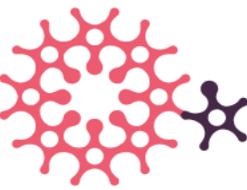


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## Issues brief

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**HESTA**



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## Key messages

- Provision of high-value health care requires an accurate diagnosis. This complex process is susceptible to error, potentially leading to significant patient harm. The issue of diagnostic errors is particularly relevant to the diagnostic imaging sector.
- There is limited data on the incidence of diagnostic errors related to medical imaging despite significant investment of public funds to improve patient access to diagnostic imaging and increasing Medicare expenditure in the past 5 years. As a result, there is an absence of a co-ordinated national strategy to prevent diagnostic errors and maximise patient outcomes from diagnostic imaging.
- Opportunities exist to measure the incidence and consequences of diagnostic errors related to medical imaging, through the Medical Indemnity Best Practice data set. Contemporary analysis of this data will establish the extent of the problem and support the development and implementation of interventions that address shortcomings in the diagnostic process. Further efforts to enhance the availability of patient-level data will be critical in assessing diagnostic imaging's value to the diagnostic process and guiding health policy.
- Several recommendations are made to improve the use of diagnostic imaging within the diagnostic process:
  - Amend Medicare regulations or the implementation of minimum data requirements through eReferral in My Health Record to improve the quality of imaging referrals.
  - Invest in the development and implementation of strategies to encourage the appropriate use of diagnostic imaging.
  - Proactive strategies to address ethical and governance concerns related to the rapid uptake of artificial intelligence applications for medical imaging.
  - Encourage uptake of My Health Record by diagnostic imaging practices to enhance information sharing.
  - Improve radiologist/referrer communication through the implementation of structured report templates.

## Executive summary

Diagnostic imaging provides images of internal tissues and organs to aid health professionals to identify the cause of symptoms and inform subsequent health care decisions. Yet, its use may contribute to failures in the diagnostic process that result in patient harm and wasted health care resources.

It is estimated that 140,000 diagnostic errors occur each year within the Australian health care system. Despite the large number of diagnostic imaging services utilised, Australian data on the incidence and consequences of diagnostic errors related to medical imaging is lacking, hampering any effort to improve the quality of diagnostic imaging services. The Government should consider contemporary analysis of medical indemnity data to develop initiatives that focus on reducing diagnostic errors and their associated health and financial burden.

Diagnostic errors related to medical imaging can occur due to communication failures between radiologist and referring clinician, referral for imaging when not clinically indicated, or image interpretation errors.

This Issues Brief identifies and discusses various health policies that have been implemented internationally to improve the use of diagnostic imaging and reduce the consequences of diagnostic errors. The implementation and effectiveness of these interventions are examined in the context of past and current Australian health policy related to diagnostic imaging.

With the increasing use of diagnostic imaging, a national strategy is needed to address the consequences of diagnostic error to patient safety. Investment to reduce diagnostic errors will improve the quality of care, reduce serious harm, and improve the sustainability of the sector through reduction in medical indemnity claims and the number of unnecessary imaging referrals.

## 1 Diagnostic errors impact on high-value care

Provision of high-value health care requires an accurate diagnosis (Institute of Medicine and National Academies of Sciences, Engineering, and Medicine, 2015). This complex and collaborative process involves gathering information from various sources to arrive at a working diagnosis that not only explains the person's condition, but also informs subsequent health care decisions for better patient health outcomes (Institute of Medicine and National Academies of Sciences, Engineering, and Medicine, 2015). This process, however, is vulnerable to diagnostic error (Box 1).

### **Box 1: Commonly used definitions of diagnostic error**

Most definitions of diagnostic error recognise the importance of accuracy, timeliness, and communication in the diagnostic process (Australian Commission on Safety and Quality in Health Care, 2020; Clinical Excellence Commission, 2015; Institute of Medicine and National Academies of Sciences, Engineering, and Medicine, 2015).

**Diagnostic process** – A complex, patient-centred, collaborative activity that involves information gathering and clinical reasoning with the goal of determining a patient's health problems (Institute of Medicine and National Academies of Sciences, Engineering, and Medicine, 2015). A conceptual model of the diagnostic process is outlined on page 34 of [Improving Diagnosis in Health Care](#) (Institute of Medicine and National Academies of Sciences, Engineering, and Medicine, 2015).

**Diagnostic error** – The failure to establish an accurate and timely explanation of a patient's health problem/s or communicate that explanation to the patient (Institute of Medicine and National Academies of Sciences, Engineering, and Medicine, 2015).

**Delayed diagnosis** – A subcategory of diagnostic errors where the correct diagnosis was unintentionally delayed (that is sufficient information was available earlier to make the correct diagnosis)(Australian Patient Safety Foundation referenced by Graber et al (2005)).

**Wrong diagnosis** – Another diagnosis was made before arriving at the correct one (Australian Patient Safety Foundation referenced by Graber et al (2005)).

**Missed diagnosis** – No diagnosis is ever made (Australian Patient Safety Foundation referenced by Graber et al (2005)).

**Near misses** – Failures in the diagnostic process that do not lead to a diagnostic error (Institute of Medicine and National Academies of Sciences, Engineering, and Medicine, 2015).

**Overdiagnosis** – When a condition is diagnosed that is unlikely to affect the individual's health and well-being (Institute of Medicine and National Academies of Sciences, Engineering, and Medicine, 2015).

In Australia, reducing diagnostic errors needs to be a priority due to the increasing incidence of errors, the consequent impact on patient outcomes through delayed or inappropriate healthcare, and the sustainability of the healthcare sector through wasted resources (Scott and Crock, 2020; World Health Organization, 2019; Singh et al., 2017; Clinical Excellence Commission, 2015).

In 2013, research presented at the [Hospital Alliance for Research Collaboration Forum](#) highlighted how the lack of Australian data on the incidence and consequences of diagnostic errors were hampering efforts to reduce their occurrence and improve patient safety (Sax Institute, 2013). Extrapolating estimates from other countries to the Australian health system suggests that 140,000 diagnostic errors occurred in 2013, with 21,000 cases resulting in serious harm and up to 4,000 deaths (Scott and Crock, 2020; Sax Institute, 2013). Contemporary estimates of the incidence of diagnostic errors are not available.

Empirical data on the prevalence of diagnostic errors in Australia are limited to medical indemnity claims (Australian Institute of Health and Welfare, 2014), public reporting of diagnostic errors in NSW public hospitals (~500 per year)(Clinical Excellence Commission, 2015), and two retrospective studies (Liu and Taylor, 2002; Wilson et al., 1995), which showed that wrong diagnoses accounted for 3.6% and 13.6% of hospital adverse events, respectively.

The Comprehensive Care Standard for clinical assessment and diagnosis from the Australian Commission on Safety and Quality in Healthcare outlines strategies to improve the diagnostic process (Australian Commission on Safety and Quality in Health Care, 2020), with programs to increase clinicians awareness of diagnostic errors provided by New South Wales' Clinical Excellence Commission (Clinical Excellence Commission, 2015). These programs should be expanded to ascertain the extent of the problem, identify factors that increase the likelihood of diagnostic errors, and increase awareness of the issue.

## **1.1 Diagnostic errors related to medical imaging**

A description of imaging modalities, the number of machines in use in Australia, and Medicare service use is listed in [appendix 1](#).

Given the primary role that the medical imaging sector plays in aiding clinicians through the diagnostic process, diagnostic errors are an important issue for this sector (Bruno et al., 2015).

Medical indemnity claims are significantly more common in general practice than in diagnostic radiology (493 and 50 claims in 2012-13, respectively)(Australian Institute of Health and Welfare, 2014). Recent analysis by a single medical indemnity insurer in Australia found that diagnostic errors were responsible for two thirds of compensation claims against radiologists, compared to one third against general practitioners (Yee, 2019; Moran and Jammal, 2018).

However, there are limitations to using medical indemnity claims that are likely to underestimate the rate of diagnostic errors related to medical imaging (Singh et al., 2021; Gupta et al., 2018). Beyond medical indemnity claims, Australian estimates of the rate of diagnostic errors related to medical imaging are lacking.

