Scientific integrity review
Identifying and acting on inappropriate metadata: a critique of the Grattan Institute Report on questionable care in Australian hospitals
P David Cooper and David R Smart

Abstract

Introduction: In an era of ever-increasing medical costs, the identification and prohibition of ineffective medical therapies is of considerable economic interest to healthcare funding bodies. Likewise, the avoidance of interventions with an unduly elevated clinical risk/benefit ratio would be similarly advantageous for patients. Regrettably, the identification of such therapies has proven problematic. A recent paper from the Grattan Institute in Australia (identifying five hospital procedures as having the potential for disinvestment on these grounds) serves as a timely illustration of the difficulties inherent in non-clinicians attempting to accurately recognize such interventions using non-clinical, indirect or poorly validated datasets.

Aim: To evaluate the Grattan Institute report and associated publications, and determine the validity of their assertions regarding hyperbaric oxygen treatment (HBOT) utilisation in Australia.

Methods: Critical analysis of the HBOT metadata included in the Grattan Institute study was undertaken and compared against other publicly available Australian Government and independent data sources. The consistency, accuracy and reproducibility of data definitions and terminology across the various publications were appraised and the authors’ methodology was reviewed. Reference sources were examined for relevance and temporal eligibility.

Results: Review of the Grattan publications demonstrated multiple problems, including (but not limited to): confusing patient-treatments with total patient numbers; incorrect identification of ‘appropriate’ vs ‘inappropriate’ indications for HBOT; reliance upon a compromised primary dataset; lack of appropriate clinical input, muddled methodology and use of inapplicable references. These errors resulted in a more than seventy-fold over-estimation of the number of patients potentially treated inappropriately with HBOT in Australia that year.

Conclusion: Numerous methodological flaws and factual errors have been identified in this Grattan Institute study. Its conclusions are not valid and a formal retraction is required.

Key words
Critical appraisal; Data; Economics; Evidence; Health; Hyperbaric oxygen therapy; Policy

Introduction
The identification and prohibition of ineffective medical therapies is of considerable economic interest to funding bodies. Regrettably, the identification of such therapies has proven problematic and a recent paper in the Medical Journal of Australia (MJA) illustrates the difficulties inherent in accurately recognizing such interventions from non-clinical, indirect or poorly validated datasets.1

Published in August 2015, this peer-reviewed article from the Grattan Institute attempted to develop a model to measure potentially inappropriate care in Australian hospitals and was based on a report previously prepared by that organization, but omitted from their published references.1,2 The authors utilized de-identified patient-level data from the Australian Institute of Health and Welfare (AIHW) to identify the hospital-specific incidence of selected diagnosis-procedure pairs that were allegedly deemed ‘inappropriate’ in previous literature. All Australian public and private hospital separations (discharges, deaths, transfers) in financial year 2010–11 were included. Five hospital procedures, including hyperbaric oxygen treatment (HBOT) were identified as having potential for disinvestment on these grounds, and punitive measures were recommended against healthcare providers with “illegitimate variation” in service provision.2

Of the five ‘do-not-do’ procedures scrutinized in the MJA article and its source document, HBOT “for a range of conditions” was surprisingly prominent, contributing 79% of the procedures identified as potentially inappropriate.1 The authors stated that “(m)ore than 4500 people a year get hyperbaric oxygen therapy when they do not need it”.2 However, this figure far exceeded the known total number of individuals treated across all Australian facilities (public and private, civilian and military, 1,276 patients) in 2010–11.3 Likewise, claims that “(o)ne in four hyperbaric oxygen treatments should not happen”2 appeared questionable when their list of ‘inappropriate’ indications included diagnoses that had been funded for HBOT under the Australian Medicare Benefits Schedule (MBS)4,5 following rigorous review of the available evidence by the Government’s own Medical Services Advisory Committee (MSAC).6
Aim

To critically evaluate the Grattan Institute Report and associated publications, and determine the veracity of their conclusions regarding HBOT in Australia.

Methods

The following processes were used to critically review the publications:

- Utilising existing published source data, the accuracy of the numbers presented in the Grattan papers was assessed against published data for 2010–11 from the Hyperbaric Technicians and Nurses Association (HTNA), AIHW and Medicare Australia.
- Basic data definitions and terminology relating to HBOT were reviewed to determine consistency and reproducibility across all documents. It was expected that definitions and terminology would be accurate and consistent.
- References were examined for consistency, relevance, source data, vertical integration and temporal applicability to ensure post-dated publications were not applied retrospectively.
- If other fundamental problems with the methodology, analysis or conclusions were identified during the review, these were documented.

