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**Article:**

Michaels, J. orcid.org/0000-0002-3422-7102 (2021) Potential for epistemic injustice in evidence-based healthcare policy and guidance. *Journal of Medical Ethics*, 47 (6). pp. 417-422. ISSN 0306-6800

<https://doi.org/10.1136/medethics-2020-106171>

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**Title:** The potential for epistemic injustice in evidence-based healthcare policy and guidance

**Running title:** Epistemic injustice in healthcare policy.

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### **Keywords**

Rationing of healthcare, distributive justice, epistemic injustice, evidence-based guidelines, health outcomes, epistemic exclusion, equity.

**Word count: 5013**

**Funding:** No funding was received for this work

**Competing interests:** Jonathan Michaels has no conflicts of interest

**Contributorship:** All aspects of the work were undertaken by the sole author

## **Abstract**

The rapid development in healthcare technologies in recent years has resulted in the need for health services, whether publicly funded or insurance-based, to identify means to maximise the benefits and provide equitable distribution of limited resources. This has resulted in the need for rationing decisions, and there has been considerable debate regarding the substantive and procedural ethical principles that promote distributive justice when making such decisions. In this paper I argue that, whilst the scientifically rigorous approaches of evidence-based healthcare are claimed as aspects of procedural justice that legitimize such guidance, there are biases and distortions in all aspects of the process that may lead to epistemic injustices. Regardless of adherence to principles of distributive justice in the decision-making process, evidential failings may undermine the fairness and legitimacy of such decisions. In particular, I identify epistemic exclusion that denies certain patient and professional groups the opportunity to contribute to the epistemic endeavour. This occurs at all stages of the process, from the generation, analysis and reporting of the underlying evidence, through the interpretation of such evidence, to the decision making that determines access to healthcare resources. I further argue that this is compounded by processes which confer unwarranted epistemic privilege on experts in relation to explicit or implicit value judgements, which are not within their remit. I suggest a number of areas in which changes to the processes for developing, regulating, reporting and evaluating evidence may improve the legitimacy of such processes.

## **Background**

Healthcare technology has developed rapidly in recent years, with escalating costs for new drugs and other diagnostic or therapeutic technologies. Demand for potentially beneficial healthcare has outstripped the supply, resulting in the need to ration limited resources. Where this occurs through informal mechanisms that restrict access to certain services, there may be overt distributive injustices due to differential access on the basis of socio-economic, geographic or demographic factors. However, where government bodies, healthcare providers or other agencies, develop evidence-based guidelines or policy, part of their role may be seen as ensuring that any rationing decisions are made on a just basis.

The requirements of distributive justice may be met by adherence to underlying substantive principles based, for example, on fair equality of opportunity,[1] maximising cost benefit,[2] or a capability approach.[3] Such principles may be in conflict, or may result in indeterminacy, and adherence to the principles of procedural justice has been suggested as an alternative or additional requirement. Commonly, the implementation of procedural justice refers to the four principles of accountability for reasonableness (AFR); transparency of the process, relevance of the decision criteria, potential for challenge and revision, and a regulatory framework.[4]

Substantive principles and procedural justice are not mutually exclusive but overlap, with claims of relevance usually involving reference to substantive principles.[5]

Whatever substantive or procedural principles are applied, the fairness and legitimacy of evidence-based guidance and policy rely on the accuracy and validity of the underlying evidence. In this paper I argue that 'evidence', as it is understood and used in such processes, is not restricted to research-based knowledge that provides the best estimates of the benefits, risks and costs of treatment. Rather, it includes implicit

or explicit value judgements, which are not necessarily in the domain of the expert advisory committees or other bodies that make such decisions. I highlight some of the systematic biases, distortions and epistemic injustices that are inherent in such evidence, and argue that evidential failings may undermine the claims to the legitimacy and fairness of the decision-making process.

### **Epistemic injustice and evidence**

Fricker suggests that *'there is a distinctively epistemic genus of injustice, in which someone is wronged specifically in their capacity as a knower'*.<sup>[6]</sup> Testimonial injustice has been described in healthcare where a patient may have unique knowledge of their experience of an illness or treatment, which is not given appropriate credibility.<sup>[7]</sup>

However, the potential to contribute to shared knowledge does not always take the form of conscious awareness in those who provide the information. We may 'know' that we have a feeling of nausea but be unaware of a fall in our haemoglobin level, without realising that both of these may have potential to add to the shared pool of knowledge about an illness or healthcare intervention. If we belong to a marginalised group that is excluded from a research study, then that exclusion may unjustly disadvantage ourselves and the group to which we belong, by distorting the results of such a study.