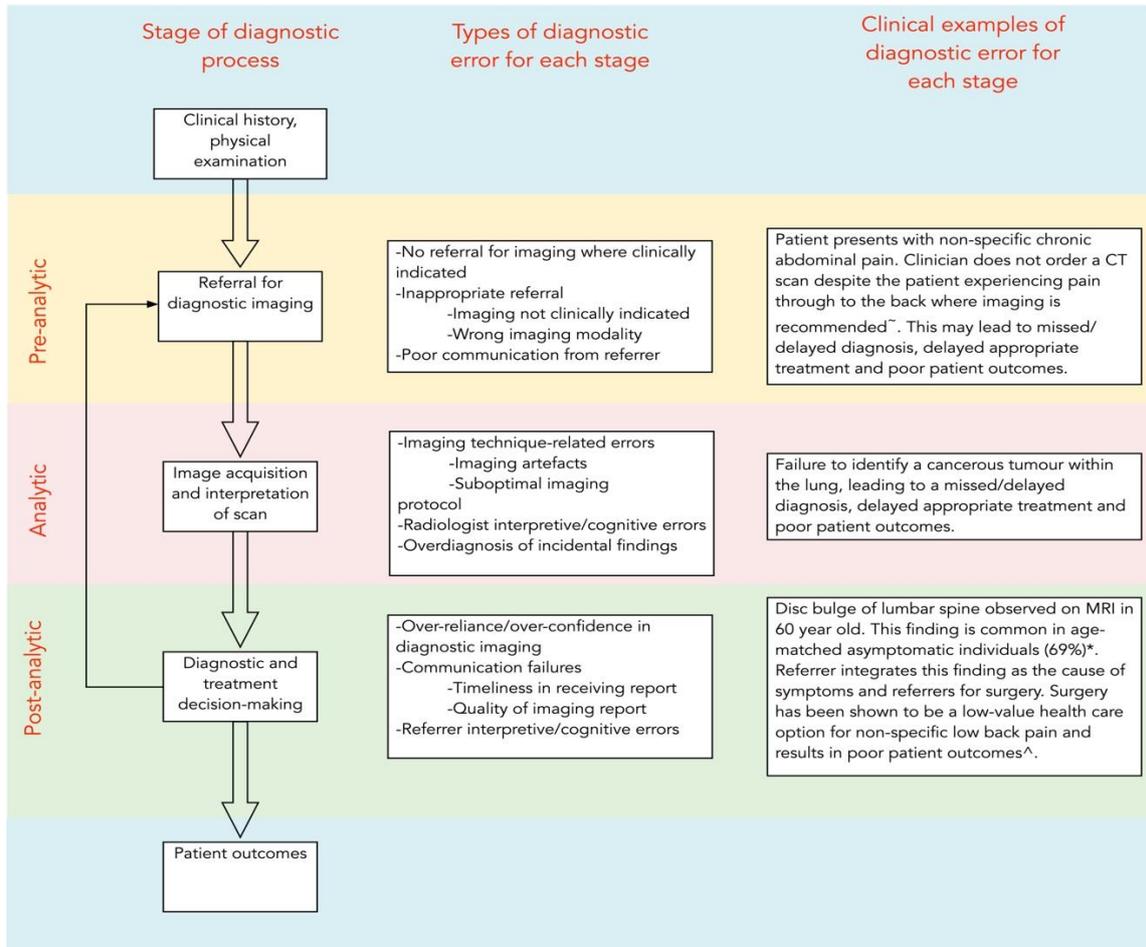
The diagnostic process occurs under considerable clinician uncertainty (Bhise et al., 2018; Institute of Medicine and National Academies of Sciences, Engineering, and Medicine, 2015), yet the goal of this process is not to completely eliminate uncertainty. Clinicians are more likely to order diagnostic imaging in cases where they have low diagnostic confidence (Hautz et al., 2020; Meyer et al., 2013), suggesting either an appropriate request to gather further information or a “stubborn quest for diagnostic certainty” (Bhise et al., 2018; Itri et al., 2018; Kassirer, 1989). Further, health professionals report using diagnostic imaging to protect themselves from malpractice lawsuits without providing benefits to patients (Li and Brantley, 2015). Improvements in the diagnostic process cannot simply be made by improving access and increasing the utilisation of diagnostic imaging.

As diagnostic imaging has become increasingly utilised and relied upon within the diagnostic process (Australian Institute of Health and Welfare, 2020; Britt et al., 2014), it is not unreasonable to suggest that diagnostic imaging is a factor contributing to diagnostic errors (Bruno et al., 2015). Reducing diagnostic errors requires a national approach, with key clinical stakeholder involvement, in the same way that reducing medication errors has received (Australian Commission on Safety and Quality in Health Care, 2017) to identify the causes of diagnostic errors and implement interventions to improve patient safety.

## ***1.2 Vulnerabilities of the diagnostic process associated with medical imaging***

The cause of diagnostic errors related to medical imaging has been separated into the three phases of the diagnostic process: pre-analytic, analytic, and post-analytic (Figure 1)(Badrick et al., 2017; Plebani et al., 2011).

**Figure 1:** An overview of the diagnostic process as it relates to the use of diagnostic imaging. Adapted from Institute of Medicine and National Academies of Sciences, Engineering, and Medicine (2015).



~ Diagnostic imaging pathway for chronic abdominal pain (Government of Western Australia, 2021).

\* Systematic review on prevalence of asymptomatic imaging findings of the low back (Brinjikji et al., 2015).

^ Unnecessary use of surgery for low back pain in Australian hospitals (Badgery-Parker et al., 2019).

### 1.2.1 Pre-analytic phase (referrals)

The large number and complexity of diagnostic tests available to clinicians makes the pre-analytic phase particularly vulnerable to diagnostic error (Bird, 2018; Institute of Medicine and National Academies of Sciences, Engineering, and Medicine, 2015). Therefore, referring patients for the appropriate imaging test at the appropriate time is critical (Mendelson, 2020).

For example, half of all medical indemnity claims for missed cancer diagnosis in the United States have been shown to be due to a failure or delay in ordering a diagnostic test, including imaging studies (Aaronson et al., 2019). In approximately 85% of these cases, missed cancer diagnoses resulted in permanent significant harm or death (Aaronson et al., 2019).

In another example, inappropriate referral to medical imaging not only exposes patients to radiation unnecessarily and wastes finite health resources, but it can alter the patient journey away from the correct diagnosis due to overdiagnosis (Mendelson, 2020).

### 1.2.2 Analytic phase (scans and interpretation)

The analytic phase consists of scan acquisition and interpretation of the resulting images by the radiologist or clinical specialists. Few errors occur during the acquisition of the scan due to standardisation of imaging acquisition protocols (Waite et al., 2017; Heriot et al., 2009). The exception may be ultrasound as the acquisition of images requires considerable skill to orientate the free-hand ultrasound probe and generate an optimal image without imaging artefacts (that is, an abnormality seen on the imaging that is not present in reality) (Leelakanok et al., 2019; Serafin-Król and Maliborski, 2017; Pinto et al., 2013).

It is estimated that the radiologist interpretation error rate is 3-5% (Brady, 2016; Waite et al., 2016), which would translate to at least 300,000 patients being subjected to a diagnostic imaging interpretive errors in Australia each year (Australian Institute of Health and Welfare, 2020). Interpretive errors occur due to a radiologist's cognitive biases or factors related to human visual perception ([Appendix 2](#)).

Based on radiological malpractice claims in the United States, nearly half of these claims (639 of 1,325 claims between 2010-14) were in the analytic phase due to misinterpretation of diagnostic studies (Siegal et al., 2017).

### 1.2.3 Post-analytic phase (information context)

The post-analytic stage is where imaging results are integrated within the context of the patient's symptoms (Badrack et al., 2017; Graber, 2013; Plebani, 2010). The most common causes of diagnostic errors in the post-analytic stage include:

- the over-reliance on diagnostic imaging in place of physical examination (Institute of Medicine and National Academies of Sciences, Engineering, and Medicine, 2015),
- inadequate clinical history and patient interviewing by the diagnosing clinician (Newman-Toker and Makary, 2013; Rao and Levin, 2012), and
- the quality of imaging reports from the radiologist (Brady, 2016; FitzGerald, 2005; Berlin, 2000).

This phase of the diagnostic process is particularly vulnerable where a high prevalence of incidental findings occur, leading to overdiagnosis and unnecessary treatment based on an imaging abnormality that is unrelated to their symptoms (O'Sullivan et al., 2018).

Communication failures between radiologist and referrer account for a quarter of diagnostic imaging malpractice claims (Siegal et al., 2017).

## 2 Medical imaging policy and reform in Australia

In the period 2013-14 to 2018-19, Medicare expenditure on diagnostic imaging per 100 Australians increased 21.2% (\$11,795 to \$14,285 per 100 people)(Australian Institute of Health and Welfare;, 2020). In 2018-19, two in five Australians (9.6 million people) underwent around 25.6 million Medicare-subsidised diagnostic imaging services, at a cost of \$3.5 billion to Medicare (Australian Institute of Health and Welfare;, 2020).

Despite the direct cost of imaging contributing to a small portion of health spending (1.7% of \$197.5 billion total health expenditure in 2018-19)(Australian Institute of Health and Welfare;, 2020), the ability of medical imaging to influence diagnostic and treatment decision-making can impact on the sustainability of the entire health care system. For example, in Australia, unnecessary MRI for osteoarthritis has been shown drive high arthroscopy rates in older individuals (Deveza et al., 2018); a costly surgical procedure that has no effectiveness (Marsh et al., 2016; Siemieniuk et al., 2017). Decision makers must consider downstream resource use following the use of diagnostic imaging, especially as it relates to health policy that increases access.

To date, health reform measures and policy initiatives relating to diagnostic imaging from the Australian Government have not directly focused on reducing diagnostic errors. Instead, policies have targeted increasing patient access to newer imaging modalities, improving sustainability of the sector, and facilitating the appropriate use of diagnostic imaging; all with the aim of improving patient outcomes. These policies are discussed below.

### **2.1 Diagnostic Imaging Review Reform Package (2011-12 Budget Measure)**

As part of the 2009-10 budget, the Australian Government announced a review into the funding of diagnostic imaging services in order to ascertain whether the level of diagnostic imaging use reflected best medical practice (Commonwealth of Australia, 2009).

The final report in 2012, highlighted that Government expenditure on diagnostic imaging had increased at an annual growth rate of approximately 7% during the period 2000-01 to 2009-10 (Department of Health and Ageing, 2012). It was acknowledged that, based on international studies, 20-50% of diagnostic imaging tests for a variety of conditions were redundant or unnecessary as they did not improve patient diagnosis or treatment (Department of Health and Ageing, 2012). It can be proposed that increases in the use of diagnostic imaging, combined with the potential for inappropriate use, may lead to increases in the number of diagnostic errors.

The review also identified that previous criteria used to allocate Medicare-eligible MRI units had created inefficiencies in patient access, with inequitable distribution of MRI units that disadvantaged rural and remote populations (Department of Health and Ageing, 2012).

Based on issues identified during the review, a five-year reform package was announced in the 2011-12 Federal Budget aimed at expanding and improving the provision of MBS-subsidised diagnostic imaging (Department of Health and Ageing, 2012), with the objective of:

- Maintaining patient access to affordable and convenient diagnostic imaging services.
- Enhancing patient access in rural and remote areas.
- Ensuring patients receive appropriate diagnostic imaging through practitioner referrals.
- Providing diagnostic imaging that reflects best practice.
- Reducing Government expenditure and improving the sustainability of the diagnostic imaging sector (Department of Health and Ageing, 2012).

