing more with less, and improving outcomes, will inevitably be key drivers.

Value when defined as the outcomes that matter to patients relative to resources or costs required (Porter and Tiesberg, 2006) can be difficult to demonstrate when the initial costs for purchasing a new technology such as a robotic arm are high and data regarding outcomes are not readily available or mature. This also must be balanced against the longer-term cost-benefits of robotic surgery, including patient outcomes as well as clinical outcomes.

However, value can be defined differently by governments, surgeons and patients making the assessment of a new purchase unclear and available evidence may not support a positive investment decision. Consideration may also need to be given to disinvestment from technologies and processes currently in use.

In Australia most states and territories are adopting their own approaches to value-based health care through policies focussing on pathways of care and organisational change. Most governments support a value-based approach to health care that puts patient outcomes and experience at the centre of care, while continuing to work towards greater efficiency and an equitable health system. There has been some limited implementation of funding methodologies to pay for value, including application in primary care through regional commissioning with associated outcomes-based payments.

While there are processes to measure the outcomes of traditional versus robotic surgery, the emerging area of patient outcomes is still in its infancy. However recent studies that include Patient Reported Outcome Measures (PROMs) show interesting results. For instance, a recent study showed 'a trend towards a greater rate of patient satisfaction and willingness to undergo surgery again' in a group of patients undergoing robotic unicompartmental knee arthroplasty compared to those undergoing a manual procedure (Clement et al., 2020).

Once clear and measurable outcomes are embedded into the health technology assessment process, health providers and funders will better be able to assess the value of new technologies.

3.2 Robotic surgery in Australia

There are different categorisations of robotic systems used throughout robotic surgery. The historical categorisation of robots includes passive, semi-active, and active systems. Passive systems such as the da Vinci surgical system must be directed by the surgeon to perform a task. Semi-active systems, such as the Mako robotic arm, constrain surgical manipulation through feedback to restrict what can be done surgically. Active systems are capable of independently performing tasks without human manipulation through algorithms and other mechanisms (Chen et al., 2018).

Depending on the surgical speciality, the procedure and the type of robotic system used, robotic technology may provide different advantages over conventional techniques. Generally speaking, robotic surgery allows doctors to perform many types of complex procedures with more precision, flexibility and control than is possible with conventional techniques. Commonly robotic surgery is associated with minimally invasive surgery for procedures such as prostatectomy and hysterectomy, with proponents listing the benefits as including fewer complications, less pain and blood loss, quicker recovery and smaller, less noticeable scars (Mayo Clinic 2020).

In the area of orthopaedic surgery, robotic technology is used for arthroplasty procedures and is associated with greater capture of intra-operative data (Sherman and Wu, 2020) and higher degree of accuracy of bone cuts and final implant position which may lead to improving joint function and longevity of the implants (Chen et al,. 2018).

Arthroplasty, the surgical reconstruction or replacement of a joint, is a major area of health expenditure. More than $1.3 billion per year is spent on osteoarthritis related hospital admissions in Australia (Australian Institute of Health and Welfare, 2014). There was a 38% rise in the rate of total knee replacements for osteoarthritis from 2005 to 2016-17 in Australia. Robotic arthroplasty is widely available in private hospitals in Australia and is increasingly being offered to patients in public hospitals.

3.3 Demonstrating value in robotic surgery

To determine whether the technology is providing value a number of outcomes must be measured including clinical outcomes, patient outcomes and cost.

Clinical outcomes include measures such as implant survival, number of complications and number of revisions required. Patient outcome measures include pain, feel of the joint post replacement and ability to perform daily activities. Cost analysis varies and can be difficult to measure due to different funding streams and funding models in public hospitals, but ideally should take into account capital outlay, all costs through the entire episode of care and identify any potential savings through improved clinical outcomes.

Numerous studies have been conducted to assess the effectiveness of robotic surgery versus manual surgery in arthroplasty procedures. Whilst a growing collection of published research suggests that robotic surgery for partial and total knee replacement results in better clinical outcomes, shorter length of hospital stay and fewer revision requirements, there is still debate as to whether robotic surgery has been found to improve patient outcomes substantially compared with conventional surgical methods and whether the measured outcomes constitute better overall value in terms of cost.