Our analysis was confined to HBOT data only and excluded the four surgical procedures scrutinized in this report, which seldom occur more than annually in any patient.

Results

1. PATIENT versus TREATMENT NUMBERS

HBOT, as a non-surgical treatment (like antibiotics, plasmapheresis, radiotherapy), is commonly prescribed as a course of 20 to 30 sessions (‘doses’) for any individual. HBOT is formally classified in the Australian Classification of Health Interventions (ACHI) as being amongst the “(n)on-invasive, cognitive and other interventions”, and appears as such in AIHW data. Of 5,888 procedures identified as ‘inappropriate’ by the Grattan Institute 4,659 were HBOT (79%). The authors interpreted this as indicating that “more than 4500 people a year get hyperbaric oxygen therapy when they do not need it”. Therefore, each admission was assumed to represent a separate patient. This is incorrect. The Report notes that the inability to correct for readmissions may deflate their hospital ‘do-not-do’ rates, making their analysis conservative – citing as an example “a person who had multiple treatments, one of which was a do-not-do treatment, would thus be counted once in the numerator and multiple times in the denominator” in their data. Comparison against the HTNA’s independent dataset demonstrates that this supposition is also incorrect. Failure to recognize HBOT as a multi-dose medical therapy inflates the numerator rather than the denominator, exaggerating the effect the authors seek to measure. This methodological flaw skews their results and misrepresents HBOT when compared against the four surgical procedures. It would have been more appropriate to examine the number of patients treated rather than the number of HBOT doses provided. Unfortunately the study methodology does not permit this. This single failure of clinical understanding leads to a 21-fold overestimation of the stated problem.

The Grattan Report’s raw data have not been published, preventing independent re-analysis of the HBOT results by diagnosis. However, applying the average number of treatments-per-patient derived from the HTNA dataset permits a reasonable first approximation. When divided by 21 the 4,659 ‘inappropriate’ episodes of HBOT equate to approximately 222 discrete HBOT courses. This filter reduces the total number of individuals subjected to the five ‘do-not-do’ procedures from 5,888 to 1,451 and the fractional contribution of HBOT from 79% (4,659/5,888) to 15% (222/1,451).

2. SELECTION OF ‘INAPPROPRIATE’ INDICATIONS

The next substantial contribution to the over-representation of HBOT arose from the selection of indications for which HBOT was deemed ‘inappropriate’ (Table 1). The authors state that they “took a selection of treatments that evidence...
The evidence base underlying HBOT has undergone three external reviews in Australia over the last 17 years. Following rigorous evaluation by MSAC, HBOT was approved for Medicare-funding for seven conditions in 2000 (Table 2).9 The list of conditions for which HBOT was deemed ‘inappropriate’ by the Grattan authors derived from those excluded from funding in this initial MSAC report.9 None of the references cited in the article, other than MJA (2010–11) was used “according to these authors.”2 Further conclusions of this study should not happen “on only guidance published before our data period (2010–11) was used”.1

<table>
<thead>
<tr>
<th>MBS item</th>
<th>Year approved</th>
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<tr>
<td>13020</td>
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<td>13015</td>
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The failure to publish original data precludes independent re-calculation of the results by diagnostic group but a reasonable first approximation of this error’s impact may be achieved. The approximately 222 patients (from point 1) potentially subject to ‘inappropriate’ HBOT may be reduced by a further 73% – resulting in a reduction in patient numbers to approximately 60 individuals. This further reduces the total number of patients subjected to all five ‘do-not-do’ procedures from 1,451 to 1,289 and the fractional contribution of HBOT from the original 79% (4,659/5,888) to < 5% (60/1,289).

Of the 1,276 patients treated with HBOT Australia-wide according to HTNA data, 176 (13.8%) were for non-Medicare-funded indications.3 These figures are very different from the 4,500+ patients and 25% of HBOT that “should not happen” according to these authors.3 Further breakdown of this group reveals that the majority (131/176, 74.4%) were treated for indications which, whilst not currently Medicare-funded, are recognized as potentially amenable to HBOT by international professional scientific societies active in this field (South Pacific Underwater Medicine Society, Undersea and Hyperbaric Medical Society (USA) and European Committee for Hyperbaric Medicine),6–18 with the remaining 45 patients classified as miscellaneous/other. This last group would include patients participating in formal clinical research trials.