Central to this package was an expansion in the number of MRI machines eligible to receive MBS-subsidies to support “faster diagnosis and earlier detection of disease”. This was estimated to cost a total of \$94.5 million (Department of Health and Ageing, 2012). As it was expected that MRI service use and Medicare expenditure would increase by increasing the number of MBS-eligible MRI machines (Baker et al., 2003), initiatives to reduce the number of inappropriate requests for diagnostic imaging services were funded through the reform package (full list of these research projects/initiatives in [appendix 3](#)). It was intended that these two objectives would improve both the diagnostic process and patient outcomes through access to appropriate imaging.

Results from the package were found to be mixed (Australian National Audit Office, 2015).

While access to MRI was improved, insufficiencies in the planning process led to a 3-fold increase in the number of MRI machines approved for MBS subsidies (Australian National Audit Office, 2015).

The audit also identified the limited progress made in the implementation of initiatives aimed at reducing inappropriate referrals for diagnostic imaging. Barriers to implementation were identified as the difficulty in affecting the required behaviour change in health professionals and the need to consult with a wide range of stakeholders (Australian National Audit Office, 2015). These limitations are important considerations for future interventions that are aimed at addressing issues of inappropriate referral and diagnostic errors.

The Auditor-General highlighted that the reform package exceeded the original estimate of \$94.5 million to approximately \$219 million ([Appendix 4](#)) (Australian National Audit Office, 2015). It is possible to speculate that the results of the reform package may have increased the number of inappropriate referrals and subsequently an increase in the number of diagnostic errors related to medical imaging.

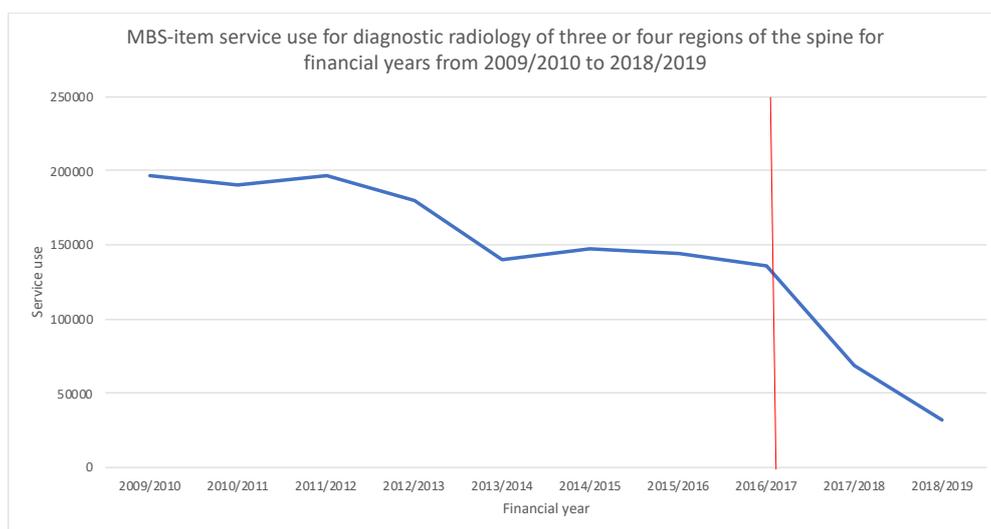
It is therefore critically important that future health policies aimed at improving patient access to diagnostic imaging address inappropriate imaging referrals to ensure that these services are allocated efficiently and do not potentially contribute to failures in the diagnostic process.

## 2.2 MBS Taskforce review – Diagnostic Imaging and Diagnostic Medicine Clinical Committee

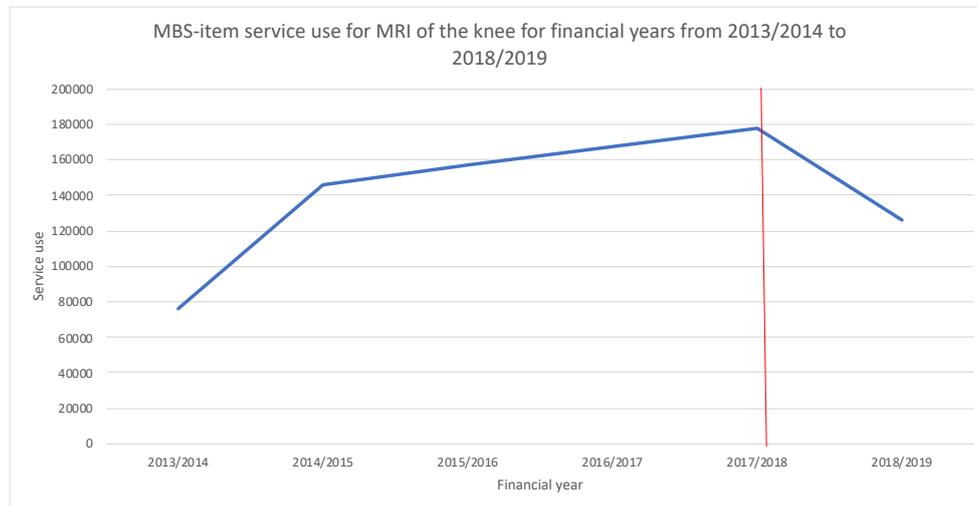
The Diagnostic Imaging Clinical Committee was established in 2015 to identify obsolete, outdated and unsafe services being funded by the Australian Government (Medicare Benefits Schedule Review Taskforce, 2019). Priority areas were identified through Choosing Wisely recommendations, the Australian Commission on Safety and Quality in Healthcare’s Atlases of Variation, and Elshaug et al (2012)(Medicare Benefits Schedule Review, 2015). The committee, plus six working groups that addressed specific clinical conditions, were established to review current MBS-subsidised imaging services, item descriptors, and service volume and recommend changes to ensure they represent best practice (Medicare Benefits Schedule Review Taskforce, 2019).

A wide range of recommendations were made by the Diagnostic Imaging Clinical Committee and its working groups ([Appendix 5](#)). A number of these recommendations were related to who could refer for, or the patients that can receive, certain imaging services. The effectiveness of these interventions is limited to service use data (Figures 2 and 3), with no data on the impact of these recommendations on patient outcomes or the incidence of diagnostic errors.

**Figure 2:** MBS-item service use\* for diagnostic radiology of three or four regions of the spine for financial years from 2009/10 to 2018/19. The red line represents the restriction of chiropractors to refer for these services based on recommendations made by the diagnostic imaging clinical committee (Services Australia, 2021b). \*(items 58115, 58120, 58121)



**Figure 3: MBS-item service use\*** for MRI of the knee for financial years from 2013/14 to 2018/19. The red line represents the restriction of GP’s ability to refer patients over 50 years old based on recommendations made by the diagnostic imaging clinical committee (Services Australia, 2021b).\* (items 63560 and 63561)



In 2017, the Diagnostic Medicine Clinical Committee was convened to provide recommendations on mechanisms aimed to support better requesting for diagnostic imaging and pathology services (Medicare Benefits Schedule Review Taskforce, 2018c). Recommendations included:

- Consumer education:** Education that empowers patients to engage with clinicians on the need and/or importance of diagnostic imaging.
- Requester education:** Increase clinical awareness about high-value diagnostic imaging referrals.
- Electronic clinical decision support:** The provision of advice at the point of care (when decisions are being made by the medical professional) that is tailored to the clinical context of the specific patient.
- Requester pattern transparency:** Allows requesters to understand how their requesting patterns compare to their peers and to review unexpected variances.
- Requesting process:** Changes in what patients can receive, and the clinical process to receive, diagnostic imaging tests can be ordered through the MBS item descriptors.
- Requester restrictions:** Restricting certain professions ability to request certain diagnostic imaging tests.
- Provider feedback to requester:** Allows diagnostic imaging providers to send feedback to directly to requesters on the value of the requested test.
- Provider service conditions:** Changes to conditions that diagnostic imaging providers are permitted to provide certain tests.

- **Payment mechanisms:** Changes in the payment system or structure that are designed to encourage a change in requesting behaviour (Medicare Benefits Schedule Review Taskforce, 2018c).

Clinical decision support (CDS) tools were identified as the key mechanism for guiding referrer behaviour towards the appropriate use of diagnostic imaging and recommended their introduction for high priority items (Medicare Benefits Schedule Review Taskforce, 2018c). The final report from the MBS taskforce have endorsed this recommendation (Medicare Benefits Schedule Review Taskforce, 2020) but there has been no response from the Government to date (Department of Health, 2021).

### **2.3 Guaranteeing Medicare – 2019-20 and 2021-22 Budget measures**

A 2015-16 report from the Australian Diagnostic Imaging Association (2017) examined the freeze on Medicare rebates for diagnostic imaging, which has been in place since 1998, and found that the average out of pocket costs to patients was \$97.34 per imaging service (approximately \$545.1 million on 9.6 million imaging services in 2015-16). They estimated that around 300,000 patients would have delayed or foregone imaging in 2016 but did not provide a source for this information (Australian Diagnostic Imaging Association, 2017).

A \$606.1 million package was announced through the 2019-20 Federal Budget targeting both out-of-pocket costs associated with imaging and poor access to imaging (Department of Health, Australian Government, 2019). This included:

- \$198.6 million was allocated to index all x-ray and ultrasound services with the Government's Wage Price Index to reduce out-of-pocket patient costs associated with imaging, which was implemented May 2020 (Department of Health, Australian Government, 2019).
- \$375 million was also allocated to increase the number of MRI machines eligible for MBS-funding; this was in addition to the MRI machines approved for MBS rebates as part of the 2011 Diagnostic Imaging Reform package (Department of Health, Australian Government, 2019).

A further \$37 million was allocated in the 2020-21 Federal Budget to modernise the diagnostic imaging sector, through financial assistance to rural and remote imaging practices in replacing outdated machines (Box 2)(Department of Health, Australian Government, 2021a).

#### **Box 2: Age of diagnostic imaging machines in Australia**

A high proportion of older diagnostic imaging machines are currently in use in remote and rural areas compared to metropolitan areas (Community Affairs References Committee, 2018).

Rural and remote imaging practices were previously exempt from the capital sensitivity measure (encourages practices to replace machines beyond their effective working age) due to the large financial burden of replacing machines (Department of Health, Australian Government, 2021b).