Clinical outcomes are the key measurement in most studies with limited data currently available on patient outcomes and experience. However, where patient outcomes are discussed many surgeons state that the outcomes are not clearly improved by using a robot and until they are the cost cannot be justified (London, 2020).

In their review of robot-assisted total knee arthroplasty, Agarwal et al., (2020) conclude that despite its merits in improving alignment and clinical scores, it is unclear whether these conclusions directly result in the reduction in pain and improved functional mobility reported by several studies. They also note that the implications of the cost effectiveness of robots and additional training burdens need to be addressed.

However, proponents of robotic surgery suggest that if the technologies can lower revision rates for joint replacements to a specific level, by way of improved precision and recovery time, robotic assisted knee arthroplasty can demonstrate a return on investment within two years (Swank et al., 2019).

Clement et al., (2020) in their study looking at partial knee replacement for medial compartment osteoarthritis conclude that knee-specific functional outcome is both clinically and statistically significantly better for patients undergoing robotic compared to manual surgery and that patients undergoing robotic surgery also had a greater generic health score than those undergoing manual surgery. They also note that robotic surgery is associated with a shorter length of hospital stay than manual surgery.

A Cost Analysis of Robotic-Assisted and Jig-Based Manual Primary Total Knee Arthroplasty provides evidence that robotic surgery demonstrates reduced costs compared with manual surgery based on significantly lower average 90-day episode of care costs and superior quality exemplified by reduced length of stay, less postoperative opioid requirements, and reduced post discharge resource utilisation (Cotter et al., 2020).

To date, health technology assessments have tended to generalise about robotic surgery. There are numerous consensus statements on robotic surgery[12] with many specifying that it is not clear that robotic surgery provides better clinical outcomes than manual surgery. A limitation is that some generalise the types of robotic technology used across multiple surgical specialities and varying procedures.

When it comes to assessing robotic technology for value it is important that each technology is compared on its own merits rather than assessing robotic technology as an overarching solution as often it is treating a condition which has specific and desirable clinical outcomes as well as differing patient outcomes or expectations. Studies looking at individual technologies as they relate to their speciality of use provide more useful evidence in determining the value of specific robots and their function.

The evidence for robotic surgery can take varying amounts of time to become clinically viable with some studies taking up to ten years to show improved survivorship. However, registries such as the Australian Orthopaedic Association National Joint Replacement Register (AOANJRR) provide a rich source of historical data with clinical outcomes demonstrated across a wide user group.

3.4 Robotic surgery at Metro North Hospital and Health Service

Metro North Hospital and Health Service (MNHHS) in Queensland identifies and assesses new technology as part of an overarching strategy. MNHHS established a governance model that includes a Robotic Surgery Plan (the Plan) to guide implementation of robotic technology through a comprehensive robotic surgery program. This includes the implementation of orthopaedic robotic surgery at The Prince Charles Hospital in Brisbane which is pioneering orthopaedic robotic surgery in public settings.

Case study:
Implementing the Mako robot at The Prince Charles Hospital, Brisbane

MNHHS has been working with one of its major public hospitals The Prince Charles Hospital in Brisbane to provide an assessment of the Mako robotic system to deliver hip and knee replacement surgery.

At present, there are 45 Mako robotic systems in Australia, only three of which are in public hospitals.

As there is no clearly defined process in Australia as to how new technology is incorporated into public hospitals, MNHHS has established its own governance model led by a Robotic Surgery Steering Committee. The steering committee provides a proactive service that looks at the effectiveness of a new technology, such as the Mako robotic system, initially through literature reviews and international data.

[1] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6441912/

[2] https://link.springer.com/content/pdf/10.1007/s00464-014-3916-9.pdf

MNHHS developed a *Robotic Surgery Plan 2018-2021*. The introduction sets out its goal; 'to ensure access for suitable patients requiring surgical procedure is provided based on best available technology and evidence and delivered in a planned, safe and cost-effective manner'.

