DEVELOPING A MULTI-CRITERIA APPROACH FOR DRUG REIMBURSEMENT DECISION MAKING: AN INITIAL STEP FORWARD

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ABSTRACT

Background
Coverage decisions for a new drug revolve around the balance between perceived value and price. But what is the perceived value of a new drug? Traditionally, the assessment of such value has largely revolved around the estimation of cost-effectiveness. However, very few will argue that the cost-effectiveness ratio presents a fulsome picture of 'value'. Multi-criteria decision analysis (MCDA) has been advocated as an alternative to cost-effectiveness analysis and it has been argued that it better reflects real world decision-making.

Objective
The objective of this project was to address the issue of the lack of a satisfactory methodology to measure value for drugs by developing a framework to operationalize an MCDA approach incorporating societal values as they pertain to the value of drugs.

Methods
Two workshops were held, one in Toronto in conjunction with the CAPT annual conference, and one in Ottawa, as part of the annual CADTH Symposium. Notes were taken at both workshops and the data collected was analyzed using a grounded theory approach. The intent was to reflect, as accurately as possible, what was said at the workshops, without normative judgement.

Results
Results to date are a set of guiding principles and criteria. There are currently ten criteria: Comparative effectiveness, Adoption feasibility, Risks of adverse events, Patient autonomy, Societal benefit, Equity, Strength of evidence, Incidence/prevalence/severity of condition, Innovation, and Disease prevention/ health promotion.

Conclusion
Much progress has been made and it is now time to share the results. Feedback will determine the final shape of the framework proposed.

Key Words: *Coverage decisions, MCDA, drugs, values*

A coverage decision for a new drug is a purchase decision, and like any other purchase decision, it revolves around perceived value, or the balance between benefits and price. But what is the perceived value of a new drug? Traditionally, the assessment of such value has largely revolved around the estimation of cost-effectiveness (C/E), or calculating a cost per Quality-Adjusted-Life-

Year (QALY), meaning that the outcome measures are limited to morbidity, mortality and quality of life.[1,3] However, very few will argue that the C/E ratio presents a fulsome picture of 'value'. In fact, it is widely argued that there are considerations that affect value outside of the C/E ratio.[4,5] The response in many cases has been to make an adjustment to the 'decision rule', i.e., the mechanism by which an estimate of cost per QALY leads to a recommendation on whether coverage should be provided or not.

Decision rule 'adjustments' can take the form of a different threshold for approval when some conditions are present, as is considered by the National Institute for Health and Care Excellence (NICE) in the UK: "The Appraisal Committees have discretion to consider whether the NHS should accept a higher opportunity cost (threshold) than they would normally recommend, for example when something new might offer the same overall health gain than it will displace, but has other elements of value not captured in the QALY".[6] This might be the case, for example, when a drug for a rare disease is being assessed.[7] However, it can be argued that making ongoing adjustments to the C/E methodology is really trying to fit a square peg in a round hole by chiselling the edges off the peg, and that this can, in itself, create new problems such as a loss of transparency due to the lack of explicitness of the adjustments. While change is often difficult, perhaps it is time, in Canada as elsewhere, to look at a different kind of peg altogether.

As it stands, an alternative approach to 'C/E with adjustments' already exists; although, to date it has not received the level of attention that the cost per QALY has. Most importantly, one could argue that the alternative described herein – based on multi-criteria decision analysis – may actually fit better with healthcare decision making. The purpose of this paper is to report on a project that aimed to develop a framework to operationalize a multi-criteria decision analysis approach incorporating societal values as they pertain to the value of drugs. The project upon which this paper is based involved two workshops with participants representing key stakeholders on the subject of value in medicine. The goal was to develop, over the course of the two workshops, the structure and basic content of an alternative approach to establishing value. With this manuscript, the intent is to publicize this work, stimulate further engagement in the process and, ultimately, finalize and put forward a framework, based on the response, that could be piloted or implemented in a health technology assessment system for drug evaluation.

BACKGROUND

A decision on the reimbursement of a new drug is fundamentally a decision of resource allocation. Any drug is an input into the healthcare system just as staff, buildings or equipment are also inputs. In a for-profit business, a decision to purchase, or allocate funding to a given input depends on the financial return on this purchase. For any input purchase considered, one can calculate an expected rate of return and if this rate of return does not meet a certain threshold, for example the average return on investment (ROI) for the industry, then the purchase is not made. It is of course difficult to know what purchases private companies have declined; but, there are multiple examples of inputs that have become too expensive to meet the required threshold, which has consequently led to operations being changed.[1] In private business, if resources are allocated to an input with a lower-than-required ROI, the company's profit margin is lower than would otherwise be without that purchase.