In 2018, concerns that older machines were resulting in lower quality images and poorer patient outcomes were raised by the Royal Australian and New Zealand College of Radiologists (RANZCR) and the Western Australian Department of Health (Community Affairs References Committee, 2018). This led to the capital sensitivity exemption measure being removed as of May 2022 (Minister for Health and Aged Care, 2020).

To lessen the financial burden on rural and remote imaging practices, a one-off \$20.7 million funding pool was announced in the 2021-22 federal budget to replace older machines (Department of Health, Australian Government, 2021b).

Assessing the effectiveness of the above policy initiatives are limited to MBS diagnostic imaging service use data, with no evidence to support that they have enhanced the diagnostic process and improved patient outcomes.

The Department of Health should consider mechanisms to assess the effectiveness of these budget measures and whether they represent value for money in improving patient outcomes and reducing diagnostic errors.

#### **2.4 The need for a national strategy to reduce diagnostic errors**

In Australia, the impact of diagnostic errors related to medical imaging on patient safety and health outcomes is not well understood. The Diagnostic Imaging Accreditation Scheme (DIAS) is the principal agency that is responsible for ensuring the safety and quality of diagnostic imaging services (Department of Health, Australian Government, 2020b). Diagnostic imaging clinics are assessed against [15 clinical standards](#) every four years via a desktop assessment to be eligible to receive MBS rebates (Department of Health, Australian Government, 2020a).

Despite DIAS being responsible for setting accreditation standards, it does not have the ability to measure the incidence of diagnostic errors, assess contributing factors, and recommend solutions. This means that, in Australia, there is an absence of a co-ordinated strategy to identify and prevent diagnostic errors within the medical imaging sector.

In the United Kingdom, the College of Radiologists audits adherence of diagnostic imaging practices against best practice standards to identify unwarranted variations between diagnostic imaging practices (The Royal College of Radiologists, 2021a). For example, as part of the audit process, non-adherence to clinical standards in the reporting of vertebral fractures on CT was identified as an area providing opportunities to intervene and improve the diagnostic process. Subsequently, the Royal College of Radiologists published a radiological guidance for the reporting of vertebral fractures; including local policy recommendations for radiological practices to address identified failings (The Royal College of Radiologists, 2021b).

In Australia, in consultation with RANZCR and the Royal Australian College of General Practitioners (RACGP), a national audit and feedback process should be developed as part of DIAS. Auditing processes for the quality of captured images have been implemented by RANZCR for CT, MRI, and mammography (Royal Australian and New Zealand College of Radiologists, 2021b).

This process should be expanded to all phases of the diagnostic process (pre-analytic, analytic, and post-analytic) to inform potential amendments to accreditation standards, or develop, strategies aimed at improving patient health outcomes following diagnostic imaging.

DIAS has limited capacity to assess the role of imaging throughout the diagnostic process (Department of Health, Australian Government, 2020b; Australian National Audit Office, 2015). For example, variations in CT of the lumbar spine and neck ultrasound use in Australia have previously been identified as factors that may negatively impact safety and quality (Australian Commission on Safety and Quality in Health Care, 2018, 2015).

While the DIAS clinical standards have been amended to align with the National Safety and Quality Health Service (NSQHS) Standards (Australian Commission on Safety and Quality in Health Care, 2021; Department of Health, Australian Government, 2020b); it is now suggested that placing the DIAS within the responsibilities of the Australian Commission on Safety and Quality in Healthcare will better enable the identification of the causes of diagnostic errors; as well improving the capacity of DIAS to produce resources aimed at reducing of diagnostic errors related to medical imaging.

### **3 Opportunities to measure the incidence and consequences of diagnostic errors**

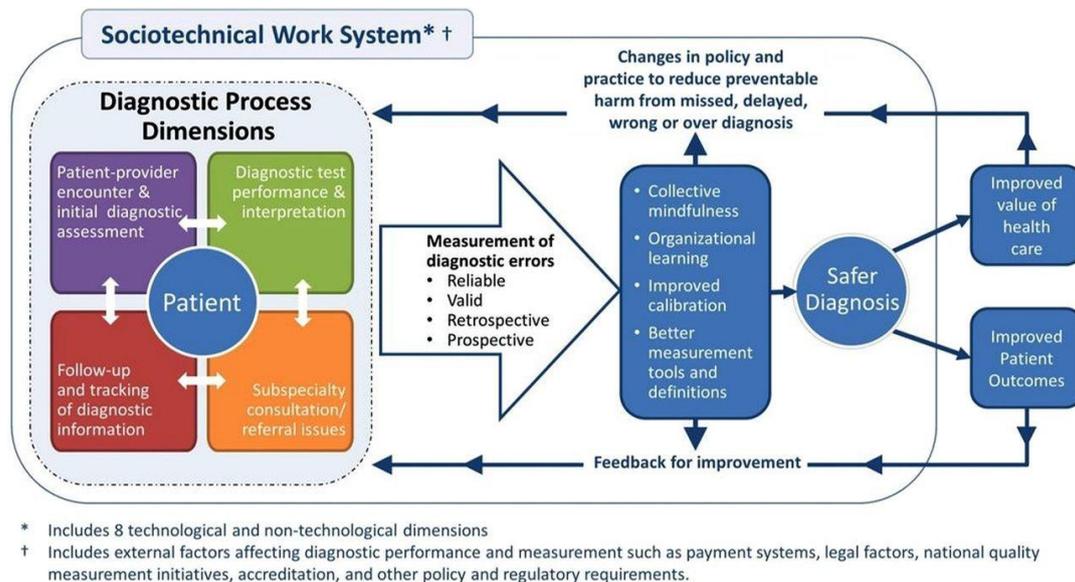
In Australia, robust data on the incidence, consequences, and causes of diagnostic errors is lacking. This has hampered meaningful intervention to reduce diagnostic errors (Scott and Crock, 2020).

In the United States, the Committee on Diagnostic Error in Health Care (Institute of Medicine and National Academies of Sciences, Engineering, and Medicine, 2015) have outlined five rationale for the measurement of diagnostic errors:

- Establish the incidence and nature of the problem.
- Determine associated and risk factors of diagnostic errors.
- To design and allow for evaluation of interventions.
- Education and training purposes.
- Accountability.

In 2015, a multifaceted framework to advance the science of measuring diagnostic errors in the States, termed the Safer Dx framework, was developed to describe how measuring and monitoring of diagnostic errors can improve quality of care and reduce patient harm (Figure 4)(Singh et al., 2019; Singh and Sittig, 2015).

**Figure 4:** The Safer Dx framework for the measurement and reduction of diagnostic errors (Singh and Sittig, 2015)



While evidence is limited, the authors stated that the implementation of the Safer Dx framework had provided useful insights on how to reduce the occurrence of diagnostic errors based on anecdotal data (Singh et al., 2019).

The Australian Commission on Safety and Quality in Health Care has a remit to collect, analyse, interpret, and disseminate information relating to health care safety and quality matters (National Health Reform Act 2011, 2011). It is recommended that the Commission should be supported to assess the incidence, causes, and consequences of diagnostic errors related to medical imaging through existing datasets (Singh et al., 2021; McGlynn et al., 2015). Analysis of existing data sets may provide important insights without the need to develop new data registries.

### 3.1 Medical Indemnity National Best Practice data set

Patients, or their family, in Australia can seek legal and financial compensation through medical indemnity claims as a consequence of serious harm caused by (alleged) diagnostic errors (Yee, 2019; Australian Institute of Health and Welfare, 2014).

It has been suggested that these malpractice claims may provide an avenue for obtaining information on the occurrence, and contributing factors, of diagnostic errors (Singh et al., 2021; Australian Institute of Health and Welfare, 2014).

In Australia, the Medical Indemnity National Best Practice data set (NBPDS) (formerly Medical Indemnity Data Set Specification) was established in 2003, as a consequence of the substantial increases in health insurance premiums observed at the time, and the collapse of Australia's biggest

medical insurers (Australian Institute of Health and Welfare, 2021). The data set contains mandatory information on:

- the primary incident/allegation (for example, relating to diagnosis, medication, procedure).
- clinical service context.
- body function or structure affected.
- the extent of harm.

Analysis of the medical indemnity NBPDS by the Australian Institute of Health and Welfare (AIHW) reported diagnostic errors as the most common allegation of public sector medical indemnity claims (232 claims in 2012-13)(Australian Institute of Health and Welfare, 2014).

Claims related to diagnostic errors were shown to increase from 21.6% in 2008-09 to 29.6% of total claims in 2012-13, where claims related to procedures or treatment had remained stable (Australian Institute of Health and Welfare, 2014).

As the outcomes of the medical indemnity NBPDS have not been analysed/published by AIHW since 2012-2013, it is unclear whether this trend has continued. Outcomes of the NBPDS can be used to inform the development of initiatives that focus on reducing diagnostic errors where the diagnostic process is most vulnerable (for example, IT solutions to facilitate timely follow-up of diagnostic tests (Dibble et al., 2017) or for clinical conditions where diagnostic errors result in significant harm (for example, implementation of double reading of imaging where the suspected diagnosis is lung cancer (Waite et al., 2016).

The Australian Institute of Welfare and Health (AIHW), in conjunction with the Australian Commission of Safety and Quality in Health Care (ACSQHC), is best placed to prioritise contemporary analysis and public reporting of this data.

Malpractice claims are a complex interplay between the patient, health care system, and society (Singh et al., 2021; McGlynn et al., 2015); analysis of medical indemnity claims are not without limitations, particularly since the majority of diagnostic errors do not lead to malpractice claims (Singh et al., 2021; Wallace et al., 2013).

In addition, medical claims against radiologist can be biased to conditions where early features of the disease process are at risk of being missed but can be retrospectively identified. For example, early features of breast cancer that were originally diagnosed as benign changes, or missed entirely, by the radiologist are more easily identified once the disease process has advanced and a final diagnosis of lung cancer is made (Brady, 2016).

While limited in the data analysis that can be achieved, analysis of medical indemnity claims can provide important information without the need to develop clinical registries (Box 3)(Singh et al., 2021).

