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Response to the Draft Report of the Health Economics Methods Advisory (HEMA): "Defining Appropriate Benefits for Economic Evaluation of Health Care Technologies"*

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Overview

Healthcare resource allocation should serve the needs of the individual people in a society who benefited from it and paid for it, not the needs of health technology assessment bodies or payers who are entrusted to manage those resources on individuals' behalf. This intuitive observation rests on a bedrock principle of economics, namely that society's values mirror what individuals in that society value. Yet, by mischaracterizing and misapplying basic economic principles, the Health Economics Methods Advisory (HEMA) draft report instead reaches the opposite conclusion. The same errors in logic lead HEMA to reject novel elements of healthcare value, which are explicitly designed to align healthcare value assessment with what individuals value. The so-called "novel" value elements derive from almost a century of settled economic theory and empirical analysis; in contrast, HEMA advocates an *ad hoc* approach riddled with internal inconsistencies and disregard for the well-being of the people whom healthcare systems serve.

HEMA offers a full-throated defense of an increasingly indefensible status quo, built around analysis of the QALY. Nowhere in their manuscript do they grapple with, or even mention, that the Inflation Reduction Act of 2022 prohibited the use of QALYs in decision making by American public payers. Nor do they acknowledge that alternatives such as Generalized Risk-Adjusted Cost-Effectiveness (GRACE) provide a legally compliant path forward [1], a considerable advantage over standard QALYs. While HEMA treats the political processes that determine the level of healthcare spending in national health systems as "reflect[ing] the preferences of the general population," (p. 27) it fails even to remark upon the preferences reflected by the US political processes that prohibited the QALY.

HEMA Ignores Both Empirical Objections to the QALY and Empirical Advantages of Novel Approaches

Summary: While HEMA argues that QALYs are strongly supported, they hold no special status and are, in fact, often rejected by the public and healthcare decision makers. HEMA also fails to mention numerous extant empirical objections to the QALY, all of which imply that it systematically fails to account for key aspects of individual preferences. At the same time, HEMA dismisses alternatives to the QALY by noting that "none has demonstrated empirical evidence that they align with either public or patient preferences" (Box 2). This assertion is undermined by a growing evidence base on more generally applicable value approaches, such as Generalized Risk-Adjusted Cost-Effectiveness (GRACE) [2]. However, even if it were correct, the right answer would be to call for further research on the topic given the clear limitations of the QALY, not to insist on maintaining a flawed *status quo*.

Analysis: HEMA's argument presumes in part that QALYs are strongly supported by empirical evidence of all kinds. On the contrary, QALY recommendations are often rejected by the public [3, 4]. Even healthcare decision makers, whom HEMA focuses on

representing, do not routinely find QALYs decisive [5, 6]. Generally, concerns arise when the less well-off are forsaken for marginal gains by the well-off [7]. Approaches like GRACE can address such issues, whereas QALYs cannot.

Other empirical evidence further conflicts with the QALY. For instance, its fundamental theory implies that, if QALYs are measured correctly, consumers would exhibit risk-neutrality over them. This would imply the absence of any disease severity premium, when in fact empirical evidence demonstrates that such a premium exists among consumers [8, 9] and even among payers [10, 11]. HTA bodies have explicitly incorporated disease severity premiums [12], as HEMA acknowledges. For example, the UK Cancer Drugs Fund [13, 14], and the use of *ad hoc* "Absolute Shortfall" and "Proportional Shortfall" adjustments [12] reflect the empirical shortcomings of QALY-based analyses.

HEMA itself makes arguments that undermine the empirical validity of the QALY. In their attempt to rebut the "value of hope," they assert that patients may overestimate the probability that a treatment will be successful (p. 26). Such systematically incorrect expectations would fall outside the framework of standard QALYs, a point that HEMA fails to appreciate. Indeed, such "optimism" or "pessimism" biases are captured in Prospect Theory [15], which readily comports with GRACE [16] and provides another reason to favor more general, novel approaches and disfavor standard QALYs.

