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**ARTIFICIAL INTELLIGENCE LARGE LANGUAGE
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**REPRESENTATIONAL MEASUREMENT AND HEALTH
TECHNOLGY ASSESSMENT**

**EUROPE: LEGACY HTA - FORTY YEARS OF
NUMERICAL STORYTELLING**

**The Absence of Representational Measurement in Teaching and
Research**

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ABSTRACT

European health technology assessment (HTA) has developed within an increasingly coordinated analytical framework centered on utility measurement, quality-adjusted life years (QALYs), incremental cost-effectiveness ratios (ICERs), modelling and reference-case analysis. National agencies, academic research centers, EUnetHTA and subsequent European initiatives have contributed to the institutionalization and harmonization of this framework. This paper asks a logically prior question: are the quantitative operations being coordinated scientifically admissible under the axioms of representational measurement and the constraints imposed by scales of measurement?

The analysis begins with the requirement that measurement precede arithmetic. A defined unidimensional attribute must satisfy the relevant axiomatic requirements before a measurement scale can be established and admissible mathematical operations determined. Particular attention is given to ratio measurement because multiplication, division and proportional interpretation require demonstrated ratio properties. Legacy HTA reverses this sequence by specifying the arithmetic required and assuming that its numerical inputs possess the measurement properties necessary to support it.

Formal examination demonstrates that conventional preference-based utility does not provide the dimensionless ratio required for proportional adjustment of time and therefore cannot support the QALY. Rasch measurement provides legitimate measurement of defined latent attributes but cannot rescue the QALY because its ratio interpretation concerns odds rather than quantities of attribute possession. The subsequent construction of Δ QALY and the cost-per-QALY ICER consequently fails, while the composite cost numerator presents an independent measurement problem. Reference-case simulation and uncertainty analysis cannot repair operations whose measurement legitimacy was never established.

A replacement framework is proposed based on two measurement pathways: linear ratio measurement for manifest attributes and Rasch logit measurement for latent attributes, followed by admissible arithmetic and empirically evaluable, replicable and falsifiable therapy-impact claims.

The implications for European HTA are substantial. Greater methodological harmonization cannot confer legitimacy on quantitatively inadmissible operations. Universities and HTA institutions therefore face both a scientific and educational responsibility: once the measurement foundations of legacy HTA have been formally challenged, institutional acceptance, professional convention and longevity cannot substitute for measurement proof. The required European transition is not toward a more elaborate legacy framework, but toward lawful measurement before arithmetic.

INTRODUCTION: LEGACY HTA AND THE FAILURE OF MEASUREMENT

Europe provides an especially important setting in which to undertake a formal reassessment of the scientific foundations of health technology assessment (HTA). Across national systems and successive European collaborative initiatives, HTA has developed around a broadly shared analytical framework centered on economic evaluation, utility measurement, quality-adjusted life years (QALYs), incremental cost-effectiveness ratios (ICERs), modelling and reference-case approaches. Although individual countries differ substantially in their decision processes and evidentiary requirements, the underlying quantitative framework has become deeply embedded across European HTA.

The development of EUnetHTA gave this environment an increasingly European dimension. National agencies, academic research centers and methodological networks participated in efforts to coordinate assessment, evidence requirements and HTA practice across jurisdictions. The subsequent European Union framework for joint clinical assessment extends this movement toward greater European coordination. Yet methodological coordination raises a logically prior question: are the quantitative methods being coordinated scientifically admissible in the first place? Are practitioners aware of the axioms of representational measurement and the scales of measurement^{1 2}.

This question has received remarkably little attention. The central problem is not whether European HTA has become methodologically sophisticated. It clearly has. The problem is that sophistication cannot substitute for measurement legitimacy. Before arithmetic can support a scientific claim, the numbers involved must represent defined attributes, the appropriate scale of measurement must have been established, and the proposed arithmetic must be admissible for that scale. This is the sequence required by representational measurement: defined unidimensional attribute → axiomatic requirements → measurement scale → admissible arithmetic → quantitative claim

Legacy HTA reverses that sequence. Arithmetic requirements determine what numbers are needed, while the measurement status of those numbers is assumed or left unexamined. This is measurement inversion. The failure becomes decisive when the scales of measurement are considered. Nominal, ordinal, interval and ratio scales do not support the same mathematical operations. In particular, multiplication, division and proportional adjustment require the appropriate ratio properties. Those properties must be demonstrated; they cannot be conferred upon a number simply because an economic model requires them.

This places the conventional QALY at the center of the European measurement problem:

$$\text{QALY} = U \times T$$

Time is ratio scaled. Utility must therefore provide the legitimate dimensionless ratio quantity required to adjust time proportionately. Conventional preference-based utility has not demonstrated those properties. The arithmetic requirement cannot manufacture them. The same problem then propagates through QALY aggregation and subtraction to ΔQALY and finally to the

cost-per-QALY ICER. The source paper sets out precisely these successive measurement demands.

This suggests that the next stage of European HTA should not be another refinement of the legacy framework. EUnetHTA, NICE and national HTA systems cannot solve a measurement problem through greater methodological harmonization. Harmonizing an inadmissible operation does not make it admissible.

What is required is a formal assessment of European HTA against the axioms of representational measurement and the constraints imposed by scales of measurement. The Australian framework proposes six such proofs: multiplication, dimensional coherence, aggregation and subtraction, division, the cost numerator, and whether reference-case simulation can rescue operations whose measurement legitimacy was never established.