The Robotic Surgery Steering Committee has a dedicated Robotic Surgery Program Manager who is responsible for the coordination and implementation of the Robotic Surgery Plan and management of data related to the robotic surgery clinical registry. The Robotic Surgery Program Manager produces monthly and quarterly reporting as well as contributing to the development of clinical practices, procedures and protocols that support the continuum of care engaging multi-specialty referencing where relevant. The Robotic Surgery Program Manager provides a vital role in building relationships and connecting the executive leadership at MNHHS and surgeons at The Prince Charles Hospital.

The Robotic Surgery Steering Committee proactively looks for innovative new technologies by assessing literature and developing programs. A working brief is developed to engage with surgeons to obtain clinically led feedback on an identified technology.

Surgeons at The Prince Charles Hospital championed the robotic technology for orthopaedic surgery based on experience using it in private hospitals. They were able to maximise their training and experience from private practice as it was implemented into the public hospital.

Procurement Process

MNHHS acquired the Mako robot through a formal tender process specifying the requirement for an orthopaedic joint replacement robotic surgical system following a literature review of existing systems. The system was to include functionality for:

- partial knee arthroplasty
- total knee arthroplasty
- total hip arthroplasty.

The tenders were evaluated on a number of technical and functional requirements to improve on surgery compared with manual techniques. The assessment of tenders was undertaken by a panel of stakeholders. Concurrently, funding for the robot was applied for through the Metro North Asset Management Committee to evaluate the budget required and its source. This meant that there was no requirement to approach the Queensland Department of Health or any associated health technology assessment body such as QPACT for funding.

Through The Prince Charles Hospital, an application form for New Health Technology, Equipment and Procedures was also submitted to the Director of the relevant clinical department, in consultation with the Executive Director of Medical Services at the Prince Charles Hospital, who is responsible for determining whether the new technology and procedure is significantly different from existing clinical practice.

Key success factors:

The following key success factors have been identified by the Robotic Surgery Program Manager in the implementation of the Mako robot at The Prince Charles Hospital:

- **Executive support and authorisation** - the Robotic Surgery Steering Committee has vital connections with both the executive leadership and key clinical influencers through a Steering Committee and Working Group that are provided quarterly and monthly updates respectively. This is used to provide a clinical and economic evaluation for all robotic surgery in MNHHS.

- **Clinical leadership and engagement** - Surgeons at The Prince Charles Hospital are key advocates for the robotic surgery and time is made for visiting surgeons to gain access to the robotic system for their patients. In its work to determine the value add of a new technology, MNHHS note that clinician engagement is vital, specifically in obtaining outcome data. The Robotic Surgery Steering Committee present the data back to clinicians through a report that measures key operational and clinical measures of robotic and non-robotic procedures.

- **Research and evidence** – supporting clinical practice through effective use of data, MNHHS maintains a Robotic Surgery Clinical Registry which collects operation and clinical data for the evaluation of all robotic surgery technology. Surgeons at The Prince Charles Hospital in Brisbane assert the importance of comparing apples with apples. As such the MNHHS registry data enables its surgeons to review patient level data that is comparing like for like, robotic to non-robotic procedures. This includes patient demographics, operating times, surgeons, complications, Diagnoses Related Group (DRG) and ortho-specific types of consumables used. The MNHHS robotic registry data set has also incorporated data from a pilot project to collect patient reported outcome measures (PROMs) defined by the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR).

- **Timeframes –** the mechanisms established by MNHHS such as the Robotic Surgery Steering Committee and its associated reporting functions allows it to proactively identify new technologies early and begin the process of evaluation. This is beneficial given the time it can take for evidence-based research to become clinically accepted. Data can be considered early and clinical trials can be organised at the hospital where appropriate.

The Robotic Surgery Steering Committee continues to evaluate the purchase of the robotic system for value through a number of ongoing KPIs and metrics including benchmarking robotic procedures against non-robotic equivalent procedures. It also provides an annual report on its progress to achieve priorities in the Plan. Through the collection of data that includes both clinical outcomes, patient reported outcomes and costs, the Robotic Surgery Steering Committee can provide the executive leadership team and clinicians evidence-based feedback to assist in determining the value of the new technology on an ongoing basis.