In dismissing alternatives to the QALY, HEMA also overlooks empirical evidence that measures novel value elements in consumer preferences. Studies have documented the presence of nonzero value of hope [17, 18], nonzero option-value [19], and non-risk-neutral preferences over health outcomes [16, 20]. Theoretically, QALYs result from applying highly restrictive assumptions about preferences to the more general GRACE framework, which accommodates novel value elements like the value of hope and insurance value [21]. Generality is always preferred to restrictiveness, all else equal; therefore, it is up to the defenders of the QALY to justify its necessary restrictions by ruling out the presence or usefulness of novel value elements. Moreover, QALY's no longer represent the only feasible approach to value assessment. GRACE estimation is now feasible using only the inputs native to a traditional QALY-based analysis along with recent estimates of individual preferences over risky health outcomes [16].

HEMA Dismisses Patient-Centered Decision Making by Misunderstanding the Normative Basis of Economics

Summary: Centering value assessment on the preferences of individuals, rather than HTA bodies, is not only possible but also essential for ensuring alignment between collective decision making and the well-being of society's individual members.

Analysis: HEMA misunderstands the theoretical basis for its own preferred approach, the QALY, and its relationship to modern welfare economics. Two passages from the HEMA report illustrate this theoretical confusion.

> *Most HTA … see benefit in terms of the health of the populations for which their health systems are responsible. This is notably different from the ideas underlying some novel value elements which relate to individual benefits expressed as patients' preferences and choices*. [p. ES2]

> *Inevitably, the specification of a benefit function will be contested – both its constituent parts and the weights - and a social consensus will be impossible. This is consistent with the long-recognized understanding in economics of the impossibility of deriving a "social welfare function" from the preferences of individuals. [p. 3]*

The first passage reveals HEMA's problematic choice to focus on what HTA bodies view as beneficial, rather than on what individual patients view as beneficial. In the second, they attempt to justify this view by asserting that social decision making cannot be coherently based on individual preferences. Not only is this latter argument incorrect, but HEMA also appears unaware that the very assumptions underlying the QALY framework they embrace also undermine the supposedly "long-recognized" impossibility result they reference.

Although they do not provide a citation, we assume they are alluding to Kenneth Arrow's "Impossibility Theorem" [22] when arguing that social welfare cannot be built upon individual preferences.[1] Yet, less than five years after Arrow published his theorem, John Harsanyi, another Nobel Laureate economist, proved mathematically that social welfare functions *can* indeed be coherently built as weighted averages of consumer preferences, so long as utility levels can be compared across people [24]. (Arrow explicitly assumed away the possibility of interpersonal utility comparison to enable his proof.[2]) Significantly, QALY-based decision making *requires* that utility be comparable across people [25], adding a layer of irony to HEMA's mistaken assertion about "impossibility." Indeed, such interpersonal comparisons remain central to economic valuations of all kinds, and the conditions for comparability are empirically reasonable: for example, if everyone assigns the same value to full health and the same value to death—conditions fundamental to HTA—then utilities will be comparable across people [26]. Arrow himself relied on interpersonal utility comparisons in his later work on health economics [27].

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[1] Arrow makes clear that his proof requires collective decision making to be limited only to rank-order voting of some sort. Yet, modern welfare theory has further demonstrated that this "long-recognized" impossibility result also fails when societies use alternatives to rank-ordered voting, such as majority judgement [23].

[2] Arrow's own restatement of his theorem makes this plain [22, p. 342] (emphasis ours): "*If we exclude the possibility of interpersonal comparisons of utility*, then the only methods of passing from individual tastes to social preferences which will be satisfactory and which will be defined for a wide range of sets of individual orderings are either imposed or dictatorial."

HEMA's focus on the QALY internally contradicts its claim that social decisions cannot be derived from individual preferences. This represents a fundamental error. By abandoning individual preferences, HEMA shifts decision making towards technocrats and away from patients, both current and future. Harsanyi showed that any social welfare function that departs from a weighted average of individual utilities fails to protect the rights and preferences of individuals [24]. Specifically, Harsanyi noted that only a weighted average of utilities respects the "Pareto principle," which ensures that collective decisions always at least favor policies that make every individual better or no worse off.

