MRI Approval, Diffusion & Uptake in the Australian Healthcare System

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The effectiveness of MRI has been under formal consideration in Australia since 1983, when the then National Health Technology Advisory Panel (NHTAP) made its first report on the subject (1). A variety of assessment techniques has been applied to the technology in subsequent decades, and these continue to evolve.

Funding of Diagnostic Imaging in Australia

The Australian Federal government, through Medicare Australia, subsidises most diagnostic imaging examinations, and a large range of other ambulatory care, at rates it determines. Providers are at liberty to charge private patients higher rates, but may be constrained by patient reluctance, adverse publicity, and commercial competition. Only procedures that have been included on the Medical Benefits Schedule (MBS) are eligible for subsidy. Inclusion on the Schedule is an administrative decision, requiring Ministerial approval.

Introduction of MRI to Australia

In the 1970s and 1980s, there was concern about the rapid (and expensive) diffusion of CT scanning in Australia. Against this background, the 1983 NHTAP report recommended a controlled introduction of MRI. This consisted of a publicly funded trial (outside the Medicare system) at five public hospital sites, using MRI systems with a variety of field strengths (0.3 – 1.5 T). Participants were required to assess the impact, if any, of the MRI examination results on patient diagnosis and management (2,3,4). This program found MRI diagnoses to be highly accurate, frequently superior to those from CT, and often (44 %) influential in patient management, with outcomes affected in 20 % (2).

As a result of this assessment, in 1990, NHTAP recommended expansion of MRI services to hospitals "with substantial activity in neurological and spinal work... and accredited for neurosurgical training" (5). Referrals were to be restricted to specialist medical practitioners.

The Federal government subsequently funded the installation (1992-4) and operation of MRI systems at 18 such hospitals, through direct grants outside the Medicare system. A condition of these grants was that clinical data be collected for each patient examined, but this data was never extensively analysed. There was no specific restriction on the types of MRI examination performed. Over the same period, a number of private MRI systems were installed, mostly in private hospitals; these did not receive government support.
Inclusion of MRI in the Medical Benefits Schedule

By the mid-1990s, there was increasing demand for MRI services from referrers and patients, resulting in long waiting lists at the publicly funded sites, while private practices were reluctant to introduce the technology in the absence of government subsidy. The Australian Health Technology Advisory Committee (AHTAC; successor to NHTAP) reviewed the literature, and consulted widely with stakeholders and the public, from 1995-7. It recommended a further expansion of MRI services (6), with new systems to be located near appropriately large referral populations, and in practices/departments with a ‘comprehensive’ range of imaging services. Referral was to remain specialist-only, and the development of clinical practice guidelines for MRI referrals was urged. No specific recommendation was made on a funding mechanism.

The government then announced that 162 selected MRI services (from a list adapted from the AHTAC review) would become eligible for Medicare rebates, at selected sites only, from September 1998. The basis for site selection was, in some cases, controversial, with 66 sites ruled eligible for rebates, but approximately 47 sites continuing to be excluded from government funding. At the time, it was already apparent that the list of ‘appropriate’ indications was conservative, leading to further criticism.

The government responded on two fronts, firstly by establishing a new advisory body, the Medical Services Advisory Committee (MSAC – 1998), to assess claims for funding of particular procedures via the Medicare system; and secondly, by commissioning a review of the new arrangements by Professor John Blandford. A key recommendation of the ‘Blandford review’ (7) was the referral of 9 additional applications of MRI to MSAC, three of these as an immediate priority (MRCP, staging of uterine cancer, and MRA in the setting of contra-indication to CTA). Three of these 9 remain unfunded in 2012 (staging of prostate cancer, characterisation of liver lesions, coronary MRA). This review again recommended the continuation of specialist-only referral, but also suggested a trial of general practitioner referral for specific indications, where MRI would be substituted for CT.

Since 2000, additional MRI sites have been included in the Medicare arrangements, often in response to population and/or political pressure, with the total now 125, for a population of approximately 22 million. There are still, however, a large number of sites (believed to be up to 100) without access to MBS rebates.

MSAC evaluations of new applications for MRI

MSAC was established to apply evidence-based techniques to the assessment of new medical procedures for inclusion in the MBS, thereby deflecting charges of political influence on funding decisions. Its brief extends to a wide range of medical procedures, with imaging procedures a relatively small part of its workload. MSAC was specifically required to provide evidence-based advice on the safety, effectiveness, and cost-effectiveness of new procedures proposed for funding (8). For each application received, an Advisory Panel was convened, comprising MSAC...
members, clinicians expert in the relevant field, and consumer representatives. In the case of diagnostic procedures, the clinical experts included both clinical referrers and diagnosticians. The panel was responsible for developing a brief to external health technology and economics specialists, outlining the pertinent issues for them to assess in regard to each application. The proponent was given a chance to comment on the brief before it was finalised. Upon completion of the consultants’ report, the Panel reviewed its content, and offered the proponent a further opportunity to comment. The panel forwarded the report to MSAC, which decided what recommendation should be made to the Minister. A key part of the brief was the identification of a ‘comparator’ technology, to which the new procedure would be compared in terms of its safety, efficacy, and cost-effectiveness.