### **Box 3: National and international medical indemnity claims relating to medical imaging**

[Avant Mutual](#), a medical indemnity provider for Australian radiologists, reported that 66% of malpractice claims against their radiologist members were due to diagnostic errors (Yee, 2019). Diseases of the respiratory system were most common. Over half of the cases were found that radiologists care met the expected clinical standards, suggesting that the failure is not in the assessment of the original image.

Analysis of malpractice claims in the United States between 2008-12 found that radiology was deemed primarily responsible for claims (Harvey et al., 2016). Radiology was the 8<sup>th</sup> most likely service to result in malpractice claims (879 claims). Approximately 60% of claims related to diagnostic errors resulting in ~\$181 million in total payment. Cancer-related diagnoses were responsible for 44% of claims, resulting in a high overall severity of injury (398 claims resulted in injuries resulting in death, permanent grave disability, permanent major disability, or permanent significant disability).

Analysis of malpractice claims in Finland between 1991-2017 in relation to imaging found that delayed or inadequate diagnosis accounted for 55% of the 1054 claims involving imaging. Medical malpractice was most common in cases of musculoskeletal imaging, breast imaging, and neuroradiology (Tarkiainen et al., 2021).

Analysis of insurance claims against Italian radiologists between 1993-2006 found that diagnostic errors account for 64.7% of the 1,424 claims against radiologist. Diagnostic errors relating to cancer and fracture were prevalent (29.4% and 27.4% of all claims). Missed breast cancers were responsible for 249 claims at an average compensation cost of €511,486 per claim (Fileni et al., 2010)

In the United Kingdom, analysis of 440 claims against radiologists from 1995-2006 found that missed diagnosis of cancer accounted for 45% of claims, with a trend that the number of cases were increasing over time.

### **3.2 Duplication of services**

In the absence of direct indicators of diagnostic errors, duplication of imaging services that are not clinically indicated could be considered as an indirect indicator of diagnostic errors (Waite et al., 2017).

In Australia, duplication of imaging studies has been attributed to issues of interoperability between medical records systems, and consequently limited access to previous imaging studies (Royal Australian and New Zealand College of Radiologists, 2019b; Tung et al., 2018; Hendee et al., 2010). It has also been proposed that duplicate imaging studies may be a consequence of patients seeking further health care as their symptoms have not improved due to diagnostic error (Box 4) (Menachemi et al., 2018; The Neiman Report, 2013).

#### **Box 4: Scenario of duplicate imaging indicating a diagnostic error**

- A patient undergoes a CT scan and subsequent treatment based on the imaging findings for non-specific abdominal pain after seeing **general practitioner A**.
- The patient presents to **general practitioner B** six months later, either due to patient choice or inability to see **general practitioner A**, with continuing abdominal pain that has not resolved.
- **General practitioner B** refers the patient for another CT scan, independent of whether they have access to previous imaging results, to gain further information for the continuation of symptoms and limited efficacy of previous treatment.

Duplicate imaging services indicate a potential waste of resources and unnecessary radiation exposure. Variation in duplication imaging rates that are not clinically indicated may identify imaging services that are at-risk of contributing to a diagnostic error.

The Australian Commission on Safety and Quality in Health Care should be supported to identify the duplication rate of imaging services contained within existing MBS data.

### ***3.3 Development of performance indicators to identify diagnostic errors***

The Addendum to the National Health Reform Agreement (Federal Financial Relations, 2020) has acknowledged that the lack of data obtained from the health system, limits the government's ability to drive meaningful improvements and assess the effectiveness of policy interventions.

Within the diagnostic imaging sector, both in Australia and internationally, the use of patient reported outcome measures (PROMS) or experience measures (PREMS) to assess value (balancing outcomes and cost) is limited (Gyftopoulos et al., 2021; Lavelle et al., 2015). Traditionally, PROMs measure the final step of the diagnostic process (the interventions effect on patient health) and provide little information on diagnostic imaging's direct value, or absence of value, to the diagnostic process (Brady et al., 2021). Diagnostic imaging does, however, provide value through its ability to provide clinical information that aids diagnosis and informs subsequent health care decisions (Brady et al., 2021). Nevertheless, a change in treatment decision-making because of a diagnostic image may not always result in improved outcomes, especially where imaging increases the use of low-value care (Jacobs et al., 2020).

Performance indicators for diagnostic imaging are needed to assess its direct value to the diagnostic process, identify the occurrence of diagnostic errors, and the outcome of the diagnostic process on patient health (Singh et al., 2019).

Efforts by the Australian Government to enhance the availability of patient-level health outcomes data will be critical to improving the ability to identify and assess the impact of diagnostic errors (Box 5).

## **Box 5: Patient-level data to aid the identification of diagnostic errors**

**Working diagnosis pre- and post-imaging:** to assess the impact of imaging on diagnostic decision-making as well as identifying diagnostic errors (Brady et al., 2021; Gyftopoulos et al., 2017). Efforts to record diagnoses for patients using nationally recognised terminology systems, such as SNOMED-CT (Australian Digital Health Agency, 2018a), will be critical to aid data analysis and inform strategies to improve the diagnostic process, reduce diagnostic errors, and ultimately improve patient outcomes.

**Linking of service use data:** to identify how use of imaging alters treatment decision-making and potentially explains variation in health care, particularly as it relates to the use of high- or low-value care (Jacobs et al., 2020).

For example, the Medicare Benefits Schedule Review Taskforce knee imaging report highlighted that MBS item descriptors lacks specificity to accurately reflect clinical practice, which directly led to the creation of new MBS items for imaging of the knee (Medicare Benefits Schedule Review Taskforce, 2017b). An inability to accurately link diagnostic imaging service use with downstream health care has hampered assessment of the diagnostic process.

Implementation of RANZCR's recommendation to create a universal language for diagnostic imaging, through a standardised radiology request set, should be supported rather than amending existing MBS item descriptors (Royal Australian and New Zealand College of Radiologists, 2020a).

**Patient outcomes:** to assess the final outcomes of the diagnostic process and drive quality improvements in the use of diagnostic imaging that enhance patient and clinician healthcare decisions (Gyftopoulos et al., 2021).

## **4 Interventions to improve the diagnostic process**

### **4.1 Quality of referrals**

In the Netherlands, a study within tertiary care found that 76% of imaging requests were inadequate due to insufficient detail or complete absence of referrer's initial impression (working or differential diagnoses), clinical information (presenting symptoms, demographic information, patient history) or diagnostic question (justification for requested imaging)(Kasalak et al., 2021).

Inaccurate or incomplete clinical history within imaging referrals contributes to diagnostic errors related to medical imaging (Tofighi et al., 2021; Kim and Mansfield, 2014). In Australia, there are no regulations that mandate the inclusion of clinical information within an imaging request (Pitman, 2017; Health Insurance Act 1973, 1973).

A systematic review of 20 international studies has shown that clinical information included within a request improves the interpretation accuracy, clinical relevance, and reporting confidence of the radiology report (Castillo et al., 2021). RANZCR's 2017 position paper on the quality of imaging referrals recommends that Medicare regulation should be amended to require the inclusion of the clinical question for which an answer is being sought through diagnostic imaging (Royal Australian and New Zealand College of Radiologists, 2017). This recommendation should now be supported,

either through changes to the Health Insurance Regulation (Health Insurance (Diagnostic Imaging Services Table) Regulation (No. 2) 2020, 2021) or the implementation of minimum data requirements through eReferral in My Health Record.

## **4.2 Improving imaging referral appropriateness**

Australian and international data describe that approximately one-third of diagnostic imaging requests are inappropriate (Jenkins et al., 2018; O’Sullivan, Albasri, et al., 2018; Chaudhuri et al., 2016; Makarov et al., 2015). Inappropriate or delayed referral for diagnostic imaging represents a failure in the diagnostic process and increases the risk of diagnostic errors occurring (Jacobs et al., 2020; O’Sullivan, et al., 2018; Webster and Cifuentes, 2010; Schiff et al., 2009).

Inappropriate use of imaging also wastes healthcare resources and risks exposing patients to radiation unnecessarily (Mendelson, 2020; Berwick and Hackbarth, 2012; Moynihan et al., 2012; Elshaug et al., 2010). In Australia, the sub-optimal use of diagnostic imaging has been identified as an issue that requires intervention (Mendelson, 2020; Australian National Audit Office, 2015; Department of Health and Ageing, 2012).

### **4.2.1 Education**

Education interventions aimed at clinicians to reduce inappropriate imaging have been implemented in Australia for a variety of conditions and imaging modalities since the Diagnostic Imaging Reforms in 2011-12 (Choosing Wisely, 2021; Royal Australian and New Zealand College of Radiologists, 2021a; Royal Australian College of Physicians, 2021; NPS MedicineWise, 2017).

However, requestor education in isolation has limited effectiveness in reducing inappropriate imaging referrals and is best implemented as part of a suite of interventions (Medicare Benefits Schedule Review Taskforce, 2018c). For example, NPS MedicineWise’s low back pain program, which includes education combined with CDS tools and audit and feedback, has been shown to reduce CT imaging utilisation by 10% with a cost saving of \$11.6 million to the Government (June 2013 to February 2015)(Morgan et al., 2019).

The Australian Government Department of Health should consider expanding the educational initiatives to include, as a minimum, CDS tools.

### **4.2.2 Clinical decision support tools**

The large number of diagnostic tests available to primary care clinicians in Australia have created a complex diagnostic process, where clinicians lack of knowledge may contribute to inappropriate referral for imaging and diagnostic errors (Mendelson, 2020).

CDS tools aid the appropriate use of imaging by using alerts or reminders to provide case-specific information at the point of care (Medicare Benefits Schedule Review Taskforce, 2018c; Bright et al., 2012). These tools have been identified by the Diagnostic Medicine Clinical Committee (Medicare Benefits Schedule Review Taskforce, 2018c) as the most effective intervention for improving appropriate imaging referrals. In 2020, the final report of the MBS taskforce recommended the expanded use of these CDS tools in primary care (Medicare Benefits Schedule Review Taskforce,

2020). This recommendation should also be supported as a policy mechanism to improve the appropriate use of imaging and reduce the risk of diagnostic errors.

