PR NEW START TRAINING MODULE PROGRAM: INTRODUCTION

REJECTING PSEUDOSCIENCE:

A NEW START IN HEALTH TECHNOLOGY ASSESSMENT

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Welcome to the PR Training Modules for a NEW START in Health Technology Assessment. These modules present the case that the existing approach to health technology assessment is an analytical dead end. More to the point: we have wasted some 30 years in advocating the creation of value claims that lack any scientific credibility. The reason is quite straightforward: The International Society for Pharmacoeconomics and Outcomes Research (ISPOR), the Institute for Clinical and Economic Review (ICER) and academic groups, following leaders in the field, have rejected the standards of normal science: the requirements that all value claims for response to therapy have to expressed as single attributes that are credible, evaluable and replicable [1].

Instead, the focus has been on assumption driven simulated claims that fail the demarcation test for science in terms of non-science; they are pseudoscience [2]. The modeled claims proposed to establish the cost-effectiveness of competing therapies are a failed methodology. They fail not only because they reject the standards of the physical sciences and the more advance social sciences, but because the entire modeling framework is a logical and mathematical impossibility. It is an analytical dead end; a barren belief system

ISPOR AND ICER are aware of the manifest deficiencies in modelled claims [3]. Yet they persevere, as shown by the recently released CHEERS 22 guidance for construction and submission of imaginary value claims for competing products to leading journals; who have in turn endorsed them [4]. The belief is that formulary committees are prepared to accept imaginary claims to support pricing and access decisions. A problem, of course, is that by changing assumptions any number of competing modeled claims can be presented. Journal editors are presumably more than happy to publish any number of assumption driven imaginary claims which have no relation to reality for an unknown future.

To understand why the current approach to health technology assessment is an analytical dead end, it is recommended you review a recent publication for CHEERS 2022 (or CHEERS 22) [5]. This offers, first, a detailed critique of why the ISPOR/ICER belief in imaginary value claims should

be abandoned and, second, why we need a new start in technology assessment that is meaningful to health system decision makers and which is not metaphysics or pseudoscience, but an analytical framework consistent with the standards of normal science.

There is, presumably, more to health technology assessment than the creation of an endless number of assumption driven imaginary simulations that leading journals are willing to publish. Of interest, perhaps, as marketing support but of no relevance to formulary decision making as any imaginary claim is as valid (or invalid) as any other.

It is not often appreciated, but the ISPOR/ICER analytical framework supports a belief system in imaginary value claims that is unique in the physical and social sciences in rejecting the standards for the discovery of new, yet provisional facts, that has been accepted for over 300 years [6]. ISPOR/ICER are devoted to a belief system which has more in common with that prevailing in the middle ages, and not overthrown until the scientific revolution of the 17th century by figures such as Bacon, Galileo, Descartes and Newton.

In this context it is worth remembering the motto of the Royal Society (founded in 1660): *nullius in verba* (take nobody's word for it). ISPOR/ICER turn this on its head by asking, in assumption driven claims, that we take anybody's word for it [7]. Any non-empirically evaluable claim is as good (or bad) as any other; just attend an annual ISPOR conference.

The purpose of this NEW START educational program is to set the stage for abandoning the current belief system in health technology assessment; it has to go lock, stock and barrel. We must accept that the standards of normal science are relevant to formulary decision making and value claims for therapy response. In the last resort it is about measurement; if the tools used to support claims for measuring response are irrelevant, failing to meet required measurement standards, then we have to reject almost all direct and indirect generic preference scores and the overwhelming majority of patient reported (PRO) instruments. They all fail the axioms of fundamental measurement.

Value claims must be disease specific and for specific attributes relevant to formulary decisions whether these are for clinical claims, quality of life claims or drug and resource utilization claims. The target must be to develop instruments that meet ratio or interval measurement properties. Blanket claims for comparative cost-effectiveness are totally unacceptable.

In short, NEW START rests on two requirements:

(1) All value claims for a product or therapeutic intervention must refer to single unidimensional attributes that meet the demarcation standards for normal science: all value claims must be credible, evaluable and replicable in a meaningful timeframe; and
(2) All value claims must be consistent with the limitations imposed by the axioms of fundamental measurement: they must meet interval or ratio measurement standards

It is no exaggeration to make the case that in health assessment we have wasted 30 years; although no leader in this field, principally academic, will admit to this. After all, to base one's professional career on a series of false assumptions, and demonstrated lack of awareness of the standards of

normal science, in particular fundamental measurement, is a failure few would care to acknowledge. If we add to this the extent to which literally thousands of students and analysts have followed this lead makes admission all the more damaging. There are now thousands of publications generating mathematically impossible quality adjusted life years (QALY) models, none of which have any pretense to scientific credibility [8].

It is not so much that health technology assessment is at the crossroads; the decision to take the wrong road was made decades ago. No, we must abandon the assessment belief system (or meme) completely. This will be defended; the wagons will be pulled into a circle. There is no option: we require a paradigm that makes analytical sense and which brings us back to the standards we have long ignored.

This educational package is in three parts

- Four modules that make the case for the standards of normal science and rejecting pseudoscience:
    - Science versus non-science
    - Ratio and interval measures
    - Assumptions and Hume's problem of induction
    - CHEERS 22: Tenacity of false belief systems in health care evaluations

- Five modules that address the failure of approximate information:
    - Truth is not consensus
    - Failure of multiattribute generic preference measures
    - The impossible QALY
    - Impossible value claims
    - Abandoning models in value claims

- Five modules that detail the standards for a NEW START in health technology assessment
    - Guidelines for value claims in formulary submissions
    - The patient voice: need fulfillment quality of life
    - Selecting PRO claims
    - Formulary submission guidelines – Patients Rising
    - Questions a formulary committee should ask

At the conclusion of each module, participants can down load (i) a copy of the slides; and (ii) notes and references to support the slide presentation.

REFERENCES

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