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Understanding Canadian Health Technology Assessment through a systems lens

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ABSTRACT

Objective: Governments around the world face challenges in maintaining sustainable, high-quality healthcare systems. Health Technology Assessment (HTA) is widely used as a method to assist in funding decisions. However, the scope and influence of HTA is still limited. We examined how policymakers can improve the usefulness of HTA.

Methods: We used Systems Thinking as a theoretical framework to examine HTA as a system. We purposely sampled stakeholders involved in Canadian HTA at a national or provincial level. We conducted 22 semi-structured interviews in September-December 2016. Data were analysed using NVivo10 and findings are presented as a concept map with explanatory text.

Findings: The HTA system is influenced by stakeholder interactions. Such interactions are, in turn, affected by stakeholders' worldviews and environmental factors. Stakeholders' worldviews includes individual's or groups' values and affect the exchange of information, and interpretation of events. External factors, such as changes to government structures, also affect the system.

Conclusion: Most stakeholder groups are supportive of the system. However, participants identified a need for change, though the exact changes being recommended differed. Some interactions were praised (formal, inclusive collaborations to provide government with policy guidance on both broad and technology-specific matters), while other interactions were criticised (two-party alliances formed around purposes other than the common good, and lacklustre patient and industry engagement on the part of provincial government).

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1. Introduction

Worldwide, governments are confronted with problems with healthcare system structures, staff expectations, growth in the development of expensive medical treatments, and the increasing involvement of diverse stakeholders in decision making [1]. Health Technology Assessment (HTA) has been adopted by developed and developing countries alike to guide governments in making healthcare funding decisions [2,3]. HTA mostly comprises structured, replicable and transparent methods to compare new and existing health technologies in terms of their safety, clinical effectiveness, cost-effectiveness, and potential implications for government and society. HTA can provide information on issues in the healthcare system, assist in the development of regulations, offer solutions to policy problems, and present alternatives on how to implement these solutions [4].

Despite HTA being used by various countries, its influence is still limited compared to its potential in guiding health policy [5–7]. Systems thinking may represent one route to overcoming barriers. In 2009, the World Health Organisation [8] launched a report urging policymakers to adopt Systems Thinking [9–12] to better understand the broader implications of introducing new interventions into healthcare systems [8].

Currently, there is a diversity of approaches to Systems Thinking research [13]. In this paper, we adopt principles from particular approaches to Complex Adaptive Systems (CAS) [14–16] and Soft Systems Methodology (SSM) [17]. From a CAS perspective, a system can be characterised as comprising agents that are diverse, inde-

pendent, and interacting locally [14]. A Complex Adaptive System is open (it does not reach a balanced state), adaptive (agents adapt to changes), and features evolving nonlinear dynamics [15,16]. A Complex Adaptive System originates from recurrent, local interactions between agents and their environment. The interactions result in emerging patterns that naturally self-organise into a structure (the system) [16]. Soft Systems Methodology (SSM) [17] comprises systemic ways of examining and acting on real-life complex situations that are created by the perceptions of individuals involved. We conceptualise HTA as a Complex Adaptive System and its stakeholders as system agents. We use SSM to take into account how the views of people involved in HTA affect their actions and interactions with others and how this affects HTA processes. We answer the following research questions. What does Canadian HTA look like when figured as a system that is complex, adaptive, and composed of individuals with diverse perspectives? What are the implications for policymakers?

1.1. The Canadian context

Canada has a national HTA agency that manages centralised drug review processes for all new cancer and non-cancer drugs and some non-drug technologies and services. The centralised drug review processes involve expert review committees, which make recommendations on reimbursement to participating federal, provincial and territorial drug plans. These committees include patient members, in the case of the cancer drug review process, and public members, in the case of non-cancer review processes. The national HTA agency has specific definitions for 'patient' and 'public' in these contexts [18]. Patient input is also incorporated into HTA through patient submissions [19].

In addition to the national HTA agency, several Canadian provinces have established their own HTA processes (stand-alone organisations or processes within their respective Ministries of Health). We focus on the process of the national HTA agency and that of one province.

2. Methods

This study is part of a larger project looking at public and patient involvement in HTA. SSM [17] informed the project design, selection of participants and methods of data collection, whereas elements of CAS [14,20] informed the interview schedules and data analysis.

