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Citizens' perspectives on disinvestment from publicly funded pathology tests: a deliberative forum

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Keywords: disinvestment; deliberative methods; pathology testing; evidence-based health policy

Running title: Citizens' perspectives on disinvestment

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Abstract **[First-level Header]**

Objective: Deliberative forums can be useful tools in policy decision making for balancing citizen voice and community values against dominant interests.

Methods: A deliberative forum of citizens was convened in Adelaide, South Australia to develop criteria to support disinvestment from public funding of ineffective pathology tests. The case study of potential disinvestment from Vitamin B12/folate pathology testing was used to shape debate. The forum was informed by a systematic review of B12/folate pathology test effectiveness and expert testimony.

Findings: The citizens identified seven criteria: cost of the test, potential impact on individual health/capacity to benefit, potential cost to society, public good, alternatives to testing, severity of the condition and accuracy of the test. The participants saw these criteria as an interdependent network but also questioned "the authority" of policy makers to make these decisions.

Conclusions: Coherence between the criteria devised by the forum and those described by an expert group was considerable, the major differences being that the citizens did not consider equity issues and the experts neglected the 'cost' of social and emotional impact of disinvestment on users and society.

Introduction [First-level Header]

Increasing expectations from patients, in combination with highly-marketed expensive or high-volume biomedical technologies, place pressure on health systems globally.(1) In this environment, decision making can be found wanting if effectiveness, budget impact and safety are addressed with inadequate attention to public acceptability and priorities.(2, 3) Public participation is increasingly relevant in development of health policy, including the assessment of new and existing health technologies, services and programs.(4-9)

Within health technology assessment, rigorous science-based knowledge is mostly undisputed and seen as unbiased and objective (10-12) whereas experiential and values evidence provided by patients and lay citizens tends to be seen as subjective and potentially biased. This 'demarcationist model'(13) presumes that lay citizens do not contribute relevant knowledge and experts and decision-makers do not contribute values to decision making. Contemporary epistemological debates challenge the demarcationist model, arguing that normative assumptions and science knowledge are co-constituted, and that experts and non-experts alike reason using both knowledge and normative assumptions.(10, 12, 13) Public deliberations, where participants consider the realities of health policy development, can be conceptualised as collective processes of inquiry maximising mutual learning and accountability within and across expert and non-expert groups.(13)

Deliberative forums provide unique opportunities for 'ordinary' citizens to engage in informed deliberation, be exposed to the perspectives and experience of others and reach consensus on recommendations for action.(1, 4, 8, 14-17) Public deliberations, employing disinterested non-expert contributors, can make explicit non-technical barriers and facilitators to health care policy.(18) As such, they balance the perspectives of dominant interests with those of less powerful citizen stakeholders.(9, 13, 19)

This paper describes the use of a deliberative forum to explore community perspectives on a complex health problem - disinvestment. 'Disinvestment' is "the process of (partially or completely) withdrawing health resources from any existing health care practices, procedures, technologies or pharmaceuticals that are deemed to deliver little or no health gain for their cost, and thus are not

efficient health resource allocations".(20, p.2) More recently, disinvestment has been rebadged as 'choosing wisely' , 'reappraisal' or 'reprioritisation' in the lifecycle of technologies.(21) Disinvestment evaluates existing health care services to redirect funding away from areas of potential inefficiency.(9) As such, disinvestment presents scientific, political and ethical challenges: in particular, stakeholders may be vested in current practice and such proposals may challenge long-held beliefs and put livelihoods at risk.(22) Some pathology services exhibit characteristics, such as low test accuracy and wide variability in test use, which suggest they may be candidates for disinvestment.(e.g. 23) In particular, Vitamin B12 pathology testing has highly variable diagnostic accuracy and across laboratory sites inconsistent cut-off values are used to define deficiency. In addition there are geographical differences in test use, indications of usage outside guidelines and combined serum B12/folate testing grew rapidly, with an annual growth rate in excess of 20% between 2000 and 2010.(23) Pathology testing, as a whole, grew in excess of any other medical activity within the Australian health system.(24)

The deliberative forum reported in this paper aimed to incorporate community values in the development of criteria to support potential disinvestment from public funding of ineffective pathology tests. A case study of Vitamin B12/folate pathology testing was used to shape debate.

Methods **[First-level Header]**

The research is part of the ASTUTE health study which, using HTA methods and deliberative democracy, developed, trialled, and evaluated a model to integrate normative and scientific evidence for disinvestment from health services with questionable safety, effectiveness and/or cost-effectiveness profiles.(9) ASTUTE also conducted deliberative forums with primary care physicians, pathologists(25) and federal government policy advisors. Findings from ASTUTE were fed back to policy advisors.