If those proofs hold in the European setting, the consequence is not modification of legacy HTA but its replacement. There is no need for an elaborate superstructure of utilities, QALYs and imaginary assumption-driven reference cases. Therapy-impact assessment can begin directly with the attribute and employ the appropriate measurement pathway: linear ratio measurement for manifest attributes and Rasch logit ratio measurement for latent attributes, followed by admissible arithmetic and empirically evaluable claims.

Europe does not need a more sophisticated system for manipulating numbers. It needs a measurement system capable of producing measures.

1. SCIENCE BEGINS WITH THE ATTRIBUTE

Quantitative analysis does not begin with numbers. It begins with a defined attribute: the particular property whose magnitude or possession is to be represented. Survival duration, hospital days, pain, fatigue and physical function are examples. Before numbers are assigned, the investigator must specify exactly what is being measured. An attribute cannot simply be nominated and numbers attached to it. Its empirical structure must support the proposed numerical representation.

The first requirement is unidimensionality. Measurement must concern one attribute at a time. A ruler can represent differences in length because length is the attribute being measured; a Rasch ruler can represent differences in possession of physical function only if the items conform to a single defined physical-function construct. If several distinct attributes are combined, the resulting number does not become a measure merely because an algorithm produces a single numerical output. One number is not evidence of one dimension.

This point is fundamental to the subsequent critique of legacy HTA. A multiattribute health-state description deliberately combines dimensions such as mobility, self-care, usual activities, pain/discomfort and anxiety/depression. These are different attributes. Applying weights to their levels and combinations may generate a composite utility number, but weighting cannot transform multiple attributes into one unidimensional attribute. The measurement failure therefore begins before the scale properties of the utility number are even considered.

Once a unidimensional attribute has been established, the investigator must determine whether its empirical structure satisfies the axiomatic requirements of the proposed measurement representation. These include, as appropriate, order, additivity, solvability, cancellation and the Archimedean condition. Only after these requirements have been addressed does it become meaningful to ask what scale of measurement has been achieved and, consequently, what arithmetic operations are admissible.

Scales of measurement

Scales of measurement are important because numbers do not acquire identical mathematical properties merely by being numbers. Nominal, ordinal, interval and ratio scales represent different empirical structures and permit different transformations. An ordinal scale establishes order but not equal quantitative differences. An interval scale supports meaningful differences but permits an arbitrary origin. A ratio scale has the additional structure required for invariant ratio comparisons.

The permissible transformations identify what remains quantitatively meaningful. If an empirical conclusion changes merely because one permissible numerical representation has been replaced by another, that conclusion cannot be an invariant measurement claim. Scale type therefore determines the arithmetic that can legitimately be performed. Mathematical software may multiply or divide any numbers supplied to it; measurement science determines whether those operations have empirical meaning.

The Axioms of Representational Measurement

The classification of a numerical representation as a measurement scale cannot rest simply upon the appearance of the numbers assigned. Representational measurement requires a correspondence between the empirical relationships exhibited by the defined unidimensional attribute and the numerical relationships used to represent them. The numerical system must preserve the relevant structure of the empirical system. This is why the axioms of representational measurement are fundamental: they specify the conditions that the empirical attribute must satisfy before a particular numerical representation can legitimately be claimed. Measurement is therefore not achieved by assigning numbers and subsequently deciding what those numbers will mean. The empirical structure must justify the numerical structure.

For quantitative measurement, the relevant requirements include unidimensionality, order, additivity, solvability, cancellation and the Archimedean condition, as appropriate to the measurement structure being constructed, together with invariance under the permissible transformations of the resulting scale. Unidimensionality is indispensable: the relationships being represented must concern one defined attribute, not a weighted combination of different attributes. Order requires that greater and lesser possession can be consistently represented; additivity requires an appropriate concatenation or conjoint structure; solvability requires that intermediate quantitative relationships can, in principle, be represented; cancellation ensures consistency among combinations; and the Archimedean condition excludes structures in which finite comparisons cannot be established. The resulting numerical representation must then remain invariant under the transformations permitted for that scale. These requirements are not optional statistical tests added

after numbers have been generated. They are the conditions that make measurement possible in the first place.

2. RATIO MEASUREMENT

Ratio measurement is the critical threshold for any analytical framework that depends upon multiplication, division or proportional interpretation. Failure to recognize this requirement virtually guarantees quantitative failure. This is precisely the problem encountered by legacy HTA. Its defining operations require utilities to act as proportional adjustments to time, QALYs to be aggregated and differenced, and incremental quantities to be divided to produce cost-effectiveness ratios. Yet the ability to perform these operations mathematically does not establish their admissibility as measurement operations. Arithmetic cannot confer ratio properties upon numbers that did not possess them before the arithmetic began. An analytical framework that starts by specifying the calculations it wishes to perform and only subsequently assumes that its inputs possess the necessary measurement properties has reversed the scientific sequence. Ratio measurement must precede ratio arithmetic.

Ratio measurement is therefore not defined simply by the presence of a numerical zero, by reporting positive numbers, or by the mathematical possibility of forming a quotient. A ratio measure must represent a defined unidimensional attribute whose empirical structure satisfies the axiomatic requirements necessary for quantitative representation. These include order, so that greater possession of the attribute is empirically distinguishable from lesser possession; additivity or an appropriate concatenation structure, so that quantitative differences have an empirical interpretation; the Archimedean property, ensuring that finite comparisons can be represented within the numerical system; solvability, allowing equivalent quantitative relationships to be established; and cancellation, ensuring consistency among comparisons and combinations of attribute magnitudes. The representation must also satisfy invariance, so that conclusions about the attribute do not depend upon arbitrary features of the numerical assignment, and the admissible transformations must preserve the ratio structure. For a conventional linear ratio scale this requires a meaningful non-arbitrary zero and transformations restricted to similarity transformations, $x' = ax$, $a > 0$. Consequently, statements such as *x is twice y* remain invariant under every admissible transformation.