2.1. Complex Adaptive Systems

In this study, we regard the HTA process as the locus of interactions shared by agents (stakeholders involved in HTA processes). The agents are the stakeholders who have diverse purposes in being involved in HTA (See Table 2. Participants). Healthcare system staff try to solve a financial problem using HTA to evaluate a health technology and then decide whether it should be reimbursed. Researchers conceptualise the HTA problem as a research endeavour and apply HTA as a methodology to answer research questions. Representatives of the health industry want to supply their products as solutions to health problems in a way that complies with the evaluation process to receive reimbursement from the government, and thereby increase their company profits. Patients and their representatives want the government to provide them with a solution to their health problems and want to contribute to this solution with useful information about their experiences or expectations. Representatives of the public want to ensure that the government spends public monies on solutions that accord with public values. We take diversity among agents into consideration because of its

Table 1
CAS Concepts.

CAS Concept	Description
Agents	Healthcare system staff, health industry representatives, public members and patient representatives (individuals who are members of national HTA agency expert committees or patient organisations who take part in HTA processes), and HTA representatives (See Table 2. Participants for details).
System	HTA processes conducted by the national HTA agency and research groups at the provincial level, along with HTA report discussions at national HTA agency expert committees for specific health technologies, namely pharmaceuticals (excluding oncology); anti-cancer drugs; and non-drug health technologies.
Environment	Aspects of the Canadian context raised by agents.
Diversity	Variation within a type of agent: the different individuals involved in HTA, who have different views on the system, personalities, and understandings of contextual factors affecting HTA. Diversity of types of agents: different stakeholder groups (for example, HTA representatives, healthcare system staff, and health industry representatives). Diversity of composition: the same basic structures that constitute the HTA system are combined in different ways in different countries, resulting in systems with different characteristics.

role in increasing or restraining complexity. We subdivide diversity into: variation within a type of agent; diversity of types of agents, and diversity of composition (See Table 1. CAS Concepts) [21]. We regard the Canadian context (at national and provincial levels) as the local environment. We describe our study findings using CAS terminology [14,21,22]: agents, system, environment, and diversity.

2.2. Soft Systems Methodology

Individuals act, interact with others, and evaluate situations based on their worldviews, which change how a situation is construed or constructed [17]. Because HTA is a social process that involves individual stakeholders, we adopted SSM to account for stakeholders' intentions and motivations as they come into play amid interactions. In SSM, a "problematical situation" is a social construct created by those affected by it (problem-owners) or by those using SSM to understand it (SSM practitioners) [17]. In Canadian HTA, the diverse stakeholders conceptualise problematical situations differently, and they act and interact with others according to their own evaluations of the situation. We chose to define HTA as the system in which HTA stakeholders (problem-owners, in SSM terminology) bring to bear their worldviews and where problematical situations are constructed.

2.3. Combining Soft Systems Methodology and Complex Adaptive Systems

In SSM, a system only exists because someone views a situation as a system. By contrast, in CAS, a system is taken to exist independently of individuals' perspectives. We adopted the SSM stance for this study to address some of the limitations in CAS for explaining complex social phenomena [23]. The worldviews from SSM help integrate people's motivations, intentions, and ways of relating to others as we are dealing with a social system. Despite the differences between SSM and CAS, some of their elements overlap. For example, the CAS idea that individual agents act locally and independently resembles the SSM idea that individuals act out of their unique worldviews. Similarly, the CAS idea of 'environment' resembles the concept of wider systems and sub-systems that SSM employs to consider external influences on individuals.

Table 2
Participants.

