

## **MAIMON WORKING PAPER No 19 OCTOBER 2024**

### **THE ABSENCE OF TRUTH VALUE: ABANDONING DECISION MODELS**

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#### **Abstract**

*The University of Wyoming New Start Certificate Program has one objective: to make the case for a new paradigm in health technology assessment (or pharmacoeconomics). The proposed new paradigm is based on ensuring that HTA is focused on meeting the standards of normal science and fundamental measurement. This means, quite simply that all value claims, whether for clinical, patient reported outcomes (PROs) or resource utilization must be presented as unidimensional, linear, interval and invariant measures. This is the only option. In the case of PROs Rasch standards must apply. This is not technically difficult. The Rasch standards are unique, they are the necessary and sufficient condition for transforming observations to measurement. Techniques for applying Rasch standards, including a number of software programs, have been applied for some 60 years globally. Why HTA has missed out, with a few exceptions, is an unresolved question. Do decision models in HTA have truth value? Do they make a meaningful contribution to assessing therapy impact? Or are they detached from truth and devoid of truth-value? The case presented here is that decision models are devoid of truth value. They are emblematic of 30 wasted years for those who subscribe to the current HTA belief system. Imaginary modelled claims have no place in HTA and health system decision making. Imaginary modeled claims make no contribution to the evolution of objective knowledge. There must be a new start in HTA where decision models are abandoned and a claim can be made for HTA as science and not non-science.*

#### **INTRODUCTION**

Health technology assessment, otherwise called pharmacoeconomics, occupies a unique place in the social sciences: the denial of the relevance of the standards of normal science and fundamental measurement in establishing value claims for pharmaceutical products and devices. To those schooled, for example in mainstream economics, this is a decidedly odd situation, as practitioners in this meme or belief system claim to follow in an economics tradition <sup>1</sup>. The absence of a commitment to normal science or fundamental measurement is seen in the focus on decision models, both generic reference case modelled simulations as well as decision modelling specific to target therapies in disease areas. In virtually all cases, by design, the decision models yield non-evaluable claims. Evidence for a failure to recognize the standards for normal science and fundamental measurement extends to the quality adjusted life year (QALY) which, given preference are ordinal composite scores, means that the QALY is an impossible mathematical construct, yet a key element in cost-per-QALY decision modelled claims <sup>2</sup>.

The purpose of this brief note is to make the case that if we seek the reason for the current non-science meme or belief system in health technology assessment (HTA) we need look no further

then the obsession with imaginary decision models. If we are to meet the required standards for evaluable value claims, the decision models must be abandoned. In attempting to bundle costs and outcomes in a decision framework the requirement that all value claims must be singular or unidimensional with linear, interval; and invariant measurement properties is ignored. The bottom line is that reference and other decision model claims lack truth value. Absent fuzzy logic or many-valued logical propositions, truth value in logic indicates whether a proposition is true or false. If it is impossible to assess provisional truth or falsity it lacks truth value and is non-science. The failure of HTA (and pharmacoeconomics) is that reference models and other decision frameworks guarantee the absence of truth value which means that the belief system is bankrupt; it is non-science<sup>3 4</sup>.

This raises the question, to be addressed here, of whether we should, in Frankfurt's terms, categorize decision models and the commitment to approximate information in HTA as "bullshit" as opposed to pseudoscience? When Frankfurt refers to a statement as "bullshit" in his essay *On Bullshit*, he is pointing to a specific disregard for the truth value of the statement<sup>5</sup>. According to Frankfurt, the defining characteristic of bullshit is that the speaker is indifferent to whether what they are saying is true or false. Unlike a liar, who is concerned with the truth but seeks to conceal or distort it, the bullshitter does not care about the truth at all. In other words, for the bullshitter, the intent to ensure the truth value of the statement is entirely absent. The speaker is more concerned with creating an impression, persuading an audience, or achieving some other goal, without regard to the statement's alignment with reality or facts. This makes bullshit fundamentally different from both truth-telling and lying, because it involves a complete disregard for truth itself. For Frankfurt, bullshit is a greater threat to scientific inquiry than lying because it undermines the very concern for truth that is central to the focus on objective knowledge.