In contrast, the GRACE framework [2, 21, 28] and numerous other novel value elements [17, 29, 30] begin with the well-established economic principle that social welfare derives from individual welfare and can be readily measured through interpersonal comparisons of utility. Indeed, the foundational theory of the QALY itself assumes that QALYs should be based on individual preferences [25, 31], a topic we revisit below.

HEMA Misunderstands and Overemphasizes Opportunity Costs in Healthcare Resource-Allocation

Summary: It has long been shown that, like any other investment, health spending should be undertaken whenever the rate of return is sufficiently high. HEMA disregards this principle and instead baselessly assumes that healthcare spending levels are fixed and that spending on new health technologies always comes at the expense of other health technologies. This assumption is no more correct than asserting that opening a new semiconductor factory provides no additive benefit and necessitates closing an existing one. The historical record makes clear that healthcare budgets are not set in stone. They result from public and private choices about how to allocate resources across healthcare and non-healthcare uses. As such, health technology assessment should focus on ensuring that health investments are made whenever the benefits to individual members of society exceed the direct costs to society and foregone otherwise. These criteria do not depend on the sunk costs embedded in prior healthcare spending decisions.

Analysis: To illustrate the flaws in their logic, we begin by noting HEMA's claim:

> *All health care systems funded collectively, whether via taxation or insurance, impose opportunity costs when they devote additional resources to new medical technologies and other interventions. This is because those additional resources are inevitably taken from interventions and services which could have benefited other patients, and the opportunity costs are the consequent reduction in those individuals' health outcomes.*

This is incorrect. As the economist Michael Grossman established more than fifty years ago, consumer spending on good health can best be thought of as an investment, featuring

upfront outlays of time and money and downstream returns in the form of good health and its attendant value [32]. As with any other investment problem, a health intervention should be paid for if its monetized stream of benefits exceeds its direct costs. If the marginal value of healthcare spending rises, so should the amount of money spent on it. HEMA ignores this fundamental economic principle, and in doing so, erroneously instructs the entire field of health economics on the purported necessity of "giving due consideration to opportunity costs" (p. ES2) in the theory of value assessment.

Moreover, from a purely empirical point of view, healthcare spending is not fixed, certainly not in the long-run. This point is obvious in the US, but it is even true in "national health" countries like the UK. The British National Health System (BNHS) budget increased by an average of 2.3 percent per year (in 2023-24 prices) from 1956 through 2022 (https://www.kingsfund.org.uk/insight-and-analysis/data-and-charts/nhs-budget-nutshell). This led to a 4.5-fold increase in real spending for the BNHS over that period. Growth was somewhat higher when Labour controlled the Parliament and lower when Conservative governments had control, but increases occurred regularly. Over the same period, the British population increased from 42 million to 69 million, so real per-capita spending nearly tripled. The BNHS response to the pandemic also undermines the "opportunity cost" logic. Facing the threat of COVID, BNHS temporarily boosted its spending by more than 20%.

This also means that, even in the BNHS, "additional resources" are not inevitably taken from other patient-benefitting services, despite the historically incorrect assertion by HEMA. Additional spending may indeed be financed through increased BNHS budgets that reduce British consumers' ability to buy other goods and services. The tradeoff between improved health and non-health consumption is clearly present, and economic logic dictates that health investments make sense if they produce value that exceeds the cost of the monetary resources invested.

HEMA Ignores the Well-Being of Future Generations of Patients

Summary: When reimbursement reflects patient preferences, innovators accrue financial rewards by serving patients. By weakening the link between measured value and patient preferences, HEMA muddies these pricing signals to innovators and encourages innovation that serves HTA bodies, not current and future generations of patients. This error could have global consequences.

Analysis: The health economist Joseph Newhouse once remarked that "the patent system is an effort to approximate a dynamically efficient price"--in other words, one that produces the optimal amount of innovation globally [33]. HEMA's approach fails to produce a dynamically efficient price and thus distorts medical innovation, harming all patients, both current and future.

