

**University of  
Wyoming**  
College of Health  
Sciences  
School of Pharmacy

**CONTINUING PHARMACY EDUCATION**  
Accreditation Council for Pharmacy  
Education



**WYOMING CERTIFICATE  
PROGRAM**

**A NEW START IN HEALTH  
TECHNOLOGY ASESMENT**

**INTRODUCTION**

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## **WYOMING CERTIFICATE PROGRAM**

Welcome to the School of Pharmacy, University of Wyoming 2023/2024 Certificate Program *A New Start in Health Technology Assessment*. This is a 14-module, ACPE 20.5 credit hour certificate program designed to introduce a new start for the evaluation of pharmaceutical products and devices.

The proposed new start demonstrates that the commitment to assumption driven modelled simulation to support cost-effectiveness claims is an analytical dead end. It meets neither the standards for normal science not the required measurement standards. The new start delivers a comprehensive package to support formulary submissions, prospective research programs to discover new facts for therapy response as well as the necessary inputs for outcomes-based contracting.

The focus of this program is to examine the appropriate theoretical and practical foundation for the methods and application of techniques in health technology assessment (HTA) that meet the standards of normal science and fundamental measurement <sup>1</sup>. This involves meeting the evidence needs of formulary committees, practitioners, patients and other health system decision makers and is critical for effective health care delivery, together with the meaningful assessment of pharmaceutical products and devices by pharmacists in everyday practice. At the same time, we require disease specific single attribute and direct patient centric measures of the benefit of a new therapy to patients and caregivers. This can be achieved by the latent construct of need-fulfillment to produce unidimensional, linear and interval measures applying the Rasch model of instrument development.

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

The Wyoming Certificate Program in three parts: (i) required evidentiary standards for product and therapy assessment (4 modules); (ii) the failure of approximate modelled information for therapy decisions (5 modules); and (iii) formulary submission value claims and protocols for a new start in product evaluation (5 modules). The program aims to make the case for rejecting 30 years of much misplaced and wasted effort in HTA. In the early 1990s the decision was made that in order to make the case for new pharmaceutical products at product launch; hypothesis testing was to be abandoned in favor of creating assumption driven modeled approximate information to support formulary decisions <sup>2</sup>. This was uncritically accepted by leaders in the field and detailed in textbooks and practice guidelines <sup>3</sup>. It was also uncritically accepted by academic centers, government agencies and analysts despite warnings to the contrary <sup>4 5</sup>. The result was the acceptance for publication of thousands of cost per quality of life (QALY) assumption driven imaginary claims which fail to meet the standards of normal science and fundamental measurement and their continued application by groups such as the Institute for Clinical and Economic Review (ICER) <sup>6 7</sup>. At the same time this acceptance of assumption driven modelled claims is open to abuse and bias <sup>8</sup>. We are still locked into this belief system with the recent publication of the CHEERS 2022 guidance for submitting imaginary modeled claims to academic journals <sup>9 10</sup>.

The new start paradigm provides a theoretical and practical foundation for the appropriate methods and application of techniques in HTA that meet the standards of normal science and fundamental

measurement. Meeting the evidence needs, including outcomes contracting, of formulary committees, practitioners, patients and other health system decisionmakers, including minimizing bias, is critical for effective health care delivery and the meaningful assessment of pharmaceutical products and devices<sup>11</sup>. This program proposes a new start in HTA to meet the needs of health system decision makers; a framework of analysis that is not only consistent with the standards of normal science and Rasch or modern measurement theory<sup>12</sup>, but one that focuses on capturing needs-fulfillment quality of life of patients and caregivers. The importance of rejecting non-evaluable value claims for conducting and assessing outcomes research will be emphasized. This rejection provides a firm empirical basis for evaluating long-term clinical, quality of life and resource utilization outcomes, including engaging with health systems to identify and even contract for key value claims as part of disease area and therapeutic class reviews.

Many practitioners are aware of the manifest deficiencies in modelled claims<sup>13</sup>. Yet the majority persevere in the belief that formulary committees are prepared to accept imaginary claims to support pricing and access decisions. The problem, is that by changing assumptions any number of competing modeled claims can be presented<sup>14</sup>. At the same time, journal editors are presumably more than happy to publish any number of simulated imaginary claims, driven by assumptions, which have no relation to reality for an impossible unknown future.