## **VALUE CLAIMS AND DECISION MODELS**

Decision models, if they are to be considered scientifically valid, must meet stringent criteria that allow for the generation of evaluable and meaningful claims. These claims must adhere to core principles: they must be unidimensional, linear, interval-scaled, and invariant. Without fulfilling these conditions, the claims derived from such models are not just imprecise or lacking rigor; they are entirely unevaluable. The result is that any decision model failing to meet these criteria cannot be regarded as legitimate or capable of supporting rational decision-making. In other words, a claim is either evaluable or it is not—there is no middle ground. Truth value is denied.

The demand for unidimensionality is fundamental. A decision model should focus on a single underlying dimension or construct, rather than combining multiple constructs into a composite output. If a model attempts to measure or evaluate different dimensions simultaneously—such as attempting to evaluate "risk," "cost," and "satisfaction" without clear delineation between them—it becomes impossible to make any meaningful interpretation of the claims it produces. Absent unidimensionality and a claim for truth value, there can be no scientifically sound propositions.

Linearity is another non-negotiable requirement. The relationship between the input variables in a decision model (such as preferences, probabilities, or various criteria) and the output (the decision or evaluable claim) must be linear. Linearity means that there is a predictable, consistent relationship between input and output, such that changes in inputs correspond proportionally to changes in the output. If this relationship is non-linear or erratic, then the resulting claims are not

only difficult to interpret but also cannot be trusted. Decision-making requires a stable, logical framework, and when this is violated, the model collapses into irrelevance. In short, if a model's outputs do not adhere to linearity, they are simply unevaluable as rational decision-support tools.

Next is the requirement for interval scaling. Claims made by a decision model must be based on an interval scale, meaning that the differences between points on the scale are consistent throughout the entire range of measurement. If a model produces claims on a scale where the difference between, say, a score of 10 and 20 is not equivalent to the difference between 30 and 40, then it is fundamentally flawed. This lack of interval scaling undermines any comparability between claims and renders the model incapable of producing reliable, evaluable outputs. Interval scaling is critical for ensuring that decision-makers can make coherent comparisons between different options, knowing that the value differences are consistent across the entire range of possible outcomes. A decision model that does not meet this criterion produces claims that are not evaluable—period.

Invariance is the final key criterion that decision models must satisfy. In the context of measurement, invariance means that the evaluable claims a model produces should not fluctuate based on irrelevant changes in the decision context or between different subgroups. For example, if a model is used to evaluate health care interventions, the claims it generates should remain stable across different patient populations unless those differences are grounded in relevant factors. If the value of the intervention varies inexplicably between two similar groups or changes based on how the question is framed, the model is introducing bias and error into its claims. Without invariance, decision models cannot be trusted to yield valid, generalizable conclusions, and their outputs are once again unevaluable.

These criteria—unidimensionality, linearity, interval scaling, and invariance—are not simply nice-to-haves. They form the foundation of any model that claims to be capable of providing decision support or evaluative output. A claim for relevance in epistemological or truth value terms. If, by intent, a decision model that cannot meet these standards does not simply produce less precise or approximate claims; it produces claims that are scientifically meaningless. Claims that are devoid of truth value. It is not sufficient to say that such models are "less rigorous" or "lacking in precision"—they fail the test of producing evaluable claims entirely. A model that does not respect these principles is a model that generates noise, not information. Noise cannot be the basis of rational decision-making.

The notion of a demarcation criterion is critical here. There must be a clear boundary between models that can produce scientifically valid, evaluable claims and those that cannot. Without this boundary, decision models would collapse into a relativist realm where all models are considered equally valid, regardless of their capacity to generate meaningful outputs. This demarcation is based squarely on the model's ability to produce claims that meet the standards outlined above. If a model fails to provide unidimensional, linear, interval-scaled, and invariant claims, it fails this criterion, and its claims cannot be evaluated in any scientific or objective sense. A claim is either evaluable or it is not. Models that fail to respect these principles cannot support rational decision-making.

## APPROXIMATE INFORMATION

It is important to consider the notion of approximate information in more detail. In HTA the term "approximate information" is a defense of decision models that fail to produce evaluable claims. This concept significantly alters the general interpretation of "approximate information," which usually denotes a level of uncertainty or lack of precision. In the context of HTA, it implies a more profound inadequacy, where the decision models do not yield actionable insights that stakeholders—such as policymakers, healthcare providers, or insurers—can reliably use to make informed decisions about health interventions or technologies.