CDS tools and criteria for appropriate use have been developed for the Australian context. This includes the [Western Australian Government's Diagnostic Imaging Pathways](#) (Government of Western Australia, 2021; Bairstow et al., 2006) and [RANZCR's Imaging Clinical Decision Rules](#) (Royal Australian and New Zealand College of Radiologists, 2015).

Studies to understand the effectiveness of these tools to improve appropriate imaging referral in the Australian context is limited. A 2010 study assessing the effectiveness of the Diagnostic Imaging Pathway has reported a 16% reduction in inappropriate imaging use (Bairstow et al., 2010). The Pathway and RANZCR's Imaging Decision Rules are currently utilised more as an education tool, rather than point of care tool to aid clinician decision making (Royal Australian and New Zealand College of Radiologists, 2019a; Bairstow et al., 2010). The United States are in the process of implementing CDS tools to improve the diagnostic process by limiting inappropriate imaging referrals (Box 6). The Department of Health should monitor these efforts to gain insights on their effectiveness and challenges to implementation.

#### **Box 6: Funding reforms and implementation of CDS tools in the United States to reduce inappropriate care**

In the United States, positive changes in imaging referral patterns have been shown to occur following the implementation of appropriate use criteria (Timbie et al., 2014). Consequently, the Centers for Medicare and Medicaid put forward alternative funding arrangements for MRI and CT imaging of priority clinical areas where inappropriate imaging referral was an issue (Protecting Access to Medicare Act of 2014, 2014). As part of the Protecting Access to Medicare Act of 2014, the use of CDS tools is required at the point of care before Medicare will pay for these services (Protecting Access to Medicare Act of 2014, 2014).

However, enacting this funding arrangement has been delayed due to resistance from various stakeholders and lobbying groups (Galewitz, 2019). Concerns relate to increased administrative burden on doctors, unintended consequences to patients, and the quality of evidence supporting CDS tools (Galewitz, 2019).

*These concerns were also raised in response to the Diagnostic Medicine Clinical Committee's (Medicare Benefits Schedule Review Taskforce, 2018c) recommendation to implement CDS tools in Australia (Australian Medical Association, 2019; Consumer Health Forum of Australia, 2019; Royal Australian and New Zealand College of Radiologists, 2019a; Royal Australian College of General Practitioners, 2018).*

Nevertheless, since the Protecting Access to Medicare Act was proposed, studies have reported improvements in the diagnostic process as a consequence of reducing inappropriate imaging (B. Lee et al., 2021; Doyle et al., 2019; Huber et al., 2018).

However, while they did include imaging service use data as their measurement of effectiveness, data on patient outcomes or incidence of diagnostic errors was absent.

In Australia, there is insufficient evidence to recommend the mandatory use or adherence to CDS tools as a way to finance diagnostic imaging services through Medicare. However, it can be suggested that they can be used to positively influence appropriate imaging referral rates (Lee et al., 2021; Doyle et al., 2019; Huber et al., 2018; Timbie et al., 2014); representing an opportunity to improve the diagnostic process, improve patient outcomes, and reduce Medicare spending (Mendelson, 2020; Medicare Benefits Schedule Review Taskforce, 2020, 2018c).

The Department of Health in consultation with the Australian Digital Health Agency should consider integrating CDS tools, such as the Diagnostic Imaging Pathway or RANZCR's Imaging Clinical Decision Rules, within eReferral in a voluntary basis for high priority MBS items (ankle/hind foot ultrasound, shoulder ultrasound, and lower back and head CT and MRI, knee MRI), as has been proposed by the Diagnostic Medicine Clinical Committee (Medicare Benefits Schedule Review Taskforce, 2018c). This would enable the Department of Health to assess the levels at which these tools are accessed and/or adhered to, the factors that influence their use, and assess patient outcomes for imaging referrals that are adherent to appropriate use criteria compared to non-adherent referrals.

#### **4.3 Artificial intelligence reducing diagnostic errors**

The use of artificial intelligence (AI) within the imaging sector is gaining attention due to its ability to aid visual perception and improve the diagnostic process (Davis, 2019; Lewis et al., 2019; Royal Australian and New Zealand College of Radiologists, 2019c; Hosny et al., 2018).

AI in diagnostic imaging practices can be used to improve abnormality detection, characterisation of abnormalities, and monitoring abnormality change over time (Lewis et al., 2019; Hosny et al., 2018). However, the evidence around its effectiveness in improving the diagnostic process and reducing diagnostic errors is lacking, and there are several policy issues that should be considered prior to widespread implementation (Box 7).

#### **Box 7: Policy considerations for the implementation of AI within the imaging sector.**

- **Bias:** AI relies on the input of data to train its decision-making processes. Biases may occur where this training data is not representative of the target population and may further inequities in disadvantaged populations (Reddy et al., 2020).
- **Privacy:** Breaches in privacy, where patient data has been shared as part of the AI training process without consent, has previously occurred in the United Kingdom (Powles and Hodson, 2017). In Australia, protection of sensitive health information will need to be ensured for the development and application of AI in imaging practices.
- **Safety and quality:** AI decision-making processes are constantly changing based on the presentation of new data. This makes the assessment of its effectiveness and safety difficult, particularly given that the decision-making processes of AI may be opaque to the developer, clinician, and patient (Reddy et al., 2020; Vayena et al., 2018).

- **Medical liability:** Current medico-legal guidelines in Australia around the use of AI and medical liabilities are unclear and should be addressed. For example, it is unclear who is liable when an AI fails and causes patient harm (Law et al., 2021; Lewis et al., 2019).

These issues have been examined in the 2019 RANZCR position paper on the ethical principles related to the use of AI in medicine (Royal Australian and New Zealand College of Radiologists, 2019c).

In the United States, Australia, Korea, Japan, and Europe the number of AI applications approved for medical imaging tripled between 2017 and 2018 (Law et al., 2021). In the United Kingdom, the National Health Service have invested £250 million to advance the development and use of AI (Davis, 2019). The Australian Government should actively address the ethical and governance concerns around the use of AI for MBS-diagnostic imaging services.

The Australian Therapeutic Goods Administration (TGA) is recognised as having a critical role in the regulation of AI, while the Medical Services Advisory Committee (MSAC) has a role in assessing the cost-effectiveness of subsidising the use of AI (Law et al., 2021; Therapeutic Goods Administration, 2021; Therapeutic Goods Legislation Amendment (2019 Measures No. 1) Regulations 2019, 2019). Both the TGA and MSAC state the importance of monitoring post-market outcomes. The performance indicators of diagnostic errors described in Box 5 should underpin the continued monitoring of AI's performance in improving the diagnostic process.

#### **4.4 Expansion of My Health Record to include radiological services**

Poor information sharing of radiology reports has been associated with an increased risk of diagnostic errors (Quinn et al., 2019; Murphy et al., 2014; Lorincz et al., 2011). In Australia, interoperability of software used in both private diagnostic imaging clinics and My Health Record was identified as a barrier to the uploading of radiology reports (Royal Australian and New Zealand College of Radiologists, 2018). However, resolution of this issue was reached through the provision of government funds, through the Australian Digital Health Agency, directly to software providers to facilitate uploading of imaging reports to My Health Record (Australian Digital Health Agency, 2017).

Despite investment in the interoperability of diagnostic imaging software and My Health Record, this injection of funds has not led to widespread adoption of My Health Record by private radiological practices. Only 23% of private diagnostic imaging practices shared imaging reports through My Health Record in 2019-20 (Australian Digital Health Agency, 2020).

The increased administrative burden borne by radiology practices was highlighted as an early barrier to My Health Record adoption (Royal Australian and New Zealand College of Radiologists, 2018). This issue has yet to be resolved. Nevertheless, primary health care professionals identified similar concerns following stakeholder consultation (Australian Institute of Health and Welfare, 2019), which led to the establishment of the Practice Incentives Program eHealth Incentive (ePIP) (Australian Digital Health Agency, 2018b). The ePIP has successfully led to 99% of general practitioners registering for My Health Record and 90% using My Health Record as of May 2021 (Australian Digital Health Agency, 2021).

The Australian Digital Health Agency continue to monitor the uptake and usage of My Health Record by diagnostic imaging practices. Incentivisation, similar to ePIP, could be considered if uptake continues to be limited or stagnates in the future. However, such a scheme should be carefully considered to ensure that the benefits of improving information sharing outweighs the cost. Offsetting the cost of an incentive program through policy initiatives that reduce inappropriate use of imaging should also be considered.

#### 4.5 Structured imaging reports

Poor communication around diagnostic imaging and its findings contributes to the occurrence of diagnostic errors (Cochon et al., 2018; Waite et al., 2017; Brady, 2016).

Written reports are the primary work product of MBS-subsidised diagnostic imaging services and facilitate radiologist/referrer communication (Box 8) (Farmer et al., 2020; Wallis and McCoubrie, 2011). General practitioners may not find images themselves informative and largely accept the authority of the radiologists through the written report (Sahraian et al., 2020; Bosmans et al., 2011). Therefore, ensuring that written reports clearly convey imaging findings is essential to the diagnostic process and informing appropriate health care decisions (Waite et al., 2017; Brady, 2016; Bosmans et al., 2011).

#### **Box 8: Structured written imaging reports**

The structure of written imaging reports has traditionally been composed of free-form text with sections separated into:

- introduction (clinical history/details on imaging technique).
- descriptions of imaging findings.
- a brief overall impression with suggestions of subsequent healthcare decisions (Schwartz et al., 2011).

Structured reports aim to present information in a uniform way by using report templates, itemised checklists, or standardised language, either in isolation or in combination (Pool and Siemienowicz, 2019; Powell and Silberzweig, 2015; Schwartz et al., 2011).

They may also include epidemiological data on the prevalence of incidental findings to aid the clinician in determining the clinical importance, or unimportance, of observed abnormalities (Jarvik et al., 2020).