While it may be provocative to draw parallels to for-profit business in the context of healthcare discussions in Canada, it is in fact the case that the same principles apply. The key is in redefining 'return' around patient and population benefit. In healthcare, if we accept that there is a finite amount of public money available, allocating resources to inputs that do not provide as much patient and population benefit as others causes the system to provide fewer overall

[1]For example, "American industrial giant Caterpillar is closing its locomotive plant in London and putting 460 workers out of their jobs just over a month after they were locked out for rejecting pay cuts of up to 50 per cent." (Toronto Star, Rob Ferguson, Robert Benzie and Tanya Talaga, Published on Fri Feb 03 2012). Caterpillar, at that time, was making a profit, but the implication was that the profit was not as high as it could be with the relocation of the locomotive plant to a lower labor cost jurisdiction.

benefits to the population than would otherwise be possible. The consequences of a less than optimal purchase decision are similar whether we are talking about private business or public money, i.e. underperformance, which means, in the case of the healthcare system, that the population overall would be worse off than it could be.

While the principles and the consequences are similar, there is a significant difference between private business and publicly-funded healthcare: the healthcare system and the drugs reimbursement administration in particular, do not have a commonly accepted gold-standard methodology to estimate value (like ROI) or a generally accepted threshold (like the average ROI for a given industry, for example). As such, *the objective of this project was to address the issue of the lack of a satisfactory methodology to measure value for drugs*. There are two fundamental building blocks, or starting points, to this work. First is acceptance that the amount of public resources devoted to healthcare is limited and therefore making funding decisions based solely on the demonstration of the existence of net benefits is likely to lead to a sub-optimal healthcare system. This means that this project is not about advocating for more resources for healthcare and that it is accepted *a priori* that the amount of resources available is not sufficient to fund all drugs that provide net benefits, i.e., choices *have to* be made.

The second building block is the selection of the multi-criteria approach as the methodology guiding the development of a new way of valuing medicine. Multi-criteria decision analysis was selected because it has been advocated as an alternative to cost-effectiveness analysis and it has been argued that it better reflects real world decision making.[8-10] For example, the Institut national d'excellence en santé et en service sociaux (INESSS) in Québec has adopted a multi-criteria approach[11] while NICE in the UK and Sweden's Dental and Pharmaceutical Benefits Board have also adopted elements of the approach.[12] In fact, at the latest European Congress of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) in Dublin, the discussion around multi-criteria decision analysis was described as follows: "Previously, discussion has focused on whether multi-criteria decision analysis should be incorporated into HTA, whereas in Dublin discussion shifted to how best to implement multi-criteria decision analysis, given it is already being used, in some form, in a number of HTA processes".[13]

Multi-criteria decision analysis is a methodology to assess value on the basis of multiple criteria. The criteria represent all the relevant considerations in the decision-making process.[14,15] Cost Effectiveness Analysis (CEA), as a decision advisory tool, is a special case of multi-criteria decision analysis where only one criterion is considered – the *cost* per unit of a specific *outcome* (usually the cost per QALY, or the Incremental Cost Effectiveness Ratio). Recognition that other considerations affect decision-making on coverage in the context of the CEA methodology leads, implicitly or explicitly, to adjustments such as variable thresholds depending on the specifics of the drug being reviewed. Multi-criteria decision analysis can be viewed as combining the 'multiple thresholds' of CEA into one framework. In this sense, adopting a multi-criteria approach should not be seen as a paradigm shift, but rather, as an attempt to increase the transparency in decision making and rigour in measurement. In fact, in many ways, multi-criteria decision analysis is already being used in Canada; however, it is not sufficiently explicit or transparent in that evaluators and decision-makers do not have a common framework that publicizes the criteria that are considered in a given context.

At the heart of the multi-criteria approach is a 'rating tool' in which options (e.g., service programs, treatments or drugs) are assessed explicitly against the pre-defined criteria.[15] Applying the rating tool to a new drug provides a summary measure of value that encompasses all the considerations relevant to the measurement of the value of a drug. The rating tool is composed of three basic elements: a list of criteria, a weight for each criteria and a rating scale for each criteria. As such, the rating tool is more than a tool to calculate an estimate of value; it is a description of what society (through the intermediary of all stakeholders) seeks in a drug. In this sense, the

rating tool is a description of the outcomes that are considered desirable by the relevant stakeholders. Accordingly, we can argue that the rating tool measures the extent to which any given drug matches the stakeholders' 'wish list'. Different drugs would be expected to provide different *forms* of value. Multi-criteria decision analysis allows for this which, in turn, allows a comparison across different types of drugs and different contexts, for example, comparing, on the same basis, the value of a drug for end of life with a drug for a common disease.