An essential aspect of this discussion is the absence of a reference point by which to judge the accuracy or proximity of the information. Without a known reference point, it is impossible to evaluate how approximate the information truly is. Stakeholders are left without a means to assess the reliability of the claims being made, leading to further confusion and misinterpretation.

Furthermore, this lack of evaluable claims raises questions about the intent behind the creation and dissemination of decision models. If a model is designed with the knowledge that it will not yield actionable insights, one must consider whether the model's creators are acting in good faith. The potential for fraudulent intent emerges when stakeholders develop or promote decision models that they know to be flawed. If these models are used to present a façade of scientific rigor or credibility, they can mislead decision-makers, leading to unethical practices and detrimental consequences for patients and healthcare systems alike. When approximate information is presented as valid, stakeholders may be persuaded to trust its conclusions without adequately questioning its reliability. This can result in healthcare interventions being adopted based on incomplete or misleading data, which could compromise patient safety and undermine the overall integrity of the healthcare system. If decision-makers rely on models that do not generate evaluable claims, they may unintentionally endorse technologies or treatments that lack adequate evidence of their effectiveness or cost-efficiency.

The question of intent becomes particularly critical in situations where approximate information is purposefully used to deceive. For instance, if a company or organization promotes a decision model derived from a consultant or paper mill—a source of low-quality or fabricated academic research—there is a clear intention to mislead stakeholders into believing that the model is credible. In this context, the use of approximate information becomes not just a failure of rigor but a deliberate act of fraud, designed to manipulate perceptions and outcomes for personal or institutional gain.

In the scenario where the truth is unknown and a decision model is used to create claims supporting a product with no factual basis, this behavior leans more toward bullshit than a traditional lie. A lie requires knowledge of the truth and a deliberate attempt to communicate something false with the intent to deceive. In this case, since the truth is not known, the individuals involved cannot be said to be intentionally falsifying something they understand. However, by constructing imaginary claims that promote a specific product, they are manipulating information for strategic gain. The key distinction is that those creating the claims are indifferent to whether these statements are true or false. Their focus is not on determining the truth but on presenting information that supports their sponsor's interests. This behavior aligns closely with Frankfurt's definition of bullshit, where

the speaker is unconcerned with the truth value of their statements and is more interested in achieving a particular outcome. While this may not meet the strict definition of lying (as no known truth is being directly falsified), it still involves misleading the audience.

Moreover, the acceptance of approximate information without rigorous evaluation can lead to a culture of complacency within the healthcare sector. Stakeholders may become reliant on models that lack the depth necessary for sound decision-making, potentially fostering an environment where decisions are made based on superficial or questionable data. This complacency can perpetuate the use of flawed models, further entrenching a cycle of poor decision-making and ineffective health interventions. As stakeholders increasingly depend on approximations, the fundamental need for robust, transparent models that produce evaluable claims diminishes, placing the integrity of healthcare decisions at risk.

The concept of approximate information in health technology assessment highlights a significant failure to provide evaluable claims essential for informed decision-making. The implications of this inadequacy extend beyond mere uncertainty; they call into question the intent of those who develop and promote such models. If approximate information is used deliberately to mislead stakeholders, it crosses the line from being merely flawed to becoming bullshit. This creates a dangerous dynamic where stakeholders may unwittingly base critical health decisions on intentionally misleading data. This does not, of course, allow a differentiation between decision models that are intentionally deceptive from those that are, hopefully in good faith, intended to produce the 'best guess' at 'approximate information based on choice of model structure and 'realistic' assumptions to create imaginary non-evaluable claims.

The distinction between pseudoscience and bullshit becomes relevant when examining assumption-driven decision models that generate imaginary, non-evaluable claims. Such models often present themselves as rigorous or scientific but lack empirical support and methodological soundness. They may use scientific-sounding language and concepts to enhance credibility, yet they do not adhere to the scientific method, making them resemble pseudoscience. In this context, pseudoscience misrepresents itself as legitimate, relying on unfounded assumptions while producing claims that cannot be tested or validated. However, these models can also embody bullshit, as they may be crafted with a disregard for truth. Their authors might not genuinely believe in the validity of the claims; instead, they focus on persuading an audience or promoting a specific agenda without concern for empirical evaluation. This indifference to whether the claims can be substantiated or evaluated aligns more closely with the concept of bullshit. Ultimately, while such assumption-driven decision models may exhibit traits of pseudoscience by falsely claiming scientific validity, they can also be characterized as bullshit due to their lack of concern for truth and empirical validation. Thus, they might be viewed as encompassing encompass elements of both categories, reflecting a failure to engage meaningfully with evidence and reality.