It is not often appreciated, but the current analytical framework supports a belief system in imaginary value claims that is unique in the physical and social sciences; rejecting the standards for the discovery of new, yet provisional facts, that has been accepted for the 375 years since the scientific revolution of the 17<sup>th</sup> century. While practitioners in HTA or pharmacoeconomics claim it is a branch of economics, this is wishful thinking. It is totally at variance with the standards of analysis both in mainstream economics and in the applied discipline of health economics, the study of the production and consumption of health and healthcare; we must not confuse the ‘standards’ of non-science with those of science. HTA follows a belief system which has more in common with that prevailing in the middle-ages; one beginning only to be overthrown with the scientific revolution of the 17<sup>th</sup> 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). This is rejected in HTA by asking, with assumption driven claims, that we take any person’s word for it; any assumption driven non-empirically evaluable claim is presumably as good (or bad) as any other.

It is worth quoting Richard Dawkins, the evolutionary biologist, on differentiating science from non-science (or simply faith in creating non-evaluable approximate information value claims):

*.....the selective forces that scrutinize scientific ideas are not arbitrary or capricious. They are exacting well-honed rules and they do not favor self-serving behavior. They favor all the virtues laid out in textbooks of standard methodology: testability, evidential support, precision, quantification, consistency, intersubjectivity, repeatability, progressiveness, independence of cultural milieu and so on<sup>15</sup>.*

Measurement is critical if value claims for competing products are to have any credibility. If the tools used to support claims for measuring response are irrelevant, failing to meet required

measurement standards, then we have to question almost all direct and indirect generic preference scores and the overwhelming majority of patient reported (PRO) instruments. Most fail the axioms of fundamental measurement and the tools of simultaneous conjoint measurement that have been practiced in other social sciences for 60 years.

At the same time, value claims must be disease specific tailored to 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. Assumption driven simulated blanket claims for comparative cost-effectiveness are totally unacceptable.

It is not so much that HTA is at a crossroads; the decision to take the wrong road was made decades ago. No, we must seriously question the pharmacoeconomic belief system (or meme). 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 is the purpose of this ACPE Certificate Program from the School of Pharmacy, University of Wyoming.

## **FROM MEME TO PARADIGM**

It is now increasingly recognized that the existing belief system or meme in health technology assessment (HTA), designed to capture blanket non-evaluable claims for cost-effectiveness through the invention of assumption driven simulations incorporating incremental cost-per-QALY claims and thresholds, is an analytical dead end. Despite the widespread acceptance of this meme evidenced by the leading textbook by Drummond et al, and the recently endorsed Consolidated Health Economic Evaluation Reporting Standards 2022 (CHEERS 2022) guidance statement and the proposed complement and possible successor to the EQ-5D-5L multiattribute generic measure the EQ-Health and Wellbeing (EQ-HWB) generic instrument<sup>9 10 16</sup>. The meme fails to recognize the standards of normal science which all claims must be credible, empirically evaluable and replicable, and the standards of fundamental evidence where, following the seminal work of Rasch in the 1950s, all claims for measurement must have unidimensional interval or ratio properties; a requirement recognized for over 50 years in measurement theory<sup>4 5</sup>. The acceptance of the current HTA meme, the self-replicating belief system, cannot be described as a paradigm; a necessary framework which supports Popper's notion of the evolution of objective knowledge in a user accessible and management framework by discarding black box simulation models<sup>17</sup>.

The result is that health technology assessment, as practiced for the last 30 years, is unique in its commitment to non-empirically evaluable claims for cost-effectiveness<sup>3</sup>. This analytical framework denies progress and the discovery of new facts in therapy impact; resting instead on the hope that formulary committees will factor in imaginary claims for cost-effectiveness into their decision-making. To those who, over the past 30 years, have been trained and believe implicitly in the role of modeled approximate information to drive decisions, putting hypothesis testing to one side, these claims, as exemplified in the practice guidelines for modeling produced by the International Society for Pharmacoeconomics and Outcomes Research (ISPOR), must appear irrational<sup>2</sup>. After all, quality adjusted life years (QALYS) have been a cornerstone of economic evaluations; unfortunately, the QALY is an impossible mathematical construct as it involves

multiplying time spent by an ordinal utility or preference multiattribute score<sup>18 6</sup>. But multiattribute or composite scores, given the standards of fundamental measurement<sup>19</sup>. Once these measurement requirements are recognized aggregate scores from Likert scales must also be rejected; they are only accepted if we can demonstrate that the relative value of each response category are treated as being the same, and unit increases across the rating scale are given equal value. The result is that that all multiattribute generic and disease specific instruments are nothing more than ordinal observations; the authors of these instruments fail to recognize that the Rasch measurement model provides the necessary and sufficient means to transform ordinal counts into linear measures to support value claims in HTA<sup>6 12 20</sup>.