Stakeholder group	Role in the HTA process	Participants
HTA representatives	Conduct HTAs and write HTA reports	Two from different provincial HTA units
		Two from the same national HTA agency
Health industry representatives	Make submissions to HTA processes	Two from medical device organisations (an umbrella organisation and one company)
		Three from pharmaceutical organisations (two from the same umbrella organisation and one from one company)
Patient members and Patient organisation representatives	Take part in recommendation meetings discussing HTA reports Make submissions to HTA processes	Three from the same HTA expert committee at the national level One from a patient organisation
Healthcare system staff	Request and receive HTA reports	Two provincial policy-related staff
		Two provincial service-delivery staff
Clinicians	Provide information to provincial HTA processes Make submissions to HTA processes	One expert in a provincial HTA process One expert making submissions to government
Public member representatives	Take part in recommendation meetings discussing HTA reports	Three from committees at the national HTA agency (two from the same committee and one from a different committee)

2.4. Participant groups

Based on the published literature and our professional experience, we considered HTA stakeholders as agents or problem-owners (See Table 2. Participants). Problem-owners are considered both as individuals and as part of stakeholder groups representing a perspective in HTA.

2.5. Sampling

We developed a purposive sampling strategy tailored to the Canadian HTA context. Moreover, we used Maximum Variation Sampling strategy [24], which aims to capture a variety of experiences to aid understanding.

2.6. Data collection and analysis

Information on HTA processes and government structures was collected via institutional websites. We do not name the province and other organisations to protect the anonymity of interviewees. We developed interview schedules tailored to each stakeholder group, including questions about HTA, public and patient involvement, relationships between stakeholders, and perceptions about the Canadian context (see Appendix). Only findings related to the conceptualisation of HTA as a system are presented here. ELM and TS conducted 22 semi-structured interviews between September and December 2016 by telephone and face-to-face. Interviews were recorded and transcribed verbatim.

We coded interviews using NVivo 10 with a pre-coded list based on the CAS terminology and open coding [25,26]. ELM and JS coded three interviews separately, compared results, and resolved discrepancies through discussion. ELM coded the remaining interviews based on the agreed coding list and, as new codes emerged, interviews were re-coded. This process resulted in 306 codes (30 initial codes and 276 emerging codes) (see Appendix).

We used the themes and codes to develop a concept map providing an overview of the system. Initial concepts were derived from themes and codes and discussions of findings between ELM and TS through an iterative process. The final concepts and links were entered in Microsoft Publisher 2013, and a concept map was generated.

3. Findings

First, we present the concept map (Fig. 1), which shows how we, as observers, conceptualise the system based on information provided by agents within the system. Later, we describe the system in terms of CAS elements, using the headings *System*, *Environment*, *Agent variation and type-of-agent diversity*, *Composition diversity*, and *Agent interactions and their implications*.

3.1. Concept map

We drew the concept map based on our interpretation of how interviewees attributed relevance to specific aspects of HTA, stakeholder groups, and HTA in relation to other structures. The rectangular box named 'HTA process' provides a static and simplified view of the Canadian HTA as a Complex Adaptive System by indicating the formal and informal interactions between agents. The bubbles within 'HTA process' box represent the stakeholders. The right-hand-side dark grey rectangular boxes represent local environmental influences outside of the HTA process. The vectors represent interactions.

Stakeholders emerge as the most influential aspect of the system. The bubbles 'HTA representatives', 'HTA patient members', 'HTA public members', 'clinicians', 'patient organisation representatives', 'health industry representatives', and 'healthcare system staff' represent the stakeholder groups and the individuals within these groups. 'Government' encompasses staff outside the Ministry of Health and also constitutes part of the local environment, since it can make changes to policies that may affect HTA processes, the healthcare system, and stakeholders' other structures or processes.

The 'HTA process' rectangle encompasses all exchanges (formal and informal) between agents that occur within the HTA process. The rectangle 'Decision Making' represents the decisions made by government officials and staff that could affect HTA processes and their stakeholders.

The system does not have boundaries and exchanges occur within and extend beyond the system. A participant described networking outside Canadian HTA to make a decision that would influence the system:

> [W]here I need to get involved with my counterparts in other jurisdictions is based on the consistency of decisions. So, if they see a review or they do a review before me because they got the drug product launched in their country first then we do keep an eye on the information that they publicly post, the decision that they make…[T]here are a few countries where I can phone up an individual to say 'talk me through your decision on this'. (Healthcare system staff 2)