Amalgamating legitimate indications with non-Medicare-funded ones in the ‘do-not-do’ category is an error of sufficient consequence to single-handedly nullify the conclusions of this study.1,2 When combined with the confusion surrounding patient- vs. treatment-numbers (point 1) the incidence of ‘inappropriate’ HBOT falls to 1.3% (60/4,659) of that reported. A seventy-fold overestimation of effect size is of sufficient magnitude as to invalidate any paper and mandate retraction. Several further concerns about this paper are identifiable, but their effects are harder to quantify.

### Table 2

| Medicare-approved (MSAC) indications for HBOT in 2010–11* |
|-----------------|---------------|
| Decompression illness | 13020         |
| Air or gas embolism | 13015         |
| Gas gangrene | 2000         |
| Necrotising fasciitis and Fournier’s gangrene | 2003         |
| Diabetic wounds inc. diabetic gangrene and foot ulcers | 2000         |
| Prevention of osteoradionecrosis | 2000         |
| Treatment of osteoradionecrosis | 2003         |
| Soft tissue radionecrosis | 2003         |
| Refractory non-diabetic hypoxic wounds* | 2003         |

*de-listed in 2012 (MSAC)9

### 3. INTERNAL VALIDITY OF PRIMARY DATA SOURCE

The AIHW is the Government agency responsible for providing “reliable, regular and relevant information and statistics on Australia’s health and welfare”.19 Diagnosis and procedure data submitted to the AIHW’s hospital database are extracted retrospectively from individual patients’ medical records by clinical coders at each institution. The internal validity of this dataset however is questionable. Although self-proclaimed as a source of “Authoritative information and statistics to promote better health and wellbeing”,17 interrogation of the 2010–2011 Procedures Data Cube reveals unexplained discrepancies.3 A total of 17,326 instances of ‘Therapeutic Intervention 1888 Hyperbaric oxygen therapy’ were documented that year, but drilling down to the next level of data elicits only 15,485 episodes [15,278 episodes of code 13020-00 (HBOT duration > 90min, ≤3hr) and 207 episodes of code 13025–00
(HBOT duration > 3 hr)], leaving 1,841 HBOT episodes unaccounted for (10.6%).

Since the ACHI only provides three possible codes for HBOT it is tempting to assume that all missing episodes fall under the third code which, for reasons unknown, was omitted from that year’s data-cube.7,8 Unfortunately this assumption raises more questions than it answers. The third code, 96191-00 (HBOT duration ≤ 90min), only applies to HBOT sessions that are not routinely used in clinical practice. The estimated incidence of such abbreviated treatments (e.g., due to patient logistics, aborted HBOT because of ear-clearing problems, oxygen toxicity, etc.) is only ~2% (personal communications, all Australian hyperbaric facilities, 2015/2016). A significant fraction of the missing HBOT episodes in the AIHW dataset therefore remain unaccounted for.

4. EXTERNAL VALIDITY OF PRIMARY DATA SOURCE

The data for this study derived from information provided annually by State and Territory health authorities to the AIHW. Comparison with the annual activity data published annually by State and Territory health authorities to the AIHW. The data for this study derived from information provided by comprehensive hyperbaric facilities Australia-wide in 2010–11.7 Only 17,326 (64%) of these episodes were recorded in the AIHW dataset.8 Failure to capture over a third of the relevant information in this patient population appears to arise from two sources. First, the data only include admitted inpatients and exclude outpatients. Administrative systems vary between jurisdictions and facilities, with some hospitals providing HBOT as an outpatient service and others as a day-admission. Therefore, those providing HBOT on an outpatient basis are not included in this dataset. The second issue arises from uncertainty amongst coders about whether to record multiple HBOT sessions during a single admission as (a) multiple discrete episodes or (b) a cumulative intervention to be recorded only once. The rules governing this aspect of inpatient hyperbaric coding nationally were only clarified in March 2016.20 Our companion paper illustrates this problem.21 Of 22 inpatient admissions where > 1 episode of HBOT was provided (132 HBOT sessions in total), none recorded more than a single episode.21 The AIHW dataset therefore fails to reliably capture HBOT patients treated either as outpatients or as overnight inpatients – providing a semblance of reality for day-admissions only.

