

MAIMON WORKING PAPERS No. 16 SEPTEMBER 2023**WILLFUL BLINDNESS AND VALUE CLAIMS IN THE HEALTH TECHNOLOGY ASSESSMENT MEME: SOME CONSIDERATIONS**

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Abstract

The question of false claims in the social and physical sciences has been a center of attention for many years, with increasing efforts to weed out those encouraging the promotion of false claims and the perpetrators themselves. The focus of much attention has been on the role of paper mills, predatory journals and even the activities of individuals, often in senior academic positions, who have shown scant regard for ethical standards in pursuit of recognition and support. There is however, another aspect to these activities which has not been fully appreciated: the apparent presence of willful blindness in advocating analytical frameworks to support the creation of value claims that deny the standards of normal science and fundamental measurement. The term willful blindness is used here in the legal sense of blocking out uncomfortable realities. This is, unfortunately, an interpretation that can be applied to many activities that constitute the core of value claim creation in health technology assessment. These include an apparent lack of awareness of the requirements for fundamental measurement or the Rasch standards for transforming observations to measurement, the commitment and promotion of composite measures that fail such standards and the widespread acceptance of incremental cost-per- quality adjusted (QALY) claims for cost-effectiveness. The extent to which the commitment over 30 years to these constructs is the focus here and the question of the extent to which this is nothing more than willful blindness.

INTRODUCTION

The failure of what has been described as the health technology assessment (HTA) meme, rather than a paradigm, to recognize and endorse the standards of normal science for credible value claims, empirically evaluable claims and the replication of these claims has been recognized for some time ¹. Add to this a failure to endorse the standards of fundamental or Rasch measurement in the importance of transforming raw observations or counts, ordinal scores, to single attribute measures with linear, interval and invariant properties. The result is that HTA has the unique and unfortunate appellation of a pseudo-scientific discipline that endorses false or non-evaluable modeled claims with no account or even apparent interest in fundamental evidence and the systematic discovery of new yet provisional facts.

The purpose of this note is to raise the question of whether this apparent disregard is evidence for willful blindness or whether it reflects a more deep-seated and worrying hallmark of HTA where the practitioners are ignorant of the required standards of normal science and measurement; they are not willfully blind, just blind.

WILLFUL BLINDNESS

In law, the concept of willful blindness, as opposed to negligence or recklessness, is a judicially-made doctrine that embraces deliberate avoidance of a crime by failing to make a reasonable inquiry about suspected wrongdoing despite being aware that it is highly probable. The notion of

willful blindness has come in for criticism in terms of the application of the meaning of knowing or knowledge with the extension to a wide range of Federal crimes, not just criminal drug use, but noncriminal contexts². In all applications the willful blindness doctrine has two components: (i) the defendant's suspicion that the incriminating fact exists; and (ii) the defendant's deliberate avoidance of the truth of that fact. That is, in terms of the Model Penal Code, the application of willful blindness requires recklessness on the part of the defendant plus a culpable motive. In these terms recklessness is where a defendant consciously disregards a substantial and justifiable risk that the fact is true. Knowledge is not required.

In application, however, knowledge and belief are critical issues; in particular, the distinction between knowledge and recklessness. A major concern is that in application the notion of knowledge and its definition is highly problematic. Is willful blindness a criterion distinct from knowledge; does it infer knowledge and what is the degree of knowledge that is inferred? When does the case of limited knowledge blend into recklessness? Does a defendant engage in an act knowingly or does the engagement denote a lack of knowledge? How much suspicion must a defendant have? Is recklessness an insufficient basis on which to judge a defendant? Can HTA be considered a defendant to a charge of willful blindness in the promotion of a belief system that many independent observers would may consider false.

RELATIVISM AND BLINDNESS

An issue raised on a few occasions goes to the question of whether HTA occupies a different belief system from that characterized by the accepted standards of normal science and measurement; a belief in symmetry when alternative explanations and claims are interpreted sociologically³. Under this view that science is created within a community of believers, all belief systems are equally valid and reflect the consensus of a social group that no one body of evidence is superior to another. The possibility that empirical claims may be falsified is irrelevant; there is no concept of objective knowledge and appeals to superior facts. The creation of imaginary claims with no chance of falsification are on an equal status with those that are designed to meet standards for demarcation. In terms of fraud: the product of a paper mill is no different from the product normal science with its focus on falsifiable claims. Falsifiability is of no interest; any claim, even where data are invented or created is of equal merit.

This belief in a parallel or many parallel belief systems, all equally valid, is not sustainable. Since the 17th century the foundation of science has been empiricism; as the motto of the Royal Society makes clear *nullius in verba* (take no person's word for it). It is ludicrous to put intelligent or design or creationism on equal status in scientific terms with evolutionary biology; it is a non-starter

If this is the case why has the HTA belief system endured? The answer is that as a meme it has been put forward as the only option to support, in an evidence-scarce environment, comparative claims for cost effectiveness. If there is no attention paid to mainstream value claims that conform to the standards of normal science and fundamental evidence, in terms of practice guidelines or even foundation courses at pharmacy schools and colleges, the beliefs will hold driven by the transmission fidelity of what has been described as a mind virus⁴. For relativists, science is about rhetoric, persuasion and authority; evidence is never discovered but constructed within a social community where any notion of the pursuit of objective knowledge; of coming to grips with reality is absent.