The vectors represent the exchanges between stakeholders and other parts of the system. These exchanges can be mediated by individuals' worldviews and are usually two-way, such as when agents formally provide information to decision-makers (solid black line)
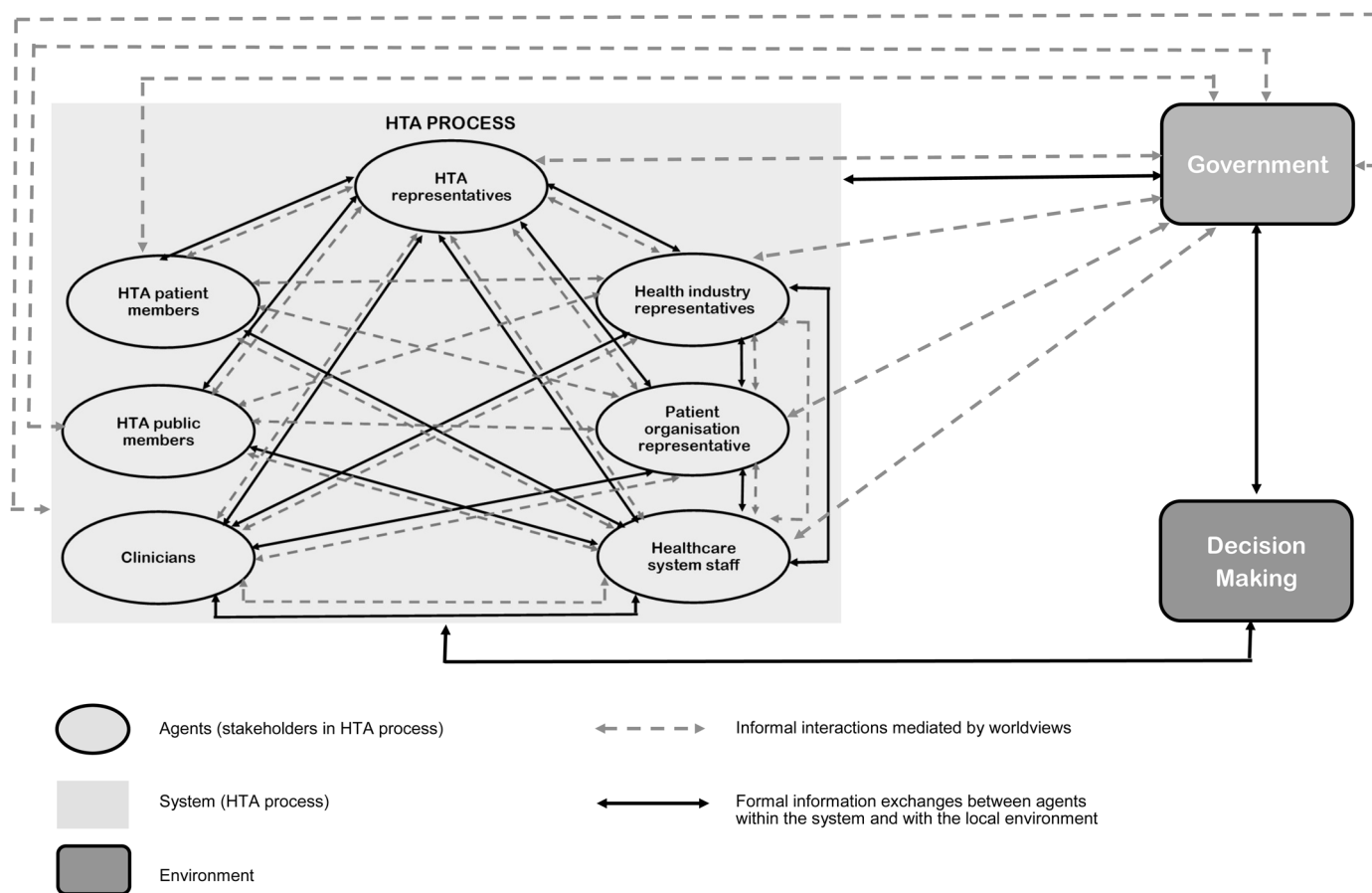
Fig. 1. Canadian HTA as a system – concept map.

or have informal conversations with other stakeholders (dashed grey line). Informal exchanges are usually mediated by agents' worldviews, such as when a participant expressed his opinion on the role that doctors occupy even while sitting on HTA committees:

I feel doctors have a role to be health advocates for their patients no matter how important it [the funding decision] *is in the global picture of things. (Clinician 1)*

The interactions between agents create a web of influences; when change occurs in one part of the system, it impacts other parts of the system. This makes it difficult to predict how small changes will impact on stakeholders and, by extension, on the system and the environment.

