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Examination of Multiple Criteria in Health Technology Assessment for Application to Instrumental Analysis

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Abstract: The instrumental-ceremonial dichotomy is the analytical concern emphasized in instrumental analysis by original institutional economists for making welfare decisions. Paul Dale Bush and Wolfram Elsner explained that warranted criteria are required in order to conduct instrumental analysis. The concern for criteria led to an examination of multiple criteria decision analysis in health technology assessment in order to improve instrumental analysis. Health technology assessment (HTA) is one of the most active and extensive areas of analysis for policy making because medical technology changes very rapidly, expenditures on it are high and growing, it can harm as well as help, and there is intense personal concern by citizens who want wellness. Although HTA, especially with regard to the analysis of multiple criteria, has made considerable progress, its appraisal has been a disappointment. Thus, the purpose of this paper is to critique aspects of multiple criteria HTA in order to further develop instrumental analysis.

Keywords: criteria, cost/effectiveness, health technology, instrumentalism

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The instrumental-ceremonial dichotomy is the analytical concern emphasized in instrumental analysis by original institutional economics (OIE) for making welfare decisions. Paul Dale Bush (1983, 1987) and Wolfram Elsner (2012) explained that warranted criteria are required in order to conduct instrumental analysis. The OIE paradigm has become one of complex systems, which includes an emphasis on the importance of multiple criteria in both the explanation of social systems and the analysis for contemplated changes. The social fabric matrix (SFM) was developed to analyze systems and provide policy recommendations for them (Hayden 2006, Hayden and Johnson 2020) The SFM "lays out a rigorous, comprehensive methodology . . . " for the study of complex real-world systems. The SFM "methodology is philosophically and theoretically developed from, and consistent with, the *original evolutionary-institutional economics* . . . and is one of the most comprehensive, empirical, and policy-relevant methodologies to come out of OIE" (Fullwiler, Elsner, and Natarajan 2009, 1).[1]

HTA is one of the most active and extensive areas of analysis for policy because medical technology changes very rapidly, expenditures on it are high and growing, it can harm as well as help, and there is intense personal concern by citizens who want wellness.[2] Although HTA,

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[1] An expanded explanation of the evolution of OIE to complex systems with multiple criteria can be found in F. Gregory Hayden and Erin Johnson (2020).

[2] The paper prepared by Robert Kemp (2019) for delivery at the 2019 Association for Institutional Thought meeting, about criteria in HTA, led to the examination of MCDA in HTA in order to improve instrumental analysis.

especially with regard to the development of multiple criteria decision analysis (MCDA), has made considerable progress, its appraisal has been discouraging with regard to multiple criteria. A recent article in *Science* about an HTA approved artificial intelligence decision process for health care is an example that clarifies the reason for disappointment. Across the United States, hospitals use an artificial intelligence algorithm to determine the amount of health care patients should receive. The results, as explained in the article in *Science* shows "that a widely used algorithm, typical of this industry-wide approach and affecting millions of patients, exhibits significant racial bias: At a given risk score, Black patients are considerably sicker than White patients, as evidenced by signs of uncontrolled illnesses. Remedying this disparity would increase the percentage of Black patients receiving additional help from 17.7 to 46.5%" (Obermeyer et al. 2019, 447). This bias exists because the HTA depended on monetary cost that had been spent on patients' health care in the past. "Less money is spent on Black patients who have the same level of need, and the algorithm thus falsely concludes that Black patients are healthier than sick White patients" (Obermeyer et al. 2019, 447). This case clarifies that much of what OIE has emphasized was ignored in the HTA. Important procedures of the HTA in this case were to (a) ignore equity concerns, (b) use monetary payments as an indicator of the sickness level of patients, and (c) not go into the field to check assumptions. Thus, the purpose of this article is to critique aspects of multiple criteria HTA in order to further develop instrumental analysis.

