The Rationale and Design of Public Involvement in Health Technology Assessment: A Systems Thinking Approach

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Submitted in fulfilment of requirements for the degree of
Doctor in Philosophy in Medicine

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Adelaide, Australia
February 2021

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Dedication

ALÉM DA TERRA, ALÉM DO CÉU

Além da Terra, além do Céu,
no trampolim do sem-fim das estrelas,
no rastro dos astros,
na magnólia das nebulosas.
Além, muito além do sistema solar,
até onde alcançam o pensamento e o coração,
vamos!
vamos conjugar
o verbo fundamental essencial,
o verbo transcendente, acima das gramáticas
e do medo e da moeda e da política,
o verbo sempreamar,
o verbo pluriamar,
razão de ser e de viver.

(Carlos Drummond de Andrade)

This thesis is dedicated to my beloved family who are always happy to join me in my crazy adventures.

Brazil
Marli Lopes da Silva Carmo
Édino Luiz do Carmo
Maria José da Silva

Spain
Marcelo Luiz do Carmo
Olga Garrido
Maiara and Luara

Australia
Katrina, George and Renae McInnes

David
Kaio
And the little ones who are not with us

Acknowledgements

First, I would like to thank my four supervisors for their support and assistance throughout my PhD. It has been a long, fun, and, at times, difficult voyage and I am finally at my destination. I could not have done it all without you.

I want to thank Jackie Street for starting me in the research path since my Master's degree and guiding me into my PhD; I am grateful for all the help and the opportunities to develop as a researcher that you provided me along the way. Tracy, thank you for welcoming me into the AHTA family and making sure that I was always looked after; your expertise was critical in the last leg of the project and helped me learn new methodologies that I find quite interesting. Tania, thank you for looking after my family and me while we were in Canada and for going above and beyond what I expected to make us feel comfortable. I also appreciate the support from everyone at the Health Technology & Policy Unit (HTPU) at the University of Alberta (particularly, Prof Dev Menon and Andrea Young) in receiving me with open arms. Drew, as my primary supervisor, I am really thankful for all your support and kindness, for encouraging me on when I was not sure I could do it; thank you for always challenging my assumptions and making me look past them. I am very grateful to the whole supervisory panel for sharing their knowledge with me and for helping me find my voice.

I would also like to say thanks to my research participants for sharing their views and perspectives – without their input, none of this work could have been done. I would also like to acknowledge the financial support received from the South Australian Government, the Australian Department of Health through the Research Training Scheme and the Endeavour Fellowship for research conducted in Canada, and the University of Alberta for travel and in-kind support while I was working in Canada.