This MNHHS governance model highlights a successful pathway to assessing new health technology in a public hospital including measures taken to demonstrate the value of the new technology to both the executive decision makers and the surgeons who were key influencers.

This case illustrates some potential opportunities given rules around training and proctoring for new technology in public hospital settings. For instance, private surgeons can translate their skill set into the public sector without additional training investment required.

4 Assessing and evaluating the evidence

Evidence regarding patient outcomes and cost is vital in determining whether the adoption of a new technology is providing 'value'. However, evidence can be difficult to obtain when a new technology enters the market and data is not yet available, or at least accepted as clinically reliable, in terms of traditional evaluation methods such as clinical trials or longitudinal studies.

In a publicly funded system and with a desperate need to integrate care for patients to achieve the best possible outcome and experience, it is more about doing the right thing at the right time, with decisions better supported by data that comes directly from patient feedback (Lewis, 2019).

However, having the right data at the right time can prove to be difficult, presenting potential barriers to adopting new technology that may exist regarding perceived costs, such as capital outlays and other implementation costs, particularly with public funding. Without clear data driven evidence, it is likely that this could outweigh probable savings and ultimately 'value' in the long term.

Resources and costs are not confined to single episodes of care (Woolcock, 2019). This implies that a value-based health care perspective will often require a longitudinal view of a person's sequence of health care encounters to properly assess the outcomes realised and costs incurred.

Data for robotic surgery is collected through several mechanisms as outlined in the sections below, but it is debatable as to how accessible the data is by the right people at the right time. In order to provide useful measurements, data collections need to allow analysts to compare apples with apples. For instance, data needs to be comparable across surgeons and patient cohorts. Likewise, it is important that specific technologies are identifiable in the data as opposed to robotic surgery in general to enable a more thorough evaluation. For instance, robotic surgery in general may not demonstrate clear overall improvements in clinical outcomes, however researchers need to be able to identify if a specific technology is providing better outcomes than others – or vice versa.

4.1 Can clinical quality registries demonstrate value?

According to the Australian Commission on Safety and Quality in Health Care (ACSQHC, 2014), in Australia there is limited capacity to measure and monitor the degree to which health care benefits the patient and how closely that care aligns with evidence-based practice. Currently, only a small number of data collections capture and report process and outcomes data for specific clinical conditions or interventions. This results in significant gaps in current Australian health information regarding the appropriateness and effectiveness of specific healthcare interventions. ACSQHC states that development of national clinical quality registries (CQRs) is a cost-effective way of addressing these gaps.

CQRs use clinical data to identify benchmarks and variation in clinical outcomes and feed-back essential risk-adjusted clinical information, to clinicians, patients, consumers, health service administrators and government to inform clinical practice and health service decision making. Registries may also provide reports to jurisdictions, healthcare providers, funders, clinical colleges, researchers, and patients and consumers (ACSQHC, 2014).

The Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) has been capturing data on hip and knee surgery since 1999 and provides a rich source of empirical evidence. The aims of the AOANJRR would seem to align well with what is required to provide clear feedback on whether new technologies such as robotic surgery are achieving value.

However, clinicians and surgeons are the primary audience for registries which presents some limitations for others that wish to access and use the data such as the funders, researchers, technology manufacturers and patients. While data on clinical outcomes is vital, other parties may wish to explore the data for purposes such as cost-benefit analysis or a consideration of overall value to a hospital by linking this data to other data sets.

While consideration needs to be given to preserving patient privacy and clinician anonymity, wider access to the data would enable more rigorous assessments from different perspectives. There is currently no consistent mechanism by which other parties can access data in the registries which raises questions around who owns the data, what can be made available and what should be made available.

There is work to expand and better define access to CQRs at a national level with the Australian Government Department of Health's National CQR Strategy and the ACSQHC's framework for Australian CQRs that aims to define the governance of CQRs.

