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**REPRESENTATIONAL MEASUREMENT FAILURE IN
HEALTH TECHNOLOGY ASSESSMENT**

**AUSTRALIA: THE PBAC AND THE FAILURE TO
RECOGNIZE PROCESS VALIDATION IN
QUANTITATIVE CLAIMS**

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ABSTRACT

Background: The Pharmaceutical Benefits Advisory Committee (PBAC) occupies a central position in Australian health technology assessment. Its Guidelines impose extensive requirements for economic modelling and model validation but fail to recognize process validation as a logically prior requirement. This omission raises a fundamental question concerning the scientific standing of the quantitative therapy-impact claims used to support reimbursement decisions.

Methods: This paper evaluates the PBAC validation framework against the requirements of representational measurement. Process validation is defined as the continuous demonstration that each arithmetic operation used to construct a quantitative claim is permitted by the measurement properties of the quantities involved. The analysis distinguishes process validation from model validation, examines the requirements of unidimensionality, scale properties, dimensional homogeneity and commensurability, and applies these standards to the conventional QALY and its downstream use in cost-effectiveness analysis.

Results: PBAC validates economic models without first requiring validation of the processes through which their central quantitative claims are constructed. The QALY is the canary in the coal mine. Its construction, $Q = U \times T$, encounters two independent measurement failures. First, U has not been established as a lawful ratio proportion of a single preference attribute. Second, even if such a proportion existed, no lawful mapping from preference space to time space has been demonstrated. The failure begins earlier, with the valuation of multidimensional health states rather than the measurement of single attributes. Subsequent aggregation, calculation of incremental QALYs, construction of cost-per-QALY ICERs and application of decision thresholds merely propagate the original failure. Conventional model validation cannot retrospectively establish the missing measurement warrants.

Conclusions: PBAC has inherited an unenviable legacy HTA framework in which arithmetic has preceded measurement for more than four decades. Past decisions relying upon QALY-based claims consequently inherit a failure in their quantitative justification, although this does not establish that the reimbursement decisions themselves would necessarily have differed. Immediate revision of the PBAC Guidelines is required to establish process validation as a mandatory gateway to quantitative therapy-impact claims. The Maimon Research nine-unit reconstruction program provides an available analytical framework grounded in linear ratio measurement for manifest attributes and Rasch measurement for latent attributes, supported by teaching, technical and professional-development resources. Failure of process validation must terminate the quantitative claim before model construction begins. The governing principle is unequivocal: measurement precedes arithmetic, and process validation must precede model validation.

INTRODUCTION

The Pharmaceutical Benefits Advisory Committee (PBAC) occupies a critical position in Australian health technology assessment. Its recommendations influence whether medicines receive public reimbursement and the conditions under which they are made available. The

credibility of this process depends upon the scientific standing of the evidence used to support quantitative therapy-impact and cost-effectiveness claims. Yet the PBAC evaluation framework fails to recognize a logically prior requirement: process validation.

Process validation is the continuous demonstration, throughout construction of a quantitative claim, that each proposed arithmetic operation is permitted by the measurement properties of the quantities involved. Before an operation is performed, the attribute must be identified, an appropriate measurement system established, the properties of the resulting scale demonstrated, and the proposed arithmetic shown to be admissible. Failure at any stage terminates the quantitative construction. Numerical availability does not authorize arithmetic.

This is fundamentally different from model validation. Process validation asks whether the analyst was entitled to perform the calculations used to construct the quantitative claim. Model validation occurs later and asks whether a model has been correctly specified, coded and implemented and whether it behaves as intended. A model may reproduce its calculations perfectly while processing quantities and arithmetic that never possessed a measurement warrant. Model validation cannot retrospectively repair failure of process validation.

This distinction creates a fundamental problem for PBAC. Its Guidelines recognize extensive requirements for economic modelling and model validation, but they do not establish process validation as a prior and continuous requirement governing the construction of quantitative claims. This is particularly consequential for QALY-based cost-effectiveness analysis. If health-state values, QALYs, incremental QALYs and cost-per-QALY ICERs cannot survive process validation, subsequent scrutiny of the model cannot give those quantities scientific standing.

The implications extend beyond current submissions. More than four decades of PBAC evaluation have created an unfortunate heritage of validation failure. Past decisions relying upon QALY-based claims inherit that failure in their quantitative justification, irrespective of whether the ultimate reimbursement decisions might have been the same for other reasons.