These requirements establish a simple but uncompromising sequence: attribute $\rightarrow$ empirical relational structure $\rightarrow$ axiomatic requirements $\rightarrow$ ratio representation $\rightarrow$ admissible transformations $\rightarrow$ admissible arithmetic. Ratio status must therefore be demonstrated before multiplication, division or proportional interpretation is attempted; it cannot be assumed because an analytical framework requires those operations. If the attribute is undefined or multidimensional, if the empirical structure required by the representation has not been demonstrated, if the zero is arbitrary, or if transformations involving an additive constant are admissible, proportional statements are not invariant and ratio arithmetic is inadmissible. This is the point at which legacy HTA was effectively guaranteed to fail. Once utilities and other numerical constructs were permitted to enter multiplication and division without first demonstrating the required ratio properties, everything constructed downstream including the QALY, Δ QALY and the cost-per-QALY ICER became vulnerable to foundational measurement failure. The issue is therefore not whether the subsequent mathematics is sophisticated or correctly

executed. It is whether the numbers entering that mathematics were measures of the required kind in the first place.

3. MANIFEST AND LATENT ATTRIBUTES

Once the attribute has been defined, its nature determines the appropriate measurement problem. The fundamental distinction is between manifest and latent attributes.

Manifest attributes are directly observable. Survival duration, hospital days, ICU hours and treatment duration are examples. Where the empirical structure satisfies the required axioms, these attributes can support conventional linear ratio measurement. There is a meaningful zero, units may be changed proportionally, and ratios remain invariant:

Latent attributes present a fundamentally different problem. Pain, fatigue, physical function and need fulfilment cannot be directly observed or physically concatenated. What can be observed are responses to items designed to provide evidence concerning possession of the specified attribute. Assigning integers to response categories or summing those integers does not create measurement. The latent attribute must first be explicitly defined and unidimensional. A measurement system must then establish an invariant continuum on which differences in possession can be represented. Rasch measurement provides this structure by locating persons and items jointly on a common logit continuum³. Importantly, the observations must conform sufficiently to the requirements of the measurement model. The model does not confer measurement status automatically upon whatever responses are supplied to it.

HTA therefore has two distinct routes: (i) manifest attribute → axiomatic requirements → linear ratio measure (ii) latent attribute → axiomatic/model requirements → Rasch logit measure. This distinction has a major consequence. There is no measurement requirement that survival, pain, fatigue, mobility and physical function be collapsed into one overarching number. Each is an attribute in its own right and must retain the measurement structure appropriate to it.

If HTA is to assess therapy impact on latent attributes such as pain, fatigue, physical function or need fulfilment, it requires a measurement framework capable of establishing and quantifying attribute possession. For more than fifty years, Rasch measurement has provided the necessary and sufficient framework for constructing invariant measures of possession from ordinal response observations. There is no alternative route that satisfies the same measurement requirements simply by scoring, weighting or statistically modelling questionnaire responses. Rasch measurement begins with a defined unidimensional attribute and requires the data to conform to the measurement model before claims for possession and change in possession are accepted. For readers wishing to pursue the measurement of latent-attribute possession and its application to therapy-impact claims, the Maimon Research nine-unit program provides the necessary introduction to this framework (see Section 9 below).

4. TWO ROUTES TO RATIO MEASUREMENT

The two routes provide different forms of quantitative representation, and their ratio interpretations must not be confused.

For a manifest attribute satisfying the requirements of linear ratio measurement:

$$X' = aX, a > 0$$

Ratios of quantities are invariant. If:

$$X_1 / X_2 = 2$$

then after a permissible change of unit:

$$aX_1 / aX_2 = X_1 / X_2 = 2$$

This structure also explains why scale properties matter for multiplication. Suppose X and Y are appropriate ratio measures and:

$$Z = XY$$

Under permissible transformations:

$$X' = aX$$

$$Y' = bY$$

then:

$$Z' = X'Y'$$

$$Z' = (aX)(bY)$$

$$Z' = abXY$$

and since:

$$Z = XY$$

then:

$$Z' = abZ$$

The derived quantity changes only by the predictable change in units.

Contrast this with a quantity permitting an arbitrary origin:

$$X' = aX + c$$

Then:

$$Z' = (aX + c)(bY)$$

$$Z' = abXY + bcY$$

and therefore:

$$Z' = abZ + bcY$$

The additional term bcY means that the transformed product is no longer simply a rescaled version of Z . The arbitrary origin contaminates the product. The ability to perform the multiplication arithmetically does not make the resulting quantity measurement-theoretically admissible.

Rasch measurement provides a different ratio structure for a latent attribute. For the dichotomous Rasch model with questionnaire items defining the assessment instrument:

$$\log[P_{ni} / (1 - P_{ni})] = \theta_n - \beta_i$$

where P_{ni} is the probability that person n gives the specified response to item i , θ_n is the person's location on the latent attribute and β_i is the item's location on that same continuum. The expression:

$$P_{ni} / (1 - P_{ni})$$

is the odds of the specified response. The Rasch model therefore represents the logarithm of those odds, the log odds or logit as the difference between person and item locations.