Epistemic contributions may occur on many different levels. We may take on the role of informant, providing knowledge of our experience of a condition, treatment or outcome, offering potential benefits to ourselves or others facing similar situations. To deny us credibility in this context seems to be a clear example of testimonial injustice. However, other situations are less clear cut, we may contribute to the

generation of shared knowledge, without holding that knowledge ourselves. In some circumstances, we may offer ourselves as an object of research, allowing our blood parameters to be measured. Such 'objectification' may not be negative; to deny us the opportunity to contribute to shared knowledge in this way may be considered an injustice.

The term 'evidence-based' carries with it an air of scientific authority, suggesting decisions that follow from a rigorous evaluation of what is known. However, examination of the evidence used in such decisions reveals that it includes information relating to values, expert judgements and alternative scenarios, the merits of which need to be considered by the decision-making body. Apart from those value judgements that inform the specific decision, the framework within which the decision is made embodies many assumptions, such as those about methodology and perspective.

Where value judgements are required for evidence-based decision making we are faced with a choice between using the values of different constituencies; empowered authorities, 'expert' advisors, patients, regional or national societal samples. The evidence required may include studies to quantify these values or develop consensus of opinion amongst these various groups, in order to justify a specific stance in relation to them. Many research methods that contribute to the evidence do not elicit what might conventionally be seen as 'factual' knowledge, but include preference-based studies, qualitative interviews or focus groups to elicit value judgements, or methods such as Delphi techniques to reach consensus amongst experts. This presentation of values and opinion in the form of scientific evidence can blur the boundary between those aspects of the evidence that relate to knowledge and those

concerned with value judgements. It may, therefore, be more useful to think in terms of *evidential injustices*, rather than purely epistemic ones.

In a decision-making context, there is potential for injustices to occur through the way in which evidence is generated and reported, or how it is interpreted and used in the decision-making process. In the following sections I explore the ways in which potential injustices may arise in each of the areas. I then go on to consider who is wronged by these evidential injustices and the steps that may be taken to try and ameliorate them.

### **Injustices in the generation of evidence**

Extensive methodological development in recent years has focussed on the evaluation of research evidence, with hierarchies of evidence and quality assessment frameworks that commonly place the systematic synthesis of the results from randomised controlled trials (RCT) as the pinnacle of evidence, regarding the outcomes of interventions. However, whatever research methodology is used, there remains a potential for biases to occur. The Centre for Evidence Based Practice in Oxford has created a “catalogue of bias”, which currently lists in detail 49 types of bias, and reports about 250 potential candidates for the catalogue (see <https://catalogofbias.org/>). In what follows, I focus on those biases that seem most likely to undermine distributive justice.

Potential injustices begin with the choice of subject areas for research. The decisions about which conditions, interventions and outcomes will be the subject of research are made by those who fund or commission the research and may thus serve the commercial or political ends of those with economic or political power. In the UK

and elsewhere, about two thirds of research funding is from the global pharmaceutical industry,[8] largely aimed at the development of drugs and devices in particularly profitable sectors that have the potential for exclusivity through protected intellectual property.[9] Even government and charity funded research suffers from biases in the selection of topics, with funding distribution matching poorly to the sectors where there is most clinical need.[10]

The mismatch between patient need and research investment may partly reflect these commercial and political influences, but the growth of evidence-based practice has also altered the emphasis of research. RCTs may privilege certain conditions, treatments and outcomes that are more suitable for RCTs, whereas complex interventions, caring processes or person-centred approaches are less amenable to such research. Expert evidence of healthcare practitioners is seen as being at the lower end of the evidence hierarchy, so professionals working in certain disciplines may suffer a credibility deficit. Such disciplines include those where there is a less established tradition of positivist scientific research and greater dependence upon interpersonal and qualitative aspects of healthcare.

This can become a self-perpetuating situation, with the research methodology becoming the *de facto* measure, not only of the scientific rigour of the research, but of the status of the researcher, leading to editorial boards, priority-setting committees and research commissioning boards being largely filled by academics who have a vested interest in such research.