This paper deconstructs the PBAC validation framework against the requirement that measurement precedes arithmetic. It distinguishes process from model validation, uses the QALY as the canary exposing the failure, anticipates the claim that existing PBAC procedures might already constitute process validation, and proposes the immediate revision of the Guidelines. The requirement is straightforward: process validation must precede model validation, and failure of the measurement warrant must terminate the quantitative claim.

1. PBAC MODEL VALIDATION

The PBAC does not ignore validation. The PBAC Guidelines explicitly require validation of model-based economic evaluations and state that validation is intended to increase confidence that model-generated results represent what they are intended to represent¹. Section 3A.7 sets out a range of model-validation procedures. These include operational validation through model traces and examination of model logic and computerization, together with assessment of external validity. Modelled outcomes should, where possible, be compared with empirical data and with outcomes generated by similar models, and additional model-validation exercises are encouraged.

These are legitimate forms of model validation. They examine whether an already-constructed model operates as intended and whether its outputs are consistent with relevant external evidence. They do not constitute process validation. They do not establish whether the quantities entering the model were lawfully constructed as measures or whether the arithmetic operations through which those quantities were created were admissible in the first place.

These are legitimate requirements. Model traces can expose coding errors, implausible transitions and inconsistencies between predicted and observed events. External comparison can identify unexplained divergence from empirical evidence, while cross-validation can reveal disagreement between models. PBAC is therefore clearly concerned with whether an economic model has been correctly constructed and whether its outputs behave plausibly.

The problem is where validation begins. By the time Section 3A.7 is applied, the quantitative architecture of the economic evaluation has already been constructed. Health-state values have been admitted, QALYs calculated, costs and outcomes accumulated, treatment differences generated and cost-effectiveness ratios produced. The validation process examines how the model handles these quantities; it does not first require demonstration that the quantities themselves possess the measurement properties necessary for the arithmetic through which they were created.

This is model validation, not process validation: process validation must precede model validation. The distinction is fundamental. Demonstrating that a model trace is logical cannot establish that a health-state preference value is a ratio measure. Comparing predicted QALYs with another model cannot establish that QALYs are lawful measures. Reproducing calculations cannot demonstrate that multiplication, aggregation, subtraction or division was admissible in the first place. The PBAC therefore begins validation after the logically prior measurement questions should already have been answered.

The issue is therefore not that PBAC fails to validate. It is more fundamental: PBAC validates the model without first requiring validation of the process through which its central quantitative claims were constructed. Model validation begins after the horse has bolted.

2. MEASUREMENT BEFORE ARITHMETIC

Process validation rests upon a fundamental requirement of quantitative science: measurement precedes arithmetic. The availability of numerical values does not establish that they are measures, nor does it authorize their addition, subtraction, multiplication or division. Arithmetic is admissible only when justified by the measurement properties of the quantities involved. The dependence of permissible numerical operations upon scale properties was made explicit 80 years ago in Stevens' seminal treatment of the scales of measurement ².

Process validation rests upon the requirements of representational measurement, given its major formal axiomatic treatment in 1971 with the publication of Volume 1 of *Foundations of Measurement* ³. Representational measurement concerns the conditions under which empirical relationships can be represented numerically while preserving the structure of the attribute being measured. Numbers do not become measures merely because they have been assigned to observations. A measurement system must establish a correspondence between the empirical

properties of an attribute and a numerical structure capable of representing them. The properties of that numerical representation then determine the transformations and arithmetic operations that are admissible.

The starting point is therefore the attribute. Quantitative measurement requires that the attribute being measured is identified and that the numerical representation refers to that attribute. For quantitative therapy-impact claims this requires particular attention to unidimensionality. Arithmetic cannot legitimately combine values representing different attributes and then assume that the resulting number measures a single quantity. Before arithmetic begins, the analyst must establish what is being measured, how it is being measured and the properties of the resulting scale.

Importantly, once the starting point for therapy-impact assessment is the attribute, the analytical framework permits a fundamental distinction between manifest and latent attributes and therefore between the measurement pathways appropriate to each. A manifest attribute is directly observable and, where the required conditions are satisfied, may be represented through linear ratio measurement, providing an invariant unit and non-arbitrary zero. A latent attribute is not directly observable and must be constructed through an appropriate measurement model; for therapy-impact assessment, this requires Rasch measurement, providing an invariant unidimensional scale in logits⁴. The distinction determines how a therapy-impact claim can legitimately be constructed and what arithmetic is subsequently admissible. The framework therefore does not begin by asking which outcome score or utility should be inserted into an economic model. It begins by asking what attribute is being claimed, whether it is manifest or latent, how that attribute can be measured, and what the resulting measurement properties permit the analyst to do with it. Process validation follows from that sequence.