Even for the day-admissions, questions remain. AIHW data record 207 instances of HBOT of duration > 3 hr (code 13025-00) out of 17,326 total instances (1.2%).4 This duration of HBOT is only approved for use in Australia for decompression illness (DCI) or air/gas embolism (AGE).4,5 However, HTNA data only record 148 patients being treated with HBOT for DCI/AGE in 2010–11.3 No hyperbaric facility in the country routinely provides more than a single treatment of this duration to DCI/AGE patients, nor do they use such treatments for any other HBOT indication (personal communications, all Australian hyperbaric facilities 2015/2016). Hence, no more than 148 instances of code 13025–00 should be available for recording in the AIHW dataset. Comparing AIHW and HTNA datasets leads to the fractional incidence of this service falling from 1.2% (207/17,326) to < 0.6% (148/26,873). This halving of the incidence of this specific service is direct evidence of inaccurate data capture by coders.

Further doubt is cast upon the credibility of the AIHW dataset in our accompanying paper.21 Seventy percent of the HBOT patients treated at our institution in 2010–11 had one or more errors in their diagnosis and/or procedure codes as recorded by the hospital’s coders. Multiple discrete error types were identified, including (but not limited to): missing patients; missing treatments; ‘additional’ treatments; ‘additional’ patients, incorrect procedure codes and incorrect diagnosis codes. Incidental observations of surgical, anaesthetic and intensive care coding errors within this cohort confirmed that problems were not restricted to hyperbaric medicine.21 Although regional variations may exist, publications from other centres indicate that these problems are not unique to this institution or State.22

5. LACK OF CLINICAL EXPERTISE

Whilst not medically trained themselves, the Grattan authors claim that the clinical relevance of their ‘do-not-do’ list was evaluated by “a panel of general clinical experts and then a selection of specialists relevant to each treatment”.23 These experts are not listed in the MJA article, but some are acknowledged in the original Report.1,2 No-one with recognizable clinical expertise or qualifications in hyperbaric medicine are identifiable amongst those listed.22 This lack of relevant clinical input helps to explain the elementary flaws outlined above.

Many smaller details reinforce the impression that appropriate clinical input was not provided, including:

- Inclusion of irrelevant diagnoses in their ‘inappropriate’ code list – e.g., T59.7 “toxic effects of carbon dioxide”23
- Inclusion of irrelevant diagnoses in their ‘potentially legitimate’ code list (Table 3).23 Multiple codes including the words ‘necrosis/necrotising/gangrene’ have been
regarded as ‘potentially legitimate’, irrespective of their relevance to hyperbaric medicine. This confusion with approved diagnoses such as necrotising fasciitis, gas gangrene or diabetic gangrene demonstrates lack of appropriate clinical guidance. Similarly, T66 “radiation sickness” was included erroneously; confusing the life-threatening effects of acute radiation sickness with the chronic post-radiotherapy injury for which HBOT is approved. Perhaps hardest to explain however is the inclusion of Z29.8 “Other specified prophylactic measures, related to communicable disease, fluoride”.

* Footnote
A large table listing the Grattan Institute ‘do-not-do’ HBOT codes with descriptions is available on request from the authors or from the DHM office. Because of its size it was not possible to include it here.
measure (related to communicable diseases)", which covers the prophylactic administration of fluoride for dental health purposes (Table 3).

- **Omission of relevant diagnoses from their ‘potentially legitimate’ list.** Several pertinent codes for air or gas embolism are missing from their ‘potentially legitimate’ list, including those arising from obstetric or cardiothoracic causes (e.g., O88.0 “Obstetric air embolism”, O88.2 “Embolism following abortion and ectopic and molar pregnancy; air embolism”, P25.8 “Other conditions related to pulmonary air leak syndrome originating in the perinatal period; air embolism”, T81.7 “Vascular complications following a procedure, not elsewhere classified; air embolism”).

Likewise, the most appropriate code for patients undergoing HBOT to prevent osteoradionecrosis developing as a result of upcoming dental surgery, Z51.4 “Preparatory care for subsequent treatment, not elsewhere classified”, was omitted (Table 3).