If therapy changes a person's location on the latent continuum from θ_1 before treatment to θ_2 after treatment, the change is:

$$\Delta\theta = \theta_2 - \theta_1$$

Because the Rasch continuum is expressed in log odds, exponentiating this difference returns the comparison to the odds scale. If the corresponding odds before and after treatment are O_1 and O_2 , then:

$$\theta_1 = \log(O_1)$$

$$\theta_2 = \log(O_2)$$

Therefore:

$$\Delta\theta = \log(O_2) - \log(O_1)$$

Using the logarithmic identity:

$$\log(A) - \log(B) = \log(A/B)$$

gives:

$$\Delta\theta = \log(O_2/O_1)$$

Exponentiating both sides:

$$\exp(\Delta\theta) = O_2/O_1$$

Hence:

$$OR = \exp(\Delta\theta)$$

where OR is the ratio of the odds associated with the two locations.

For example, if:

$$\Delta\theta = 1$$

then:

$$OR = \exp(1) \approx 2.72$$

Equal logit differences have equal multiplicative interpretations on the odds scale regardless of where the difference occurs.

For example:

$$-3 \rightarrow -2: \Delta\theta = -2 - (-3) = 1 \rightarrow OR = e^1 \approx 2.72$$

and:

$$2 \rightarrow 3: \Delta\theta = 3 - 2 = 1 \rightarrow OR = e^1 \approx 2.72$$

Likewise, a two-logit change anywhere on the continuum gives:

$$OR = e^2 \approx 7.39$$

and a half-logit change gives:

$$OR = e^{0.5} \approx 1.65$$

The important qualification is that this does not mean that the *probability* increases by the same amount at every location. Odds and probabilities are related nonlinearly. The same one-logit change produces the same multiplicative change in odds, but different absolute changes in probability depending on the starting location.

The odds associated with the second location are therefore approximately 2.72 times the odds associated with the first. This is the ratio interpretation supplied by the Rasch logit structure. It is crucial, however, not to misinterpret it. It is a ratio of odds, not a ratio of quantities of the latent attribute itself. A change from 1 to 2 logits does not mean that the person has twice as much physical function, need fulfilment or another latent attribute. This distinction becomes decisive when considering whether a Rasch measure could ever provide the proportional adjustment to time required for a QALY.

The ratio is therefore an invariant ratio of odds. It is not a ratio of the numerical logit coordinates themselves. A person at 2 logits does not possess twice as much of the attribute as a person at 1 logit. This distinction is decisive. Linear ratio measurement permits direct ratios of quantities; Rasch logit measurement permits invariant differences and corresponding ratios of odds. Neither structure can be changed simply because a subsequent HTA calculation requires a particular type of number.

5. DIMENSIONLESS RATIOS AND DIMENSIONAL HOMOGENEITY

The preceding mathematics establishes what happens when quantities are multiplied. The next requirement is particularly important for the QALY: what kind of number can legitimately be used to adjust ratio-scaled time proportionally?

Consider a patient who spends 18 hours of a 24-hour observation period satisfying a precisely defined condition A. The proportion of time in A is:

$$D = \text{time in A} / \text{total time}$$

so:

$$D = 18 \text{ hours} / 24 \text{ hours} = 0.75$$

Both numerator and denominator measure the same attribute time on the same ratio scale. The units cancel:

$$[D] = [T] / [T] = 1$$

D is therefore dimensionless. Its value is also invariant to the unit chosen. Expressing the same quantities in minutes gives:

$$D = 1080 \text{ minutes} / 1440 \text{ minutes} = 0.75$$

More generally, if:

$$D = X / Y$$

and X and Y are commensurable ratio measures of the same attribute, then under a permissible change of unit:

$$X' = aX$$

$$Y' = aY$$

and:

$$D' = X' / Y'$$

$$D' = aX / aY$$

$$D' = X / Y = D$$

The dimensionless ratio can therefore legitimately rescale time:

$$T = D \times T^*$$

with:

$$[T] = [1]/[T] = [T]^*$$

This is dimensional homogeneity. The calculation begins with time and ends with time because the multiplier is a genuine dimensionless proportion. This gives us a simple but demanding test. If a number such as 0.75 is to adjust time proportionally, we must be able to ask: 0.75 of what?

What is its numerator? What is its denominator? What single attribute do they measure? Are both ratio measures? What units cancel? A decimal between zero and one is not automatically a proportion. Its proportional meaning must arise from its measurement structure. This requirement provides the direct test for conventional utility.

6. THE QALY FAILS LINEAR RATIO MEASUREMENT

The conventional QALY begins not with a unidimensional ratio attribute but with a multiattribute health-state description. A utility algorithm applies weights to the dimensions and levels defining that description, conventionally anchoring full health at unity and applying decrements to generate the utility score. In simplified form: $U = 1 - \sum d_i$

The resulting U is therefore a numerical representation of a weighted multiattribute health-state description. It is not a demonstrated measure of a single unidimensional attribute satisfying the axiomatic requirements for linear ratio measurement.

The decrement structure may also generate: $U < 0$ with negative values conventionally representing health states worse than dead. Whatever preference interpretation is given to such numbers, this is not the structure of a conventional proportion constructed from a positive linear ratio attribute.

Yet the next step treats U precisely as a proportional adjustment:

$$QALY = U \times T$$

If:

$$U = 0.75$$

then one year is transformed into:

$$0.75 \times 1 \text{ year} = 0.75 \text{ QALYs}$$

The critical question is now unavoidable:

What is $U = 0.75$ a proportion of?

A lawful dimensionless proportion would require:

$$U = X / Y$$

where X and Y are commensurable ratio measures of the same defined attribute. Then:

$$[U] = [A]/[A] = 1$$

But no such construction exists for conventional utility. There is no demonstrated ratio-scaled numerator, denominator or single attribute whose units cancel. $U = 0.75$ has not been demonstrated to mean 75% of anything.