Those scale properties determine the arithmetic that is admissible. This relationship between measurement scales and permissible numerical operations has been recognized for decades. Nominal scales provide classification and ordinal scales provide ordering, but neither provides the quantitative structure required for the arithmetic operations central to therapy-impact claims. The critical distinction for such claims is therefore between interval and ratio measurement.

Interval measures possess equal units but an arbitrary zero and therefore support differences but not invariant ratios. Ratio measures possess both an invariant unit and a non-arbitrary zero, permitting meaningful ratio comparisons and the multiplicative operations that depend upon them. The desired calculation cannot determine the scale properties of its operands.

Two further requirements are critical. Dimensional homogeneity requires quantitative expressions to preserve the dimensional meaning of the quantities involved. Commensurability requires quantities entering a ratio intended to represent a proportion to be measures of the same attribute on the same measurement basis. Dimensional cancellation alone cannot establish commensurability or create a legitimate proportional adjustment.

Process validation therefore operates continuously. Every operation must earn the right to proceed. Weighting requires a warrant. Aggregation requires a warrant. Multiplication requires a warrant.

Subtraction requires a warrant. Division requires a warrant. The output of one calculation cannot acquire measurement standing merely because it becomes the input to another.

This is the requirement missing from the PBAC validation framework. A computer can perform an inadmissible operation as accurately as an admissible one. Correct coding, internally consistent equations and reproducible calculations establish only that the specified arithmetic has been executed correctly. They do not establish that the arithmetic was scientifically permissible.

The first validation question for PBAC should therefore not be “Was the calculation performed correctly?” It should be: “Were we entitled to perform the calculation at all?”

Section 3 applies that question to the QALY: the canary in the coal mine exposing the consequences when process validation is absent.

3. THE CANARY IN THE COAL MINE

Few constructs in health economics have acquired the authority accorded to the QALY. In much of legacy HTA it is treated with a respect approaching that afforded to the great achievements of quantitative science as though $Q = U \times T$ possessed something of the intellectual standing of Einstein's field equations. It does not. The QALY is instead the foremost example of what happens when arithmetic is allowed to proceed without process validation. The formal proof is provided in a companion paper ⁵

The QALY claims to be a measure of quality-adjusted time by multiplying a health-state preference or utility value, U , by duration, T :

$$Q = U \times T$$

The interpretation assigned to U is explicitly proportional. If $U = 1$, duration is left unchanged. If $U = 0.6$, one year in the health state is treated as 0.6 quality-adjusted years. If $U = 0.5$, one year is treated as one-half of a quality-adjusted year. U is therefore not functioning merely as a numerical description of a health state. It is being used as a proportional adjustment factor for time. The requirements established in the preceding sections can now be applied directly to this claim.

The first requirement is that U must itself possess lawful proportional meaning. If $U = 0.6$ is to mean 60% within preference space, there must be a defined preference attribute, A_p , measured on a ratio scale, together with two commensurable measures $P1$ and $P2$ such that:

$$A_p = P1 / P2 = 0.6$$

Only then would it be legitimate to state that $P1$ represents 60% of $P2$. Conventional health-state preference systems do not establish this measurement relationship. A health state assigned $U = 0.6$ is located numerically within a preference-value system, commonly anchored by values such as 1 for full health and 0 for death. Those numerical reference or preference points do not establish a non-arbitrary zero, an invariant unit, unidimensionality, commensurable ratio measures or the legitimacy of proportional comparisons. Consequently:

$$U = 0.6$$

does not establish:

$$P1 / P2 = 0.6$$

This is the first failure. U has not been demonstrated to be the lawful ratio proportion required for proportional adjustment. Although U may be assigned a numerical value, it is undefined as a measure: no single attribute, invariant unit, non-arbitrary zero or ratio-scale structure has been demonstrated.