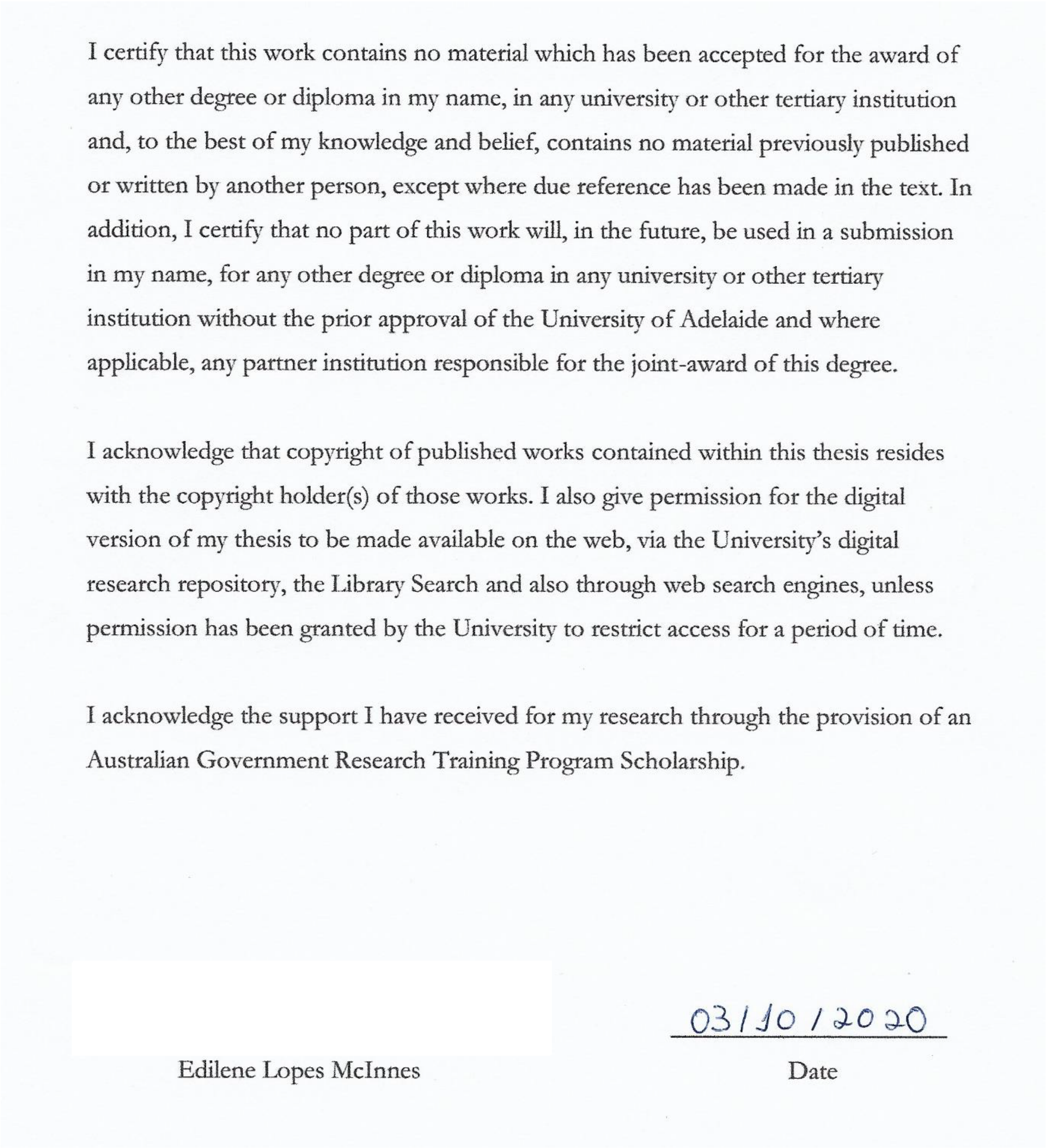
At the University of Adelaide, I would like to thank Jaklin for being there when I needed it most, Lynne for helping me in the very beginning of my degree, the administrative assistance from Rebecca, Lashan, Isabel, and Daphne, IT support from Paul, and statistical support from Jana and Stuart. I would like to show my appreciation

to my PhD colleagues (some of whom became really good friends) during this time: Shiau, Ali, Lucy, Jana, Ash, Emma, Ashlea, Sana, Mazna, Paula, Nadine, Gizachew, Blesson, Magdalena, Mah Laka. You all were present at different stages of the PhD, and the chats, coffees, lunches, dinners, conversation in the corridor, or having a good time outside the walls of the University were an enjoyable part of my time at the School of Public Health.

I dedicated this thesis to my family; their love is an essential part of my life. My parents have always encouraged me to pursue my dreams and to believe that the sky is the limit. Thank you for being so close even being afar and for being part of our lives in Australia, Canada, Spain and wherever else we are. I love that my grandma was able to live some of these experiences with her great-grandchildren and us.
I would like to thank my brother and his family for our video-calls and some trips together, which helped our little ones to stay close and me not lose sight of the important things.

I do not know how even to begin to thank David and Kaio for their love. I am looking forward to the next stage of our lives or as Kaio says: ‘Let’s go on an adventure, it will be fun!’