The proposed vision of the national CQR strategy is that national CQRs are integrated into Australia's health care information systems and systematically drive patient-centred improvements in the quality and value of health care and patient outcomes, across the national health care system. This meets the aim of national CQRs to collect longitudinal health outcome data for the entire eligible or in-scope population of the clinical domain, and to generate risk-adjusted reports on the appropriateness and effectiveness of health care.

To enable evidence-based analysis to support value-based health care decisions, data collections need to be open (with safeguards around patient privacy) and provide a mechanism to enable the data collected to evolve to meet the needs of a broader audience.

At the same time, consideration needs to be given to the purpose of data collections ensuring too much burden is not placed on clinicians, clinical staff and patients.

4.2 Measuring patient outcomes

An important part of new health technology assessment from a value perspective is ensuring that the patient reported outcome measures (PROMs) and/or patient reported experience measures (PREMs) are incorporated into the evaluation process. PROMs and PREMs can be a vital part of the picture in determining the value of investment in a new technology.

The Addendum has provision for a national approach to PROMs and this will be a critical component for consideration in the national health technology assessment framework to support decision-making on and funding for innovative technology purchasing in the public system (Council of Federal Financial Relations, 2020).

PROMs are questionnaires that help patients to report on outcomes relating to their health. These questionnaires focus on various aspects of health, such as symptoms, daily functioning, and quality of life. PROMs are usually measured on two or more occasions to enable comparisons to be made over time, (ACSQHC, 2014).

Patient reported outcomes can enhance the communication between patients and their clinical teams and therefore have a range of uses in supporting shared decision making, acting as triggers for key conversations and as a needs assessment, long before we have acquired larger datasets for analysis (Lewis, 2020).

PROMs are being increasingly included in data collections in Australia including the AOANJRR which began a PROMs collection pilot in 2018. This includes some standardised measures such as EQ5D which measures health-related quality of life in cost-effectiveness analysis, the Oxford Score which assess function and pain specifically for hip and knee surgery, and additional questions which include expectation and satisfaction as well as affected joint pain and lower back pain.

All Australian states and territories note in their submissions to the Independent Hospital Pricing Authority's most recent consultation on its Pricing Framework that they are collecting or planning to collect PROMs in some form and are generally supportive of collecting PROMs data to assist in moving to an outcomes-based model of care that is centred around the patient. The Consultation Report notes significant support for PROMs to be included in the Commonwealth Government's National Clinical Quality Registry Framework. A few jurisdictions, however, note challenges to implementing PROMs citing the 'additional burden that collection places on clinicians and patients, the subjectivity of patient experience and the need for any PROMs collection framework to be well considered if it is to result in improvements in patient outcomes,' (Independent Hospital Pricing Authority, 2020b*;* pg 23).

The Addendum specifically provides for the development of a national PROMs collection in its overall objectives which specify that Commonwealth and States recognise that improving value in our health system means developing and implementing reforms that: improve outcomes, experiences, quality, safety and efficiency of care through public reporting, such as promoting the uptake of Patient Reported Measures (Council on Federal Financial Relations, 2020; pg 7).

PROMs and PREMs are being collected across different health services at both the primary and hospital level through varying mechanisms and software with no standardised approach. For example, the AOANJRR PROMs pilot does not make it mandatory to report international measurements such as hip disability and osteoarthritis outcome score (HOOS) and knee injury and osteoarthritis outcome score (KOOS). Nor does it align with international standards such as the International Consortium for Health Outcome Measurement (ICHOM) Standard Sets[3] which means

[3] ICHOM Standard Sets are standardised outcomes, measurement tools and time points, with risk adjustment factors, for given conditions. They are developed by clinical experts in consultation with patient

that international benchmarking is not possible. As such, it is not standard practice for most orthopaedic surgeons to collect these data.

This raises questions more broadly about the standardisation of PROMs in a similar way to CQRs regarding what information should be captured and for what purposes and who should be able to access this information.