The QALY then encounters a second and independent failure. Suppose, purely for argument, that a preference attribute could be measured on a lawful ratio scale and that:

$$P1 / P2 = 0.6$$

had been established. This would demonstrate that P1 is 60% of P2 within preference space. It would still provide no measurement warrant for reducing duration to 60% of its original value. The required proportional relationship within time space remains:

$$At = T1 / T2 = 0.6$$

A separate measurement relationship must therefore demonstrate:

$$P1 / P2 \rightarrow T1 / T2$$

The conventional QALY provides no such mapping. Instead, it takes the numerical value $U = 0.6$ from preference space and applies it directly to duration:

$$Q = 0.6 \times T$$

The construction therefore assumes precisely the relationship that measurement must first demonstrate. The fact that a preference ratio and a time ratio might both be dimensionless does not establish their equivalence. Nor does their numerical equality. A ratio of 0.6 within one measurement space cannot simply be declared to represent a ratio of 0.6 within another.

The proof therefore consists of two independent failures:

Failure 1: U is not demonstrated to be a lawful preference proportion.

$$U = 0.6 \text{ does not establish } P1 / P2 = 0.6$$

Failure 2: Even if a lawful preference proportion existed, there is no demonstrated mapping from preference proportion to time proportion.

$$P1 / P2 = 0.6 \text{ does not establish } T1 / T2 = 0.6$$

Failure at either stage is sufficient to invalidate the QALY. The conventional construction fails at both.

The conclusion follows directly. $Q = U \times T$ can be performed arithmetically, but its product cannot be interpreted as a lawful measure of quality-adjusted time. U has not been established as the required proportional measure, and even granting such a measure cannot establish the required mapping from preference space to time space. The QALY is therefore an impossible measurement construct. There are no missing measurement properties waiting to be demonstrated. The failure is inherent in its construction.

The implications extend to the terminology of HTA itself. The term QALY should be excised from the lexicon of health technology assessment. It is not simply that the QALY has been demonstrated to be a failed measurement construct, as though it were one unsuccessful measure that might be repaired, recalibrated or replaced by an improved version of itself. The more fundamental conclusion is that there is no lawful quantitative object corresponding to what the term claims to represent. There is duration, which can be measured in time space, and there are numerical representations of health-state preferences, but their multiplication does not create a new measure called quality-adjusted time. Once the arithmetic convention is shown to violate the requirements of measurement, there is nothing left to preserve under the name. The QALY is a will-o'-the-wisp: an apparent quantitative object that has led generations of HTA practitioners, researchers and students along a measurement path that never existed. It belongs not in the continuing vocabulary of quantitative HTA but as a historical footnote to the consequences of allowing arithmetic to precede measurement.

The attention given to the QALY as an unlawful construct with no meaning in measurement terms can obscure a more fundamental failure. It risks presupposing that the preceding operations necessarily satisfied the requirements of process validation. They did not. The entire legacy HTA edifice is built upon the valuation of health states, rather than, as required for quantitative measurement, the measurement of single attributes. The failure therefore precedes the QALY. Once this is recognized, subsequent operations involving QALYs become redundant. Aggregating and subtracting QALYs, constructing cost-per-QALY ICERs, and applying cost-per-QALY thresholds merely extend arithmetic to a quantity that was never established as a measure. Downstream arithmetic cannot rescue an upstream measurement failure.

4. AN UNACCEPTABLE SITUATION: REVISED PBAC GUIDELINE REQUIREMENTS

The position confronting PBAC is unacceptable. Its evaluation framework places substantial emphasis on the construction, verification and validation of economic models while failing to impose the logically prior requirement that the quantitative claims entering those models must first survive process validation. The result is an inversion of scientific priorities. Considerable effort may be devoted to validating a model after quantities have been created through arithmetic operations for which no measurement warrant was established.

PBAC might respond that its existing procedures already amount to process validation. Submissions are critically appraised; assumptions are examined; health-state values and other

inputs are scrutinized; model logic is tested; calculations are checked; uncertainty is explored; and model outputs may be compared with external evidence. These are important activities. They are not process validation.

The distinction can be resolved without semantic argument. The issue is not whether the PBAC uses the word “validation.” It is what the PBAC validates, when it validates it, and against what measurement standards. The test is straightforward. Where do the PBAC Guidelines require, before a proposed arithmetic operation is performed, that the analyst identify the attribute being measured, demonstrate the measurement system through which numerical values were obtained, establish the properties of the resulting scale, and show that those properties permit the proposed arithmetic operation? Where is the requirement that failure to provide this measurement warrant terminates the calculation? Unless PBAC can identify these requirements in its Guidelines, its existing validation procedures cannot be retrospectively described as process validation.

