Identifying existing health care services that do not provide value for money

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In Australia, one projection of total health expenditure (in 2002–03 dollars) envisages an increase from 71.4 billion in 2002–03 to 162.3 billion in 2032–33.¹ As a proportion of total gross domestic product (GDP), this represents an increase from 9.4% in 2002–03 to 10.8% in $2032–33^1$ — an annual growth of 0.5% above the overall economic growth rate. Coupled with this projected increase in cost are concerns for the sustainability and quality of the Australian health care system.² Debate continues on issues such as hospital emergency and surgery waiting lists, models of funding and care, pharmaceutical benefit subsidies, workforce shortages, Indigenous health disadvantage and the role of primary prevention — to name but a few.

To address the problems, federal and state/territory jurisdictions have several options, including accepting the increase in the proportion of GDP allocated to health care expenditure, thereby constraining spending in other portfolios, such as education and defence. However, we propose that potential exists for a cost-saving or cost-neutral agenda of resource reallocation within the existing health budget, aimed at improving the quality of care and health outcomes. In Australia, there is scope to identify ineffective interventions (relative to the cost of their subsidy by the taxpayer) and to assess the potential for reducing their use or removing them from government and insurance funding schedules. This would allow reallocation of funding to interventions and programs that offer more in terms of overall health gain and (cost-) effectiveness. As the resources available for health care are finite, this would reduce the extent of unnecessary suffering and premature death arising from the use of health technologies and practices that deliver less than the best-available value for money.^{3,4}

Here, we propose a dedicated program in Australian health policy that explicitly supports this undertaking. Internationally, the process has been referred to as "disinvestment", ⁵⁻⁷ although it perhaps aligns better with notions of displacement and reallocation, or reinvestment. In the United Kingdom, disinvestment has been adopted by the National Health Service — utilising the services of the National Institute for Health and Clinical Excellence (NICE) — as a formal policy entitled "optimal practice reviews".⁸ Spain, France and Canada are also considering, or have adopted, similar formal policy initiatives.

These countries recognise that the strategy offers promise in the face of ageing populations, increasing chronic disease, and the ensuing strain on health care sustainability. It also appears ethical to strive for appropriate, high-quality and effective care for the populations (and taxpayers), served at a cost they can afford. Finally, this strategy aligns with one of the "top ideas" developed from the long-term health strategy stream of the Australia 2020 Summit:

[to] ensure better data for evidence-based allocation of resources \dots [and to use those] data to allocate resources across the system based on hard evidence. Public funding would be added and removed on the basis of clearly demonstrated effectiveness.⁹

ABSTRACT

- Health systems can be improved appreciably by making them more efficient and accountable, and enhancing the quality of care, without necessarily requiring additional resources.
- Australia, like other nations, cannot escape making difficult health care choices in the context of resource scarcity, and the challenge of delivering quality care, informed by best available evidence, to an ageing population with multiple comorbidities.
- An opportunity exists for a cost-saving or cost-neutral agenda of reallocation of resources within the existing health budget, through reducing the use of existing health care interventions that offer little or no benefit relative to the cost of their public subsidy. This would allow reallocation of funding towards interventions that are more cost-effective, maximising health gain.
- Criteria based on those developed for health technology assessment (HTA) might facilitate the systematic and transparent *identification* of existing, potentially ineffective practices on which to *prioritise* candidates for assessment as to their cost-effectiveness.
- The process could be jointly funded by all relevant stakeholders but centrally administered, with HTA groups resourced to undertake identification and assessment and to liaise with clinicians, consumers and funding stakeholders. MJA 2009; 190: 269–273

Potentially ineffective health care practices

A policy of identifying and assessing ineffective or non-costeffective practices, reducing their existing use (and redirecting those resources) undoubtedly represents an option for improving sustainability and quality in health care. However, Australia has a poor track record in achieving this, particularly outside the area of pharmaceutical assessment.⁵⁻⁷ A significant challenge is the need for, and requisite development of, a fair and systematic method to identify practices for which assessment is appropriate, based on an agreed framework.⁷ Failure to undertake this in a systematic and transparent manner has the potential to entrench stakeholder resistance. Mechanisms already exist to identify interventions that can be demonstrated to be harmful or ineffective before they are adopted in Australia. As well as enhancing and extending these mechanisms to consider interventions in current use, a further step would be to identify interventions that, although safe and effective, are not sufficiently cost-effective to warrant widespread use in routine practice.