The focus on RCTs leads to the potential for certain groups to be systematically excluded from the collection of evidence. This may result from the explicit exclusion criteria used in many clinical trials. Van Spall et al[11] show that many studies excluded the elderly, women, children or those with other diseases, without

justification, and Cherubini et al highlight the biases caused by excluding older people from studies of heart failure.[12]

Some of the forms of epistemic exclusion may be less explicit. For example, methods used for establishing outcomes are often based upon questionnaires that may only be accessible to those who are literate in a particular language.[13] There may also be indirect forms of exclusion, such as those based upon geography. On a national scale, large research studies tend to take place preferentially in areas associated with leading teaching hospitals, where practices, patient demographics, equipment and staffing may not match that available in other areas.[14] For international trials, recruitment may be driven by the costs and regulatory arrangements in different jurisdictions and there is evidence that this has led to questionable practices in clinical trials.[15]

Other aspects of trial design may also lead to distortions. The comparator may be selected to maximise the expected benefit, trials may be placebo-controlled or use a comparator that is not considered the best available in routine practice. Such comparator bias is likely to result in the exaggeration of any potential benefits of the new intervention.[16]

The selection of outcomes may also lead to biases. Important outcomes may be rare or delayed, in which case it may be impractical for studies to be large enough, or sufficiently prolonged, to accurately estimate their occurrence and sponsors are keen to minimise the cost, size and duration of clinical trials. This may lead to the use of composite outcomes, where several different events may be counted together, as in the use of major adverse cardiac events (MACE) in cardiovascular trials.[17] Another common adaptation is the use of 'surrogate' outcomes; where an outcome of interest is difficult to measure, due to the timescale or other factors, an alternative that is more 'objective', immediate or easy to measure may be found. For example, important

clinical outcomes in cancer treatments may be the length and quality of survival, but these are difficult to measure and confounded by complex treatment pathways and the need for prolonged follow-up, so that measures such as progression free survival, time to progression or tumour response rates are often used as surrogates.[18]

Further biases occur in the reporting of trial outcomes. It is estimated that about half of trials that take place never result in published or publicly available data[19] and there is evidence of distortion or selective reporting in those that are published.[20, 21] This is compounded by editorial policies that make it more likely that positive results will be published and widely cited, leading to publication bias.[22]

Many studies are halted or abandoned and data from these may not be available, creating further distortions.[23] In 2013 the RIAT (restoring invisible and abandoned trials) initiative promoted the reanalysis of data from such trials and demonstrated examples of trials where reanalysis challenged the original conclusions.[24] One famous example of such distortions is the history of ‘Study 329’, a trial of paroxetine, which was reported as showing this to be an effective and well tolerated treatment for depression. Subsequent investigation showed that GSK had failed to report safety data and in 2012 the US Department of Justice settled criminal and civil proceedings with a record \$3bn fine for GSK, although it was estimated that they had made \$30bn profit through the illegal promotion.[25] In 2012 the British Medical Journal devoted an entire issue to the problem of hidden data from clinical trials, citing this and multiple other examples of potential distortions and misleading reports.[26]

One of the key aspects of the treatment of cancer from the patients’ perspective, and an essential aspect of the evaluation of cost effectiveness, is an assessment of quality-of-life outcomes. A review of RCT protocols and publications of 173 cancer trials[27] showed that only 52% included quality-of-life outcomes in the protocol and,

of these, only 39% reported the quality-of-life outcomes, 20% limited reports to other outcomes, and the results of 41% remained unreported. Submissions of evidence for the UK National Institute for Health and Care Excellence (NICE) appraisals show that companies sometimes fail to divulge the results of such measures, even when they are known to exist, preferring to use other methods that may produce more favourable estimates of cost effectiveness.<sup>1</sup>

### **Injustices in the interpretation of evidence**

Evidence is frequently incomplete or conflicting, so that it is necessary to use some degree of interpretation, extrapolation or make assumptions to fill any gaps. If this is done in such a way that certain groups or individuals are disadvantaged, then this is another area in which injustices may arise.

At this point it seems relevant to return to the question of the role of the ‘expert’ in the decision-making process. In discussing the relationship between healthcare professional and patient, Carel and Kidd discuss the appropriateness of assigning epistemic privilege to an expert. “... *we claim that it is useful to distinguish between warranted and unwarranted epistemic privilege, e.g. healthcare professionals warrant epistemic privilege in their interpretation of a CT scan, but not in deciding where a patient should die (e.g. in hospital or at home).*”[7]

In current decision-making processes, there are many areas of potentially relevant expertise; various clinical disciplines, pharmacology, medical science, health economics, utility analysis, decision analysis, medical ethics, statistics and public

<sup>1</sup> For example, in an appraisal of Golimumab (TA255), SF-36 data collected in the trials were excluded from the manufacturer’s submission and requested twice before being submitted (see; <https://www.nice.org.uk/guidance/ta225/history>).

health. Specific aspects of evidence may warrant epistemic privilege for a particular group of experts, but it may be difficult to identify those areas of a complex technical argument where such privilege is unwarranted. An expert may be operating within a particular paradigm that presupposes some underlying set of values or assumptions, which are not directly within their area of expertise. Alternatively, the presentation of a rational and highly technical scientific argument may obscure the nature of some of the underlying value judgements.