Unfortunately, current analytical standards in pharmacoeconomics or health technology assessment (HTA) fail to meet the required evidentiary standards. The misplaced focus on approximate information, assumption driven simulated and non-empirically evaluable modelled claims for cost-effectiveness. At the same time, in focusing on disease specific value claims, and rejecting multiattribute generic preferences and quality adjusted life years (QALYs), there is a pressing need to understand the impact of modern or Rasch measurement rules to construct patient reported outcome (PRO) instruments that support meaningful claims for response to therapy.

## **CORE VALUE CLAIMS**

The proposed new start in HTA puts aside imaginary assumption-driven simulations and impossible claims for cost-effectiveness, including the mathematically impossible QALY, in favor of a transparent commitment to single attribute value claims, supported by protocols, that are empirically evaluable to support formulary decision making; a concrete and transparent approach to support managerial decisions. An approach consistent with both the standards for normal science recognized in other disciplines and the limitations imposed on patient-reported outcomes by the axioms of fundamental measurement; a program that meets the neglected evidence requirements in health system decision-making.

The focus of the proposed new start in HTA is agreement on core value claims in disease areas and for target patient populations. These value claims must encompass, at least for the entry of new product or first assessment of existing products: (i) clinical [instrument based] claims; (ii) patient reported outcome claims [disease symptoms as well as aspects of quality of life as a latent construct], (iii) drug utilization [uptake on market entry and compliance], and (iv) other resource utilization impacts [as units not costs]. The three premises for value claims are:

- All value claims must be proposed as single attributes which meet the standards of normal science: credibility, empirical evaluation and replication
- All value claims must meet Rasch standards for fundamental measurement (interval or ratio measures]
- All value claims must be presented with a supporting protocol for evaluation and reporting within a meaningful timeframe

The Certificate Program makes clear that these three premises are the basis for any guidance documentation to manufacturers for formulary submission. Submissions that fail to meet these standards must be rejected. This means that the majority of patient reported outcome (PRO)

instruments, multiattribute and disease specific will be rejected; they will fail Rasch standards <sup>21</sup>. Single attribute PRO claims must be unidimensional with at least interval measurement properties, captured by either Rasch dichotomous modeling, the polytomous Rasch Rating Scale Model or Partial Credit Rasch Model <sup>5</sup>. Also excluded will be assumption driven simulation models with non-evaluable claims for cost-effectiveness; the use of quality adjusted life year (QALY) claims and non-evaluable constructs such as multiattribute efficiency frontiers.

The overall intent is to apply the criteria that can justify HTA as science and not non-science or pseudoscience; it must meet the demarcation criteria <sup>22</sup>.

## MEASUREMENT

A recurring theme in the Certificate Program is the imperative of measurement from the requirement that before responses from assessments can provide measurement, they have to be transformed to provide measurement properties. This is made an imperative in Rasch or modern measurement theory where, following Andrich and Marais, *assessment* is the engagement of that entity with some instrument, with a protocol recording the observations or counts of the engagement, while *measurement* involves some kind of transformation and is defined as the *estimation of the amount of a unidimensional trait relative to a unit*. The unit derives from a scale of equal units that provide the measurement on linear continuum while scaling locates an entity on that scale. Assessment precedes measurement; we measure the properties of entities that are of interest, not the entities themselves; for example, we don't measure persons but the manifested psychological attributes, traits or constructs of that person that are of interest. To capture the construct of interest we require a procedure to manifest or assess the property of interest.

The critical distinction, as Wright and Linacre, express it is between observations, counts of observed events and the transformation to quantitative measures, the arithmetical property of linear scales. In the terminology of measurement theory, the transformation from ordinal (or nominal) data to interval (or ratio) linear measures. This sets the objectives in modern measurement (but not quite modern as it has been recognized for some 60 years or more) to transform observations or instrument assessments, the entities construct of interest, to a unidimensional, interval (or ratio) scale. To enable this transformation, we require procedures or rules, these are provided by a unique solution which is termed Rasch measurement. Why unique? Because the Rasch measurement model provides the necessary and sufficient means to transform ordinal counts to linear measures.