Case studies such as the Continuous Improvement in Care–Cancer Project demonstrate that clinicians are keen to minimise duplicate data capture and try wherever possible to capture information that will satisfy both the ICHOM standard set and any CQRs in place locally, nationally or internationally (Saunders et al., 2019).

Researchers implementing value-based health care programs suggest that ICHOMs Standard Set indicators should be included as a key element early in a project as they are difficult to integrate into IT systems later (Saunders et al., 2019). However, it is also noted that the ICHOM collection can add burdensome requirements for both clinicians and patients. From a government perspective it is possible that focus will increasingly be applied to standardised measures such the PaRIS indicators[4] which are already used for international benchmarking purposes through Australia's Organisation for Economic Cooperation and Development (OECD) participation.

In terms of assessing patient outcomes resulting from robotic surgery it is important that the patients' interpretation of outcomes is considered as well as the clinical outcomes in order to assess whether the robotic surgery genuinely provides value.

Evidence-based guidelines may not consider the patients' context and shared understanding of their situation with their clinician which in turn may influence choices made about the appropriateness of an intervention for that individual. Lewis states that 'we can and should back up that decision making with ongoing outcome data capture including patient-reported outcomes as part of real-world evidence generation (Lewis, 2020).

To take full advantage of the potential beneficial impact of data and innovations on the patient, priority in the allocation of resources should be given to achieving interoperability and safe data sharing across different data systems, such as through immediate access to patients' records across healthcare organisations (Royal College of Surgeons, 2018; pg 92).

As the collection of patient outcomes and experiences matures, it will assist those in public hospitals such as the MNHHS Robotic Surgery Steering Committee and decision makers across the health system in measuring the value of technologies such as the Mako robotic system beyond clinical outcomes.

representatives in the relevant field. The intention of Standard Sets is to focus on the outcomes that matters most to patients. There are currently Standard Sets covering 34 conditions, with a further five being developed. Further information can be found at https://www.ichom.org/faqs/.

[4] Patient-Reported Indicator Surveys (PaRIS) is an OECD international initiative to develop, standardise and implement a set of indicators that aim to measure the outcomes and experiences of health care that matter most to people. Further information can be found at http://www.oecd.org/health/paris/.

5 Applying a value-based approach to health technology assessment

In their paper on implementing a value-based health care approach for the Continuous Improvement in Care–Cancer Project, Saunders et al., (2019) note that engagement of clinicians and health service management is vital to the success of value-based health care, both for research and for long-term implementation into everyday clinical practice.

In the public hospital sector, it is important to ensure that as part of the assessment of any new technology, the focus on equity is not lost, and that services and treatments using new technologies will be available to those who need these most.

Some of the key success factors outlined in the MNHHS case study demonstrate enablers of a value-based healthcare approach for assessing a new technology in a public hospital. Specifically, this includes clinician leadership and their involvement in the collection of data and research.

Raymond and Hegde (2020) also comment on the importance of team culture in their journey to value-based health care at Dental Health Services Victoria. 'Workforce culture played a notable role in the change process. Team attitudes of early-adoption, collaboration and commitment to care were perceived to relate to the successful uptake of new practices and processes' (pg 9).

The UK Royal College of Surgeons' *Future of Surgery Report* (2018) recommends that medical students, surgeons in training and consultants should be encouraged to step on and step off traditional training and career pathways to spend time in industry, academia, teaching or abroad to bring back innovation to the healthcare system (pg 94).

Value-based health care will require modelling for future workforce requirements, taking into account not only change in demographics and burden of disease, but also modelling the impact of technological change on the type of services that will be provided in the future, and the skill sets required to provide those services (Woolcock, 2019).

5.1 Ensuring equity of access to new technologies

New technology can provide a major challenge to equity in terms of whether all Australians have equal access to the best available treatments. The decision around cost-effectiveness versus accessibility is a difficult one.

In the public hospital sector, it is important to ensure that as part of the assessment of any new technology, the focus on equity is not lost, and that services and treatments using new technologies will be available to those who need these most.