To properly delineate our aim of developing a framework that operationalizes the multi-criteria approach, some terms need to be defined (*see Text Box 1*).

TEXT BOX 1: Key Terms

- The *value* of a drug is an economic term that captures the concept of opportunity cost: what we would give up by not funding a particular drug.
- The value of any drug depends on 'values'. The economic *value* is a function of *values*, meaning preferences, beliefs or principles; for example, the belief that everyone should be treated the same, irrespective of wealth.
- A *values* framework is one that makes explicit the relevant preferences, beliefs or principles that determine *value*.
- Ethical principles are used to resolve conflicts between stakeholders regarding how *values* are to be included in the *value* framework.

METHODS

Two workshops were held, one in Toronto on November 17, 2013 in conjunction with the Canadian Agency for Population Therapeutics (CAPT) annual conference, and one on April 6, 2014 in Ottawa, as part of the annual Canadian Agency for Drugs and Technologies in Health (CADTH) Symposium.

On November 17th, stakeholders from five groups (pharmaceutical industry, patients, healthcare professionals, decision-makers – representatives from public drug reimbursement programs, and HTA experts – academics specializing in HTA) were invited to Toronto, Ontario to begin developing a framework to estimate the value of drugs for the purpose of coverage decisions. The workshop included 41 participants and was comprised of three parts: 1) an explanation of the starting points, or building blocks of the project as well as its scope, and presentations on economics and ethics by academic experts in the field of healthcare priority setting; 2) breakout sessions, by stakeholder group, to discuss the elements that should be included in a valuation framework for drugs, followed by a summary report of each group's discussion to all workshop participants; and 3) a plenary session the same afternoon at the main CAPT conference to revisit the morning's progress and talk about next steps.

Notes were taken in each of the group discussions as well as during the plenary session that followed. The data collected was analyzed using a 'grounded theory' approach.[16] The notes from all sessions were combined, and codes were developed and refined, until saturation was reached, i.e., no more new codes were identified across any of the sessions. The codes were then organized by idea and the ideas were organized by themes, which are groupings of related ideas. The objective was to reflect, as accurately as possible, what the participants of the November 17th workshop put forward, without any normative judgement. The results of this analysis were reviewed by a group of ten workshop participants selected across the stakeholder groups for this purpose and some minor changes were made. The amended results were presented in a report that was provided as a pre-reading for the April 6th meeting.

The April 6th meeting included 42 participants (from four stakeholder groups, as there were no healthcare professionals present), nine of whom were also present at the November workshop. While in the first workshop

participants were fairly evenly distributed amongst the stakeholder groups, in the second workshop about 80% of participants were from industry. The disproportionate involvement of industry was likely a result of multiple workshops being held at the same time at the CADTH Symposium, the importance of the subject to industry and the fact that, as opposed to the first workshop, attendance was open to all who registered to the CADTH Symposium (the first workshop was by invitation only). Because of the composition of the second workshop, the authors recognize the need to further validate the framework with a broader group of stakeholders.

The second workshop was comprised of four parts, which were designed to build on the results of the first workshop. First, there was a presentation of the highlights of the summary report on the first workshop. This presentation was designed to bring all new participants up to speed on the project's objectives and progress to date. The second part involved small group discussions of the key elements of the valuation framework for drugs, as they emerged at the November meeting. The participants – who were not organized by or separated into representative groups this time – were asked to discuss the clarity of the elements proposed as well as their relevance and to look for any missing pieces, i.e., clarification on the societal values in the framework as well as discussion of the relevance of the values included and the identification of any societal values that may be missing from the framework. The third part was a presentation to the full group of the points made in the small group discussions. Finally, the workshop participants were asked for input on the relative importance of the framework's draft criteria. The proceedings of the entire workshop were recorded using software from Queen's University Executive Decision Centre that collected and organized the points made in all discussions, in real time. The data was then analysed in the same way as the data from the first workshop: points made were coded, grouped by idea and then organized by theme. Again, normative judgements were not made in presenting the material in this paper; rather, the intent is to reflect, as accurately as possible, what was said at the workshops.