- **Confusion of unrelated clinical conditions.** Several months prior to official publication of the MJA article and its underlying Grattan report, a near-identical ‘draft’ version of the Grattan report was circulated at high levels within relevant Australian Federal Government agencies.24 This draft lists "diabetic wounds and ulcers" amongst the ‘do-not-do’ indications for HBOT. Although subsequently changed to "non-diabetic wounds and ulcers" in the final version, the fact that misrepresentation of this condition as its exact opposite went undetected prior to dissemination of the report beyond the Grattan Institute further strengthens the impression of a lack of appropriate clinical involvement.24

6. MUDDLED METHODOLOGY

Soft-tissue radionecrosis (STRI) is clearly listed as a ‘potentially inappropriate’ indication for HBOT in the published MJA article.1 Curiously, it is not mentioned by name at all in the main Grattan report (which only alludes to “a range of conditions including osteomyelitis, cancer, and non-diabetic wounds and ulcers” in their ‘do-not-do’ list without specifying which, if any, other conditions were included).2 Scrutiny of that report’s separate methodological supplement however reveals that multiple STRI codes were included in their ‘potentially legitimate’ list (e.g., K52.0, “gastroenteritis and colitis due to radiation”; K62.7, “radiation proctitis”; N30.4, “irradiation cystitis” (Table 3).25 Without original source data, it is impossible to determine whether STRI was analysed as an ‘inappropriate’ or ‘legitimate’ diagnosis. In point 2, we have assumed that the MJA article (being the last-published and only peer-reviewed document arising from this study) provides the definitive answer, and STRI was analysed alongside NDHW as an ‘inappropriate’ indication. If, however, the MJA article is incorrect and STRI was analysed as a ‘potentially legitimate’ indication (per the methodological supplement) then the approximation in point 2 will be incorrect. The HTNA dataset included 659 patients who would be viewed as receiving ‘inappropriate’ HBOT by MJA-article criteria (219 STRI, 264 NDHW, 176 other). If STRI is removed, the proportion of their ‘do-not-do’ patients incorrectly identified as receiving ‘inappropriate’ HBOT fall from 73% (483/659) to 60% (264/440). Under these circumstances the number of patients potentially subject to ‘inappropriate’ HBOT increases by ~ 50%, from 60 (27% x 222) to 89 (40% x 222), but remains far short of the 4,500+ individuals claimed in the Grattan report.2

7. TRANSPARENCY OF METHODOLOGY

From 2011 onwards, the MJA stopped publishing full research articles and their associated references in print. The casual reader is, therefore, presented with a single-page, reference-free ‘executive summary’, and obliged to trust that the peer-review and editorial processes have appropriately assessed the veracity of an author’s assertions. The more interested reader needs to access the online edition to peruse the full article and supporting references. Even here, however, article word limits (2,500 words and 25 references for original research) work against full disclosure of all pertinent information.25 This issue is not unique to the MJA and many journals now provide the opportunity to include supplementary material in an on-line appendix. No such appendix was provided with this MJA article, nor was any reference made to supplementary material being available elsewhere.1 Therefore, even the interested reader was left with inadequate methodological information and data to independently verify the results. Similarly, an impression was created that the 23 listed references provided all the supporting information upon which the authors framed their original hypothesis and developed their methodology.

It is only by dint of a general internet search that the concerned reader might, eventually, identify the unreferenced, differently-titled and non-peer-reviewed Grattan Institute report upon which the MJA article was based.2 This 43-page document, written more as a political discussion document than an academic research paper, includes 106 references (only 13 common to the MJA article) but contains little additional methodological information. To locate this the most assiduous reader is finally referred to a separate 17-page methodological supplement containing a further six references (four new).25 The methodology however remains opaque as the ‘potentially legitimate’ and ‘do-not-do’ diagnoses and procedures are not defined in full. The (now exhausted) reader is confronted with a list of over 560 three- to seven-digit alphanumeric codes that are meaningless without access to the relevant coding manuals – currently available as a five-volume set for AUD490.00 (excluding GST) or in electronic format under licence through a registered institution.2,26 It is only upon ‘cracking’ these codes that many of the fundamental methodological issues described previously become apparent (*refer to footnote p.48).
8. USE OF REFERENCES

Further muddying the waters was the whimsical manner in which supporting documents were referenced. References are essential to the readership’s ability to assess the validity of an author’s claims. Several areas of inconsistency or concern were identifiable in this article:

In the Medical Journal of Australia:
Despite using only 23 of their available 25 reference slots, there is no reference to the source documents (Grattan Institute report and methodological supplement) in the peer-reviewed publication.1 There is no evidence that reviewers or editorial staff were aware of the existence of this supplementary material. In the absence of this knowledge the references listed in the MJA would appear to be the extent of the background evidence upon which the authors based their arguments.