3.2. System

Policy-related healthcare system staff saw HTA as an independent source of information that assisted decision making.

Key objectives of the government: they want a health system, the publicly funded health system, to work in the public interest, to be effective and, like many health systems these days, we worry about providing effective services at the right cost. So, we have systems [because] *we really feel we need to lower the cost curve and improve outcomes. Health Technology Assessment processes can play a really significant role in that context, both because it talks about the merits and the economic effectiveness of certain technologies vis-à-vis others in the system. . . But also how do they fit in the system, what do they do better than other methods, what do they replace or displace in a system that is increasingly hard to add new money to. (Healthcare system staff 3)*

Most stakeholder groups were supportive of HTA as a tool to aid government decision making: some health industry representatives (from pharmaceutical companies), national and provincial HTA representatives, clinicians, HTA patient members, and HTA public members. Some participants, however, suggested adjustments, such as shortening the timeframe for assessment processes:

I think that is where there is room for improvement. [Name of committee] *takes five to six months from start to finish of a review. . . But most of that work starts after* [Name of regulatory body] *has approved a drug. . . Although it takes five to six months, which most people would say is a reasonable time to start and finish a HTA review, it adds to the timeline because it's primarily a sequential process. . . When you add all of that the average timeframe from time of submission to* [Name of regulatory body] *to the time when an access decision is made the shortest timeframe is, I would say, two and half years. Timeframe is increasing and an analysis has showed us it's up to four to five years on average. (Health industry representative 1)*

On the other hand, service-delivery healthcare system staff, some health industry representatives and patient organisation representatives criticised HTA as being inappropriate for assessing some health technologies.

The methodology employed in the use of HTA was never designed for, nor is easily or appropriately applied when we talk about any form of truly innovative therapies and certainly not for rare diseases with small patient populations. . . Actually it's developed not for innovative therapy, it's comparative to old therapies, it's incremental improvement, and oftentimes on existing therapies. (Patient organisation representative)

3.3. Environment

Participants raised a range of issues associated with the Canadian HTA environment; for example, participants questioned whether regulatory and reimbursement processes should run concurrently or sequentially. Participants also observed that, at the national level, only patient organisations could submit information during a HTA. In contrast, at the provincial level, individual patients can take part in the process. Participants viewed this difference as hindering patient participation in national HTA processes rather than as minimising the introduction of personal biases.

Participants also raised issues of inequity in access to health technologies when treatments are funded in one province but not in another due to the differences in the management of provincial healthcare systems. Finally, participants noted the potential impact of more political pressures on health technology funding decisions:

You can have the best evidence out there, you can have a really good process in place, but if politically you don't have the environment to say no or, in some cases, to disinvest and take something away from individuals that were getting it already, then it doesn't matter how solid your HTA review is, it comes back to that certain environment, politics. . . (Healthcare system representative 2)

3.4. Agent variation and type-of-agent diversity

Individual agents (Agent variation) can have different views of the system: their position on a given issue can originate from their values, contextual influences, and worldviews. For example, health industry representatives (from pharmaceutical companies) had opposing views on the importance of HTA process: two were supportive of HTA as a decision-making tool for provincial governments, whereas a third one argued that other methods are better suited to government funding decision making.

Having diverse opinions does not mean that agents oppose one another; they can still work towards a common objective. For instance, the three health industry representatives cited above agreed that making some changes to how HTA fits within government processes could shorten the timeframe for public reimbursement of pharmaceuticals in Canadian provinces.

Agents belonging to different groups (Type-of-agent diversity) sometimes have similar perspectives, and this can result in alliances. For instance, two health industry representatives (from medical device companies) expressed doubts as to whether HTA methodologies are appropriate for assessing non-drug health technologies. A patient organisation representative also shared a similar opinion. These agents could work together to change how non-drug health technologies are assessed, even if this change originated from different motivations and will have different consequences for each agent.