Deliberative process [Second-level header]

The forum was held over a weekend in Adelaide, July 2011, during which a general medical practitioner, epidemiologist, health economist and pathologist presented information and responded to participants' questions. The evidence provision reflected an evidence-based approach in keeping with the format for the forums with clinicians and policy advisors.(9, 25) An independent facilitator was engaged but withdrew due to ill-health. A research team member, with qualitative research expertise, undertook the facilitation task. A court reporter provided immediate verbatim identified transcription of forum proceedings. The forum participants were asked the following questions: (1) What things should be considered when making decisions about how much we should publicly subsidise B12/folate pathology tests? (2) Who should be involved in deciding which pathology tests are publicly subsidised? The forum schedule is provided [on-line](#).

Commented [JMS1]: Reference needed to location of supplementary material

Recruitment of community forum participants [Second-level header]

Using stratified random sampling, jurors were recruited by an independent recruitment company from a database drawn from a state-wide survey.(26) Sixteen participants were recruited to fulfil gender, age and household income criteria but five withdrew prior to the forum. One female participant did not return on day two, leaving 10 participants. An honorarium of \$200 was provided.

Theoretical perspective and approach to analysis [Second-level header]

Our analysis drew on realist approaches to discourse analysis particularly thematic analysis described by Braun and Clarke.(27) Transcripts were coded independently by two authors (PC & JS), with ongoing discussions throughout the analytic process.

Findings [First-level Header]

The makeup of the forum mostly fulfilled the recruitment criteria: half were male, age ranged 20-66 years (median 41.5 - Australian median age is 36.9) and four participants had a weekly household income less than \$800 (median Australian household income).

The citizens identified seven criteria, four primary and three secondary. (Table 1) In doing so, they drew not only on the evidence provided in the forum but also on their experience and understandings of medical care provision and community values.

Cost of test [Second-level header]

Participants agreed that the cost of the test was a central point to consider for potential disinvestment, although discussion focused on high item test cost or high overall budgetary impact rather than high cost by volume per se.

P8: I don't think anyone else is saying cost in and of itself would be one factor in isolation that we use, you would weigh it up. [sentence omitted] With a finite amount of resources the cost of every individual test surely is significant, surely has some bearing on your decision making about whether you are going to fund or not.

Participants traded cost against potential outcomes, including accuracy of the test or as the following extract demonstrate the severity of the illness:

P11: Cost versus potential outcome. If you are spending a thousand dollars testing for something, which could have dire consequences for somebody, yes; maybe it's worth it. If you are spending \$10 on a test for a nosebleed or something, who cares?

Potential impact [Second-level header]

a) Potential for benefit

Participants linked disease severity, potential life years gained and overall capacity to benefit. High potential for benefit was constructed as worthy of funding, with the value of quality of life improvements frequently given equal footing with extension of life.

P5: I put down quality of life. So is having the test and subsequently having the treatment, did that prolong their life? Is it going to make their life better?

Participants focused on capacity to benefit for specific subgroups, including vulnerable groups. In doing so they drew on their understandings from interventions for seasonal influenza vaccination. Participants rated access by high risk patient subgroups highly since those subgroups would benefit most from testing thereby improving test accuracy or 'hit rate'. Equity arguments per se were not used to justify these choices.

P2: Depending on the disease, depending on who is more prevalent to actually get that type of disease ... Obviously you are going to want to have a hit rate that is going to be higher than just the broad community. For example, the flu, they say they give it to the young, the elderly because they are the ones that are going to be more affected by that particular type of thing.... You have to look at the big picture of who would get the best benefit out of having the test.

In contrast, lifestyle choice, for example, the role of a vegan lifestyle in Vitamin B12 deficiency, even though the individual may have high capacity to benefit, was constructed as a possible restrictive condition on eligibility. Participants disagreed on this issue: some participants argued that restricting funding in this way was discriminatory but there was little disagreement about the need to protect those without choice. One participant summarised a stance that all supported:

P2: ... this child is displaying those symptoms, being born by a vegan parent, to me that would be an automatic inclusion. It's something they haven't chosen.

b) Cost to community of not testing

In addition to examining the individual test cost, attention was paid to the potential ongoing *cost to the community of doing nothing*. Participants recognized that the cost of not doing a test could be catastrophic for individuals and also very costly for society particularly in the long term. .