RESULTS

The results represent where the framework stands after the second workshop. They are organized along the themes that emerged from the analysis of the data from the first workshop as this categorization was carried over to the second workshop. There are three themes, or broad groupings of ideas, that we identified as follows: 'overarching context', 'guiding principles' and, finally, 'criteria'. The 'overarching context' contains thoughts and ideas that justify and shape the value framework in the sense that they define its role. The 'guiding principles' are the values and process features that participants felt must be reflected in the value framework, i.e., in the criteria and how these criteria will be used. The 'criteria' are the considerations against which the value of the drug is measured and, as such, they operationalize the guiding principles.

1) Overarching context:

- There is a current disconnect between industry and government regarding how value should be measured that must be addressed and that will necessarily draw in other stakeholders (each with specific interests). In developing a value framework for drugs, input should be sought from a variety of sources to ensure a comprehensive understanding, e.g., patient groups regarding impact on quality of life.
- Need for sustainability is acknowledged in that there is a recognition that the money available is limited and thus any framework needs to be set in the context of choice making, as it is simply not realistic to expect that all drugs providing a net benefit should receive reimbursement coverage.
- The entire process should be about health technology management in that it is about decision-making within the context of limited resources; opportunity cost (i.e., forgone benefit) must be explicitly considered in any framework for valuing drugs.
- Costs must be 'net' costs (i.e., all additional expenses minus any savings, such as those created by a shorter length of stay), and include all aspects of the healthcare system, i.e., we must look at the system impact – it is about

efficiency of the entire health system (and possibly efficiency at the societal level, e.g., cost to caregivers).

- When criteria are identified to inform the construct of value within a value framework, the criteria must have a scale of effect to measure the magnitude of benefit. This will help in making difficult choices amongst competing claims on limited resources.
- The value framework should accommodate rare diseases and end of life contexts. Implicitly, this means that a single framework should be developed that would allow for trade-offs to be made between drugs for common diseases and those perhaps warranting 'special consideration'. This can be done by explicitly including in the framework the considerations or societal values that are currently used to justify adjustments to the CEA methodology for rare diseases or end of life such as compassion and dignity, for example.

2) Guiding principles:

- Evidence-based- desire for decisions to be informed by rigorous facts: the development of the framework is where the discussion on values and their relative merits takes place. Then, implementation of the framework must rest on the use of the best available evidence. There must be flexibility in the meaning of what qualifies as evidence and there should also be consideration of evidence generation.
- Consideration of individual patient needs- refers to patients' preferences: fundamentally, this decision is about patients and their needs. This should translate into a formal mechanism to include the patients' context in the decision-making process on coverage. This principle highlights the need to consider 'perceived' value, not strictly clinical value.
- Fairness: also referred to as equity – e.g., balancing population and individual priorities, consideration of age, alternative treatments available, equity across jurisdictions, vulnerable populations, etc. Note that values can vary across provinces.
- Transparency: does not mean that there is no confidentiality but means that the decisions must be explained and reached in a replicable fashion (i.e., not simply the opinion of the decision-makers directly involved). This implies that the framework must include all considerations/factors that affect decision-making. However, it is acknowledged that the decision-making process will not be strictly 'mechanical' in that decisions will not necessarily follow precisely from the framework, but variations would have to be explained. Including all relevant considerations allows transparency but also informs industry on the preferences of governments, which can in turn inform research priorities as well as pricing structures and other business considerations.
- Sustainability: an acceptance that choices must be made and that budget impact matters. Linkages to the entire healthcare system must also be stressed, so savings or cost increases in one place in the system are traced back to the budget that funds drugs.
- Political commitments cannot be ignored: refers to health system priorities that must be accommodated in the framework. 'Political commitments' could be restated as 'system priorities'; stresses the potential conflict between short term and long term perspectives.
- Ultimate goal: Improve both population health gain and individual health gain, i.e., individual benefit must be considered in the context of population benefit. This can lead to a conflict between individual and population gains. Developing a framework based on societal preferences will inform how this principle is translated into results.

3) Criteria:

An initial set of criteria was identified in the first workshop and then refined in the second workshop, resulting in the following list:

- Comparative effectiveness: is considered to be *the* key criteria, meaning that there seems to be consensus that it should be the highest weighted criteria. Change in effectiveness should be measured over a lifetime horizon.[2] This

[2]Issues around unmet need and absence of alternatives would be handled in this criterion. Concerns over compliance/adherence should also be included in the measurement of impact. One key concern is the ability to capture changes in quality of life (and patient preferences should be reflected in measurement of quality of life).

construct goes beyond hard endpoints (e.g., risk of mortality) to include more subjective changes such as changes in the level of pain.