3.5. Composition diversity

Composition diversity in this project considers the three national HTA agency expert review committees: one dealing with cancer drugs, one dealing with non-cancer drugs, and one dealing with non-drug health technologies and services. These three committees have some similarities and some differences in their membership composition and in how they relate to provincial governments, which affects how their recommendations are used. One agent comments on these differences:

I think it's impossible to generalise in the Canadian context. The national HTA agency on the drug side. . . They have got very close relationships with government and their processes are very influential in terms of coverage, placing new drugs on provincial formulary. On the non-drug side I think it's much less clear. . . So

I think it varies even within the national HTA agency. (HTA representative 4)

3.6. Agent interactions and their implications

The system mainly consists of interactions between agents. Agents exchange information and share their perspectives, including their interpretations of what is happening in the system and local environment. The interactions draw on the purposes of different individual stakeholders and stakeholder groups.

Some participants mentioned formal initiatives that brought stakeholders together to collaborate. For example, participants spoke of a forum that includes clinicians, healthcare system staff, government staff, health industry representatives, and researchers that meets regularly to advise the provincial government.

Various participants, including some health industry representatives, policymakers and HTA public and HTA patient members, viewed the interaction between provincial governments and the national HTA agency as productive. Provincial governments often utilised national HTA reports and initiated dialogue with the national HTA agency to better interpret the significance of reports for the provincial context.

So, I think it's a good relationship in terms of the structure because the provinces, who are the government agency you are asking about, participate in the process, so they provide the implementation, they review the evidence, they provide the implementation report, and they have an opportunity to provide feedback on the initial recommendation. (Patient member 1)

However, participants criticised particular types of interactions. A recurrent theme for various participants was the potential conflict of interest involved in interactions between the health industry and other stakeholders, and such exchanges were seen as suspicious:

The problem is we always say how we need all the stakeholders involved and they [health industry companies] are a stakeholder in the process so you can not eliminate them. However, obviously we all know that they have an agenda which is to have their drug funded and to make profit from their drug. (Clinician 2)

Provincial governments were also criticised for their interactions with others. Participants suggested that one provincial government could improve its interactions with patients, patient organisations, and health industry companies by establishing more structured and thorough-going engagement:

I feel that government opens the door and asks industry or patients for very specific tasks when it suits them, but there is no ongoing commitment to building a relationship, to understanding how they would like to be involved, to actually involving them on an ongoing basis in a way that is meaningful for them and also meaningful to the decision-making process. (HTA representative 2)

4. Discussion

We considered HTA as a system that is complex, adaptive, and composed of individual agents who have worldviews that shape their actions and purposes. We also discussed influences on the HTA system that include the environment (or wider systems and subsystems). Personal values could also be identified, such as when a participant said that doctors always have a role to advocate for patients independent of the broader objectives of the government. Our own perspectives were involved in defining the problematical situation and the problem-owner groups [17].

SSM can be applied to different settings, as demonstrated by Checkland and others [27], and it is useful in explaining how

diverse worldviews can affect government processes. Accommodations between worldviews can be reached if the perspectives of all stakeholders are taken into account. Kalim et al. [28] used SSM to examine the UK's National Health Service policy framework for service delivery to people with diabetes. The authors analysed the problematical situation (uncertainty about the right policy guidelines for patients with diabetes). They proposed feasible changes, taking into account stakeholders' diverse worldviews and the wider systems and sub-systems involved. Our findings provide a starting point for HTA policymakers to do likewise.

Examining individuals' interactions within and outside of their stakeholder groups highlights how alliances are developed for different purposes and which interactions are considered to be problematic by some stakeholders. Interactions between health industry companies and patient organisations were especially criticised and thought to result in actual or perceived conflicts of interest [29]. Participants used the term 'conflict of interest' to refer to a conflict between the interest of the industry-patient alliance in getting a technology funded and the interest of other HTA stakeholders in accurately assessing the value of a health technology. HTA patient members and HTA public members indicated that there was a need to develop mechanisms to counterbalance the influence of health industry companies on funding decisions. In particular, these participants praised the creation of the pan-Canadian Pharmaceutical Alliance (pCPA) because it helped provinces to negotiate as a group with health industry companies.