The authors state that “(p)otentially ineffective treatments were drawn from published lists of, or recommendations about, inappropriate care”, but “(o)nly guidance published before our data period (2010–11) was used”.1 However, of their 23 references, 9 were published after these dates, including 3 of the 14 references apparently drawn upon to provide clinical guidance about the appropriateness, or otherwise, of various procedures.10,27,28 It was inappropriate to expect medical practitioners in 2010–11 to have applied the conclusions of these reports to their practice.

Of the 14 clinical references, only the three MSAC reviews described above (point 2) make any reference to HBOT, but only two of these were published prior to the study period.5,8,10 Their ‘do-not-do’ indications for HBOT were drawn from just the first, and the approval of HBOT for two further indications (STRI and NDHW) in the second was ignored – leading to their incorrect inclusion in this paper’s ‘do-not-do’ list.6,9 The third MSAC report, withdrawing funding of NDHW, was published after the 2010–11 period studied and was, therefore, irrelevant.10 This post-dated reference was also cited inaccurately, omitting the words “non-neurological soft tissue radiation injuries” from the title.1 Apparently intended to provide credibility to the MJA article, this document actually contradicts their assertions regarding STRI.18 It is curious that, if the authors deemed this document sufficiently important to include despite publication outside their selected timeframe, the dissenting report of the clinical experts on that third MSAC review (available on-line at the same Government website) was not also included amongst their references.29

In the Grattan Institute Report:
This document reiterates that “advice about more than 1200 treatments was publicly available during the period covered by our data” and “[f]indings published during or after our data period (2010-2011) were not used”.2 Of the 106 references listed, however, 38 were published during or after these dates, including 5 of the 31 references apparently drawn on to provide guidance about the clinical appropriateness of a given intervention.27,28,30–32

Of the 31 clinical references, only two contain any reference to HBOT. Closer scrutiny reveals that the second of these references is actually a duplicate, simply cited differently.2 Both citations refer to the original MSAC 1018–1020 (2000) report.9 No reference is made to the second (2003) or third (2011) hyperbaric-relevant MSAC reports and it would appear that these documents were subsequently added to the MJA article’s reference list as an afterthought.1 This omission could explain how STRI and NDHW ended up on the ‘do-not-do’ list. Likewise, duplication of the single HBOT-relevant reference and omission of the relevant 2003 report from the Grattan document, together with the inclusion of the two later MSAC reports in the MJA article (even if they were not used), make it appear that the supporting evidence base was more comprehensive than was actually the case.

In the Methodological Supplement:
Of the six references listed in the Grattan Institute’s methodological supplement, four are new.23 Only one of these was published prior to 2010–11. This is the 2004 Cochrane review of HBOT for chronic wounds.33 This systematic review reported no compelling evidence of benefit in wounds of non-diabetic aetiologies and concluded that “the routine management of such wounds with HBOT is not justified by the evidence”. This is a critical issue as, in Australia, HBOT has never been a routine therapy for NDHW, but rather a ‘salvage’ intervention when standard care has failed. This appears to have been the only hyperbaric-relevant reference, other than the initial 2000 MSAC report, utilised by the Grattan authors.

Extensive use of secondary sources (review articles) was made to guide decisions in the Grattan Report. This might be appropriate for non-clinicians, since they would lack the requisite skill-set to meaningfully appraise the primary studies themselves. However, failure to consult primary sources is an increasing problem even in clinical circles, as thousands of new articles are published each month. This increasing dependence on secondary sources comes at significant cost. With so much primary research being published, secondary articles rapidly become progressively less relevant. The Cochrane review referenced in the Grattan’s methodological supplement illustrates this point. Five clinical trials were reviewed in 2004, but by the time the next version came out (2012) there were nine trials to include.33,34 All four of the new trials were published before or during 2010–11 and could reasonably be expected to have influenced clinical practice during the study period.