- Adoption feasibility: refers to impact on the entire system, e.g., new imaging requirements triggered by the use of the drug, and to budget impact.[3] This criterion requires clarity about what budget we are talking about, e.g., drug versus hospital budgets. Focus is on a dynamic measurement where a new drug may cause many changes throughout the system.
- Risks of adverse events: revolves around assessing risk and tolerance to adverse reactions from both the patient and healthcare provider perspectives.
- Patient autonomy: also referred to as self-management and can be broadened to include what the patient values (notion of client experience) so long as it is clearly differentiated from comparative effectiveness.
- Societal benefit: includes family (caregiver), other parts of healthcare system and society more broadly. Should include the impact on productivity (for both the patient and the caregiver).
- Equity: across individuals (conditions) and jurisdictions, ensuring the relationship to access is clearly delineated.
- Strength of evidence: measure of uncertainty relating to all criteria; would include, for example, validity of quality of life measurement.
- Incidence /prevalence /severity of condition: both the magnitude of the condition as measured through standard epidemiological constructs and the severity of the condition meaning the overall impact of the problem on an individual's or the population's health level.
- Innovation: in itself, independent of the likely impact in terms of effectiveness or equity; the value that is placed on 'newness' or 'novelty' separate from the actual improvement in health or wellbeing.
- Disease prevention/ health promotion: potential avoidance of disease or increase in likelihood of staying healthy, including upstream investment to prevent downstream utilization.

As part of the second workshop, a weighting exercise was conducted to assess, for this group of workshop participants, what the relative importance of the criteria might be. Participants were asked to individually identify the four criteria that they thought were the most important.

The criteria that emerged as being identified in the top four in importance by the most participants, by calculating the number of times each criterion was listed in the top four, were:

- Comparative effectiveness
- Societal benefit
- Adoption feasibility
- Strength of evidence

This list reflects the opinion of the participants at the second workshop and it could certainly have been different if there had been broader representation of stakeholders at that meeting. As such, it is preliminary and subject to further consultation, and only represents the first step in the setting of criteria weights.

DISCUSSION

The objective of this project is to develop the structure and basic content of a framework to estimate the value of drugs. Specifically, the framework is to be based on societal values as they relate to the value of drugs and be operationalized through a multi-criteria analysis approach. The first workshop focused on outlining the structure and populating the content of the framework. Points made at that workshop were divided into three categories: overarching description of the shape and purpose of the framework, the relevant values and process features, and the criteria. The second workshop focused on fine-tuning the elements proposed at the first workshop and allowed for clarifications, possible deletions and additions. In both workshops, participants were widely engaged and many spoke of the perceived importance of this work. One of the public participants stated in the

[3]Issue of what costs to count comes up here, e.g., societal costs or government payer costs.

plenary session of the CAPT conference that this work could not be completed fast enough.

What has resulted to date is a set of guiding principles and criteria, all with some degree of elaboration in terms of specific meaning. Interestingly, some of the comments made in the process of refining the structure and content at the second workshop identified some concerns with the project overall. These comments can be viewed as illustrative of concerns that stakeholders might have and are presented here to foster further dialogue. With each concern, we also present a response that should improve the understanding of the framework.

1. *How do we measure accurately the impact of a drug on each criterion?* For many criteria, the measurement of impact goes beyond 'hard evidence'. In adopting a framework such as is proposed, one has to be open to multiple forms of evidence, including expert opinion. Criteria are included in the framework because they represent considerations that affect the coverage decision, whether or not their impact is difficult to measure. If 'difficult-to-measure' criteria are left outside the framework, they will still affect the final decision, and without any better quality information on impact.

2. *How do we reconcile conflicting evidence?* Principles of ethical decision-making must be used to arrive at reconciliation that all stakeholders can live with. Features of an 'ethical' process to resolve conflict would include[17]: openness and transparency (i.e., the resolution should be publicly defensible), reasonableness (i.e., the resolution should be based on relevant evidence), inclusiveness (i.e., stakeholders should be engaged in the process), and accountability (i.e., choices made should be made in a timely manner, and allow for appeals).

3. *A framework like this can't get away from the 'judgement call' that intrinsically limits transparency.* A transparent process can include judgement calls. Transparency is about being clear as to where those judgement calls were made in the decision process and explaining the rationale supporting the choices that were made.