In Australia, stakeholders overwhelmingly prefer structured reports (80.3% of health practitioners) and support the use of terminology with commonly agreed meaning (97.4% of health practitioners) (Pool and Siemienowicz, 2019).

Inadequate imaging reports are characterised as being overly complicated, ambiguous in anatomic or descriptive language, and lack description on the likelihood of age-related changes as opposed to genuine pathology (Pool and Siemienowicz, 2019; B. Lee and Whitehead, 2017; Brady, 2016; McCullough et al., 2012; Bosmans et al., 2011). In the United States, communication breakdowns

attributed to poorly written reports has been shown to contribute to one in four diagnostic errors related to medical imaging (Siegal et al., 2017).

In Australia, a 2003 study reported a strong correlation between medical oncologists satisfaction and the use of standardised radiology reports (Koczwara et al., 2003).

The impact on reducing diagnostic errors through structured reporting has yet to be evaluated in Australia. International evidence has shown that structured reporting can improve aspects of the diagnostic process across a range of conditions ([Appendix 6](#)).

In 2020, RANZCR, released the [Clinical Radiology Written Report Guidelines](#) supporting the development and use of report templates to improve the quality of communication (Royal Australian and New Zealand College of Radiologists, 2020b). However, in the absence of formal evaluation, concerns have been raised by stakeholders that structured reporting may be time-consuming, detract from the core task of analysing and interpreting images, unsuitable for rare and complex imaging findings, and increase the reporting rate of clinically-unimportant incidental findings (Pool and Siemienowicz, 2019; Brady, 2018, 2016). In addition, RANZCR's Written Report Guidelines state that the use of structured reports should be voluntary, but evidence for this decision is lacking (Pool and Siemienowicz, 2019).

In the United Kingdom and United States, structured templates have been developed to aid standardisation of written reports and improve referrer/radiologist communication throughout the diagnostic process ([Appendix 6](#)). Following implementation of structured templates, report auditing and feedback as part of practice accreditation has improved template adoption, quality of written reports, and improved the diagnostic process (Rosenkrantz et al., 2016). The use of structured reports has also supported policy decision making processes through the facilitation of data mining and quality and safety research (Pool and Siemienowicz, 2019; Schwartz et al., 2011).

It is recommended that DIAS, in consultation with RANZCR and other stakeholders, investigate the feasibility of implementing structured imaging reports. To ensure that the benefits of structured reporting are maximised, particular focus on those conditions that result in medical indemnity claims due to diagnostic error is recommended.

## 5 Conclusions and Recommendations

Diagnostic imaging has a critical role in aiding clinicians through the diagnostic process and is increasingly being utilised by health care professionals. Despite the implementation of policies that have improved the availability of advanced imaging modalities and patient access, the impact of these policies on the diagnostic process or patient outcomes is unclear. Diagnostic errors related to medical imaging require government attention as it has a significant impact on patient safety and the quality of health care.

A co-ordinated national strategy is needed to address the impact of diagnostic errors and enhance the effective use of diagnostic imaging.

There is little data on the incidence, causes, and consequences of diagnostic errors related to medical imaging to guide policies that reduce preventable harm from missed, delayed, wrong, or over diagnosis.

Opportunities and international evidence exist for effective interventions that minimise the occurrence of diagnostic errors. It is critical that these interventions are multi-disciplinary and address the referral, interpretation, and communication of diagnostic imaging. Stakeholder education and engagement is necessary to guide how best to implement these interventions and ensure their effectiveness.

### ***5.1 Recommendation 1: A national strategy to identify and prevent diagnostic errors related to medical imaging***

The Australian Government Department of Health should consider strengthening the Diagnostic Imaging Accreditation Scheme to audit diagnostic imaging practices, identify variations in clinical practice that may lead to diagnostic errors, and develop quality improvement strategies. Including the responsibilities of the Diagnostic Imaging Accreditation Scheme within the Australian Commission on Safety and Quality in Healthcare will better enable these processes.

### ***5.2 Recommendation 2: Contemporary analysis of medical indemnity claims to measure the incidence and consequences of diagnostic errors***

Analysis of the Medical Indemnity National Best Practice data set will provide useful information on the incidence, clinical conditions at risk, and causes of diagnostic errors without the need to develop a new clinical registry. These data can inform interventions that reduce the number of diagnostic errors that result in serious patient harm, as well as reducing the financial burden of medical indemnity claims.

### ***5.3 Recommendation 3: Support the development of performance indicators to assess the value diagnostic imaging***

The development of performance indicators that measure the direct value of imaging to the diagnostic process are required to enhance its safe and effective use. In the context of rising Medicare diagnostic imaging expenditure, these performance indicators will aid the quality delivery and sustainable use of diagnostic imaging. Performance indicators include:

- Working diagnosis pre- and post-imaging to assess imaging's impact on diagnostic decision-making.
- Enhance the linking of services use data to identify how imaging influences treatment decision-making.
- Patient outcomes to assess the final outcomes of the diagnostic process.

#### **5.4 Recommendation 4: Improve communication throughout the diagnostic process**

Effective communication between referrer, radiologist, and the patient is essential in minimising the risk of diagnostic errors. Opportunities exist through the National Digital health strategy to improve communication, including:

- Minimum data requirements through eReferral for diagnostic imaging services.
- Sharing of diagnostic imaging reports through My Health Record.
- Development of structured reporting templates, particularly for those conditions vulnerable to diagnostic errors.

#### **5.5 Recommendation 5: Invest in strategies to improve the appropriate requesting of diagnostic imaging**

Inappropriate use of diagnostic imaging represents a waste of finite resources, unnecessary radiation exposure, and increases the likelihood of diagnostic errors. Addressing the sub-optimal use of diagnostic imaging has been highlighted by several government reports, including most recently the final report from the Medicare Benefits Schedule Taskforce Review. While addressing this issue is complex and requires behaviour change, international evidence should be used to guide policy direction. Education initiatives and the use of clinical decision support tools should be considered as policy options to ensure the efficient use of imaging and reduce the incidence of diagnostic errors.

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**Appendix 1: Description of diagnostic imaging modalities, number of machines and services.**

Imaging modality	Description	Number of machines	Medicare service use (2019-20 FY) <sup>e</sup>
X-ray	Utilisation of x-ray radiation to generate a 2-dimensional image. Particularly useful for the visualisation of bone <sup>a</sup>	3,921 units <sup>b</sup> 16.2 units per 100,000 Australians <sup>b</sup>	10,377,151
Computed tomography (CT)	Similar to x-ray, yet uses contiguous 2-dimensional images to render a 3-dimensional image and provide greater clarity on bones, internal organs, soft tissue and blood vessels <sup>a</sup>	7 units per 100,000 Australians <sup>c</sup>	3,714,716
Ultrasound	Non-invasive form of imaging that does not emit radiation. Utilises reflection of ultrasound waves to create a real-time, dynamic image of various structures of the body <sup>a</sup>	8,629 units <sup>b</sup> 35.6 units per 100,000 Australians <sup>b</sup>	11,028,023
Magnetic resonance imaging (MRI)	Generates a strong magnetic field to provide detailed 3-dimensional imaging of a wide range of structures in the body. Does not emit any radiation <sup>a</sup>	1.5 units per 100,000 Australians <sup>d</sup>	1,314,824
Nuclear medicine imaging	Usually involves injecting, inhaling or swallowing a radioactive agent that emits gamma-rays that is used to visualise bones and organs. <sup>a</sup>	530 units <sup>b</sup> 2.2 units per 100,000 <sup>b</sup>	746,832

<sup>a</sup> Imaging Explained (NPS MedicineWise, 2019)

<sup>b</sup> Number of diagnostic imaging units in 2015-2016 from the *Availability and accessibility of diagnostic imaging equipment around Australia* Senate report (Community Affairs References Committee, 2018)

<sup>c</sup> Number of CT units in 2019 from the Organisation of Economic Co-operation and Development data set (OECD, 2021a)

<sup>d</sup> Number of MRI units in 2020 from the Organisation of Economic Co-operation and Development data set (OECD, 2021b)

<sup>e</sup> Medicare group reports – Category 5: Diagnostic Imaging Services (Services Australia, 2021a)

**Appendix 2:** *Cognitive biases and perceptual errors that increase the risk of diagnostic errors in the analytic phase (Itri et al., 2018; Brady, 2016; Waite et al., 2016; C. S. Lee et al., 2013).*

<b>Cognitive biases</b>	
Anchoring	Reliance on early interpretation/impression and that the diagnostic process fails to adapt or change diagnosis on the presentation of new diagnostic information
Framing	Reading of the diagnostic image is unduly influenced by how the clinical question or problem is framed
Availability	Diagnoses are made by those diagnoses that more likely to come to mind.
Confirmation	Only evidence that is congruent with the diagnostic hypothesis is sort, with refuting evidence is ignored
Satisfaction of search	Further information is no longer sort once an initial diagnosis is made
<b>Perceptual errors</b>	
Visual fatigue	Physical discomfort, eye strain, or lack of motivation due to prolonged and continuous visual analytic tasks
Conspicuity of abnormality	A tendency that abnormalities that are obvious are more likely to be observed
Decision (mental) fatigue	Occurs because of prolonged and continuous decision making