The MNHHS Robotic Surgery Plan 2018-2021 *(*2018) notes decisions around whether the model will be centralised or de-centralised – that is, where the robot is located and whether more robots should be purchased. In a public hospital it is presumed this would be based on clinical need as well as cost-effectiveness and clinician capabilities.

Given Australia's commitment to universal health care, and national health policy efforts to achieve both equity and public value, it is timely to consider the challenges and opportunities presented as value-based health care approaches are implemented (Verhoeven et al., 2020).

The definition of equity proposed for the United Kingdom's National Health Service is 'the equitable, sustainable and transparent use of the available resources to achieve better outcomes and experiences of care for every person' (Hurst et al., 2019; pg 3).

In a news article, Royal Australasian College of Surgeons South Australian chair, Phil Worley, notes that 'one of the problems with robotic surgery at the moment is access to the robots — and that's even a problem in our major cities, much more of a problem in our regional and remote cities'. He goes on to note that boosting the number of robots on the market could have benefits for regional areas.

The location of surgical robots and centralised services need to be much better planned in the future to ensure cost-effectiveness and access across the country (Royal College of Surgeons, 2018; pg 95).

Value-based health care must focus not only on delivering value at an individual level, but also at a societal level, or equity gaps will be further exacerbated, (Verhoeven et al., 2020). A clearer national process as proposed in the Addendum could assist in ensuring that equity is considered as a strategic priority as new technology is assessed, purchased and implemented.

One such option is looking at how a bundled payment system could incorporate the cost of new technologies particularly around procedures such as hip and knee replacements that have an established pathway of care.

Health systems where value-based health care programs are well-established are transitioning from funding arrangements that support payment for episodes of care to payments for the full cycle of care for patients. These bundled care funding arrangements not only support greater clarity for patients regarding the costs of their care but also provide a mechanism for identifying and addressing equity issues for individuals and for patient cohorts (Dawda, 2015).

Planning for and developing appropriate responses to potential equity issues should be specifically designed into bundled care pricing arrangements to ensure cost transparency is backed up by tangible actions to support equity in healthcare and health outcomes (Verhoeven et al., 2020).

6 Conclusion

Determining value when conducting new health technology assessments for public hospitals in a universal health care system is a challenge. Evidence-based studies with a focus on clinical outcomes are vital as is cost benefit analysis, but this must be enhanced with data on patient outcomes and experiences in order to fully assess the value of the investment.

With new technologies set to become more sophisticated (and potentially more expensive) through advances in areas such as artificial intelligence and precision medicine such as genomics, governments as well as public hospitals will need more consistent and responsive approaches to assessing the value of such technologies.

A clear process is required for Australian public hospitals in their assessment of new health technologies and whether they are achieving value. The Addendum to the National Health Reform Agreement 2020 - 2025 provides a way forward towards to assessing new technology with the

agreement of the Commonwealth, states and territories to a strategic, systematic, cohesive, efficient and responsive national framework for health technology assessments (Appendix).

The Robotic Surgery Steering Committee at MNHHS provides some useful examples of how new technologies can be assessed with a focus on value and implemented through executive leadership, clinical buy-in, and strategic data collection. As demonstrated by the MNHHS case study, strategies need to be undertaken to ensure that clinicians are involved and engaged with overall hospital objectives to ensure that they continue to see the benefit of data collections particularly around patient reported outcome measures.

However, unlike MNHSS, for many public hospitals the initial capital outlay for a new technology is currently reliant on funding through a health technology assessment process which is unclear and presents lengthy timeframes. A more standardised approach to health technology assessment will enable other public hospitals access to new technologies such as robotic surgery that may be providing better value than existing processes.

The new framework proposed in the Addendum provides an opportunity to include consideration of how the new technologies will be funded, such as through a bundled payments and whether this would impact the overall cost. The Addendum supports the investigation of this type of approach through its objectives to implement arrangements for a nationally unified and locally controlled health system which will improve patient outcomes, patient experience and access to services; including by focussing on what matter most to patients, supporting innovative models of care and trialling new funding arrangements (Council on Federal Financial Relations, 2020; pg 7).