But the failure to consider truth value in the HTA belief in decision models goes further than pseudoscience; there is a complete rejection of the standards of normal science and fundamental measurement. As the decision models completely reject the standards of normal science and fundamental measurement while embracing a relativist position, they are unequivocally bullshit. This approach undermines the very foundations of rational discourse and empirical inquiry, opting instead for a framework where anything can be deemed "true" based solely on individual or

cultural perspectives. Such models are not just misguided; they are a blatant disregard for the evolution of objective knowledge. Instead of a belief in a mind independent reality, decision models create a mind dependent reality; a reality that is created rather than observed.

By dismissing established scientific standards, these models craft imaginary, non-evaluable claims that serve no purpose other than to mislead, manipulate, or promote an agenda. They lack any commitment to truth or reality, prioritizing subjective interpretations over objective evaluation. This indifference to verifiable evidence and the genuine pursuit of understanding is the hallmark of bullshit. In essence, these models represent a conscious choice to prioritize rhetoric over reason, contributing nothing of value to genuine knowledge or decision-making. Rather than engaging with the complexity of reality, they provide a convenient façade that masks their emptiness. Any claims made within this relativist framework are devoid of substance and serve merely as tools for persuasion, not for enlightenment. They deserve to be called out for what they are: bullshit that undermines both intellectual integrity and the pursuit of truth.

## **BELIEF IN INDUCTION**

Without exception, HTA decision models, notably the assumption driven lifetime assumption driven modelled simulations designed to create imaginary cost-effectiveness claims, fall short in their failure to understand a simple logical point: the problem of induction, first recognized by David Hume in 1748. The issue is one of simple logic: from the fact that all past futures have resembled past pasts it does not follow that all future futures will resemble future pasts. The principle of induction cannot, as made clear by Russell, be proved or disproved. To argue from past experience overlooks those instances that were not observed. This leads to a circularity that in order to make the case induction from past observations we have to first accept the principle of induction. Endorsing decision models where imaginary future claims for cost-effectiveness are driven by assumptions derived from the literature is to deny the problem of induction; endorsing a belief that such assumptions are realistic for an unknown future is nonsense.

The lack of appreciation of the problem of induction is compounded by the timeframe for reference case models. A model that makes assumptions for the future than extends for decades is ridiculous, more so when by design the resulting cost-outcomes claims are non-evaluable, resting their laurels on QALYs that are mathematically impossible. It should also be noted that the choice of assumption is often limited to one or two references; there is no concept even of confirmation of past futures. Utility scores, for example are often based on one or two references with different utility scores limped together. There is no account taken of the merits of an assumption; a previous modelled or therapy impact claim that may be false. Even so, if attention were given to the ‘quality’ of assumptions, these long-term reference case modelled claims still lack truth value. The amount of attention given is surprising given reference claims cannot play, from an epistemological viewpoint, a role in resource allocation. With the application of thresholds, defined again in model terms with impossible QALYs, health care is allocated, in a true eugenic tradition, by an analytical decision framework that is not a serious intellectual pursuit.

If we allow inductivism, modeled claims about the future that are not empirically evaluable can be criticized on inductivist grounds, in addition to being considered "bullshit" due to their lack of concern for truth. Inductivism posits that reliable claims about the future must be based on observed patterns from the past, where empirical evidence—gathered from repeated

observations—supports generalizations or predictions. When a model is constructed in a way that prevents empirical testing, it undermines the foundational principles of inductive reasoning.