The possibility of negative utilities makes the distinction especially transparent. If:

$$D = X / Y$$

with:

$$0 \leq X \leq Y$$

then:

$$0 \leq D \leq 1$$

A negative utility cannot represent a negative proportion of a positive ratio-scaled attribute. The utility number and a dimensionless ratio are different mathematical objects.

The QALY construction therefore depends upon three successive transitions, none of which has the required measurement foundation. The first is the movement from a multiattribute health-state description to a weighted utility score. Combining and weighting different health attributes may produce a single numerical value, but it does not establish a single unidimensional attribute possessing the empirical and axiomatic properties required for linear ratio measurement. The

second transition occurs when this utility score is reinterpreted as a proportional adjustment to time. This requires the utility to be a dimensionless ratio constructed from commensurable ratio measures of the same attribute, yet no such ratio structure has been demonstrated. The third transition is the multiplication $U \times T$ and the declaration that the result is a QALY. Multiplication cannot supply the measurement properties missing from the utility input, nor can it create a new linear ratio attribute representing time adjusted for health-state experience. At each stage, the arithmetic proceeds without the measurement structure required to justify it.

Multiplication by time cannot manufacture the missing measurement properties. Under the requirements of linear ratio measurement and dimensional homogeneity, the conventional QALY cannot be constructed.

7. THE QALY FAILS RASCH LOGIT RATIO MEASUREMENT

The failure of conventional utility does not mean that health-related latent attributes cannot be measured. Rasch measurement provides a route to quantitative claims for defined unidimensional attributes such as pain, fatigue, physical function and need fulfilment. But Rasch measurement does not rescue the QALY. It closes the alternative route to its construction.

For the dichotomous Rasch model:

$$\log[P_{ni} / (1 - P_{ni})] = \theta_n - \beta_i$$

where θ_n represents person location and β_i item location on the latent continuum.

If therapy changes a person's location from θ_1 to θ_2 :

$$\Delta\theta = \theta_2 - \theta_1$$

and the corresponding ratio interpretation is:

$$OR = \exp(\Delta\theta)$$

Suppose:

$$\theta_1 = 1 \text{ logit}$$

and:

$$\theta_2 = 2 \text{ logits}$$

It would be incorrect to calculate:

$$\theta_2 / \theta_1 = 2$$

and conclude that the second location represents twice as much attribute possession. The zero of the logit continuum is not an absolute absence of the latent attribute. The legitimate quantitative statement is:

$$\Delta\theta = 2 - 1 = 1$$

and therefore:

$$OR = \exp(1) \approx 2.72$$

This is an invariant ratio of odds. It is not a statement that the person possesses 2.72 times as much physical function, pain relief or need fulfilment.

This distinction defeats any attempt to convert a Rasch measure into the proportional adjustment required by: $QALY = U \times T$

Rescaling a logit continuum to produce numbers between zero and one does not solve the problem. A transformed value of 0.75 does not thereby become 75% possession of the latent attribute. Numerical rescaling cannot create an absolute zero or convert a ratio of odds into a linear proportion.

Rasch measurement therefore permits rigorous claims concerning change in possession of a single latent attribute, but it cannot produce the dimensionless linear proportion required to adjust time. There is only one possible lawful route to such an adjustment. It must concern a single defined attribute already demonstrated to possess linear ratio properties, from which a genuine dimensionless ratio can be constructed: $D = X / Y$ where X and Y are commensurable measures of that same attribute. For latent attributes, Rasch measurement provides no such D. Nor can separate measures of pain, fatigue, physical function and other latent attributes be collapsed into a universal quality proportion.

The two legitimate measurement routes therefore close the argument. Linear ratio measurement rejects conventional utility because it is not a demonstrated dimensionless ratio. Rasch logit measurement rejects the conversion of latent-attribute possession into the linear proportion required to adjust time. There is no measurement-theoretic route from a multiattribute health-state description or a latent-attribute measure to the conventional QALY.

8. THE COLLAPSE OF THE REFERENCE CASE

The failure of the QALY removes the denominator of the conventional cost-effectiveness reference case. But the numerator presents a separate measurement failure. The familiar expression $ICER = \Delta C / \Delta QALY$ appears to represent the division of one quantitative measure by another. It does not. The denominator has already failed. Conventional utility cannot provide the dimensionless ratio required to adjust time, while Rasch measurement cannot convert latent-attribute possession into such a proportion. Consequently: $QALY = U \times T$ cannot provide the required measure, and neither aggregation nor subtraction can repair it: $\Delta QALY = QALY_1 - QALY_0$

The cost numerator is constructed differently but encounters the same requirement that measurement begin with a defined attribute. Conventionally:

$$C = \sum(q_i \times p_i)$$

where q_i may represent hospital days, ICU hours, physician visits, doses, laboratory tests or procedures, and p_i represents the corresponding unit price.

The resource quantities are heterogeneous attributes. A hospital day is not a physician visit; an ICU hour is not a dose. Multiplying each by a price and adding the monetary results may provide an accounting total, but it does not create a unidimensional ratio measure of resource utilization. The appropriate therapy-impact claims remain attribute-specific: Δ hospital days; Δ ICU hours; Δ physician visits or Δ doses

There is a further requirement. Even if numerator and denominator were independently ratio measures, this would not automatically make their quotient a meaningful measure. The attributes must be compatible with the derived quantity being claimed. For example:

$$\text{distance} / \text{time} = \text{speed}$$

has the coherent dimensional structure:

$$[L]/[T] = [LT^{-1}]$$

Similarly:

$$X / Y$$

for commensurable measures of the same attribute produces:

$$[A]/[A] = 1$$

But mathematical divisibility does not mean that any ratio measure can be divided by any other ratio measure to create a scientifically meaningful new attribute. The ICER therefore fails at every level. ΔC is a price-weighted composite of heterogeneous resource inputs; $\Delta QALY$ is not a defensible ratio measure; and their quotient does not establish a measured attribute called cost-effectiveness. The reference case cannot be repaired by changing utility instruments, discount rates, model structures or uncertainty methods. Its defining quantitative architecture has failed before those refinements begin.