P8: ... we thought it was important because it was investment in saving money down the track possibly

[Two lines removed] P1: preventative rather than cure

Community impact was directly linked to disease severity, with ongoing emotional and financial cost for families highlighted, with one participant drawing on their understanding of the impact of spina bifida:

P3: The example I was thinking of was spina bifida. The folate test, spina bifida could be prevented apparently and if you have someone with spina bifida. It's that person's life ruined, and probably their family, extended family. There's cost of care, wheelchairs, ramps, ongoing medical; the cost never ends, whereas the initial test would have hopefully prevented that.

The participants engaged with the potential for community impact broadly: for example, Vitamin B12 deficiency was seen as having less potential for community impact than folate deficiency and therefore, as the following quote indicates, the imperative to fund the associated diagnostic test was less.

P9: if you don't have the [serum Vitamin B12] test and you aren't treated for it, it still affects that person in a negative way but not to the point that it is going to impact the community heavily.

c) Public Good

As shown above, public good was frequently prioritised over individual benefit in many of the arguments raised by participants. Risk to others, particularly with respect to infectious disease diagnosis, was seen as a special case because of potential impact on the broader community. This criterion intersected with the criterion, cost of service, since participants saw the impact would be to amplify overall cost:

P2: ...if someone has an infectious disease and it's not brought to the attention of that person or other professions, they are going into the community and they are going to infect so many more people, then they are going to have to go through the same process with the same costings and that costing gets blown out...

Alternatives to testing [Second-level header]

The participants all agreed that having 'alternatives to testing' was an important criterion. They primarily focused on inexpensive non-invasive alternatives, including education and over-the-counter medications. One forum member suggested preemptive treatment may be a solution:

P9: If you can identify suitably with a range of symptoms that you have a certain disease without the test and you can try to treat it beforehand, I think, then performing the test itself is a waste of time and money.

whereas another proposed more emphasis on prevention:

P8: ...how many of us wear a hat when we go outside on a 30 degree day? How many of us wear sunscreen and how much [sic] wear long sleeve tops when it's hot? That is an alternative. Rather than testing for skin cancer, the alternative was to provide communication, at a government level, about slip, slop, slap. I would argue that actually may have been more effective than doing lots of skin cancer tests.

Disease severity [Second-level header]

The severity of the illness and therefore its potential community impact played a crucial role in participants' understandings of whether or not a test should be funded.

P3: It depends on the disease. If it's flu, flu goes through the community. If it's Ebola that is really going to do harm, you have to be more aggressive.

Participants related degree of disease severity and seriousness of the treatment to test accuracy. The extract below is an example of how participants reasoned that more burdensome diseases and treatments might require greater test accuracy if they are to be funded.

P4: Just expanding on that, you would want to test if you are going to lose a kidney over it, you would want it to be extremely accurate. While a test, say for [Vitamin] B12 really the treatment is not

invasive, the treatment is not painful; we can afford a bit more of a gap in the accuracy because it's not going to harm the person...

[4 lines excluded]

P8: *I think there should be minimum accuracy across the board...*

[2 lines excluded]

P11: *That makes sense. With the common diseases with no great consequence, your accuracy would not have to be as great as for the more serious...*

Accuracy [Second-level header]

Accuracy (which might be more broadly construed as efficacy) was included as one of four primary criteria to consider for disinvestment decisions but was rarely considered in isolation from the other criteria. In the following extract accuracy was coupled with disease severity in deciding which of two tests should be funded:

P1: I think for me, I'm thinking of a couple of examples where you can say there are two tests, one is extremely accurate and expensive, one is less accurate and expensive, there may be some circumstances where you want the less accurate one because you are saving resources, money.

[7 lines omitted]

P2: Depends on the consequences of the result. If you have got a disease that is far more serious, you are going to want it to be as accurate as possible...

In general, less accurate tests were not considered financially 'worthwhile'.

F: *... What do we need to know to feel this is accurate enough that we are going to put money behind it and fund it?*

P5: *It has to be worthwhile.*

P4: *It can't be hit and miss.*

Test accuracy was constructed both in terms of financial cost and health system impact but also emotional toll on patients as this participant indicated:

P4: Accuracy for the false positive, what would be the impact on this person once this test is run... with the false positives? How angry would those people be.... and the financial implication of that.

F: We'll break that down into the impact on the patient of those false positives.

P4: It's not just the patient; it's the impact on the health system.

Futility [Second-level header]

Futility was not included in the list of criteria but some participants argued that, without appropriate treatment, spending money on diagnostic tests was a waste of money and would adversely impact on 'quality of life' whereas others described the social value of a diagnosis. Interestingly several participants saw a diagnosis without the possibility of treatment as a 'personal choice' and therefore falling outside the scope of government funding as the following interchange demonstrates:

P6: ... Why would you want to ruin your quality of life up to the point where you do die, knowing you are going to die of something they can't fix. You may as well die of something they can't fix and enjoy the time

P3: I would like to know

P6: I'm just putting it out there

F: At a policy level that is a question we have to ask. Are we happy to put money into something that just does that; that just lets you know you have this amount of time before you die?