This may be further clarified by a couple of examples from the processes used by NICE in making decisions on behalf of the NHS in England and Wales, which are likely to be representative of the type of decisions made in many other jurisdictions. The first example relates to the way in which NICE estimates utility for the cost-utility calculations that form the basis of many judgements.

Although NICE states in its documentation that it does not subscribe to a purely utilitarian approach to distributive justice[28], many of the decision-making processes that it applies are centred around a calculation of cost effectiveness and, although there are a number of flexibilities in the process, there is often a statement to the effect that the committee determined a ‘most plausible incremental cost effectiveness ratio (ICER)’. The ICER is a measure of cost effectiveness, usually presented as a cost per quality adjusted life year (QALY), calculated in line with their guidance on methodology.[29]

The calculation of the cost per QALY is based upon a process of health economic modelling that involves a complex technical exercise, drawing together evidence from a variety of sources, the development of a computer model and choosing between a series of alternative assumptions and calculations. The ICER is only one of a variety of different parameters that may be relevant to decision-making, the QALY is only

one of a number of measures of effectiveness and NICE methodology uses a specific way of calculating the QALY, each stage requiring a series of assumptions and value judgements.

The outcome measure which NICE advises for calculating the QALY is the EuroQol – a measure based upon five ‘dimensions’ of health each of which are scored at three levels<sup>2</sup> and then converted to a utility weighting based upon a tariff that is specific to England (EQ-5D).[30] The relative value of these dimensions varies between individuals and has also been shown to vary systematically between different racial and ethnic groups.[31] Furthermore, there are many aspects of healthcare that may be important to individuals or groups that are not captured at all in such measures. For example, studies have demonstrated that the EQ-5D is insensitive to levels of hearing loss[32] and may not adequately capture the outcome of interventions that affect mental health,[33] dementia[34] or multiple sclerosis.[35] Such measures also fail to include other widely valued aspects of healthcare such as processes of care,[36] compassion, dignity and autonomy. It seems inevitable that rationing decisions based upon evidence that fails to quantify areas such as mental health, disability or compassionate care will result in displacement of healthcare that provides benefits in these domains.

The result of NICE methodology is that experts, such as health economists and systematic reviewers, often acting on behalf of commercial sponsors, produce extensive and highly technical documentation, often running to many hundreds of pages. These generate numerical estimates of a parameter, the ICER, which drives decision-making. However, although these experts may warrant epistemic privilege in interpreting the research evidence and in the process of calculation, there may be

<sup>2</sup> A more recent version of the EQ-5D with five levels has not currently been adopted by NICE.

unwarranted epistemic privilege deeply embedded and obscured within this apparently objective process, particularly relating to the weights and values assigned to the various aspects of risks and benefits.

A further example is that of discounting costs and benefits in health economic (and other public policy) evaluations.[37] This is common practice and there are a number of different opinions and justifications for using particular rates that relate to economic growth, budgetary constraints and time preferences for expenditure and outcomes.[38] This has recently been the subject of considerable debate amongst experts in the field of economics and health economics, often providing highly technical arguments for using particular rates[39] or for and against the use of differential rates for costs and benefits.[38]

However, it is worth considering the overall effects of these differences on the outcome of the decision-making process. Tied up in this debate is a value judgement about our preferences, either as a society or as individuals, for immediate versus future gains and losses. A higher discount rate results in future costs and benefits becoming less important in any decision-making process. For example, higher discount rates will make screening and preventative medicine less attractive, due to the up-front costs and deferred benefits, or in a non-health example, would reduce the value of measures to address climate change that would benefit future generations.[40] There is a danger that to defer to technical experts to advise on appropriate discount rates is to lose sight of the underlying value judgements that may not be a proper subject for such epistemic privilege. This is a particular concern if there is a risk of bias in the process for developing methodology, since industries with the resources to influence such decisions have a vested interest in minimising

discount rates to maximise the price that can be justified for technologies with deferred and uncertain benefits.