Underlying the value-based approach to assessing new technology is the need for more open data that is accessible to the right people at the right time. This data needs to be accessible to governments, clinicians, patients, researchers and manufacturers in a format that can be appropriately interpreted and linked. Data collections should be incorporated into national datasets and standardised where possible to ensure that international benchmarking is possible while also ensuring that clinicians are not overburdened with data collection requirements.

Finally, consideration must be given to equity of access as part of the decision as to whether the technology is providing overall value to the health system and not just to those who can afford them.

Appendix

National Health Reform Agreement – Addendum 2020-25

Schedule C – Long term health reform principles

Nationally cohesive health technology assessment (page 57)

C7. Australia requires a strategic, systematic, cohesive, efficient and responsive national framework for health technology assessments (HTA). The current approach to the use of HTA to inform investment and disinvestment decisions in Australia is fragmented and does not facilitate coordinated and timely responses to rapidly changing technologies.

C8. Separate processes exist across all levels of the health system, which has the potential to duplicate effort, create inefficiencies and inconsistent advice, and delay access to innovative and emerging technologies. Proactive planning will optimise financial and organisational access to innovative and emerging technologies.

C9. The Parties agree that:

a. HTA is an important means of delivering value to patients and the broader health system;

b. the Commonwealth and States must determine how to prioritise spending on health technologies within the constraints of limited budgets, and do so in a way that is consistent, equitable and efficient; and

c. the development and implementation of a nationally cohesive approach to HTA is an opportunity for governments to make informed decisions to deliver safe, effective and efficient care that is financially viable and improves population health.

C10. The Parties further agree to jointly develop a federated approach to health technology assessment, with a view to towards a unified framework in the longer term. The goal is to increase the impact of HTA on policy, funding (investment and disinvestment) and service delivery decision making at all levels of the health system. The Parties acknowledge that a unified framework is ambitious and commit to testing and trialling this strategy within an initial narrow and defined scope.

C11. The Parties agree that funding arrangements for new high cost, highly specialised therapies (HSTs), recommended for delivery in a public hospital setting by the Medical Services Advisory Committee, will be determined on the basis of hospital funding contributions specified in Schedule A with the following exceptions for the term of this Addendum:

a. the Commonwealth, for these types of therapies, will provide a contribution of 50 per cent of the growth in the efficient price or cost (including ancillary services), instead of 45 per cent; and

b. they will be exempt from the funding cap at clause A56 for a period of two years from the commencement of service delivery of the new treatment.

c. Upon commencement of service delivery of the new treatment in a State, the State

National Health Reform Agreement – Addendum 2020-25 may request advice from the Administrator on the operation of the cap exemption for that treatment in that State.

C12. The Parties agree that there will be joint decision making by Chairs of MSAC and PBAC and a nominated representative of CHC, on the referral for HTA of applications for a new HST likely to be offered within public hospitals. This decision will consider potential impact on other public hospital clinical services, as well relevant legislation guiding the HTA process. This decision will occur within 30 days of the application so that HTA is not unreasonably delayed by early consideration of implementation. The governance process for these arrangements is outlined at Appendix B.

C13. The reform will also include the following components:

a. establishment of a process to facilitate a consistent approach to HTA nationally, identify and prioritise technologies that would benefit from national level HTA;
b. development of a national HTA framework, including processes for HTA to inform advice on implementation, investment and disinvestment opportunities at Commonwealth and State levels;
c. establishment of an information sharing platform to enable collaboration between relevant jurisdictional and national bodies;
d. Production of public and stakeholder guidance; and
e. Review and support of HTA workforce.

C14. The Parties agree that the Australian Health Ministers' Advisory Council (AHMAC) and its relevant authorised committees will oversee the design and delivery of the HTA federated approach.

C15. The Parties jointly agree to ensure that other relevant agencies and committees directly or partially engaged in HTA remain informed of and consulted on the progress of this long term health reform.

C16. The Parties agree to continue to work together to improve the engagement with, and transparency of, HTA processes where the item under assessment is likely to be delivered in a public hospital setting.

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