For diagnostic imaging proponents, this procedure involved a large amount of paperwork (guidelines for applications ran to nearly 100 pages, and the blank application form itself to 29 pages), and long delays (Table 1). Given that many MRI services continued to have substantial waiting lists, there was little incentive to embark on the process. Even quite small indications, such as that for staging of rectal cancer (estimated to cost the government a little over AUD$1.1 million/year in a health budget of over $50 billion/year) were required to go through this process. It was also apparent that there were limited resources to support the economic assessments required. Despite the attempt to include all stakeholders in the Advisory Panel for each proposal, there was criticism of some MSAC recommendations from those who did not feel that their views had been adequately represented; this was a key factor in the long delay in the assessment of MRCP.

Once a positive recommendation was made to the Minister, and accepted, it was up to the Health Department to define the precise ‘descriptor’ for the new Medicare item, a process that could be subject to considerable debate, depending in part on the quality of the relevant MSAC report.

Table 1: Applications to MSAC for funding of MRI procedures, 1998-2010

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Application</th>
<th>Recommendation</th>
<th>Outcome</th>
<th>Adopted</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staging cervix cancer</td>
<td>August 2000</td>
<td>November 2001</td>
<td>Initial staging only</td>
<td>Nov 2002</td>
</tr>
<tr>
<td>MRCP</td>
<td>August 2000</td>
<td>March 2005</td>
<td></td>
<td>Jan 2006</td>
</tr>
<tr>
<td>Breast cancer screening</td>
<td>May 2005</td>
<td>Nov 2006</td>
<td>High-risk only</td>
<td>Feb 2009</td>
</tr>
<tr>
<td>Staging rectal cancer</td>
<td>Sept 2006</td>
<td>Oct 2008</td>
<td>Initial staging only</td>
<td>July 2009</td>
</tr>
<tr>
<td>Liver iron estimation</td>
<td>July 2008</td>
<td>July 2010</td>
<td>Negative</td>
<td>-</td>
</tr>
</tbody>
</table>
Recent developments at MSAC and elsewhere
In 2008-9 there were reviews of both MSAC, and the Federal processes for health technology assessment in general, prompted both by external criticism, and the need to co-ordinate processes for hybrid technologies. As a result, modifications to the MSAC process are being developed (8). The Advisory Panels are being replaced with a standing ‘Protocol Advisory Sub-Committee’, which is to work with proponents, economic advisors, relevant craft groups, and the public, to develop an agreed protocol for assessment of the proposal. This will include a decision analytic flowchart, incorporating arms for both current practice and the proposed new model, and an analysis of resource usage in each step of these decision pathways. Proponents will then have a choice of conducting the assessment of evidence (addressing issues identified in the agreed protocol, and including costings) themselves, or of seeking public funding for a contracted systematic review. If the proponent provides the review of evidence, MSAC will commission an independent critique; for reviews contracted by MSAC, the proponent will be invited to comment. The review and comments will then be assessed by an ‘Evaluation Sub-Committee’ (ESC) for completeness. The ESC will also consider which of several funding categories may be relevant –
- funding supported by evidence,
- funding supported by incomplete evidence (eg where a new treatment may be the only option for some patients),
- funding, with monitoring of utilisation
- interim funding, subject to the generation of further evidence; and
- non-MBS funding
Finally, MSAC will collate the above reports and comments, and formulate advice to the Minister on the basis of safety, efficacy, and cost-effectiveness.

Meanwhile, the government has announced that it will open up access to rebates for selected MRI examinations requested by general practitioners, initially for paediatric patients (2012), and the following year for a limited range of adult indications. It is intended that these measures be supported by referrer education campaigns and the use of other decision support aids to appropriate utilisation. The aim is to reduce delays in the diagnostic process, particularly for patients in rural and remote areas.

Conclusion – open issues
The use of MRI in Australia has grown steadily, despite constraints imposed by the funding system; growth and diffusion have certainly been slower than they would have been under some other models of funding. However, this has been at the price of limiting access for patients in some clinical groups, and in some geographical areas. In some situations, the funding system has encouraged continued use of CT when MRI would likely have been superior diagnostically (and would have obviated any ionising radiation exposure).
The new evaluation system relies heavily on stepwise decision analysis and economic modelling. It is unclear how well these models will capture the complexities of day-to-day clinical care of common clinical problems.

It seems likely that the process will remain slow, despite the attempts to streamline protocol development and evidence review, not least because of the limited pool of health economists and evidence assessors available for the potentially large number of imaging and other applications. In this situation, political pressures are likely to again be brought to bear on the approval process.

The MBS system for MRI funds examinations performed for specific clinical indications, but has few means of ensuring that the actual clinical situation matches that in the descriptor. It will be interesting to see what the impact of electronic health records, and electronic decision support, will be here.

The new system encourages proponents to fund their own evidence review, a procedure adopted from the Pharmaceutical Benefits assessment process, but which is less suited to the imaging market, in which proponents seldom have patent rights and natural advantage. The changes do not address the paucity of cost and outcome data in Australian diagnostic imaging (and other fields). There is still little incentive for individual radiologists, practices, or suppliers to mount applications for funding of new techniques, and hence there is potential for a vicious circle: unfunded --> not done often --> not done well --> not much benefit --> little evidence to support funding --> no application --> remains unfunded.

The profession has recognised the need to build research and evaluation into daily experience, and moves are afoot to develop capacity for multi-centre trials of new techniques, learning from local and overseas models.

References:

1. National Health Technology Advisory Panel, Nuclear magnetic resonance imaging. Department of Community Services and Health, Canberra, 1983.