These examples highlight the potential risks of increasing specialisation that relies upon specialist expertise to generate or process evidence. This may require them to consciously or unwittingly provide judgements that may be outside their area of expertise and may disadvantage those who are subject to the decision, whose evidence is never sought or represented.

Vandana Shiva used the term ‘epistemological violence’ to describe the potential injustices that may be introduced between the scientific expert and non-expert;

*“Here violence is inflicted on the subject socially through the sharp divide between the expert and the non-expert - a divide which converts the vast majority of non-experts into non-knowers even in those areas of life in which the responsibility of practice and action rests with them.*

*But even the expert is not spared: fragmentation of knowledge converts the expert into a non-knower in fields of knowledge other than his or her specialization.”[41]*

In this respect, it is not just the patients who are the ‘non-knowers’, but those healthcare professionals who, as consumers of the guidance, do not have the resources to re-examine or challenge any underlying data or assumptions.

### **Who is wronged by evidence-based guidance?**

If the evidence underpinning rationing decisions is flawed this may undermine efforts to ensure distributive justice. Injustices may occur either through denying access to technologies, which would have been available had unbiased evidence been available

or, conversely, through approval of technologies that would have been rejected. In the former circumstances, the wronged parties are easily identified as those who may have benefited from incorrectly rejected technologies, but I would suggest that this is a less common situation. Since most evidence is generated, analysed, reported, and often interpreted, by an industry with commercial interest in the new technology, the direction of any bias is likely to exaggerate the benefits and underestimate the costs and risks of such treatments. Furthermore, such overt rationing decisions are transparent and open to challenge, the individuals who are wronged are identifiable, and those with a commercial interest in a positive recommendation have the financial, scientific and legal resources to challenge a negative decision.

It seems more likely that any evidential failings will result in inappropriately liberal guidance, in which case the wronged parties are less easily identifiable. In this situation the injustice relates to opportunity costs and occurs through the diversion of limited resources away from aspects of healthcare which, given unbiased evidence, would have been seen to better serve the aim of distributive justice. Since the wronged parties are not easily identifiable or linked to the specific guidance, the aims of transparency and openness to challenge cannot be achieved, exacerbating potential injustices.

Some general points can be made about the areas and groups that are likely to be wronged. Disinvestment decisions rarely relate to specific technologies or are evaluated with the same rigour as those regarding new and costly technologies.[42] Attempts to identify an appropriate threshold[43] and studies of the effects of financial pressures[44] suggest that displacement of resources is likely to occur in particular areas, potentially increasing waiting times, diluting care and limiting access

for patients with chronic conditions, such as mental health, chronic physical conditions and disability.

Such wrongs are not necessarily limited to rationing decisions, but may occur with any evidence-based guidance. Although other guidance is rarely mandatory, there may be performance indicators or incentives for healthcare professionals to adhere to such guidance, and the underlying biases and value judgements may not be transparent to individual professionals or patients relying upon the guidance. For example, where trials have unjustifiably excluded elderly people or other specific groups, decision makers face a choice between advising against providing a potentially beneficial treatment or recommending its use, based upon the research from which these groups were deliberately excluded.

### **Addressing potential evidential injustices**

Decisions regarding the allocation of limited healthcare resources will always be complex, requiring trade-offs between competing priorities and recognition of practical limitations. However, regardless of the methods used to achieve distributive justice, the legitimacy of such procedures relies upon a foundation of unbiased evidence. There are a number of practical steps that might be taken to improve the current situation.

### ***Shifting the research agenda***

Since most research is undertaken by those with vested interests in marketing costly new technologies, evidence focusses on these areas and risks displacing healthcare activities that are not subject to such research, despite being highly valued by society. For example, I would suggest that society puts a high value on dignified and compassionate care for those with terminal cancer, dementia, mental health or other

chronic health problems. However, such caring processes are of less commercial interest, dignity and compassion are rarely evaluated and do not form a part of the calculation of healthcare benefit, resulting in these areas being potential targets for disinvestment. Addressing this would require incentives and public research funding to be directed at these ‘Cinderella’ subjects and to include studies to identify methods to quantify such benefits and incorporate them into the value frameworks used in decision making.

### ***Regulating trial design***

Whilst some regulatory authorities, such as the Food and Drug Administration and the European Medicines Agency, currently have input into the design of trials for regulatory approval, they are primarily concerned with safety and efficacy. However, estimates of comparative effectiveness or cost effectiveness may require different outcomes, comparators or data collection. Extension of the powers of regulatory bodies or input from those responsible for rationing decisions may be appropriate, to ensure that studies collect data that makes them fit-for-purpose in informing such deliberations.