The failure in the current HTA belief system is that, with only a handful of exceptions (which have been red flags for decades) the many HTA practitioners, the authors of thousands of peer-reviewed and published papers, have not recognized the need to transform ordinal observations to interval measures; measures which must have unidimensional properties. We are locked into a 'measurement' meme which denies the ability to provide meaningful measures of response to therapy defined in unidimensional and interval terms. Instead, the gold standard is to create, from raw counts or observations, multiattribute measures which fail at the first hurdle; bringing down with them the multitude of studies that provide incremental cost-per-QALY claims, where the QALY is an impossible mathematical construct.

In contra-distinction to the CHEERS 2022 guidance for submitting assumption driven non-evaluable cost-per-QALY claims to journals is the recently released (at almost the same time as CHEERS 2022) are the Rasch Reporting Guidelines for Rehabilitation Research (RULER)<sup>23 24</sup>. These are not a recent innovation; studies reporting Rasch measurement in the context of rehabilitation outcomes were first reported in 1988. The purpose of RULER is to provide peer-reviewed, evidence-based and consistent guidance for reporting studies that apply Rasch measurement theory in a rehabilitation context so that there are uniform expectations on how to write and evaluate research on rehabilitation outcomes assessments. The RULER template is one that should be applied across disease areas if we are to evaluate Rasch-based claims for therapy response. Such a commitment from decision makers should be seen as an essential part of a new start in health technology assessment, incorporated in submission guidelines for health systems.

## **ASSUMPTIONS**

A further theme for the Certificate Program is what we may call the ‘misuse of assumptions’; in other words, a failure in simple logic to recognize the implications of Hume’s problem of induction. This misuse is pervasive, despite the preoccupation of philosophers of science with its implications over the past 250 years or more since its first appearance in the work of David Hume (1711-1775), a Scottish philosopher in 1748. The issue is the relation, if any, between claims from the past and claims on the future; expressed as the notion of the realism of assumptions. The application is pervasive: the construction of assumption driven simulated model claims on the future, typically the lifetime of a hypothetical population, to make a case for incremental cost-per-QALY claims and, supported by sensitivity analyses, threshold-based recommendation for cost-effectiveness, pricing and product access. This was effectively demolished by Russell in 1912 with his example of the farmer who feeds a chicken each day to fatten it up until the day when the former comes out, the chicken approach expecting to be fed and the farmer wrings its neck. Put less evocatively: the fact that all past futures have resembled past pasts does not mean that all future futures will resemble past futures. Induction, or confirmation of a claims, is logically impossible. We cannot even argue probabilistically because the data on which the claim is based are only a sample of all possible claims. Hence, we cannot say that one assumptions or set of assumptions (and there can be dozens from the literature and even guesses from experts) to support a simulation model are any different (less, equally or more realistic) than any other. In short, no one simulation model, such as those produced by the US Institut of Clinical and Economic Review is any better (or worse) than another. Apart from the fact that these models are multidimensional, lack evaluable claims and were only designed as vehicles for approximate information; in the last case, of course, it not clear as to what they are approximating. Add to this the fact that these models are an invitation to reverse engineering to support a sponsor’s claim for cost-effectiveness at a price that meets the sponsors revenue projections.

This critique does not deny the role of models and assumptions supporting those models; a common feature of research in the physical and more mature social science (supporting paradigms and not memes). If the model is designed to generate credible, evaluable and replicable claims then if it fails to meet assessment standards for provisional acceptance, the entrails or assumptions of the model can be reviewed.

## **PROTOCOLS**

Protocols are an integral part of the proposed new start in HTA just as they are integral to product development. Once, however, marketing approval is secured, the application of protocols is put on the back burner (apart from Phase 4 trials) for value claims assessment. This is a critical mistake; if we are to support value claims assessment for a product over its life cycle, protocols are front and center in support of value claims, in providing a framework for evaluating and re-evaluating the merits of value claims. Recognizing the asymmetry between proof and disproof, a protocol should support a value claim in presenting that claim in a format that recognizes the role of falsification of claims; strictly, a protocol should maximize the likelihood of a value claim being falsified <sup>25</sup>.

Recognizing the importance of falsification as the demarcation criteria between science and non-science, the focus on falsification is the basis for the provisional acceptance of value claims over the product life cycle is essential. This sets the new start in HTA apart from the relativistic acceptance of non-evaluable formulary proposals, and claims for a fair price modelling driven by fixed parameters and limited assumption options. At all stages of product formulary acceptance and continued approval, placement and pricing there must be strong and explicit commitment to transparency and not black-box models to support ersatz outcome claims. Ongoing value claim protocols are the basis for this continued re-evaluation or evolution in objective knowledge, supporting if required outcomes-based contracting

At the same time the proposed new start recognizes that over a product life cycle pricing and access are provisional. At product launch information and extant value claims are limited. Pricing negotiations must reflect the standards of existing claims while requiring the initial formulary submission to present value claims to be assessed in a short and meaningful time horizon. The protocol details the assessment process and must be agreed with the health system. There is the possibility of core and supplementary claims, specific to indication approved disease areas or target patient populations. Ongoing pricing and access reviews will be dependent on the outcome of value claim assessments.