Multiple Criteria in Complex Systems

As has been clarified, to understand a system, the active role of criteria needs to be articulated (Hayden 2006; Hayden and Johnson 2020). The same is true for the evaluation of parts of the system and for policy changes contemplated. In both cases, institutionalists have emphasized the assessment of technology. Thus, we draw from the literature about MCDA for HTA in order to learn about the use of multiple criteria. Agencies in societies across the globe expend considerable resources to evaluate medical technology for use in real-world settings—real world settings that include the pain and turmoil that accompanies much of the technology, and, ultimately, too often include disability and lawsuits. Medical technology is a very embedded and active part of modern society, with the judgments and decisions of medical institutions, insurance companies, medical technology corporations, families, and government agencies involved. It escalates rapidly because new health technology is combined at a rapid rate in the medical field.

There has been a history of serious disagreement about how to conduct HTA. Traditionally, monetary criteria from neoclassical economics dominated HTA; however, not surprisingly, that did not provide for valid results.[3] Therefore, MCDA is emphasized to "indicate a paradigm shift toward transparency in using other criteria along with the traditional cost-effectiveness (C/E) analysis" (Thokala and Duenas 2012). The idea of the multiple criteria approach is to "provide a structured and transparent approach to identify a preferred alternative by clear consideration of the relative importance of the different criteria and the performance of the alternatives on the criteria" (Thokala and Duenas 2012).

[3] With regard to the history of HTA, Robert Kemp stated: "As more central health authorities require comprehensive evaluation of health care technologies, they are moving away from their initial attraction to simple reductionist models based on cost-benefit arithmetic to open models reflecting the complexity of the decisions at hand and toward the open-systems modelling that inspired Hayden in his construction of the social fabric matrix approach" (Kemp 2019).

The concerns considered here are from the article, "Multiple Criteria Decision Analysis for Health Technology Assessment" by Praveen Thokala and Alejandra Duenas (2012). The purpose of their article was to develop a general hypothetical multiple criteria formula to use in order to explain and compare different approaches of HTA.[4] We address generic concerns from the general MCDA model without discrimination among or comparison of the models. Technology is combined, elaborated, differentiated, and implemented by system institutions. The process of operationalizing new technology makes it clear that the elaborate process of research, combination, testing, criteria application, government approval, advertisement and promotion, implementation, use, and monitoring of and about medical technology demonstrates that technological change and advancement are not self-generated and/or self-propelled by technology (as is sometimes claimed). The implementation of new technology is disruptive and often destructive. Traditional ideology has been that such implementation and consequences should be accepted—an example is Schumpeter's pronouncement, without presenting research results or evidence, that it is "creative destruction." Such pronouncements are no longer accepted; thus, the need for multiple criteria technological assessment.

Critique of HTA Criteria with Hypothetical Formula

To complete multiple criteria assessment, the formulation of the criteria needs to be consistent with the socioecological system; so we next critique the general approach of MCDA, as articulated by Thokala and Duenas (2012). The HTA approach in Formula 1 "is based on constructing a single overall value for each alternative [technology] to establish a preference order of alternatives" (Thokala and Euenas 2012). In order to compare the basics of different approaches for conducting HTA, Thokala and Duenas defined a generic formula, stated here as Formula 1.

$$V(a) = \sum(W_{c/e} \times C/E) + (W_{eq} \times EQ) + (W_{I} \times I) + (W_{pc} \times PC) + (W_{QE} \times Q \qquad (1)$$

The terms in Formula 1 are defined as:

- V(a) – The overall value of alternative technology a.
- W – The weight representing the relative importance of a criterion. The subscripts indicate the criterion to which the weights apply.
- C/E – represents the performance score for the cost/effectiveness criterion expressed as a ratio.
- EQ – represents the performance score for the equity criterion.
- I – represents the performance score for innovation, which is an estimate of how innovative the technology is.
- PC – represents the performance score for patient compliance.
- QE – represents the performance score for quality of evidence.[5]

The initial glance at Formula 1 should make us suspicious of the formula as: (a) being isomorphic, with the whole being defined as the sum of its parts (all variables are added together to get a total), (b) lacking any negative feedback, so that the positive feedback of every variable will lead to growth and decay for the formula as a whole, and (c) being closed to the surrounding environment. All three are true for Formula 1 because the terms are multiplied

[4] The criteria utilized in the formula are taken from the United Kingdom National Institute for Health and Clinical Excellence assessment process.