WILLFUL BLINDNESS

If the analytical content of HTA is focused on the creation of evidence, a position unchanged for 30 years with the latest reinforcement in guidelines for creating imaginary claims with CHEERS 2022, then by the same token it is really an open invitation to create more evidence⁵. The message of HTA is that it provides the justification, an ever-open door, where assumptions can be manipulated to support any non-falsifiable proposition or value claim. If the gold standard for HTA practitioners is the creation of assumption driven modelled simulations to produce non-empirically evaluable claims for a hypothetical future then there are no barriers to an endless proliferation of such claims and their ready acceptance by journals and the more gullible health system decision makers. The knowledge of how to create such claims is trivial, widespread and accepted by decision makers in health care systems; the message is one of continuing repetition and the creation of non-falsifiable claims; CHEERS 2022 is merely a guide for paper mill production.

The impossibility, in an imaginary world, to set up any criteria that might enable demarcation of sense from nonsense sets the stage for accusations of endemic willful blindness to standards for discovery. HTA is blind to the assessment standards of normal science; the HTA belief system fortunately has absolved itself of any need to acknowledge their role and has made clear it does not require them. There is a willful acceptance of created value claims deliberately designed to avoid any hint of falsification.

It is important to consider the elements of the message of the HTA meme to consider the extent to which leaders in the field of HTA and their supporters have failed to consider the required standards for discovery; discovering provisional facts associated with an external reality. HTA is distinguished by a lack of interest, indifference or just willful blindness towards the standards of normal science and fundamental evidence. They are foreign to HTA's remit or belief system; there is no willingness or wish to engage.

Whether clearly articulated or not, neglect of fundamental measurement is indispensable for the survival of the HTA meme; a willful blind spot in claims for cost-effectiveness. The failure is clearcut: the application of multiattribute generic instruments such as the EQ-5D-3L/5L to create composite scores which are believed to represent preference or utilities fail to meet the required single attribute measurement standards⁶. These are nothing more than ordinal scales, to term them measures is a misnomer. As ordinal scales they cannot support parametric statistical operations, to include multiplication, and hence QALYs. The HTA message must always support impossible composite value claims; perhaps the message and belief is that much stronger, willfully blind, because the QALY is an impossible construct⁷.

This case has been presented on numerous occasions; the response, notably in the US by the Institute for Clinical and Economic Review (ICER) is denial; ICER holds to the belief that health economists have confidence that multiattribute instruments create ratio scales. This is complete nonsense and shows, not only a distressing lack of knowledge of fundamental measurement but a dogged insistence on a belief that lacks any concept of knowledge and, in the advocacy of the HTA message, is nothing short of reckless. The essential failure in HTA is the failure to recognize fundamental measurement. To support the Rasch framework, to produce claims for single attribute value claims with linear, interval and invariant properties is a bridge too far; it is opening up a line of enquiry and practical application that would destroy the commitment over 30 or more years to invent or create evidence by assumption⁸.

IGNORANTIA SIT BEATITUDO

Concerns regarding the lack of understanding in HTA regarding the standards of normal science and fundamental measurement are amplified by an apparent willful blindness or deliberate indifference to measurement theory and, most telling, a complete lack of reference or discussion of Rasch measurement⁹. The most widely used textbook in HTA makes passing reference to the various scales of measurement as a confused defense of incremental cost-per-QALY and cost-effectiveness modelling and claims, but falls flat because of a failure to understand the impossibility of composite preference scales¹⁰. The authors fail to grasp the essential point in measurement theory: value claims must not only be empirically evaluable but must be presented as single or unidimensional attributes with linear, interval and invariant properties. Instead, readers are led to believe that composite multiattribute scales are actually measures, which they are not, and that faith can continue to reside in instruments such as the EQ-5D-3L/5L. The fact that Rasch measurement for counts or observation been accepted for over 60 years is apparently of no interest for those seeking training in HTA. The fact that Rasch modelling provide the necessary and sufficient means for observations to be transformed to interval or ratio scales is not an area of needed inquiry; composite measures must prevail.

Presumably, one reason for ignoring fundamental measurement in textbooks is that the questions raised effectively demolish the assumption driven simulation model. To these concerns should be added the question of the so-called realism of assumptions. The problem of induction is another area to be avoided; if readers are unaware of the problem, then inconvenient questions can be avoided when modeled simulations are defended on the grounds that the assumptions selected are realistic for the acceptance of non-evaluable value claims.

After all, if students have not been exposed to the philosophy and practice of science (with a dose of logic) in their undergraduate and graduate programs, then why rock the boat? Like all too many memes, HTA can best survive if it manages to deflect criticism; the easiest was is not to raise issues that may undermine the belief in simulated non-evaluable composite claims for cost-effectiveness. A behavior which is appropriately characterized as willful blindness; a refusal to admit knowledge that may dilute the content of the HTA message as it is transmitted from one generation of acolytes to the next. The focus must be on minimizing any possible suspicion that all is not well in the HTA garden with the HTA believer's training to put any suspicions aside; to deny the existence of incriminating facts.