Thesis declaration



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I acknowledge the support I have received for my research through the provision of an Australian Government Research Training Program Scholarship.

03/10/2020

Edilene Lopes McInnes

Date

Publications included in this thesis

Lopes E, Carter D, Stafinski T, Merlin T, Street J. HTA stakeholders' perspectives on public involvement in HTA settings in Canada. 2020 (Unpublished)

Lopes E, Carter D, Bednarz J, Street J, Stafinski T, Merlin T. Is trust in government rational, relational or both? An empirical study of predictors of trust in the South Australian government. Submitted for publication to the Journal of Public Administration Research and Theory (Manuscript number: MS2020419). 2020.

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Lopes E, Street J, Stafinski T, Merlin T, Carter, D. The rationale and design of public involvement in health-funding decision making: Focus groups with the Canadian public. International Journal of Technology Assessment in Health Care. 2020.; 36(6):592-598. https://doi.org/10.1017/S0266462320000537

Street J, Stafinski T, Lopes E, Menon, D. Defining the role of the public in Health Technology Assessment (HTA) and HTA-informed decision-making processes. International Journal of Technology Assessment in Health Care. 2020; 36(2):87–95. https://doi.org/10.1017/S0266462320000094

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List of abbreviations and acronyms

This is a list of abbreviated terms that appear in the thesis. These terms are written in full the first time they appear in a chapter.

Augmented Component-Plus-Residual (ACPR)

Breast Cancer Network Australia (BCNA)

Canadian Agency for Drugs and Technologies in Health (CADTH)

American Centres for Medicare and Medicaid Services (CMS)

Complex Adaptive Systems (CAS)

Swedish Dental and Pharmaceutical Benefits Agency (TLV)

Dutch Health Care Insurance Board (CVZ) (currently, National Health Care Institute (ZIN)

German Federal Joint Committee (G-BA)

Haute Autorité de Santé (HAS) / French National Authority for Health

American Health Systems Agencies (HSAs)

Health Technology Assessment (HTA)

Health Technology Assessment - Australia (HTA-Aus)

Health Technology Assessment international (HTAi)

Health Technology Assessment international - Patient and Citizen Involvement Group (HTAi/PCIG)

Incremental Cost-Effectiveness Ratio (ICER)

Interdisciplinary Economic Evaluation and Public Health Committee (CEESP)

Medical Services Advisory Committee (MSAC)

National Institute for Health and Care Excellence (NICE)

pan-Canadian Pharmaceutical Alliance (pCPA)

Pharmaceutical Benefits Advisory Committee (PBAC)

Pharmaceutical Benefits Scheme (PBS)

Pharmaceutical Management Agency of New Zealand (PHARMAC)

Principal Components Factor Analysis (PCFA)

Public and Patient Involvement (PPI)

Public Understanding of Science (PUS)

Quality-Adjusted Life Years (QALYs)

Soft Systems Methodology (SSM)

Standard Deviation (SD)

Statistical Areas 1 (SA1s)

Variance Inflation Factors (VIFs)

Thesis abstract

Governments worldwide utilise an evaluation methodology named Health Technology Assessment (HTA) to decide which medical treatments they will fund. HTA evaluates the safety and (cost-) effectiveness, and broader implications of introducing new interventions into a given healthcare system. Involving the public in HTA is considered an appropriate way to collect information on the social and ethical implications of new medical interventions.

This thesis examines why and how the public should be involved in HTA processes and healthcare funding policymaking. Its objective is to propose directions on how to improve public involvement in HTA based on an understanding of stakeholders' perspectives.

The thesis uses a theoretical framework based on two Systems Thinking approaches: Complex Adaptive Systems and Soft Systems Methodology. The thesis is composed of four studies. First, there is a survey of members of the public to examine public involvement in policy decisions. Then, there is a theoretical piece on how to define which types of public might take part in HTA. Finally, there is a Canadian case study comprising two studies. The first study features interviews with HTA stakeholders to understand their views about public involvement processes, and the second study features focus groups with members of the public to ascertain their views on being involved in HTA.