The economic literature makes plain that innovation becomes efficient when a technology's price depends on the value it produces for individual members of society, current and future [34, 35]. When prices instead reflect value to HTA bodies, firms will innovate to serve HTA bodies rather than patients. This corruption of innovation incentives harms the well-being of future generations of patients, who are denied a stake in decisions that affect their health and life expectancy.

This point also highlights a deep and troubling incentive problem inherent in HEMA's approach. Neither HTA bodies, nor governments, nor private firms pay for medical technology. People do, in the form of insurance premiums, taxes, and out-of-pocket payments. Thus, HEMA's approach would have individual people pay to serve the preferences of HTA bodies. Instead, the HTA process ought to represent the preferences of individuals, not diverge from them. Pricing new technologies according to the value accrued by individual patients ensures efficient incentives for innovators. Put more plainly, since innovators will focus on earning the highest reward for their efforts [36-39], society should align those rewards with the needs, values, and preferences of the individual people that pay for medical technology and receive its benefits.

This issue spans international borders. New medical innovations benefit people all over the world. At the same time, the US market produces an outsized impact on innovation incentives, accounting for at least two-thirds of global pharmaceutical profits [40]. Thus, getting US prices wrong harms people all over the world. For example, prior research demonstrates that importing European pricing policies into the US market would reduce longevity for Europeans almost as much as it would for Americans, even though only American policy would be changing [41].

HEMA Misunderstands Risk in Value Assessment and Unjustifiably Dismisses Risk-Related Novel Value Elements

Summary: HEMA asserts that HTA bodies should disregard health risks when making decisions. This assertion violates both economic theory and the common sense of all the human beings who worry about the risk and uncertainty associated with disease and poor health. Because of this faulty assumption, HEMA fails to refute novel alternatives to the QALY that properly account for the way individuals perceive and respond to health risks.

Analysis: HEMA argues for the dismissal of novel value elements related to risk—e.g., the "value of hope," "insurance value," and the GRACE framework. Their argument rests on another theoretical error: HEMA argues that healthcare decision makers ought not to care about risk—in economic parlance, HEMA assumes they are "risk-neutral." However, maintaining the presumption of "risk-neutrality" conflicts both with the theory of the QALY

that HEMA appears to embrace and with economic principles concerning the analysis of societal welfare.

Specifically, HEMA appears to confuse the concept of risk-neutrality over QALYs with risk-neutrality over health outcomes. This confusion undermines HEMA's dismissal of GRACE and all related novel value elements that capture patient risk preferences. Specifically, HEMA's unequivocal defense of traditional methods is contradicted by foundational theoretical work on the QALY, which explicitly notes that individuals may have non–risk-neutral preferences over underlying health benefits [25, equation (3a)], a point echoed in subsequent work [31, equation (4)].

As these and numerous other works make clear, one important purpose of the QALY is *to account for risk preferences over health improvements*. If in fact these risk preferences are fully accounted for, only then will preferences become risk-neutral over the QALY itself. Risk-neutrality over QALYs is entirely different from and does not imply risk-neutrality over health benefits, a critical distinction that gets lost in HEMA's misreading of the QALY literature.

Using this flawed logic, HEMA attempts to dispute that risk preferences should be accounted for in health technology assessment. Yet, the theory of the QALY on which they themselves rely has long settled this dispute in favor of the opposite conclusion: risk preferences over health benefits must be accounted for. This is settled theory, not a novel proposition requiring confirmation.

HEMA's reasoning also rests on an implausible assumption about aggregate health outcomes. For instance, HEMA asserts:

> *Decision makers who use HTA are typically assumed to be risk neutral with respect to each decision they make about individual health technologies because the health of the populations they serve is only marginally impacted by each individual reimbursement decision*.

Here, HEMA advocates abandoning person-centered economic analysis in favor of HTA-centered analysis. Implicitly, they assume that losses to one patient can be offset by gains to others, so long as aggregate population health improves. This framing treats health as if it were a divisible, transferable asset in a collective portfolio. Obviously, however, patients cannot redeem the survival or well-being of others to compensate for their own loss. Each person bears the consequences of uncertain health outcomes directly, and the ethical legitimacy of HTA cannot rest on the presumption that individual harms are acceptable so long as population averages improve.