P8: We could spend that amount of money into research into it

P2: That is what I am saying, it's a personal decision whether you want to have that defined answer or not. Why would you want to fund that when that is a personal thing? If they want to know, that's fine, they can have the test...

P6: The question is whether you would subsidize that test

P2: Yeah, I don't think you would subsidize something like that because I think that is a personal choice

Network of criteria [Second-level header]

The participants did not treat their derived criteria as discrete entities. Rather, trade-offs were made continuously, with participants' reasoning forming a network of criteria which they used to justify recommendations. The participants themselves were acutely aware of this: many participants commented that the exercise was difficult because the criteria could not be considered in isolation from one another:

P1: ... these things are not stand alone. You would have to take them all together. If you found that a test was very cheap but not very accurate, you'd have to weigh that against a test that was more expensive but extremely accurate. You couldn't just take one principle by itself; you had to look at all those principles. We felt that whatever five priorities we picked up we couldn't just go through a standard single checklist for that particular item, there'd have to be a relationship between the two.

The nature of disinvestment [Second-level header]

Beyond developing a set of criteria, participants also engaged with the nature of a potential disinvestment process. Some participants questioned whether policy makers had "the authority" to make these clinical decisions or whether the responsibility should lie with GPs either supported by "a set guideline" or monitored through auditing. Others considered this meant the situation would not change and the problem would continue. Tighter guidelines or descriptors for administering the test were seen as potential ways of disinvesting, along with education and treatment strategies which would avoid the need to test.

P8: ...you would run through a checklist of things and not that you would ask every person in every instance to go and do all those, go and take a vitamin supplement first. But it might narrow down and it may determine – I don't know if this is possible...

The 'checklist' for a test was seen as a way of supporting GPs to disinvest from relatively ineffective technologies:

P8: Having that checklist takes some of the pressure off the doctor who can say "look sorry, I can't write out that particular test for you because you haven't met this criteria and that is the national standard".

Partial subsidies were proposed for tests which might be considered futile or where the condition might be due to lifestyle factors. The following quote discusses a GP-patient encounter and a possible response to a patient who might be B12 deficient because of dietary choices.

P8: If you have had six questions and they are questions about what types of food you eat things like that, and the patient answers the question in such a way you go, "I'm not surprised" you might consider if they get a full subsidy of the test or a partial subsidy.

Some participants considered that assessing individual tests in isolation was not the best approach for containing health care costs.

P2: we have this big pool of money to cover all funding of all tests. ... I'm saying we should be doing [them] relative to each other. If we have a whole group of tests, if we try and bring our budget down, have a group of tests that come under the same kind of classifications, what one should be saying, is [one] more important than another.

Discussion **[First-level Header]**

Citizens engaged successfully in complex deliberation on a low profile technology, indicating that deliberative engagement is possible for issues that may be seen as comparatively banal, as they sit outside the big moral topics which normally form the basis of deliberative exercises (e.g. public funding of genetic testing or nanotechnologies).(8)

Coherence between the findings of the forum and an expert-derived list of criteria described by Elshaug et al. (28) is considerable, although the forum recommendations were presented using different language and focus. The cost of service or test, potential impact in terms of likely health impact, capacity to benefit and cost effects, cost-effective alternatives such as prevention and disease

burden in terms of disease severity, all find their place in non-technical language within the community forum's criteria.

The major differences between the list generated by the citizens' deliberative forum and the experts' framework are shown in Table 1. In particular, the forum failed to consider equity whereas, unlike the expert's framework, they did consider 'cost' of social and emotional impact of disinvestment on users and society. The absence of the latter in the experts' framework could be seen as a major omission. Reflecting their role as potential recipients of these services, the forum participants often put themselves in the recipient's position to justify chosen criteria. They also focused, however, on overall community good and societal impact, sometimes at the expense of individual patient well-being, and, perhaps as a consequence, they failed to incorporate considerations of equity into their recommendations. The participants also indicated that they saw the criteria not as discrete entities, but as an interconnected network. In particular, accuracy played a pivotal role for the participants in understanding whether or not a test was worth funding, and other factors, such as cost and severity, were reasoned in relation to test accuracy. This is not unreasonable since test accuracy is the first line in evaluation of a diagnostic test: if a test is not accurate, testing cannot be efficacious.(29)