The reasons for involving the public in policy are clarified; engagement processes are used to increase trust and transparency in decision making as part of governance strategies. A taxonomy for defining and differentiating the public from other types of stakeholders in HTA is proposed, along with the reasons and goals for engaging with each group. Examining HTA as a system shows that the HTA process and its outcomes are influenced by stakeholders' worldviews and values both at a personal and group level. Members of the public report being suspicious of the interests driving HTA stakeholders and see public input as a counterbalance to those interests. Members of the public also suggest the use of a mixed-methods approach to public involvement to provide information to HTA processes and meet the public's democratic aspirations to take part in government decisions.

This research shows that the challenges related to increasing and improving public involvement in HTA do not pertain exclusively to methodological problems such as a lack of standards for the design and evaluation of such processes. The main challenge is the differences in worldviews of those involved in HTA and those not directly involved. However, if all stakeholders' worldviews are explicitly considered, conflicts can be managed with provisional agreements that enable policy decisions to move forward. The inclusion of members of the public adds a set of values that may be different from the values of actors already involved in HTA and thus may warrant significant changes to current HTA processes. This body of work indicates that establishing formal procedures to foster discussion between stakeholders was seen a useful by those directly or indirectly involved in HTA as it allows them to understand a range of viewpoints and access potential solutions to challenges in this field.

Chapter 1: Introduction

In this chapter, a story about public reimbursement for a specific drug is used to illustrate some of the current concerns related to the need for public involvement in Health Technology Assessment (HTA) and healthcare funding decisions. Building on this illustrative story, the thesis aim is then presented followed by a summary of the thesis structure.

1.1 An illustration of the problem

This thesis investigates the involvement of the public in Health Technology Assessment (HTA) and healthcare funding decision making. Government healthcare funding decisions in various countries are informed by HTA. HTA has been defined as a multidisciplinary process that assesses the safety, effectiveness, costs and broader social and ethical dimensions of health interventions through their lifecycle, and in comparison to their alternative health interventions. The HTA process employs rigorous, systematic and transparent methods in its assessment of evidence. The health interventions investigated can be used to prevent, treat, diagnose, monitor, and manage the health of the public (1). Public influence in government healthcare policy can be a contentious issue, as the public reimbursement of the drug Herceptin in both Canada and Australia demonstrates.

In May 2005, researchers at the American Society of Clinical Oncology annual meeting discussed some promising results of trastuzumab (brand name: Herceptin) for treating the early stages of breast cancer. This discussion moved beyond academic circles with the topic receiving broad media coverage and public discussion. Ultimately, this resulted in fast-track approval of Herceptin for public reimbursement by some Canadian provinces in July 2005 (2, 3) even before the drug trial results were published in The New England Journal of Medicine (4, 5).

In Australia, back in 2001, Herceptin for late stage breast cancer was not recommended for subsidy by the Pharmaceutical Benefits Advisory Committee (PBAC). PBAC is a government committee that provides advice to the health minister based on HTA reports on whether the Australian government should subsidise particular medicines through its Pharmaceutical Benefits Scheme (PBS) (6). Cancer patient organisations, including the Breast Cancer Network Australia (BCNA), campaigned to have the drug publicly subsidised (7). This issue received broad media coverage, as was the case in Canada. In Australia, 2001 was also a federal election year, which may have added some pressure to government and candidates to be publicly seen as concerned with the healthcare system and patients.

The Australian government is bound by the National Health Act 1953 to only subsidise medicines through the PBS if they receive positive recommendations from the PBAC (6). Because this was not the case with Herceptin for late stage cancer, the government was forced to create a special access program - outside the PBS - through Medicare Australia to be able to publicly reimburse Herceptin for late stage breast cancer (8, 9). Five years later, in 2006, following the subsidy approval of Herceptin for early stage breast cancer in Canada, the BCNA organised an 'Early breast cancer Herceptin campaign' (10). This time, after undergoing an HTA and receiving a positive recommendation from PBAC, Herceptin for early stage breast cancer was added to the PBS (8).