## **PATIENT BENEFIT**

If we are to provide an assessment of the direct benefit to patients are caregivers of a new therapy then this must be a direct and not an inferred benefit from purely clinical considerations <sup>26</sup>. Certainly, we can report the clinical outcomes of pivotal trials, but we need to move to a holistic measure that manifests the needs-fulfillment latent construct. Needs which are subjectively reported by patients and which can then be transformed to linear interval measures by applying Rasch rules. As patients are the ultimate beneficiaries of health care interventions, where quality of life is impacted significantly by health status, notably in chronic diseases, then we need to assess needs by the difficulty of meeting them and the benefit from meeting more of the needs from a new therapy. We put aside, therefore. terms such as ‘efficacy’ and ‘effectiveness’ in favor of ‘needs fulfillment’.



## **SUBMISSIONS: DISEASE AREA AND THERAPEUTIC CLASS REVIEWS**

The proposed new start sets the stage for evidence-based decision making; evidence which meets the required standards for normal science and fundamental measurement. To achieve this the Certificate Program proposes a format for the assembly of product dossiers, to include questions that a formulary committee or other health system decision makers should address to ensure the submission is acceptable. These questions are relevant irrespective of whether the requested and submitted dossier, with protocol, is for the evaluation of a new product or device, for ongoing disease area and therapeutic class reviews or outcomes-based contracting.

The key point is data assembly; feedback from core value claims that are assessed with real world evidence to support the evolution of what Popper has described as objective knowledge. Therapy claims are not static; they represent a step in the discovery of new facts, to meet evidence gaps, in the support of a product over its life cycle. Creating simulated modelled assumption driven claims is not a starting point. Blanket claims for cost-effectiveness are not the basis for any process of discovery, particularly when they fail the standards of normal science and fundamental measurement.

## **CERTIFICATE PROGRAM STRUCTURE**

The Certificate Program comprises an on-line Introduction and 14 modules. Each module provides an audio/visual presentation supported by extensive notes/references and a true/false and multiple-choice assessment. Passing the module assessments is a prerequisite for Certificate Program ACPE credit. ACOPE Certificate number 0653-23-001-CP. At the conclusion of each module, participants can download (i) a copy of the slides and (ii) the notes and references to support the slide presentation. Each module has its own ACPE Certificate number.

The Certificate Program is presented in three parts:

- Part I: Required evidentiary standards for product and therapy assessment (4 modules);
- Part II: The failure of approximate modelled information for therapy decisions (5 modules); and
- Part III: Formulary submission value claims and protocols for a new start in product evaluation

### **Certificate Program: Introduction**

This Introduction, which is free on-line for all who wish more information before Registration (link CERTINTRO), details the structure and content of the Certificate Program in terms of the themes evaluated as a basis for formulary submission proposals, disease area and therapeutic class reviews, and outcomes-based contracting.

### **Certificate Program Part I**

The four modules in Part I have two objectives. First, to detail the required evidentiary standards for any value claim for product performance in terms of (i) the standards of normal science and

(ii) the failure of assumption driven multiattribute modeled simulations to produce value claims that meet the required standards; this is achieved by deconstructing the recently released Consolidated Health Economic Evaluation Reporting Standards 2022 (CHEERS 2022) Guidance for creating imaginary cost-effectiveness claims.

The modules are:

Module 1: Science versus non-science [ACPE 0653-0000-23-001-H99-P]

Module 2: Ratio and interval measures [ACPE 0653-0000-23-002-H99-P]

Module 3: Assumptions and Hume's problem of induction [ACPE 0653-0000-23-003-H04-P]

Module 4: CHEERS 2022: Tenacity of false belief systems in pharmacoeconomics [ACPE 0653-0000-23-004-H0A-P]

### **Certificate Program Part II**

These five modules focus on the failure of assumption driven modeled simulations in health technology assessment, in the quest for approximate information, to pass the demarcation test: they fail to meet standards for credibility of claims, the ability to be empirically evaluated and replicated in other target patient populations within a disease area. The practice of health technology assessment with the belief in assumption driven simulations means that it is non-science or pseudoscience.