RECKLESS BLINDNESS

In the legal sense, willful blindness is focused on the messenger or carrier; but the phrase is equally valid when applied in HTA to leaders in the field, instructors and the global HTA membership in their self-ordained responsibility to maintain the *status quo* through tailored messaging. All share a common core of knowledge, a core that effectively excludes any consideration of competing and superior viewpoints. No one looks outside of the box; a commitment to a knowledge base that is clearly fails the demarcation test. Whether the observer would judge this behavior as reckless and negligent is one that faces jury instructions in willful blindness cases. To what extent is the messenger remiss in not pressing the point to alleviate suspicions; deliberate avoidance or deliberate ignorance? Is there a conscious disregard of a substantial and unjustified risk in endorsing the message?

But reckless behavior, the creation of evidence through assumption driven models all have a major downside for the credibility of this relativist HTA framework. Once a discipline endorses the creation of imaginary cost-effectiveness claims, it opens the doors to systemic fraud. Irrespective of the guidelines in place for authors to submit imaginary modeled cost-effectiveness claims to leading journals, the effect is to give a well defined path for paper mills to market imaginary claims to support cost-effectiveness pricing. There is every incentive to see assumption driven simulated claims for cost-effectiveness as an invitation to employ simulated claims as marketing tools. There is no difference to encouraging paper mills to create, if they have not already, fee-for-service models to support cost-effectiveness claims and the willing embrace of predatory journals to support marketing through publication.

CONCLUSIONS

The endorsement of non-evaluable claims is a gift that keeps on giving; it strips away the major supports for scientific integrity, demarcation and falsification. It is unusual to find a discipline such as HTA which turns its back on standards of normal science and measurement theory. This has been described as willful blindness to these standards in a continuing a 30-year effort to promote and maintain the transmission fidelity of the HTA message. The result is a discipline that, in a true relativist sense, believes, or professes to believe, that evidence or knowledge is never discovered, but constructed. The driving force within the HTA meme is in pursuit of the holy grail of a single allocative metric, cost-effectiveness. For the leadership and supporters of HTA it is imperative that this rejection of normal science and measurement must be defended against any hint of apostasy.

This critique may not seem an unduly harsh judgment given the global acceptance of the meme for constructed evidence, assumption driven modeled simulations, that are deemed to provide needed approximate information by a necessary and sufficient analytical methodology. A methodology that turns its back on the practice of science that has evolved over some 400 years. Fortunately, we can easily turn our backs on the willful blindness or deliberate indifference to the practice of science by adopting, not only the standards of normal science but the standards set for modern measurement and the critical role of single attribute credible and falsifiable value claims.

REFERENCES

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- ¹ Langley P. Nothing to Cheer About: Endorsing Imaginary Economic Evaluations and Value Claims with CHEERS 22 [version 1; peer review: 2 approved]. *F1000Research* 2022, 11:248 (<https://doi.org/10.12688/f1000research.109389.1>)
 - ² Simons K. The Willful Blindness Doctrine: Justifiable in Principle, Problematic in Practice. *Ariz State Law J.* 2022; 54(1)
 - ³ Wootton D. *The Invention of Science*. New York: Routledge, 2015
 - ⁴ Dawkins R. *A Devil's Chaplain*. New York: Mariner Books, 2004
 - ⁵ Husereau D, Drummond M, Augustovski F et al. Consolidated Health Economic Evaluation Reporting Standards 2022 (CHEERS 22) Statement: Updated reporting guidance for health economic evaluations. *ValueHealth.* 2022;25(1):3-9 [https://www.valueinhealthjournal.com/article/S1098-3015\(21\)03146-6/pdf](https://www.valueinhealthjournal.com/article/S1098-3015(21)03146-6/pdf)

⁶ McKenna S, Heaney A. Composite Outcome measurement in clinical research: The triumph of illusion over reality? *J Med Econ*. 2020;23(10): 1196-1204
<https://www.tandfonline.com/doi/pdf/10.1080/13696998.2020.1797755?needAccess=true>

⁷ Langley PC and McKenna SP. Measurement, modeling and QALYs [version 1; peer review: 2 approved] *F1000Research* 2020, 9:1048 <https://doi.org/10.12688/f1000research.25039.1>

⁸ Wright B, Linacre J. Observations are always ordinal; measurements, however, must be interval. *Arch Phys Med Rehabil*. 1989; 70(12):857-60
https://www.researchgate.net/publication/20338407_Observations_are_always_ordinal_measurements_however_must_be_interval/link/5563b02408ae9963a11ef326/download

⁹ Bond T, Yan Z, Heene M. Applying the Rasch Model: Fundamental Measurement in the Human Sciences. 4th Ed. New York: Routledge, 2021

¹⁰ Drummond M, Sculpher M, Claxton K et al. Methods for the Economic Evaluation of Health Care Programmes. 4th Ed. New York: Oxford University Press, 2015