The QALY makes the distinction impossible to avoid. Scrutinizing the source of a health-state value does not demonstrate that the value is a measure of a single attribute. Checking the implementation of a utility algorithm does not establish its scale properties. Testing the calculation $Q = U \times T$ does not demonstrate that U is the lawful ratio proportion required to adjust ratio-scaled duration. Comparing modelled QALYs with QALYs produced elsewhere does not establish that either quantity has measurement standing. Sensitivity analysis merely demonstrates what happens when numerical assumptions are changed. None answers the logically prior question: was the arithmetic admissible?

This omission has a long history. PBAC economic-evaluation guidelines were first issued in draft form in 1990, revised in 1992 and made mandatory for submissions in January 1993. Across the subsequent development and revision of the Guidelines, process validation has not been established as the mandatory prior requirement governing quantitative claims. For more than three decades of formal PBAC economic-evaluation guidance and across almost four decades of Australian cost-effectiveness practice the question “Were we entitled to perform this arithmetic?” has not been made the required gateway through which a quantitative claim must pass.

PBAC should therefore revise its Guidelines to establish process validation as a mandatory first stage in the assessment of every quantitative therapy-impact claim. Each submission should be required to identify the attribute, specify its measurement system, demonstrate the properties of the resulting scale, identify every proposed arithmetic operation and establish that each operation is admissible under those properties.

The governing rule should be unequivocal: Failure of process validation terminates the quantitative claim. Only claims surviving this stage should proceed to model construction and conventional model validation. The distinction should be explicit:

Stage 1: Process validation — Was the quantitative claim lawfully constructed?

Stage 2: Model validation — Was the lawful quantitative claim correctly implemented within the model?

Stage 2 cannot compensate for failure at Stage 1.

This requirement extends beyond the QALY. The QALY is simply the canary that exposes the larger methodological failure. Every quantitative therapy-impact claim submitted to PBAC should be subject to the same requirement. Where the attribute is manifest, the appropriate pathway is linear ratio measurement. Where the attribute is latent, the appropriate pathway is Rasch measurement. Numerical scoring systems, preference-elicitation procedures, weighting algorithms and conventional psychometric instruments cannot be assumed to provide measurement merely because they generate numbers.

The implications for the conventional QALY are immediate. Process validation fails before, or at the latest at, $Q = U \times T$. Subsequent aggregation of QALYs, calculation of incremental QALYs, construction of cost-per-QALY ICERs and application of cost-per-QALY thresholds cannot restore the missing measurement warrant. Downstream arithmetic cannot rescue an upstream measurement failure.

PBAC therefore does not need another layer of conventional model validation. It needs a prior process-validation requirement that determines whether the quantities and arithmetic proposed for inclusion in a model have scientific standing in the first place. The change required is conceptually simple but methodologically decisive: measurement must precede arithmetic; process validation must precede model validation; and failure of the measurement warrant must stop the quantitative claim.

AN ANALYTICAL FRAMEWORK FOR REVISED PBAC GUIDELINES

PBAC does not need to construct the required analytical framework from first principles. A structured program for making the transition from legacy HTA to representational measurement has already been developed by Maimon Research: *Reconstructing HTA Programs: Measurement before Arithmetic*⁶. The nine-unit program provides a practical foundation for developing revised PBAC Guidelines in which process validation precedes model validation.

The program is not intended to add a measurement component to the existing reference case while leaving its analytical structure unchanged. Its purpose is to reverse the existing sequence. Instead of beginning with a desired decision calculation and searching for numerical inputs with which to perform it, the program begins with the attribute and asks what can legitimately be measured and what arithmetic those measurements permit.

Across nine units, the program addresses measurement before arithmetic; the definition of attributes and measurement claims; scale properties and admissible arithmetic; dimensional homogeneity and commensurability; manifest attributes and linear ratio measurement; latent attributes and Rasch measurement; attribute possession and change; process validation and measurement compliance; and the construction, empirical evaluation, falsification and replication of therapy-impact claims.

The baggage of legacy HTA is put aside because it fails to meet the standards of lawful measurement. This includes not only multiattribute health-state utilities and the QALY, but the

reference-case framework constructed around them. Once the QALY fails process validation, its downstream products incremental QALYs, cost-per-QALY ICERs and cost-per-QALY decision thresholds lose their claimed quantitative standing. The nine-unit program therefore does not attempt to repair or modernize the legacy reference case. It replaces it with an attribute-based measurement framework in which therapy-impact claims must first be established through lawful measurement and continuous process validation. Imaginary cost-per-QALY claims give way to quantitative claims whose attributes, measurement properties and admissible arithmetic can be explicitly demonstrated.