4. *This is a big shift from the current paradigm that will be challenging in political terms.* The framework does not change reality: the factors that affect decisions now will remain the same. The difference is that the process will be more explicit and transparent. With explicitness comes a reduction in 'discretionary' authority, which may sometimes be difficult to accept, but this is offset by having decisions that are more publicly defensible and therefore reduces the political pressure to act unilaterally on specific cases.

5. *What happens when there is no appropriate comparator?* In every case, impact is measured by comparing to best available current care. If current care is no care, then the incremental impact of the drug on each criterion is equal to its total impact. That does not, in itself, bias the process towards drugs for conditions where there are currently no treatments available.

6. *Are all patients equal? How do we consider age or health status?* Societal values on these issues will be embedded in the process through the criteria rating scales and weights. If societal value based choices are not made *a priori* on the worth of one type of patient vis-à-vis another then ultimately individual decision maker values will be inserted into the decision process.

More generally, work has recently been conducted on identifying existing criteria within healthcare priority setting activity.[18,19] While our intent was to focus on developing a framework for valuation of drugs specifically, it is interesting and perhaps not surprising to note that a number of our identified criteria overlap with the criteria most commonly cited as having been used in real world priority setting exercises in healthcare more broadly, including comparative effectiveness, budget impact, equity, quality of evidence and number of people impacted.[19] However, some criteria that regularly appear in the broader context did not come up in our context, such as alignment to policies of the organization or system and ability to access the service, while the broader exercises do not seem to report a high frequency of inclusion of criteria such as risk of adverse events, patient autonomy, societal benefit and innovation.[19]

Building on the work accomplished in the two workshops, the next steps involve finalization of the criteria selection and refinement of the

criteria definitions to ensure clarity and minimize potential overlap between criteria. Further, criteria weights have to be set, and each criterion needs a rating scale. And finally, the completed framework should be tested for validity with some past submissions to examine the robustness of the entire rating tool. Work on these tasks should be guided by the feedback on the work done that is presented here. That being said, these next steps must be taken in the context of two main limitations of this project. First, workshop participants had a limited amount of time to reflect and dissect values, principles and criteria pertaining to valuation of drugs. Second, the mix of participants, especially in the second workshop, clearly was not representative of the broader Canadian public. Because of both of these limitations, it is essential that this work be publicised so that other stakeholders can join the discussion. A trite response might be that we will never be able to come up with a single framework that will adequately represent society. While we recognize that there is complexity and differences in the underlying values that make unanimity very unlikely, a framework that has as broad an appeal as possible will be a step forward in that it will improve the transparency of the situation and hold decision makers more accountable for the decisions being made.

Once work is completed on the framework, it can be used to estimate the value of new drugs. The estimate will not be expressed in dollars per QALY gained. It will be in units of benefits gained for the net cost involved. This is a type of balance sheet approach that has been previously advocated for in priority setting in the UK.[20,21] The unit of benefits will refer specifically to the set of criteria used and will not be comparable across jurisdictions in that each jurisdiction (e.g., province/territory or country) would need to come up with their own criteria and establish their own rating tool based on locally relevant principles and values. Furthermore, the entire framework should be reviewed periodically to reflect possible changes in societal principles and values over time. Importantly, we are not suggesting that the framework proposed here should mechanistically become the decision-making process for coverage decisions, but that the estimate of value that is produced should be a key input in the actual decision-making process. A coverage decision can be different from what the estimate of value indicates but in such cases, there should be a clear explanation provided since all relevant considerations should already have been accounted for.

As stated succinctly in a recent paper on MCDA in which the authors go into some detail both on the theory and specific methods around a multi-criteria approach to decision making, "[the] most pressing needs in HTA and reimbursement decisions are to develop tools that will allow investing in most valuable and disinvesting in least valuable interventions – thus a value index that is complete, meaningful, and comparable such as MCDA is needed."[22]

CONCLUSION

Participants at the first workshop made it clear that the current system to arrive at decisions on coverage of new drugs in Canada is unsatisfactory. Clearly this is not a situation unique to Canada, noting that NICE in the UK, for example, is dealing with similar concerns. A multi-criteria approach is advocated for on many fronts. In this project, we wanted to go beyond making the case for a multi-criteria approach and actually get to work on developing what such an approach could look like in real life. Much progress has been made and it is now time to share the results. Feedback will determine the final shape of the framework proposed. The success in broadening the discussion and solidifying details around criteria definitions, weights and rating scales will ultimately determine the value of our proposed framework for valuation of drugs.

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