9. THE COST-EFFECTIVENESS DEBACLE AND NORMAL SCIENCE

The measurement failure exposes a deeper problem. The reference-case cost-effectiveness result is not designed primarily as an empirically evaluable therapy-impact claim. It is constructed to provide a decision variable: modelled ΔC / modelled $\Delta QALY$ = cost per QALY. Yet normal

quantitative science requires claims that confront observation. They should be capable of evaluation, independent replication and falsification.

Consider a claim that a therapy reduces hospital utilization by two days over six months in a defined population compared with a specified alternative. The attribute and unit are explicit. The claim can be tested prospectively. Another investigator can attempt replication. Most importantly, observations can demonstrate that the claim is false.

The same principle applies to a properly constructed Rasch claim concerning a latent attribute. A claim for improvement in physical-function possession can specify the ruler, population, comparator, timeframe and expected change:

$$\Delta\theta = \theta_2 - \theta_1$$

with:

$$OR = \exp(\Delta\theta)$$

Again, the claim can confront evidence and fail.

The reference-case claim occupies a fundamentally different position from an ordinary empirical therapy-impact claim. Before questions of replication or falsification even arise, the model assumes that its numerous numerical inputs can legitimately be combined arithmetically. Health-state descriptions, utility scores, transition probabilities, event rates, resource quantities, prices, discount factors, survival estimates and other inputs are brought together within a common mathematical framework. Yet these inputs are not required to demonstrate the ratio-scale properties, dimensional compatibility or admissible transformations necessary for the operations performed upon them.

The reference case therefore fails before any question of empirical evaluation arises. Its inputs are combined arithmetically without first establishing the scale properties, dimensional relationships and permissible transformations required to justify those operations. The resulting QALY denominator is not a defensible ratio measure; the composite cost numerator is not a unidimensional measure of resource utilization; and dividing these two constructs does not create a measured attribute called cost-effectiveness.

The decisive question is therefore not whether $ICER = \Delta C / \Delta QALY$ can subsequently be replicated or falsified. The prior question is more fundamental: does the quotient have any defensible quantitative meaning? If neither its construction nor the relationship between numerator and denominator satisfies the requirements of measurement, the answer is no. Arithmetic can always generate a numerical quotient, but numerical calculability does not establish measurement meaning. A number can be calculated to any desired number of decimal places and remain scientifically meaningless.

This makes the conventional discussion of uncertainty secondary. Deterministic sensitivity analysis can substitute alternative input values, and probabilistic sensitivity analysis can attach

distributions to those inputs and generate distributions of model outputs. Neither addresses the prior measurement question. Uncertainty analysis around an inadmissible construct cannot make the construct admissible. Greater sophistication in manipulating the inputs cannot supply the measurement properties that were absent before the model began.

The cost-effectiveness claim therefore fails at a more elementary level than replication or falsification. There is no scientifically established quantity to replicate or falsify or as a decision construct. The reference case produces a number intended to guide a decision, but it has not demonstrated that this number represents a measurable attribute with a coherent quantitative interpretation.

That distinction should be made explicit. Empirical evaluation, replication and falsification are requirements for meaningful scientific claims. They cannot rescue a numerical construct that has already failed the prior requirements of measurement. The first obligation of HTA is therefore to establish the attribute and its lawful measurement. Only after that has been achieved does it become meaningful to ask whether the resulting therapy-impact claim survives empirical evaluation, replication and attempts at falsification.

The implications are difficult to overstate. This is not an inconsequential academic construct confined to methodological exercises. The cost-per-QALY reference case is intended to influence whether a medicine is admitted to a formulary, whether patients obtain access to it, what restrictions are placed upon its use and, directly or indirectly, the price at which it is made available. Decisions with substantial consequences for patients, manufacturers and healthcare systems are therefore being informed by a numerical construct whose claimed quantitative meaning cannot be established under the required standards of measurement.

The extraordinary feature of legacy HTA is not simply that such a construct was devised, but that it acquired institutional authority and has been taught and applied for more than forty years without its defining operations first being required to demonstrate their measurement legitimacy. A decision maker may, of course, make judgements about access and price. What cannot be defended is conferring scientific quantitative authority upon an imaginary cost-effectiveness measure merely because an arithmetic model can generate a number. If the number has no defensible measurement meaning, it has no legitimate claim to guide formulary admission or pricing as a quantitative measure of cost-effectiveness.

10. TRANSITION TO LAWFUL MEASUREMENT

The transition to lawful measurement requires more than demonstrating the measurement failures of contemporary HTA. It requires a replacement framework grounded in representational measurement. The Maimon Research nine-unit transformation program provides that framework⁴. Beginning with the principle that measurement must precede arithmetic, the program progresses through the definition of attributes, scales of measurement, admissible arithmetic, dimensional homogeneity, manifest and latent attributes, linear ratio measurement, Rasch measurement, attribute possession, and the construction of empirically evaluable therapy-impact claims. The purpose is not to add measurement to the existing HTA paradigm while leaving its analytical

structure intact. It is to replace that structure with one in which quantitative claims must first satisfy the requirements of lawful measurement and can then be evaluated, falsified and replicated.