Although many of the primary studies upon which the secondary-source authors based their recommendations were published prior to 2010–11, backtracking to the primary studies upon which the Grattan articles’ references were based reveals many that were still subject to robust scientific
debate amongst clinicians and should not have been used as the basis for definitive statements on the legitimacy of a given therapeutic intervention. Furthermore, secondary sources provide filtered information that cannot always be assumed to be free of bias. By selecting reviews that support their own agenda, whilst omitting those that do not, authors of tertiary studies such as this *MJA* article can (intentionally or otherwise) obscure the original science, with all its limitations, behind layers of superposed opinion to provide ‘definitive’ advice which will ultimately prove to be incorrect.

Recommendations that “*the Australian Commission on Safety and Quality in Health Care publishes up-to-date do-not-do lists*” and that “*the Commission should review them at least every two or three years*”\(^2\) whilst superficially appealing, are likely to prove unworkable in practice. Such lists become obsolete long before their next planned update (denying patients timely access to the latest developments in medical care) and the costs of the bureaucracy required to comprehensively review every indication for every procedure in the *MBS* every two to three years would likely dwarf any potential cost-savings accruing from whatever restrictions they might recommend. Furthermore, since those who are best placed to appropriately interpret new research are those with the greatest training and experience in the relevant field, such guidelines would require the diversion of limited clinician resources away from direct patient care, further compromising health outcomes.

### 9. TEMPORAL MISREPRESENTATION

The timeline confusion described in point 8 is not restricted to use of reference material but carries over into the discussion. Assertions that “*the procedures used here as examples have either been shown in academic studies to be inappropriate or are recommended against in guidelines, or both. What we have shown is that, despite this advice, and even defunding in the Medicare Benefits Schedule, the procedures are still being performed*”\(^11\) appear disingenuous when it is realized that this 2015 paper was based on 2010–11 data and that the defunding of NDHW in the *MBS* did not occur until November 2012.\(^10\)–\(^14\) Current practices cannot be inferred from five-year-old data when the regulations governing those practices have changed in the interim.

### 10. REGIONAL VARIATION

Tasmania was illustrated as the most remarkable outlier by State, with a rate of ‘do-not-do’ HBOT ten times higher than any other jurisdiction.\(^2\) This figure was not consistent with our knowledge of local hyperbaric medicine practices and required explanation. Tasmania has only a single comprehensive clinical hyperbaric facility and we, its medical co-directors, have an obligation to our patients, colleagues, funding bodies and the broader community to detail the multiple issues that negate this study’s conclusions.

In Tasmania, the Royal Hobart Hospital hyperbaric database reveals that 1,734 individual hyperbaric treatments were provided to a total of 100 patients in 2010–11. Of those, 1,613 (93%) were for Medicare-approved indications in a total of 87 patients, and 121 treatments (7%) in 13 patients were for non-Medicare-funded indications.\(^21\) These figures compare favourably with HTNA data, which demonstrate a national average of 13.8% of patients being treated for non-Medicare-funded indications.\(^3\) Of these 13 Tasmanian patients, nine were provided with HBOT as an emergency life-, limb- or sense-saving intervention for indications recognized as potentially amenable to HBOT by the international scientific societies mentioned previously, and for which no alternative treatments with higher levels of supporting evidence were available. Clearly identification of Tasmania as an outlier is erroneous.

Multiple reasons for regional variation in the provision of HBOT have been identified previously.\(^35\) Disease prevalence, chamber logistics, Health-service administrative systems, local geography and population distribution relative to the regional hyperbaric facility all contribute to such variation. It has been suggested that rather than demonstrating inappropriate over-utilization in high treatment-rate locations this variation is potentially indicative of unmet need in lower treatment-rate regions.\(^35\) However, the importance of administrative systems in that article was limited to the potential for bureaucratic territoriality to hinder patient flow across health-service boundaries.\(^35\) This issue is not encountered in Tasmania, with its single health service. However, administrative systems can also create factitious variation between regions. As discussed in point 4, hospitals providing HBOT on an outpatient rather than a day-admission basis were not included in the AIHW dataset. Furthermore, our forthcoming companion article illustrates that regional variation in coding error-rates may also exist, varying from 25 to 70% in different locations.\(^21,22\)