Two measurement pathways provide the foundation for therapy impact assessment:

Manifest attribute → Linear ratio measurement

Latent attribute → Rasch ratio measurement

Process validation operates continuously within both pathways. At every proposed arithmetic operation, the measurement warrant must be demonstrated. If it cannot be demonstrated, the operation does not proceed. Only quantitative claims surviving this process become eligible for incorporation into a model and subsequent model validation.

This framework provides the analytical foundation for a revised PBAC therapy impact framework. It would enable PBAC to specify what constitutes an acceptable quantitative therapy-impact claim, the measurement evidence required to support it, the arithmetic operations that are admissible, the circumstances in which a claim must be rejected, and the point at which conventional model validation becomes appropriate. It would therefore replace the present assumption that numerical inputs are available for modelling with an explicit requirement that their measurement standing first be demonstrated.

Maimon Research can support this transition through its existing body of published papers and technical notes, worked teaching materials and class notes, curriculum and knowledge-base evaluations, measurement and process-validation frameworks, and faculty and professional-development materials. These resources can support the development of revised methodological standards, training in process validation, evaluation of proposed quantitative claims and the transition from the legacy reference case to a measurement-based PBAC framework.

There is therefore no requirement for PBAC to wait for a new international consensus, another ISPOR task force or another generation of methodological debate. The analytical framework required to begin reconstruction is available now.

CONCLUSION: AN UNENVIABLE PBAC LEGACY HTA HERITAGE

PBAC has inherited an unenviable legacy HTA heritage. For more than four decades, quantitative claims have been accepted within a framework in which model construction, model validation and decision analysis were allowed to proceed without the logically prior requirement of process validation. The central question asking were these arithmetic operations permitted by the

measurement properties of the quantities involved was never made a mandatory gateway to quantitative claims.

The QALY is the canary in the coal mine. Its failure is not an isolated technical defect. The failure begins earlier, with the valuation of multidimensional health states rather than the measurement of single attributes. It becomes explicit when U, undefined as a measure, is employed as though it were a lawful ratio proportion capable of adjusting ratio-scaled duration. From there the failure propagates through total QALYs, incremental QALYs, cost-per-QALY ICERs and decision thresholds. Each operation should have been a process-validation checkpoint. Instead, the previous arithmetic operation became the warrant for the next.

This creates an uncomfortable historical consequence. Past PBAC decisions relying upon QALY-based quantitative claims inherit this failure. This does not demonstrate that every reimbursement decision would necessarily have been different. It demonstrates something more precise: the QALY-based quantitative justification offered in support of those decisions cannot retain scientific standing when the measurement warrant for the quantities employed was never established. A decision cannot retrospectively validate the quantity used to justify it.

PBAC did not create this problem. It inherited an international HTA framework in which preference valuation, QALYs, cost-effectiveness modelling and model validation had already become institutionalized. But inheritance is not validation. Forty years of acceptance cannot substitute for a measurement warrant. Globally, decisions on the pricing of and access to therapies have relied upon numbers, differences and ratios that have no demonstrated existence as measures in representational measurement terms. The arithmetic may produce numerical results, but numerical results do not acquire scientific standing merely because they are used to make decisions.

The decision framework changes once the failure is made explicit. PBAC can no longer assume that increasingly sophisticated model validation will resolve a problem that occurs before model construction begins. A perfectly validated model can perfectly reproduce a process-validation failure. The proverbial cat is now out of the bag. The absence of process validation has been exposed and can no longer be defended by convention, historical acceptance or institutional practice. Resistance is inevitable: too much of the legacy HTA framework depends upon quantitative claims constructed without the required measurement warrants. But resistance cannot constitute a methodological defense. Change must occur.

The required response is therefore the immediate revision of the PBAC Guidelines. Every quantitative therapy-impact claim should be required to pass process validation before entering an economic model.

Process validation failure at any stage must terminate the claim. The principle could scarcely be more elementary: measurement precedes arithmetic. Process validation must therefore precede model validation. PBAC's unenviable heritage cannot be changed retrospectively. Its continuation can. The QALY was the canary. Its failure exposed the mine. The PBAC must now confront what the canary has revealed.

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