At the same time, the nine units provide the substantive foundation for a graduate course in lawful measurement for HTA. Comprising approximately 45,000 words of structured instructional material, the program provides sufficient depth to move beyond a brief introduction to measurement theory and support a systematic transition from the legacy HTA framework to one grounded in representational measurement. Its sequence can be translated directly into a graduate curriculum progressing from measurement preceding arithmetic, attributes and scales of measurement through admissible arithmetic and dimensional homogeneity to manifest and latent attributes, linear ratio measurement, Rasch measurement, attribute possession and the construction of empirically evaluable therapy-impact claims.

As far as can presently be ascertained, this is the only program available internationally designed specifically to support the transition from legacy HTA to an HTA grounded in the requirements of lawful measurement. That distinction is important. The program is not intended to add a measurement component to contemporary HTA while leaving utilities, QALYs and reference-case modelling undisturbed. It provides a structured pathway for reconsidering the scientific foundations of the discipline itself and for rebuilding quantitative therapy evaluation around measurement before arithmetic, ratio measurement and claims capable of empirical evaluation and falsification.

The resulting course would replace the conventional emphasis on utilities, mapping, QALYs and reference-case modelling with an alternative scientific structure: defining the target attribute, determining whether it is manifest or latent, constructing the appropriate linear or Rasch ratio measure, and using that measure to formulate empirically evaluable claims. The nine-unit program therefore provides not simply a critique of the legacy framework, but the content and organizing structure from which its educational replacement can be built.

Faculty and practitioners who enroll will have access to a 24/7 question-and-answer support service, providing continuing assistance as they work through the implications of representational measurement for teaching, research and HTA practice. This becomes particularly important where faculty are using the program as the foundation for curriculum development. Questions concerning course structure, individual topics, measurement concepts, examples, assignments and their application to existing HTA material can be addressed as they arise. Participants are therefore not expected to complete the nine units and then independently determine how an unfamiliar scientific framework should be translated into teaching or practice. Continuing support is intended to make the movement from understanding to implementation an integral part of the transition.

Additional faculty and institutional support can also be arranged on an agreed basis. This may include Zoom seminars and workshops, assistance with graduate-course and curriculum redesign, development of teaching materials, recommended references and readings, and guest lectures addressing particular aspects of representational measurement and its application to HTA. Support can be tailored to individual faculty members, courses, departments, research centers or professional groups. The nine-unit program should therefore be understood as the starting point for a managed transition to lawful measurement. It provides the replacement scientific framework,

the substantive elements required to construct a graduate course around that framework, and continuing access to the expertise and educational resources required for implementation. The objective is not simply to demonstrate why contemporary HTA must change, but to provide faculty and practitioners with the foundations and practical means to build, teach and apply its replacement. There is no going back.

11. THE RESPONSIBILITY OF EUROPEAN HTA AND THE UNIVERSITY

The extraordinary feature of European legacy HTA is not simply that a methodological mistake has been made. It is that an extensive analytical architecture has been progressively institutionalized without its measurement foundations first being formally secured. National HTA agencies have provided methodological centers of gravity within individual countries, while EUnetHTA and successive European initiatives have encouraged greater coordination and harmonization across jurisdictions. University and research infrastructures, as far as can be established from their publicly represented knowledge bases, have largely reproduced rather than fundamentally challenged that architecture.

After decades of development, institutionalization itself has become one of the principal barriers to reassessment. The framework is familiar. It is embedded in national guidelines and professional standards. Researchers have built careers around it. Universities teach it. Consultants apply it. Manufacturers are expected to comply with it. Decision makers receive outputs expressed in its language. European cooperation increasingly seeks to coordinate elements of the assessment process.

None of these facts establishes that the underlying quantitative operations are scientifically admissible. Harmonization cannot confer measurement legitimacy upon an operation that lacked it before harmonization began. Scientific validity is not established by longevity, consensus, professional acceptance, institutional authority or European coordination. It depends upon whether the claims being made satisfy the measurement requirements necessary for those claims to possess scientific meaning. This is the same distinction emphasized in the source analysis: institutional acceptance and extensive professional use do not establish admissibility.

The formal measurement sequence exposes the problem: no defined unidimensional ratio attribute → no legitimate dimensionless utility ratio → no lawful proportional adjustment to time → no QALY → no Δ QALY → no cost-per-QALY reference case

The independent measurement failure of the conventional composite cost numerator closes the remaining route to the claimed cost-effectiveness quantity. Mathematical manipulation can produce a numerical quotient. It cannot create measurement meaning that the constituent numbers and their relationships do not possess.

If these proofs stand, European HTA faces an uncomfortable conclusion. The appropriate response is not reform, refinement or further methodological accommodation. It is rejection of those quantitative operations that cannot survive formal assessment against representational measurement and the scales of measurement.

This does not imply retrospective blame. European researchers and faculty were educated within an international HTA paradigm in which utilities, QALYs, ICERs and reference-case modelling had already acquired professional legitimacy. Faculty subsequently taught what they themselves had been taught. National agencies required analyses constructed within the same framework, while academic centers developed the expertise necessary to meet those requirements.

That explains how the legacy was transmitted. It cannot justify transmitting it again once the measurement failure has been formally identified. It is at this point that the responsibility of the university becomes central.

A European university is not merely a training organization supplying graduates proficient in the methods required by NICE, national HTA agencies, European institutions or the pharmaceutical industry. Its responsibility is to subject established professional practice to critical scientific examination and distinguish between methods that are conventionally accepted and quantitative claims that have survived the standards necessary for scientific validity.