Common across the Australian and Canadian cases was extensive media coverage, which incited a public debate that some researchers claim could have affected government decisions to publicly subsidise Herceptin despite the evidence being immature (11, 12). Mackenzie and colleagues (12) investigated the media attention Herceptin received in Australia and argued that:

> The Herceptin case suggests that media influence can have an important impact on the government funding of medicines. The PBAC monopsony inevitably leads to pressure from a range of competing interests, including a federal government increasingly concerned with PBS costs,[86] clinicians, patients, advocacy groups and multinational drug manufacturers who have 'unequalled power within healthcare'. (12)

For at least 25 years, there has been a debate over whether patients and patient organisations should be included in HTA processes or decisions informed by HTA (13) and, more recently, the discussion has expanded to include the public (14). The chain of events in the Herceptin case discussed above highlights the main concerns of those arguing for the need to involve patients and the public in HTA. When such groups are not officially included in the process, they still interact with other stakeholders (government staff, health industry representatives, patient organisation representatives, and HTA practitioners) outside the formal HTA process and this can impact the outcomes of healthcare funding decisions (11, 12).

Just before the beginning of this PhD project in 2015, a survey conducted by Whitty (15) found that many HTA organisations were already trying to involve what this author called 'lay members' in their processes – in most cases patients and their representatives and, in a few cases, members of the public. Since this PhD project started, the interest in engaging the general public in HTA processes has increased, various methods are being used to achieve this aim, and the research in this field has grown. However, there are still relatively few studies on this topic. Most of the challenges that were an issue in 2015 remain problematic: a lack of clear reasoning for public involvement, a lack of agreed definitions and views on precisely which stakeholder groups ought to be involved in the process, and uncertainty regarding the most appropriate methods to engage patients and the public in HTA.

1.2 Thesis aim

This project aims to fill a gap in the literature outlined above: what are the reasons for involving the public in healthcare funding decision making informed by HTA and how should this involvement take place? It also intends to lay bare the underlying arguments that can impact how public involvement is conceptualised and implemented in HTA and related healthcare funding decisions. This thesis purports to advance a strong rationale for engaging the public in HTA and proposes how this can be achieved while taking into account the diverse aspirations of HTA stakeholders and considering HTA from a macro, government policy decision-making level.

The project was conceived with the idea that any innovations to policy-related processes can originate from people within or outside those processes or from external factors, such as changes to healthcare department structures and funding. It is necessary to uncover the perspectives of those proposing innovations, those who will be affected by them, and those who may be responsible for enabling or obstructing change in order to understand whether alterations in health policy will be welcome or not and, therefore, likely or unlikely to succeed. Based on this premise, the project was designed to identify the views of those who are actually or potentially affected by the implementation of public engagement exercises in HTA: HTA practitioners, policymakers, people working in the health industry, patient organisations, patients, and members of the public.

1.3 Thesis structure

This thesis is presented as a thesis by publication and is composed of nine chapters. The current chapter (Chapter 1) introduces the main themes and structure of this thesis. Chapter 2 presents the theoretical orientation that guided the design of the research, states the research questions, and outlines how the analysis was carried out to answer these questions.

Chapter 3 substantiates why the public should be involved in policy decision making by presenting a brief review of the literature that provides a rationale for engaging the public based on the need to increase trust between government and the public. This rationale is examined in a linear regression analysis of the results of a survey with members of the public that took part in government public involvement processes.

Chapter 4 provides an overview of the background knowledge that informed the development of the project and explains the challenges related to public involvement in HTA. Chapter 5 discusses problems in defining who the ‘public’ is in HTA and proposes a taxonomy for different groups that can be involved. Chapter 5 also presents some goals for public involvement from the perspective of HTA practitioners (evaluation agencies that provide HTA reports to the government).