[5] To demonstrate an applied example of Formula 1, Thokala and Daenas (2012) present a numerical expression for technology a as follows:

$$V(a) = \sum(8 \times 0.72) + (1 \times 0.14) + (3 \times 0.19) + (2 \times 0.93) + (3 \times 0.82) = 12.92$$

within each variable, are additive across variables, and are not defined to calculate outputs from or inputs to the system environment. There is nothing in the formula to indicate the normal range of delivery of medical care among institutions, as would be defined by criteria in a SFM approach to policy analysis.

Weights are Used Incorrectly in HTA: Isomorphic Category Mistake

The criteria (listed above in Formula 1) in HTA formulae are each weighted in order to add together their separate contributions, under the misguided assumption of being able to arrive at a single aggregate number for each health technology being assessed in order to compare alternative technologies. That is, HTA takes the isomorphic approach to modeling whereby it is assumed that the whole is the sum of its parts. Weighted criteria are simple to use; however, poor performance on a criteria for a technology can be overcome in the formula by doing well in other criteria depending on the weights (Thokala and Euenas 2012).

We need to recall two important concerns about real-world social-belief criteria. First, they are used to judge whether social activities are acceptable in an institutional setting and how important they are, without respect to how much is provided. Second, criteria also exist to judge whether the level provided is sufficient. For societal institutions to fit together, society normalizes flows among institutions that are to be maintained within a certain range (Hayden 2006, 192–194). Thus, it is possible to have too much or too little; the requirement that expenditures in the Canadian HTA formula for cancer treatment per case are not to exceed a pound limit and in the United States a dollar limit are examples. The idea of using weights ignores the normalized range and, instead, sets a weight coefficient that is held constant irrespective of how much is provided. Thus, an unimportant criterion that guides the selection of a low-flow level can, wrongly, be given a high weighted total in an aggregated formula. Unfortunately, much of HTA stresses the aggregated total at the expense of concern for the social meaning of the criteria.

Even if a criterion is very important to society, adverse performance for that criterion by a health technology can be ignored in an HTA formula if (a) other criterion score high and/or (b) other criteria are weighted heavier. "Weights are assigned independently of the alternatives to provide consistency across comparisons . . ." (Thokala and Duenas 2012). For example, the equity performance level of all technologies being assessed is multiplied by the same weight, and the patient compliance performance level of all technologies is multiplied by a different weight. Weights are used to attempt to indicate the relative importance of different inputs in the formula without respect to what needs to be delivered by each institution in the socioecological system. However, it is not possible to show whether a medical technology will meet the normal level of deliveries expected among the parts of a system with the use of weights. Instead, weights are playing the role of a common denominator to convert the performance scores of very different criteria into an additive property. This is the same mistake that is made when a carton of cigarettes and a drug prescription, with the same price, are multiplied by their monetary price so they can be aggregated in GDP. Neither prices nor weights are common denominators. To use weights as common denominators is a category mistake.

Additionally, it is inappropriate to assign weights without respect to the socioecological system that is the context where the technology is to be used. As social context changes, so

do the expected benefits of technology. For example, a social context might require that poor people not be allowed access to a certain medical treatment (which we know is common in the real world), so the expected benefits would be much different than in a social context with a requirement that all citizens have access to the treatment. However, HTA does not analyze the socioecological system to find the weights. For example, in the Canadian multiple criteria analysis, the weights are assigned by a panel of experts. Expert opinion is no substitute for SFM analysis.

Furthermore, it is not possible to aggregate the relevant deliveries across a system. For example, in a SFM analysis, deliveries include social belief criteria, technological criteria, and ecological criteria—both legitimate and variant (illegitimate) criteria. Such real-world criteria cannot be aggregated, irrespective by what they are multiplied—whether by weights or prices. Their meaning and consequences are due to the relationships in a socioecological network.