Box 1 lists examples from a 2008 report from the Institute of Medicine in the United States of widely adopted health interventions now deemed "ineffective or harmful",¹⁰ although arguably the list focuses on those that are harmful. Additional items are shown in Box 2 where the concern is less about safety and more about clinical and

1 Examples of health interventions widely adopted in the United States but now deemed ineffective or harmful

- Autologous bone marrow transplant with high-dose chemotherapy for advanced breast cancer
- Diethylstilbestrol (DES) to prevent miscarriage
- Electronic fetal monitoring during labour without access to fetal scalp sampling
- Episiotomy (routine) for birth
- Extracranial–intracranial bypass to reduce the risk of ischaemic stroke
- Gastric bubble for morbid obesity
- Gastric freezing for peptic ulcer disease
- Hydralazine for chronic heart failure
- Lidocaine to prevent arrhythmia and sudden death in acute myocardial infarction
- Mammary artery ligation for coronary artery disease
- Optic nerve decompression surgery for non-arteritic anterior ischaemic optic neuropathy
- Quinidine for suppressing recurrences of atrial fibrillation
- Radiation therapy for acne
- Monitoring uterine activity at home to prevent preterm birth
- Supplemental oxygen for healthy premature babies
- Thalidomide for sedation in pregnant women
- Triparanol (MER-29) for cholesterol reduction
- Chelation therapy to prevent or reverse atherosclerosis
- Spinal manipulation to treat migraine or cluster headaches
- Traction to treat low-back pain
- Antihistamines and oral decongestants to treat otitis media with effusion
- Fenfluramine plus phentermine to treat obesity
- Subcutaneous interferon alfa-2a to treat age-related macular degeneration

Source: US Institute of Medicine (2008)¹⁰ (pp. 3–10). Originally adapted from Goodman (2004).¹¹

cost-effectiveness — although in some cases these cannot readily be separated. This list is not exhaustive, nor do we infer judgement of (in)effectiveness or cost-ineffectiveness. Rather, as these practices have been debated in recent peer-reviewed publications, we present them as potential candidates for assessment.

Towards a framework for identifying and prioritising practices for assessment

Items listed in Box 2 have attracted much debate regarding whether (or to what extent) their use is justified in modern, subsidised health care. To ensure a maximally productive debate, any process for selecting health care practices with a view to evaluating them for displacement should follow a protocol with pre-specified, transparent selection criteria.

In the field of health technology assessment (HTA), criteria have been developed for determining priorities for assessing individual new or emerging health interventions. In Box 3, we build on these criteria to propose a framework to facilitate systematic and transparent identification of existing, potentially cost-ineffective practices. The categories in this framework are a guide for identifying technologies that warrant evaluation. Box 4 explores criteria that might inform the prioritisation of candidates for detailed assessment.

2 Health care practices and the context for suggesting they are candidates for formal assessment as possibly ineffective or non-cost-effective*

Antidepressant medications in treatment of mild-moderate depression

Context: A meta-analysis/regression of 35 trials (n = 5133) showed that drug–placebo differences in antidepressant efficacy increased as a function of baseline severity but were relatively small, even for patients with severe depression. The relationship between initial severity and antidepressant efficacy was attributable to decreased responsiveness to placebo among those with severe depression, rather than to increased medication responsiveness. (Kirsch et al, 2008.¹²)

Tympanostomy tubes (ear grommets) for fluid in the inner ear in children

Context: 6000 children with no known risk factors for developmental delay were followed up from infancy to age 11 years; those with persisting fluid were assigned to early insertion of tubes or to delayed surgery, 9 months later (no surgery if cleared in the interim). For otherwise healthy children, waiting and watching for up to a year or longer did no harm to any aspect of the child's development, including learning abilities. (Paradise et al, 2007.¹³)

Implantable cardioverter defibrillators for ischaemic cardiomyopathy

Context: A microvolt T-wave alternans (MTWA) test can discriminate who will or will not benefit from implantable cardioverter defibrillators. All 768 patients with ischaemic cardiomyopathy underwent MTWA, but test results were not used in patient management. Half went on to defibrillator implantation, with 3-year follow-up. The authors suggested that, if the test were used on most defibrillator candidates, up to a third could be spared implantation, without increasing their risk of sudden death. (Chow et al, 2007.¹⁴)

Overprescribing of proton-pump inhibitors for dyspepsia

Context: An editorial claimed that studies consistently show protonpump inhibitors are being overprescribed worldwide in primary and secondary care. Between 25% and 70% of patients taking these drugs have no appropriate indication. Proton-pump inhibitors cost more than other agents, yet effective and less expensive alternative drugs, such as H₂-receptor antagonists, are available. (Forgacs and Loganayagam, 2008.¹⁵)

Tension-free repair versus watchful waiting for inguinal hernia

Context: Six community and academic centres examined costs, quality-adjusted life-years, and cost-effectiveness at 2 years of follow-up (n = 724 men, randomised). At 2 years, watchful waiting was a cost-effective treatment option for men with minimal or no hernia symptoms. (Stroupe et al, 2006.¹⁶)

Upper airway surgery for obstructive sleep apnoea in adults

Context: The intervention is resource-intensive with a high degree of clinical heterogeneity, and low and inconsistent clinical effectiveness. Cost-effective, non-invasive treatments are available. Over 60% of recipients report pain and persistent adverse side effects, with almost a quarter regretting surgery. Success rates are improved with multilevel procedures, but many patients do not persist. (Elshaug et al, 2008.¹⁷)

* Text paraphrased from original abstract or report.