**Appendix 3: Projects funded through the Diagnostic Imaging Quality Program (Australian National Audit Office, 2015)**

Organisation	Project title	Funding provided	Outcomes
RadLogix	Electronic Decision Support in a GP Practice	\$329,384	Completed July 2013 No further information provided
Australian Society for Ultrasound in Medicine (ASUM)	Point of Care Ultrasound Qualifications	\$166,969	<a href="https://www.asum.com.au/cahpu/">https://www.asum.com.au/cahpu/</a>
Royal Australian and New Zealand College of Radiologists (RANZCR)	Inside Radiology – Update 2013	\$294,589	<a href="https://www.insideradiology.com.au/">https://www.insideradiology.com.au/</a>
RANZCR	CT Dose Optimisation	\$196,255	<a href="https://www.ranzcr.com/our-work/quality-standards/past-quality-projects">https://www.ranzcr.com/our-work/quality-standards/past-quality-projects</a>
RANZCR	Educational Modules	\$1,023,587	<a href="https://www.ranzcr.com/our-work/quality-standards/education-modules">https://www.ranzcr.com/our-work/quality-standards/education-modules</a>
Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG)	Nuchal Translucency Reflections on Effectiveness	\$223,300	<a href="https://nuchaltrans.edu.au/">https://nuchaltrans.edu.au/</a>
QLD Health	CT Dose optimisation	\$165,000	<a href="https://www.health.qld.gov.au/healthsupport/businesses/biomedical-technology-services/medical-physics/ct-radiation-dose-optimisation-program">https://www.health.qld.gov.au/healthsupport/businesses/biomedical-technology-services/medical-physics/ct-radiation-dose-optimisation-program</a>

Organisation	Project title	Funding provided	Outcomes
University of Sydney	Evaluation of the linear feature extraction algorithm	\$297,410	Expected completion in March 2018 No further information provided
University of Sydney	BEACH – Image Ordering by Australian GPs	\$156,417	Britt et al (2016)
Consumer Health Forum	Diagnostic Imaging and Informed Consumer Consent	\$303,407	Consumer Health Forum of Australia (2013)
WA Health	Diagnostic Imaging Pathways	\$248,848	<a href="http://www.imagingpathways.health.wa.gov.au/">http://www.imagingpathways.health.wa.gov.au/</a>
Australasian Association of Nuclear Medicine Specialists (AANMS)	Provision of enhanced information to referrers and patients	\$48,400	No further information provided

**Appendix 4: Budget costings versus expenditure associated with the initiatives related to the Diagnostic Imaging Reform package (Australian National Audit Office, 2015)**

		<b>2011-12 (\$m)</b>	<b>2012-13 (\$m)</b>	<b>2013-14 (\$m)</b>	<b>2014-15 (\$m)</b>	<b>Total (\$m)</b>
Budget costings	GP-requested MBS-eligible MRI items under 16 years	0.6	5.0	6.6	6.8	19.0
	GP-requested MBS-eligible MRI items 16+ years			29.5	46.1	75.5
	<b>Total</b>	<b>0.6</b>	<b>5.0</b>	<b>36.1</b>	<b>52.9</b>	<b>94.5</b>
Expenditure	GP-requested MBS-eligible MRI items under 16 years		4.2	8.9	10.2 <sup>1</sup>	23.3
	GP-requested MBS-eligible MRI items 16+ years			56.4	109.0 <sup>1</sup>	165.4
	Bulk-billing extra incentive	1.3	9.0	10.1	10.1 <sup>2</sup>	30.5
	<b>Total</b>	<b>1.3</b>	<b>13.2</b>	<b>75.4</b>	<b>129.3</b>	<b>219.2</b>
<b>Additional expenditure over Budget costings (percent)</b>		<b>117%</b>	<b>164%</b>	<b>109%</b>	<b>144%</b>	<b>132%</b>

<sup>1</sup> These values were originally based on conservative ANAO estimates, based on no growth in services use or change in bulk billing rates compared to 2013-14. The actual values are in the table based on data from Services Australia (2021a). The actual values were 14% and 28% greater than the ANAO estimates

<sup>2</sup> The bulk-billing extra incentive was an ANAO's conservative estimates, based on no growth in services use or change in bulk billing rates compared to 2013-14.

**Appendix 5: Recommendations made by the Diagnostic Imaging Clinical Committee and its working groups.**

Working Group	MBS items reviewed	Recommendations made
Diagnostic Imaging Clinical Committee (Medicare Benefits Schedule Review Taskforce, 2019)	Over 50 items related to diagnostic imaging	<p>A total of 38 recommendations were made by the committee. These recommendations include:</p> <ul style="list-style-type: none"> <li>• Removal or addition of item codes for specific imaging modalities and clinical conditions</li> <li>• Funding of research to better understand GP referral patterns for certain MBS items</li> <li>• Amending item descriptors to better clarify its use</li> <li>• Restrict radiologists co-claims attendance items for specified diagnostic imaging items</li> <li>• Remove MBS subsidies for scans taken on outdated imaging modalities</li> <li>• Consideration be given to the issue of high out-of-pocket costs associated with diagnostic imaging, especially in the context of a cancer diagnosis</li> <li>• The Department consider the development of clinical decision support tools for the requesting of diagnostic imaging (including CT of the cervical spine, CT of the head, musculoskeletal ultrasound).</li> </ul>

Working Group	MBS items reviewed	Recommendations made
Low back pain (Medicare Benefits Schedule Review Taskforce, 2016a)	45	<ul style="list-style-type: none"> <li>• Allow GP’s to refer for MRI of the lumbosacral spine for defined indications</li> <li>• Limiting CT for low back pain referred by GP’s</li> <li>• Amending item descriptors to clarify indications for low back pain for each imaging modality</li> <li>• Prohibit allied health professionals from requesting three or four region radiography of the spine</li> </ul>
Bone densitometry (Medicare Benefits Schedule Review Taskforce, 2016b)	7	<ul style="list-style-type: none"> <li>• New items for repeat testing that restrict intervals for bone densitometry for person over 70 years of age</li> <li>• Clarification of who can perform dual-energy X-ray absorptiometry (DEXA)</li> <li>• Remove items for quantitative computed tomography (QCT)</li> <li>• Interpretation and report provided by a specialist or consultant physician</li> <li>• Site measurements for QCT and DEXA items</li> </ul>
Pulmonary Embolism and Deep Vein Thrombosis (Medicare Benefits Schedule Review Taskforce, 2017a). Cont.	33	<ul style="list-style-type: none"> <li>• Explanatory notes should consider including Choosing Wisely recommendations</li> <li>• Restricting co-claiming Duplex ultrasound for DVT and venous disease</li> <li>• Implement a mechanism to reduce the number of item numbers that related to older equipment</li> </ul>

Working Group	MBS items reviewed	Recommendations made
Knee (Medicare Benefits Schedule Review Taskforce, 2017b)	22	<ul style="list-style-type: none"> <li>• Remove requirement for mandatory plain radiograph before MRI for patients &lt;16 years old</li> <li>• Remove GP referral for MRI for patients &gt;50 years old</li> <li>• Separate the MBS item for knee from the current X-ray items, which encompass foot, ankle, leg, knee, and femur</li> <li>• Separate the MBS item for knee from the current CT items, which encompass all extremities</li> </ul>
Breast imaging (Medicare Benefits Schedule Review Taskforce, 2018a).	39	<ul style="list-style-type: none"> <li>• Creation of new item code for ultrasound-guided breast biopsy</li> <li>• Amend item descriptor for bilateral mammography to encourage appropriate use</li> <li>• Creation of new item code for bilateral mammography to encourage uptake of digital radiography mammography</li> <li>• Remove obsolete MBS item code for mammary ductogram</li> <li>• Amend item descriptor for breast MRI to reflect contemporary best practice</li> <li>• Remove obsolete MBS item codes for stereotactic breast biopsy</li> <li>• Explanatory note for breast biopsy to encourage use of mechanical breast biopsy over fine needle aspiration</li> <li>• Creation of new item code for insertion of a breast biopsy localisation marker</li> </ul>

Working Group	MBS items reviewed	Recommendations made
Breast imaging (Medicare Benefits Schedule Review Taskforce, 2018a)	39	<ul style="list-style-type: none"> <li>• Increase fee for breast biopsy</li> </ul>
Nuclear medicine (Medicare Benefits Schedule Review Taskforce, 2018b)	107	<p>A total of 24 recommendations were made on a wide range of imaging item codes. These recommendations include:</p> <ul style="list-style-type: none"> <li>• Removal or addition of item codes for specific imaging modalities and clinical conditions</li> <li>• Amending item descriptors to better clarify its use</li> <li>• The level of MBS rebates for certain items relating to contrast agents</li> </ul>

**Appendix 6: Examples of the impact of structured imaging on various aspects of the diagnostic process**

Clinical condition	Findings	Reference
Prostate MRI	<ul style="list-style-type: none"> <li>• Decrease in major and minor mistakes of tumour position</li> <li>• Decrease in radiologist re-consultation</li> <li>• Increase in value in clinical decision-making and surgical planning</li> </ul>	<ul style="list-style-type: none"> <li>• Wetterauer et al (2020, 2019)</li> </ul>
Prostate MRI	<ul style="list-style-type: none"> <li>• Improved sensitivity for peripheral zone prostate lesions, but no change in specificity</li> <li>• No change in specificity for non-peripheral zone prostate lesions</li> </ul>	<ul style="list-style-type: none"> <li>• Shaish et al (2018)</li> </ul>
CT enterography for inflammatory bowel disease	<ul style="list-style-type: none"> <li>• More key features reported on (either absence or presence)</li> <li>• Improved accuracy of multifocal disease</li> </ul>	<ul style="list-style-type: none"> <li>• Wildman-Tobriner et al (2017)</li> </ul>
CT scan for internal herniation after gastric bypass surgery	<ul style="list-style-type: none"> <li>• Improved sensitivity, positive predictive value, and accuracy</li> <li>• No change in specificity or negative predictive value</li> </ul>	<ul style="list-style-type: none"> <li>• Ederveen et al (2020)</li> </ul>
Radiology report for brain tumours	<ul style="list-style-type: none"> <li>• Improved consistency, radiologist/physician communication, facilitation of patient management, and confidence</li> <li>• Decrease in ambiguity of report</li> </ul>	<ul style="list-style-type: none"> <li>• Gore et al (2019)</li> </ul>
Head and neck ultrasound	<ul style="list-style-type: none"> <li>• Pathologies described in more detail</li> <li>• Improved completeness and user-satisfaction</li> <li>• Decrease in mean time to complete</li> <li>• Very-high interrater reliability</li> </ul>	<ul style="list-style-type: none"> <li>• Ernst et al (2019)</li> </ul>

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