There are similarities between our study and a citizens' jury (16) used to develop criteria applicable to investment decision making for new health technologies in Canada. Despite examining quite different technologies, using a more traditional jury format and looking at investment rather than disinvestment, the criteria proposed in the Canadian citizens' jury were similar to those described in our forum. There were differences, however, in the level of priority accorded to the chosen criteria. In particular, the Canadian jury prioritised first those technologies with potential to benefit many. This would equate to our forum's secondary criteria of potential for public good. Other prioritised criteria in both studies included enhancement of quality of life (over extension of life span) and the lack of viable alternatives. The Canadian jury concurred with the forum in this study, that future costs associated with not funding a technology were important. They differed on the importance of technology unit cost – the Canadian jury indicated this should never be a funding criterion whereas the Australian forum described this as an essential item for consideration.

Participants' concerns about policy makers' authority in disinvestment echo senior health policy stakeholders' own experience in negotiating "political sensitivities associated with...overt restrictions on clinical autonomy and patient choice".(20) The forum participants, in common with Australian policy makers,(20) saw the need for coupling cost with quality of care in disinvestment decision making. Given these shared concerns, attention to the use of language and reasoning by the forum may help policy makers better engage in conversations about disinvestment in the broader community.

Limitations [First-level Header]

Forum participants were not provided with information about the political barriers to disinvestment, including falling community trust in government, nor were relevant ethical arguments brought to their attention. This may have impacted on the nature of the recommendations and, in particular, their inattention to equity issues. Thus, the deliberations cannot provide guidance to policy makers on how to manage the political aspects of disinvestment which will be important to overcome the inertia inherent in the system.(28) These issues were not discussed with the forum. In addition, the short time for deliberation and the absence of a truly independent facilitator may have compromised the ability of the participants to deliberate.(8) Although the final forum, fulfilled most of the recruitment selection criteria, diversity in the forum may have been compromised by the high drop-out rate.(8)

Conclusions [First-level Header]

Participants in this study identified issues important to citizens but neglected in the technology assessment process including the societal impact of funding or not funding a technology and the social and emotional fall-out from inaccuracy in a test reading. They also placed greater emphasis on the importance of public good than on individual benefit.

Taxpayers are a significant force in the broader polity and, as such, their informed values, garnered in considered deliberation, deserve respect as well as potentially providing a bulwark against vested

interests of other stakeholders. This study demonstrates lay citizens can participate in deliberations which form the basis of decision making for health technology assessment even where the technologies have low public visibility. The ability of the forum participants to generate criteria that have universal resonance supports the use of deliberative processes for the full range of health technologies not only those which hold high public value and interest.

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Table 1. Criteria to inform the prioritisation of candidates for detailed review and potential disinvestment	
Expert criteria (Elshaug et al., 2009, (25))	Lay citizen criteria from jury
<p>Cost of service: High cost per procedure (e.g., high item cost of the Medicare Benefits Schedule or Pharmaceutical Benefits Scheme), high cost by volume, or an aggregate of these.</p>	<p>Cost of test (secondary): High cost per procedure with little emphasis on cost by volume although the overall cost was an impetus for action. The participants traded cost per procedure against the cost of doing nothing, the potential value associated with possible outcomes, the availability of alternatives and the potential for waste if the item were funded.</p>
<p>Potential impact:</p> <ol style="list-style-type: none"> i. Likely health impact (e.g., crude estimate of quality-adjusted life-years lost per patient). ii. Likely cost effects (e.g., 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). iii. Overall assessment relating to the maintenance of equity in care should this health care intervention be displaced (e.g., access by patient sub-groups). 	<p>Potential impact</p> <ol style="list-style-type: none"> i. Potential to benefit (secondary)- severity of health condition linked to potential life years gained and potential for improved quality of life and/or extension of life. Possible exclusion where the condition is related to lifestyle choices. ii. Cost to community (not patients) of not testing (primary) – financial cost to the health system as well as ongoing financial and emotional cost to individuals and families. iii. Public good (secondary): in terms of preventing contagious/infectious

	disease and improving quality of life
Cost effective alternative: When a cheaper but more, or equally, effective alternative exists, is identified or emerges.	Alternatives (primary) : Including education, prevention and alternative treatments
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.	Severity (primary): with respect to both the individual and the community
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.	Accuracy (primary but always considered in relation to other criteria) Accuracy is related to severity of disease and relative to other tests
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.	This area was not discussed by the forum
Futility: An intervention that is highly unlikely to result in “meaningful survival” or benefit. 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.	Futility – Although futility was not one of the final criteria, some participants deemed as futile testing where there was no potential for effective treatment whereas others described the value of a diagnosis.