### ***Transparent reporting of results***

It seems inconsistent that we go to great lengths to ensure that all research on human subjects goes through strict ethical evaluation and yet fail to enforce the aspects of the Helsinki Declaration that deal with the reporting of the outcomes of such trials[45]. Human subjects consenting to participate in clinical trials do so on the assumption that the gains in knowledge from the research will benefit society as a whole. To allow the results to be distorted, withheld or mis-interpreted for commercial reasons is to undermine the ethical basis of that research.

### ***Independent evaluation***

Improved legitimacy for the identification, review and synthesis of evidence might be achieved by ensuring this is carried out at arm's length by independent academic bodies, without a vested interest in the technology. In the original process developed by NICE for evaluating new technologies (now known as Multiple Technology Appraisal, MTA) independent academic groups were commissioned to review the evidence, with safeguards to avoid potential conflicts of interest. However, a new Single Technology Appraisal process (STA) process was introduced in 2005 in which the sponsor of the technology is responsible for the identification and evaluation of evidence. This is now the process used for the majority of technology appraisals, despite the clear conflicts of interest and a review of the process, commissioned by NICE, which expressed concerns about the lack of balance in the process[46].

### ***Conditional approval and continued data collection***

Even with tighter controls on research methods, greater transparency and independent review, it is known that early trials of new technologies tend to overestimate benefits and under-estimate risks compared to real-world use,[47] and the validity of extrapolation of short-term and surrogate outcomes cannot be beyond doubt for a novel technology.[48] This suggests that there is a place for far greater use of post-approval monitoring of outcomes, conditional approval that is subject to review, and outcome-based payment schemes.[49]

### ***Representation for those subject to epistemic exclusion***

One of the key areas for potential injustice relates to epistemic exclusion. This occurs not only when a person is wronged by exclusion from participating in the process of generating knowledge[50] but also from situations "...where social meanings are

*made and legitimated*".[7] In the context of evidence-based healthcare this includes the lack of opportunity to contribute to the value judgements inherent in the interpretation of evidence. As we have seen, the lack of explicit consideration of the opportunity costs of displaced healthcare means that those who are excluded are likely to be unaware that they will be adversely affected by a decision and are, thus, also excluded from the opportunity to challenge such decisions. Addressing this imbalance would require a mechanism to specifically seek input from, and represent the interests of those who are likely to be disadvantaged. Such measures might include specific studies to seek the views and preferences of such groups, more transparent and rigorous examination of disinvestment decisions, and an independent process to represent the interests of unidentified groups whose services may be displaced.

### ***Moving the goalposts***

The potential shortcomings, distortions and injustices that are inherent in evidence-based processes may be partially addressed by some of the measures discussed above. However, change is likely to be slow and incomplete and outside the control of those who must make decisions, so interpretation of the available evidence will remain a vital aspect of decision-making. As highlighted by Bales,[51] it is important to distinguish between 'rightness criteria' that reflect the ethical principles that underpin the desired outcome of any guidance or policy decisions, and the decision methods themselves. It may be that a just outcome that reflects the desired distributional principles is most likely to be achieved by a process that does not directly implement these principles. A sailor who sets a course based upon examination of the evidence from a map, is likely to miss their intended destination if they do not allow for the crosswinds, tides and currents that may alter their course. To take evidence at face

value, without considering the inherent biases and injustices, may lead to decisions that fail to hit the mark. To inform decisions, evidence needs to be sought, not only related to the effectiveness and cost effectiveness of the technology under consideration, but also on the systematic biases and injustices that may be relevant to its interpretation.

## **Conclusions**

Biases in research evidence are well recognised but rarely addressed specifically in developing guidance, leaving certain groups subject to epistemic injustices and exclusion. Whether applying procedural and/or substantive principles of justice, a process that is based upon biased or flawed evidence, has questionable legitimacy. Existing processes for the generation and interpretation of evidence are likely to favour the commercial and political interests of those who fund and commission research. Addressing such injustices would require a rebalancing of power through shifting the research agenda, regulation of research, independent evaluation of evidence, transparency of research outcomes, and a means to represent the interests of those marginalised or excluded groups with a legitimate interest in the process. Failing to generate evidence that adequately captures important benefits relating to particular disease areas or treatment modalities makes it likely that some patients will have the care they require unjustly displaced by new technologies. There is a danger that evidence-based healthcare results in value being assigned to those aspects of healthcare that are measured, rather than measuring and thus promoting, those aspects that society values.



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