Researchers have an ethical obligation to apply due diligence and ensure their data validity prior to publication. Identification of outliers (if genuine) can be an important source of progress in scientific research, informing new directions of enquiry. The authors of the *MJA* paper do not describe what, if any, steps they took to confirm data.
validity. It may be that they accepted AIHW at face value as a source of “(a)uthoritative information and statistics”.35 However the presence of such dramatic outliers as Tasmania should have triggered a cross-check of data validity against other available data sources. Even basic cross-referencing against other (albeit incomplete) Government datasets would have alerted the authors to re-examine their source data. Medicare data, for example, demonstrate major regional inconsistencies in HBOT use when compared against AIHW figures. Of 15,579 hyperbaric treatments billed nationally to Medicare in 2010–11, only two were from Western Australia – several orders of magnitude fewer than in the AIHW dataset.36

11. FINANCIAL IMPACT

The methodological supplement uses data from the Independent Hospital Pricing Authority (IHPA) to estimate the average cost of their various ‘do-not-do’ procedures. The IHPA is the Government agency responsible for determining the “National Efficient Price” for public hospital services.37–40 The Grattan authors’ analysis of these data reported an average cost for HBOT in 2010–11 (adjusted to 2014–15 dollars using the IHPA’s indexation rate of 4.7%) of $1,298.23 This figure approximates the IHPA’s own published cost of $1,445 for 2010–11.37 However, that year was an outlier in the IHPA data, with an average cost more than three times greater than the previous (AUD479) and succeeding years (Table 4).37–40 It is ironic that the Report utilized a financial outlier as source data whilst seeking to eliminate clinical outliers. Whether this profound variation reflects a typographical error or a deeper issue (e.g., alteration in data collection or statistical analysis) is unclear. It was appropriate that the authors used IHPA data for the relevant year, but use of this non-representative figure leads to a significant overestimation of the cost of ‘inappropriate’ HBOT.

A more realistic service price of $501.50 (the average of the other four years’ publicly-available IHPA data) for HBOT is 6–8 times lower than their calculated costs for the ‘do-not-do’ surgical procedures (vertebroplasty, arthroscopy, uterine nerve ablation) they assessed (AUD3,252–4,412).23 This failure to compare like-with-like calls into question the author’s claims that “(w)e identified in just five examples more than 5,000 unnecessary procedures happening every year. This means there are probably 5,000 people who need surgery who aren’t getting it”.41 Statements to the media of this nature seriously misrepresent the financial reality.

12. PUBLICATION STRATEGY

Of particular concern is the manner in which the authors chose to disseminate their questionable results. A draft version of the Grattan Institute report was circulated “for discussion purposes” in policy-influencing circles several months prior to general publication.24 The final version of this report was then published on-line, together with an associated media release, the day prior to publication of the peer-reviewed MJA article.1,2,42 These actions appear to contravene the MJA’s publication requirements, which state: “Manuscripts and letters must be offered exclusively to the Journal. This means that all submissions should not be submitted simultaneously to other journals nor made available to others, including news reporters, while they are being considered for publication in the MJA. This embargo continues up to 12.01 am on the day of publication for all submissions that are accepted”.25 A co-ordinated multi-media campaign then started before sunrise on the day of official MJA publication.41,43–47 This strategy pre-empted broader clinical scrutiny of their paper and undermined legitimate scientific debate. The time and resources necessary to disprove spurious generalizations (based upon misinterpretation of unrepresentative data by individuals disconnected from the provision of clinical care) would be better invested elsewhere.

Conclusions

This review identifies major concerns about this Grattan Institute report. Confusion of basic terminology, inappropriate selection of ‘do-not-do’ indications, lack of appropriate clinical input, muddled methodology, compromised data sources, retrospective application of post-dated references, use of non-representative financial information and a publication strategy that undermines the established scientific peer-review process all combine to invalidate its conclusions. We have not analysed their other ‘do-not-do’ treatments, but the errors identified from HBOT alone are of sufficient magnitude to necessitate withdrawal of this paper.

Impetuously embracing the results of a dramatic new study, no matter how worthy its intentions, is unwise before it is subject to appropriate scrutiny and debate. Calls to enforce a particular agenda with punitive measures are premature if the data upon which that agenda was predicated are flawed. The Australian public have a right to expect that the health economic data used to support disinvestment in healthcare are as robust as the clinical evidence necessary to support applications for new investment. A level playing-field must exist in debates of this importance to the nation’s health.

The underlying assumptions of the Grattan Institute Report are incorrect, its data source compromised, its methodology problematic and its conclusions erroneous. If the Grattan Institute wishes to regain academic credibility, the MJA paper and its underlying report must be formally retracted.

References


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Declaration of interests:

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