From evidence to policy to practice

Two key questions remain. First, who should be responsible for funding, oversight, assessment, decision making, and implementation in this process? Second, after selection, assessment and a decision, should reductions in use be sought through the development and implementation of clinical practice guidelines and/or

3 Criteria for identifying existing, potentially non-cost-effective practices as candidates for assessment*

New evidence: New evidence on safety, effectiveness and/or costeffectiveness may come to light that changes previously held conclusions and is sufficiently useful for decision making. Sources include subsequent trials, cumulative meta-analyses, post-market surveillance, audits and registry data. It could also include longerterm datasets, where evidence becomes available on patientrelevant outcomes, rather than surrogate outcomes used previously; and developments in diagnostic parameters (and treatment outcome measures) that have undergone evidence-based reclassification.

Geographic variations in care: Geographic variations (eg, the Dartmouth Atlas of Health Care²⁰), after adjusting for demographics and location of centres of excellence, suggest differences in clinical opinion about the value of the interventions.

Provider variations in care: Clinical heterogeneity of procedure, where the choice of intervention varies (eg, surgical variation) for the same class of disease or condition (seek coupling with evidence of a long learning curve, and inconsistent or operator-dependent safety and effectiveness).

Temporal variations in volume: A trend in item volume between time-points (eg, 2, 3 or 5 years), of a substantial percentage (say 30%, 50% or 80%). Most often this is a decrease. An increase after adjusting for trends in incidence may flag "leakage" (usage beyond the restriction/indication) or indication "creep".

Technology development: When an intervention has evolved to the point that it differs markedly from the initial or prototype intervention that was originally assessed or funded, then the initial intervention should be reviewed (eg, 256-slice compared with four-slice computed tomography). Note: this may be identified as a volume variation if marketing data are used, but not if the data source is a Medicare item number (Medicare describes the service, not the technical indications for undertaking that service). Perhaps an indicator that the unit cost of the intervention may be increasing unduly.

Public interest or controversy: Expressions (to media, letters to editors, enquiry submissions) from patients, consumer advocacy and support groups, and community groups, highlighting negative (or ineffective) experiences following treatment. To be substantiated by evidence.

Consultation: Consultation with clinical, nursing, allied health and technical staff, health care administrators and funders (including both public and private health insurance).

Nomination: A process (potentially anonymous) established where individuals, associations and colleges (from medical, nursing, research, allied health or the general public) could nominate interventions and justify their choice. To be substantiated by evidence.

Assess new intervention — displace old: When a new intervention is presented to the relevant committee(s)[†] for regulatory assessment, and is considered a potential replacement for (an) established comparator(s) for that indication, then that comparator for that patient indication is automatically considered and assessed for disinvestment.

Leakage: Technology use (with reimbursement) outside the evidence-based indications (see also *Temporal variations*, above).

Legacy items: Long-established technologies that have never had their costeffectiveness assessed — look for coupling with other identification items.

Conflict with guidelines: Where practice is inconsistent with clinical practice guidelines, clinical college position statements, Cochrane Review recommendations (and where there is no Cochrane Review on that technology).

* Items adapted from criteria for health technology assessment,¹⁸ including horizon scanning processes.¹⁹

† The Medical Services Advisory Committee (http://www.msac.gov.au) advises the Minister for Health and Ageing on evidence for safety and (cost-)effectiveness of medical technologies and procedures. This advice informs decisions about public funding. The Pharmaceutical Benefits Advisory Committee (http://www.health.gov.au/ internet/main/publishing.nsf/Content/health-pbs-general-listingcommittee3.htm#pbac) assesses applications for listing of medicines on the

committees.htm#pbac) assesses applications for listing of medicines on the Pharmaceutical Benefits Scheme.

through policy-guided controls (leverage) on reimbursement drivers (such as removing or restricting item numbers, or tightening indications)? A complication is the reality of multiple funding sources in Australia, including federal, state/territory and private health insurers.

In a recent qualitative investigation, a group of Australian policy stakeholders suggested that responsibility is best situated within an expanded Medical Services Advisory Committee (MSAC) or parallel committee.⁷ The process for assessing new practices and technologies for listing on the Medicare Benefits Schedule is seen as a foundation for this new undertaking.²³ This responsibility sits within the mandate of the MSAC - to advise the Minister for Health and Ageing on evidence for safety and (cost)-effectiveness of medical technologies and procedures. However, the considerable workload of this committee in assessing new technologies limits its activity in assessing existing items.⁷ Some also include the National Institute of Clinical Studies and the Australian Commission on Safety and Quality in Health Care as having important roles in this process, as well as state health departments. Southern Health, the largest health network in Victoria, is currently exploring these processes within the local health service setting.