Academic freedom unquestionably protects the right of faculty to defend conventional utility measurement, QALYs, ICERs and reference-case modelling. It equally requires an intellectual environment in which their foundations can be challenged.

What becomes increasingly difficult to defend is the continued presentation of a contested quantitative framework to students as settled scientific methodology without providing them with the measurement principles required to determine whether it is admissible. This follows directly from the responsibility identified in the source: universities should provide an environment in which conventional methods can be challenged rather than shielding them from the scientific standards capable of testing them. This creates what can appropriately be described as a duty of care to students.

Students enter European universities with the reasonable expectation that quantitative methods presented as scientific methods have either satisfied the relevant scientific standards or, where those standards are disputed, that the dispute will be disclosed. They should not invest years in graduate education, doctoral research and professional specialization without being informed that the measurement legitimacy of the framework upon which that specialization depends has been fundamentally challenged.

The consequences extend beyond future students. Current doctoral candidates may be constructing dissertations around utility measurement, QALYs and cost-effectiveness modelling. Recent graduates may have invested heavily in acquiring those skills. Early-career academics may be building publication programs around them. Students may be preparing for careers in which mastery of national or European HTA requirements is treated as a central professional competence.

Given the formal measurement critique, continuing to reproduce the legacy without disclosure does not protect these students. It increases their exposure to a framework whose scientific standing may become progressively more difficult to defend.

Nor can European universities reasonably wait for NICE, EUnetHTA, national agencies, professional organizations or European institutions collectively to decide how to respond. The scientific question precedes the institutional response. Measurement cannot simply be added to legacy HTA. The responsibility cannot be discharged by adding a lecture on measurement theory to an otherwise unchanged HTA curriculum.

Once students understand that measurement precedes arithmetic, that an attribute must first be defined, that unidimensionality is required, that scale properties determine admissible transformations, that multiplication and division require appropriate ratio properties, and that dimensional homogeneity must be respected, they can immediately apply those principles to everything else they are being taught.

The university's responsibility is not to dictate the answer. Faculty who are sure the proofs are mistaken should identify precisely where they fail. If utility is a ratio measure, its empirical and axiomatic foundations should be demonstrated. If multiplication by time is admissible, the required scale properties should be established. If QALYs constitute legitimate quantities, their measurement structure should be specified. Appeal to NICE, EUnetHTA, national guidelines, European convention, accumulated publications or professional consensus cannot substitute for those demonstrations. The source makes the same point in the Australian setting: institutional practice is not an answer to a measurement proof.

12. THE EUROPEAN TRANSITION

Rejection of legacy HTA does not imply rejection of the accumulated expertise of European researchers, faculty or graduates. Expertise in clinical evaluation, epidemiology, trial design, data analysis, health-services research and pharmaceutical policy remains valuable. What must change is the measurement foundation upon which quantitative therapy-impact claims are constructed.

That transition begins with the attribute rather than the model: defined unidimensional attribute → representational-measurement axioms → appropriate ratio scale → admissible arithmetic → empirically evaluable therapy-impact claim

For manifest attributes this requires appropriate linear ratio measurement; for latent attributes, the alternative pathway is Rasch logit measurement. The endpoint is not an imaginary universal cost-effectiveness number generated by a reference-case simulation. It is an attribute-specific therapy-impact claim capable of empirical evaluation, replication and falsification.

Europe therefore faces more than another methodological choice. Its universities and HTA institutions face an educational and scientific responsibility. They can continue transmitting the inherited analytical framework because national agencies require it, European organizations recognize it and previous generations accepted it. Or they can recognize that, once its measurement foundations have been formally challenged, students are entitled to know that the challenge exists and to possess the scientific tools necessary to judge it.

The duty of the European university is not to protect legacy HTA from uncomfortable questions. It is to protect the conditions under which valid scientific inquiry is possible. Once the

measurement problem has been exposed, another generation of European students cannot simply be taught the same framework as though nothing has changed.

The required transition is therefore from an institutionalized legacy methodology to a science of therapy evaluation in which measurement precedes arithmetic, scientific validity precedes professional convention, and the educational interests of current and future students take precedence over preservation of an inherited analytical framework.

13. CONCLUSION

European HTA now faces a choice that is more fundamental than further methodological refinement or greater harmonization. The issue is whether its quantitative framework can survive formal assessment against the axioms of representational measurement and the constraints imposed by scales of measurement.

The accumulated evidence points to a foundational failure. Legacy HTA was constructed around arithmetic before the measurement properties required to support that arithmetic had been established. Utilities, QALYs, ICERs and assumption-driven reference-case models became institutionalized across national agencies, academic research centers and European HTA networks without first demonstrating that their defining operations were quantitatively admissible.

Greater European coordination cannot resolve this problem. Harmonization of an inadmissible quantitative framework merely harmonizes the failure.

The required transition is therefore from numerical manipulation to lawful measurement. Therapy-impact assessment should begin with a defined unidimensional attribute, establish the appropriate measurement requirements and construct either a linear ratio measure for a manifest attribute or a Rasch logit measure for a latent attribute. Only then should admissible arithmetic be undertaken and empirically evaluable, replicable and falsifiable claims constructed.

The challenge to European HTA is consequently straightforward. Those who believe the legacy framework remains scientifically defensible should demonstrate where the measurement proofs fail. Appeals to convention, guidelines, institutional authority or decades of application are not sufficient.

The future of European HTA does not require a more elaborate version of the legacy framework. It requires measurement before arithmetic.

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⁴ Maimon Research. HTA Reconstruction. <https://maimonresearch.com/hta-reconstruction-program-and-fees/>