Instead of weights, ranges of deliveries around the norm for each criteria should be what is measured, consistent with the needs of the relevant socioecological system. Deliveries outside the accepted range call for adjustments in the technology or rejection of the technology.[6]

Equity is an Efficiency Concern

"Health policy decision makers internationally so far have been considering . . . equity and fairness and prioritization of interventions for vulnerable populations, in a deliberative manner" (Thokala and Duenas 2012). Consideration of equity criteria in HTA has also led to confusion consistent with neoclassical confusion about equity and efficiency. First is the mistake to assume that equity is not an efficiency concern. Efficiency means the ability to achieve a desired effect. If the desired effect is to have a drug available for all citizens with a disease, then the equity criteria for making decisions about the efficiency of the adoption of the drug should include that desired effect. Thus, equity is a kind of efficiency concern and should be judged as such with equity criteria. Second is the mistake that there is always a negative tradeoff between equity and other efficiency criteria (for example, performance or cost criteria). If a health technology is available for all adults under age 65, and if the technology cures a disease so labor returns to work as productive workers, we can expect cost in the economy to decrease, which increases the effectiveness in the HTA analysis. Thus, it is not a tradeoff between equity and efficiency. Equity and cost/effectiveness (C/E) criteria are both efficiency criteria, and it is necessary to include in the analysis how they are related and how society wants them related. Third, it is a mistake to assume that equity and C/E performance measures do not influence each other in the HTA, as explained in the next section.

Cost/Effectiveness Analysis: Reified Fallacy of Misplaced Concreteness

C/E leads to a ratio of a numeraire of monetary cost over a denominator of the results of interventions by medical technology. It is a replacement for neoclassical cost-benefit analysis, which failed in HTA for many of the reasons institutional economists have explained as the weaknesses of neoclassical economics.

[6] In addition to the weight assigned in HTA to the C/E variable, the prices used to arrive at cost also serve as weights. Exploitive prices charged by monopolistic and oligopolistic firms are examples that need to be adjusted before cost figures are accepted.

There are a number of weaknesses in C/E analysis that are usually not recognized. First, equity and C/E measures affect each other. For example, if, in C/E analysis, the medical intervention is to be provided to a high-income segment of the population that has had high quality health care and nutrition throughout life, the consequences per dollar of cost will be higher than if equity beliefs require that low-income citizens with poor quality of health and nutrition are to be included. Furthermore, if an intervention with new technology requires a large government subsidy for low-income patients, that subsidy increases the dollar cost of the program per unit of effectiveness; thus, decreasing the C/E score, while improving health. Thus, one concern is how much equity is given up to increase effectiveness. To know that, and how to measure it, can only be determined by knowing the relation between the two, which, in turn, requires knowledge about the societal beliefs about both and the context in which the technology is to be applied. Neither cost nor effectiveness is a simple concept, except when a heavy dose of reified fallacy of misplaced concreteness is applied.

Second, effectiveness includes a number of different measures, each of which needs its own criterion or set of criteria. Thus, effectiveness is really a set of different criteria about which measures need to be completed and judgments made, just as is the case for other variables like equity. This means, that effectiveness is a single variable only in vague and abstract descriptions.

Third, cost and effectiveness criteria should not be combined as a ratio in the same variable. This ratio approach is a mistake left over from the rejected cost/benefit ratio. Cost and effectiveness should be listed as separate variables, each with its own criteria, and they should be judged according to what society has established as social beliefs about each according to the consequences delivered in the SFM that is utilized to evaluate the medical technology being considered for adoption.[7]

Conclusion

A general conclusion is that the set of criteria and its application in HTA were formulated without an analysis of the socioecological system for which the technology is intended. More specifically, we found principles for OIE and instrumental analysis, as follows:

First, is reinforcement of the theories of Veblen and Ayres that pecuniary flows are not a measure of value or welfare (Sturgeon 2009, 40–41). When they are used as a measure or weighting coefficient, assessment is not viable.

Second, the use of the same secondary indicator units (for example dollars) for different primary criteria (for example cost and effectiveness) does not mean that combining those secondary indicators through mathematical calculations provide meaningful conclusions about the primary concerns.

Third, all systems are based on multiple criteria that need to be recognized in analysis.

Fourth, equity is an efficiency concern.

Fifth, studies need to be completed to determine what kinds of relationships exist between equity and efficiency for a particular technology for a particular situation.

Sixth, weighing variables in a formula do not provide for a common denominator. Common denominators are rare.

Seventh, individual agents are not the relevant decision makers.

[7] The Patient Protection and Affordable Care Act (Obama Care) banned the use of C/E analysis by government agencies to complete HTA for different reasons than the concerns discussed here (Neumann and Weinstein 2010).

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