The modules are:

Module 5: Truth is not consensus [ACPE 0653-0000-23-005-H0A-P]

Module 6: Failure of multiattribute generic preference measures [ACPE 0653-0000-23-006-H99-P]

Module 7: The impossible QALY [ACPE 0653-0000-23-007-H99-P]

Module 8: Impossible value claims [ACPE 0653-0000-23-008-H99-P]

Module 9: Abandoning models in value claims [ACPE 0653-0000-23-009-H99-P]

### **Certificate Program Part III**

These four modules set out the standards for establishing and evaluation value claims for therapies in health technology assessment that ensure that they are a firm basis for formulary submissions. Not only must all value claims be presented as single attributes whether for clinical claims, patient reported outcome claims, drug utilization and resource utilization, but they must be supported by an evaluation protocol and, if required, support outcomes-based contracting and ongoing disease area and therapeutic class reviews. Of particular importance a question managers and other formulary committee members should ask to support product value claims, pricing and formulary positioning.

The modules are:

Module 10: Guidelines for value claims in formulary submissions [ACPE 0653-0000-23-010-H04-P]

Module 11: The patient voice: Need fulfillment quality of life [ACPE 0653-0000-23-011-H05-P]

Module 12: Selecting PRO claims [ACPE 0653-0000-23-012-H04-P]

Module 13: Formulary submission guidelines [ACPE 0653-0000-23-013-H04-P]

Module 14: Questions a formulary committee should ask [ACPE 0653-0000-23-014-H04-P]

In addition, two live discussion sessions will be held: one that highlights materials in Modules 1 to 7 [ACPE 0653-000023-015-H99-P] , and the second that highlights modules 8 to 14 [ACPE 0653-000023-016-H99-P].

## **READING AND REFERENCE MATERIALS**

There is no textbook for this program as there is none that meets the required standards for health technology evaluation. Instead, the course is built around a series of 14 modules with slides/audio presentation supported by extensive notes (over 85 pages) and references. Existing textbooks are out of date in terms of the appropriate analytical framework and techniques for health technology assessment- focused on supporting products over their lifetime. The references have been selected because they support the arguments presented in the modules to support a new start in the techniques of health technology assessment and formulary submissions.

For those who wish to pursue in more detail the role of Rasch or modern measurement theory to support the new start in HTA, the following is recommended:

Bond T, Yan Z, Heene M. Applying the Rasch Model: Fundamental Measurement in the Human Sciences (4<sup>th</sup> Ed.). New York: Routledge, 2021

Also, there are a number of on-line introductions to Rasch modelling on YouTube (keywords Rasch, Wright map, WINSTEPS, RUMM2030).

## **PRE-PROGRAM READING**

Before beginning this program, please read the following four key references:

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>

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>)

Langley P. Facilitating bias in cost-effectiveness analysis: CHEERS 2022 and the creation of assumption-driven imaginary value claims in health technology assessment [version 1; peer review: 2 approved]. *F1000Research* 2022, 11:993 (<https://doi.org/10.12688/f1000research.123709.1>)

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

## **PROGRAM REGISTRATION**

If you have not registered for the Certificate Program and wish to do so enroll here. (ENROLL)  
The fee for the Certificate Program is US\$875.00

## **PROGRAM CONTENT INQUIRIES**

The program has been developed and is presented by Dr Paul C. Langley, Ph.D., Adjunct Professor, College of Pharmacy, University of Minnesota, Minneapolis MN and Adjunct Faculty, Instructor, School of Pharmacy, College of Health Sciences, University of Wyoming, Laramie WY. Dr Langley is also Director of Maimon Research LLC, a consulting company based in Tucson, AZ. Dr Langley is not affiliated with or has a financial interest in any ineligible organization.

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## **REFERENCES**

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<https://doi.org/10.12688/f1000research.109389.1>

<sup>2</sup> Neumann P, Willke R, Garrison L: A Health Economics Approach to US Value Assessment Frameworks – Introduction: An ISPOR Special Task Force Report. *ValueHealth*. 2018; **21**: 119–123

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- <sup>4</sup> Merbitz C, Morris J, Grip J. Ordinal scales and foundations of misinference. *Arch Phys Med Rehabil*. 1989;70(4):308-12
- <sup>5</sup> 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
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- <sup>11</sup> Wootton R. *The Invention of Science: A new history of the scientific revolution*. New York: HarperCollins, 2015
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