What then is the incentive to preserve risk-neutrality at such high cost to patients? One possibility is that not everyone agrees with their colleagues on which methods should guide HTA. Risk-neutrality glosses over these disputes, seemingly permitting a wide array of methods for measuring "utility." Risk-neutrality offers a broad and welcoming tent for HTA

researchers. However, we find it troubling that the assumption of risk-neutrality appears to aid researchers more than it does patients.

HEMA's Conclusions Rest on an Undefined and Inconsistent Concept of "Group" Preferences

Summary: In place of focusing on individual preferences, HEMA advocates for a fuzzy and ill-defined concept of "average" group preferences. This approach runs roughshod over clinical and preference diversity in a population of patients. Imagine a society where two-thirds of people with a disease benefit more from a blue pill, but the other third benefit more from a red pill. "Average" preferences would seek a single rank-ordering – everyone gets the blue pill, everyone gets the red pill, or perhaps they all get a "purple" pill. Clearly, these "average" preferences efface individual diversity and harm large minorities of patients.

Analysis: Curiously, HEMA asserts the principle that "benefits must be aggregated (valued) appropriately and consistently with average preferences of the general population rather than preferences of specific individuals" (p. ES1). "[A]verage preferences of the general population" are never precisely defined, but to the best of our ability to interpret the term, it appears fundamentally inconsistent either with the rational allocation of resources or with HEMA's exclusion of individual preferences.

If the term "average preferences" corresponds simply to an average of individual utility functions, then HEMA would implicitly be accepting the principle that individual consumer preferences reign supreme, contrary to their assertions elsewhere. Let us assume they are not embedding such a fundamental contradiction. Instead, we presume that they have in mind some concept of a group preference ordering distinct from a linear combination of individual preferences. However, Harsanyi proved that the only way to create a rational and Pareto-consistent preference structure for a group is to use a weighted average of individual preferences [24]. The only way we can see to make sense of "average preferences of the general population" is thus to compute weighted averages of individual preferences, precisely what HEMA incorrectly advises against.

HEMA Lacks Any Budgetary Basis for Excluding Consumer and Patient Preferences in Valuation

Summary: In this response, we have shown that HEMA lacks any basis in economic theory for excluding patient and consumer preferences in value assessment. They also lack a pragmatic or budgetary basis for this assumption, because health economists can now use GRACE to conduct patient-centered value assessment without needing to expand healthcare budgets. Prior research on GRACE reveals that QALY-based modeling has spent too little on severe disease, but *too much* on milder illness, and that on balance,

recentering value assessment on patient preferences saves about the same on mild disease treatment as it spends on severe diseases [42].

Analysis: Recent analysis of the GRACE framework —which incorporates patient preferences for health states and addresses discriminatory aspects of traditional cost-effectiveness analysis—demonstrates this infirmity in QALY-based allocations. When GRACE was applied to 69 pharmaceuticals previously evaluated by ICER, it increased value-based prices for treatments of severe diseases while decreasing prices for treatments of mild conditions [42]. The net result was a mere 2% aggregate increase in total spending, with resources redistributed toward more severe, less prevalent illnesses that patients value more highly and away from mild diseases that traditional QALYs over-reimburse. (If desired, strict budget-neutrality could be ensured with a trivial reduction in the willingness-to-pay threshold.)

This finding fundamentally challenges the zero-sum narrative that constrains health technology assessment. Rather than creating an inexorable budget expansion, methods that incorporate patient perspectives can identify where traditional cost-effectiveness analysis undervalues treatments (severe disease) and overvalues others (mild disease). The budget-neutral redistribution demonstrates that person-centered value assessment need not come at the expense of fiscal responsibility—it simply allocates resources more efficiently according to how patients themselves value health improvements.

Summary

Economic thought rests squarely on individual liberty and respect for the diversity of individual preferences. HEMA focuses not on this broad arc that bends toward human freedom, but instead on the defense of a QALY-based *status quo* that has outlived its usefulness. Economics rigorously and thoughtfully centers welfare on the people that inhabit a society, not on technocrats or regulators. It is long past time for economic evaluation in healthcare to follow suit.

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