Forecasting how stakeholders will interact, whether they will form alliances or object to others' alliances, is challenging in the context of complexity since the diversity of agents and types of agents can add many perspectives to be considered. Interactions between different individuals and groups of agents are more influential at particular times and formal or informal negotiations can be weighed differently depending on the circumstances. The value of the system perspective for the policymaker, therefore, lies in knowing which stakeholders and interactions to continually monitor and address while seeking to find accommodations that best serve everyone.

Opportunities for system change were identified. In the statements made by various participants, there is a common theme of 'the need for change' (change in processes, structures or relationships). The emergence of such themes resemble the emergence of patterns that is characteristic of complex systems, as cited earlier [16,30]. In particular, a point of agreement clearly emerged among healthcare system staff, health industry representatives, and patient organisation representatives. These stakeholders seek the quicker funding of health technologies and thereby advocate for regulatory and reimbursement processes to run in parallel. However, across the other stakeholder groups, individual agents envisaged different types of change being needed, and this is not surprising given the diversity of individual and group perspectives.

In HTA, stakeholder groups differ in their conception of the problematical situation depending on their purpose for engaging in HTA. Examining stakeholder accounts helps to identify the points on which stakeholders converge and diverge, and this can help to identify accommodations of differing worldviews. Involving stakeholders with a diversity of views in the planning of changes to HTA has the potential to contribute to a more comprehensive picture of possible changes and consequences. This more comprehensive picture will also help when assessing the impact of changes. Striving to achieve accommodations between stakeholders can increase the value and usefulness of HTA to all involved, minimising problems after a policy is implemented, and thereby saving time and resources in the short and long term.

5. Conclusion

In this paper, we characterised Canadian HTA as a Complex Adaptive System to identify implications for policymakers. HTA is a social enterprise involving diverse people with differing worldviews. It sits within wider systems that include government processes and specific economic and political contexts, and it contains sub-systems that include stakeholder organisations and their internal structures. Stakeholders constitute the most influential aspect of the system. Wider government and decision-making processes form a vital part of the local environment, since non-HTA policy changes can affect HTA processes and stakeholders. Stakeholder interactions centre on exchanging information and interpreting what is happening in the system and environment. They are influenced by the environment along individuals' worldviews and values.

Most stakeholder groups were supportive of HTA as a tool to aid government decision making. Participants identified a need for change in Canadian HTA, but the exact changes being commended differed. For instance, the restriction of information submission to patient organisations was viewed as hindering patient participation in national HTA processes. Participants also raised broader concerns about inequities in access to health technologies resulting from divergent provincial funding decisions. Participants endorsed some types of interaction among stakeholders, such as formal initiatives that brought stakeholders together to collaboratively make recommendations to government. But other types of interaction were criticised, for example, the alliance between health industry companies and patient organisations, which could conflict with the interests of others. Provincial governments were also criticised for failing to establish more structured and thorough-going engagement with patients, patient organisations, and health industry companies.

Policymakers should be aware of the above commendations, criticisms and questions that prevail among HTA stakeholders, especially where stakeholders hold conflicting views. Policymakers would do well to establish mechanisms for stakeholders to share and discuss their views, allowing for more thorough-going and transparent communication about problems and potential solutions as those appear from the diverse perspectives of stakeholders. Further research could be conducted using SSM to examine how stakeholder interactions change when HTA processes are changed.

6. Limitations

There were limitations to sourcing all relevant stakeholders in Canada to examine the HTA system from SSM and CAS perspectives, and this project examined only the pan-Canadian HTA process and one provincial process. Some agent interactions and contextual influences (such as provincial political matters related to HTA process) were not examined. Our characterisation of the system is necessarily a simplified version of the actual Canadian HTA system at the time of the interviews. Worldviews are themselves complicated and dynamic, constantly changing and adapting to new circumstances and, in this project, we examined the system as a somewhat static structure. Collecting information on the system at different time points has the potential to better capture aspects of the system in flux.

Declaration of Competing Interest

they do not have a conflict of interest with this project. TS has participated in Health Technology Assessment for the pan-Canadian and provincial processes but declares that she does not have a conflict of interest with this project.

Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.healthpol.2020.06.014.

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