To prevent duplication, the process could be jointly funded by all relevant stakeholders but centrally administered. HTA groups could be resourced to undertake the identification and assessment processes and to liaise with clinicians, consumers and funding stakeholders, who would direct which practices take priority for assessment. Further, we propose that proponents of identified technologies carry the burden of providing sufficient (new or revised) evidence of cost-effectiveness in order to have continued government funding, as occurs under current review processes for pharmaceutical benefits.

While some items listed in Box 3 are used in HTA for identifying and assessing *new* practices, the criteria framework outlined has not yet been tested for *existing* practices with questionable cost-effectiveness. There is, therefore, scope for it to be tested and evaluated for impact and outcome, and for marginal analyses of benefits derived from the implied resource reallocation.²⁴ There is a need for empirical investigation to identify categories that best identify technologies ripe for disinvestment, and to shape decision rules for prioritisation. These analyses must incorporate the complexities of assessing practices and technologies that have existed for some time within the health care system, as opposed to assessing new technologies.⁶

We can sometimes improve the health system by making it more efficient and accountable, and enhancing quality of care, without necessarily asking for additional resources. A recent report into disinvestment planning by NICE showed that there are risks associated with identifying practices and technologies as ineffective in some circumstances, suggesting that there may have been considerable training and infrastructure development, and that some stakeholders may prefer that the status quo be maintained.²⁵

4 Criteria to inform the prioritisation of candidates for detailed review after identification*

Cost of service: High cost per procedure (eg, high item cost on the Medicare Benefits Schedule or Pharmaceutical Benefits Scheme), high cost by volume, or an aggregate measure of these.

Potential impact:

- Likely health impact (eg, crude estimate of quality-adjusted lifeyears lost per patient).
- Likely cost effects (eg, crude estimate of cost savings per patient; liberation of additional resources, including downstream costs such as theatre time required for corrective procedures, and sunk costs of human and physical capital, including costs of retraining, and costs associated with length of hospital stay).
- Overall assessment relating to the maintenance of equity in care should this health care intervention be displaced (eg, access by patient subgroups).

Cost-effective alternative: When a cheaper but more, or equally, effective alternative exists, is identified or emerges. See also Box 3 item Assess new intervention — displace old.

Disease burden: Conditions associated with low degrees of disability or morbidity or low rates of mortality (but excluding orphan conditions) may influence priority differentially to those with high degrees or rates. "Low" may reduce the potential for controversy; "high" may represent greater scope for reinvestment/ reallocation of resources.

Sufficient evidence available: Rigorous assessment requires robust evidence on which decisions can be made. While evidence is rarely 100% conclusive, it should be available and adequate to offer decision-making utility.

Scope for time-limited funding with "pay for evidence" or "only in research" provisions: If there is not new, adequate or sufficient evidence, but other criteria are met and/or there is a moderate indication of (cost-)ineffectiveness within existing evidence, then there should be scope for "(time-limited) funding with evidence generation" to assist decision making. Time-limited funding (standard subsidy) is conditional on patients being enrolled in a controlled clinical trial. Internationally, this is known as "pay for evidence", "only in research" or "coverage with evidence development".²¹ The need or extent of new evidence required to meet "sufficient evidence" (item above) might inform prioritisation.

Futility: An intervention that is highly unlikely to result in "meaningful survival" or benefit.²² For example, life-saving treatments for the seriously demented (especially those who have given advance directives); procedures that require multiple stages to which patients have poor adherence due to pain or side effects; and treatments with high relapse rates.

* It is likely that points of identification would be incorporated in parallel into assessments of prioritisation, as determined by decisionmakers.

The report concludes that "these are not reasons not to ask the difficult questions nor to shy away from making unpopular recommendations". Given these sensitivities, a framework such as the one proposed here may improve consultation, transparency and overall governance.

If governments, the professions and the community really want and expect a "better" health system, then it is time to start asking questions about resource reallocation, in a spirit of transparency, with an explicit statement of values, and supported by a systematic and evidence-informed framework. The answers have the potential to enhance the sustainability and quality of health care.

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Competing interests

Janet Hiller is Director, Tracy Merlin is Manager, and Adam Elshaug is a Fellow of Adelaide Health Technology Assessment (AHTA), which is contracted to complete evaluations of health technologies. John Moss provides health technology assessments to the Australian Government as a consultant. In all other respects, we declare we have no competing interests.

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