Such modeled claims violate the inductivist requirement that future predictions must be potentially verifiable against future observations. If a model is designed to evade scrutiny—through vague predictions, isolation from real-world outcomes, or other means that prevent empirical evaluation—it fails to satisfy the basic tenets of inductivism. This leads to a dual critique: first, the lack of empirical grounding means the model does not derive its claims from past observations, and second, its inability to be tested renders it useless for inductive reasoning. From an inductivist perspective, the validity of a claim hinges on its ability to be confirmed through empirical observation, which these modeled claims explicitly avoid. This makes them not only epistemically weak but also philosophically problematic under the framework of inductive logic. Consequently, such claims can be justifiably criticized for their lack of empirical basis and their design that ensures they remain untestable, reflecting a fundamental disregard for the principles of inductive reasoning.

## **THE STANDARD FOR VALUE CLAIMS**

A value claim is considered to lack truth value when it cannot be assessed as true or false due to insufficient evidence or inherent limitations that prevent empirical evaluation. This typically occurs when the claim is speculative, anecdotal, or based on theoretical constructs that do not adhere to the standards of scientific inquiry. In such cases, the claim is not regarded as credible or valid, as it cannot be substantiated through observation or experimentation. Furthermore, if a claim has no chance of ever being empirically evaluated, it should be dismissed as lacking truth value. This rejection underscores the importance of evidence-based assessment in determining the relevance of value claims. Without the ability to test or verify a claim, it remains speculative and cannot be taken seriously within a scientific framework; it lacks epistemological value. Ultimately, a claim lacking truth value highlights the necessity for rigorous standards in evaluating knowledge, ensuring that only those claims supported by empirical evidence are accepted as meaningful yet provisional.

There is one and only one standard for value claims in HTA: they must have truth value. Given the presumption that practitioners in HTA intend to participate in what Popper has described as the evolution of objective knowledge, then HTA must reject the analytical dead end of decision modelling generating assumption driven non-evaluable claims for cost-effectiveness <sup>6</sup>. While many, if not the majority of HTA participants might argue that the role of HTA is to create approximate information with imaginary decision models to support health care decision making or marketing, this will only guarantee their position as a non-science, alongside creationism or intelligent design <sup>7</sup>. If so, it is difficult to see if HTA will continue to be taken seriously, least of all as part of academic curricula; if it continues it will be seen as a niche area of non-science interest with followers embracing an HTA cult.

Popper's philosophy emphasizes that for claims to contribute to objective knowledge, they must possess truth value, which requires empirical evaluability. According to Popper, scientific theories should be testable and falsifiable; they gain credibility only when subjected to rigorous scrutiny and experimentation. Claims that lack truth value—those that cannot be empirically evaluated—

fail to advance our understanding and remain in the realm of speculation. In this framework, the evolution of objective knowledge relies on the ability to assess assertions through observable evidence. Only claims that can be rigorously tested can enrich scientific discourse and contribute to a cumulative understanding of reality. Thus, Popper underscores that the pursuit of knowledge is intrinsically tied to the truth value of claims, reinforcing the necessity of empirical validation in distinguishing credible theories from unsubstantiated ideas. This alignment of truth value with empirical rigor is essential for the advancement of knowledge in any scientific field.

## **VALUE CLAIM PROTOCOLS**

The role of protocols to detail how clinical claims are proposed and assessed should be the model for all value claims; they are completely absent in HTA decision modelling. Transparency is key to establishing the credibility of a claim, its empirical assessment and the importance of claim replication. This does not mean that clinical protocols are not designed to hopefully ensure the best case for a product. As value claims for new products are typically placebo controlled, the importance of comparator claims in real world treatment environments is essential for both the phase 3 protocol to replicate claims as well as reproduction of claims in a more diverse target population. There are long standing concerns over the quality of pivotal clinical trials primarily due to issues related to methodological rigor, data integrity, and publication bias. While there has been an ongoing debate over replication with real world data and guidelines issued to support such efforts, little attention has been given to the possible role of protocols to support value claims or the standards for value claims. An agreed protocol for a value claim will not only support transparency but go towards alleviating long-standing concerns regarding the difficulties of replicating and reproducing clinical trial protocols. This will set the stage for ongoing disease area and therapeutic class reviews, together with value-based contracting. In the last resort no value claim should be accepted unless it is supported by an agreed protocol and replicated in the target patient population.

The extent to which fraud, the intent and knowledge of making false or misleading statements about the benefits, efficacy, safety, or other characteristics of a product, is present in decision modelled claims is unknown, but with the thousands of reference models presented in the literature it is undeniably present <sup>8</sup>. Fortunately, the overwhelming majority of these reference case publications will never be revisited. They will have served the purpose of claiming cost-effectiveness for the sponsor's product with a leg up to get the product on formulary. Unfortunately, few formulary members have either the skills nor the time to evaluate reference case model claims; it is sufficient for manufacturers to claim they meet guideline checklist requirements. As these guideless typically skirt around questions of the standards of normal science and fundamental measurement, the exercise is very much an invitation to bias and fraud <sup>9</sup>.

## **CONCLUSIONS**

Are decision models worth the effort in health technology assessment? As presently practiced in HTA the answer unequivocal: the must be rejected. HTA decision models serve no useful purpose despite the claim that they provide approximate information. They make no contribution to the evaluation of competing therapies in terms of clinical, PRO and resource utilization claims; they lack truth value and any contribution to the evolution of objective knowledge. They are bullshit. No attempt is made to consider an external mind-independent reality; a contribution to the



evolution of objective knowledge. Rather, they are mind dependent creations, supported by guidelines that open the door to a myriad of subjective claims that not only fail the standards of normal science and fundamental measurement but assiduously promote impossible constructs such as the QALY.

The implications of this relativist position are significant. When the reality of claims is viewed as entirely subjective, existing solely in the mind of the decision model builder, it embodies a radical form of idealism or subjectivism. In this context, the claims reflect the builder's personal beliefs, experiences, and biases rather than any objective criteria or empirical evidence. Consequently, these claims become non-evaluable by external standards, lacking the ability to be objectively tested or validated. This subjectivity fosters a perspective that permeates a belief system where conflicting claims can coexist without a clear basis for adjudication, leading to a fragmented understanding of reality. The focus shifts from truth-seeking to manipulation and persuasion, allowing claims to be tailored to achieve desired outcomes without regard for predictive integrity. This undermines the integrity of the decision-making process. Finally, seeing reality as entirely subjective diminishes the accountability of the decision model builder. They may operate without the responsibility to align their claims with observable evidence or objective standards. This raises significant philosophical challenges regarding the value of claims made in such a framework and highlights the potential consequences for rational discourse and effective decision-making, ultimately questioning the legitimacy and reliability of the claims produced.

If there is a commitment to rejoining the mainstream and formulate a new start in HTA that recognizes the standards of normal science and fundamental measurement then the standard for value claims is clear cut: all value claims must be credible, evaluable and replicable with the claim presented as a unidimensional, linear, interval and invariant measure. This means rejecting the existing standards and commitment in HTA to decision modelling. Indeed, we might go far as to say that the failure of the HTA belief system in HTA is due in large part to the long standing and uncritical acceptance of decision modelling and the consequent rejection of truth value.

The case for a new start in HTA has been detailed in a recently issued Certificate Program from the School of Pharmacy, University of Wyoming.

## **UNIVERSITY OF WYOMING CERTIFICATE PROGRAM**

### **A NEW START IN HEALTH TECHNOLOGY ASSESSMENT**

For those who are interested in following up the arguments presented here for Rasch standard patient centric value claims, the recently released on-line University of Wyoming Certificate Program: A New Start in Health Technology Assessment is recommended.

The Certificate Program is in three parts:

- Part I: Required evidentiary standards for product and therapy assessment
- Part II: The failure of approximate modelled information for therapy decisions
- Part III: Formulary submission value claims and protocols for a new start in product evaluation in health system management

The Certificate Program package includes extensive notes (overall for the 14 modules 85,000 words), audiovisual presentations and a short true-false and multiple-choice assessment for each module. The cost of the Certificate Program is \$875 USD with 20.5 hours of ACPE credit. For those who do not need ACPE accreditation, the University of Wyoming will provide a Certificate of Completion. Following interest already expressed, for those introducing the proposed new start standards for technology assessment there will be a program of one- and two-day workshops and on-line seminars to support course development and alternative program structures to meet local needs. There will also be a series of working papers to explore specific aspects of the new start program.

The link to register in the Certificate Program is:

<https://www.uwyo.edu/pharmacy/resources/certificate-program-a-new-start-in-healthtechnology-assessment.html>

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