Chapters 6, 7, and 8 are part of a case study conducted in Canada to examine HTA from a Systems Thinking approach. Chapters 6 and 7 present the results of semi-structured interviews with policymakers, health industry representatives, patient organisation representatives, and HTA agency representatives. Chapter 8 reports the results of four focus groups conducted with members of the public. Chapter 9 finalises the thesis by bringing together the results of the individual studies and interprets the implications for the field of public involvement in HTA.

1.4 Chapter references

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Chapter 2: Methodology

In Chapter 1, the thesis aim and structure were presented. In this chapter, the overarching rationale of the thesis is explained. It starts with a description of the epistemological position adopted and how this informed the selection of the theoretical framework and the development of the research questions. The theoretical framework is outlined and discussed in relation to the topics explored in the thesis. This chapter ends with a description of the project's four major studies and an explanation of how each of them will help to build an overarching argument to answer the main research question.

2.1 Project rationale and epistemological position

The primary purpose of this thesis is to propose directions on how to improve public involvement in Health Technology Assessment (HTA) and healthcare system funding decisions based on a better understanding of stakeholders' viewpoints. Hence, we had to explore the interconnection between three areas of scholarship: government policy development (1), healthcare system evaluation methods, more specifically, HTA (2, 3), and engagement of the public in policies involving technical and scientific knowledge (4). These fields have differing epistemological underpinnings, and this has been considered, as demonstrated below.

Current widespread healthcare evaluation methods to inform policymaking, and HTA in particular, have links to the concept of evidence-based medicine (5). Evidence-based medicine postulates that the medical profession ought to search for the best available information (evidence), critically appraise this evidence, apply it in practice to treat patients, and evaluate the results. This closely aligns with the principles guiding the way HTA, an evaluation method used by various countries to inform healthcare system funding decisions, is conducted (6). HTA researchers utilise systematic reviews, meta-analyses, and specialised economic modelling (and other methodologies when necessary) to collect, critically appraise, and evaluate evidence and compare newly developed health technologies to the health technologies already funded or in use in a healthcare system (6). The knowledge supporting the development of evidence based-medicine and HTA - and its most commonly used methods (7) - follows a positivist tradition, which features an emphasis on a deductive approach (8). In this approach, knowledge is expanded through experiments that are reproducible and with results that can be generalised to other settings (9). HTA, in its initial theoretical conceptualisation, did not privilege this positivistic approach (10). Over time, some initiatives have been developed to emphasise the constructivist aspects of HTA, such as the development of Constructive Technology Assessment (CTA). CTA takes into account the role of social actors in the development and implementation of technologies (11). However, most of HTA processes adopted in English-speaking nations, such as Australia, Canada and the UK, implicitly adopt a positivist approach as there is an emphasis on cost-effectiveness analyses in comparison to the consideration of stakeholders' values. Recent initiatives, such as INTEGRATE-HTA (created in 2012) (12) and VALIDATE (created in 2018) (13) have been developed to try to change this trend and incorporate the views of stakeholders effectively into the HTA process.

In contrast to the positivist approach common to HTA, at least in English-speaking countries, most studies related to public involvement in science (14) and policy decision making (15) are conducted using a constructivist approach. In this approach, social phenomena are investigated as contextualised and historic interpretations constructed by people and their interactions with others and their environment (16).

This body of work aimed to investigate public involvement in HTA and related government health funding decisions as social phenomena grounded in a political and historic context. Therefore, it was necessary to adopt an epistemological position that would allow the integration of the perspectives traditionally informing HTA, public involvement, and policy decision making. Pragmatism (17) was selected to guide the development of this research project to achieve this aim. The pragmatic position of this research is based on Dewey's stance, in which knowledge is constructed as an interplay between the dynamic characteristics of the natural world (which are generally investigated using deductive approaches, such development of experiments to test a priori hypotheses) and the constructed experiences of the social world (which are usually investigated using inductive approaches, which utilise strategies that account for the cultural and social contexts surrounding a particular phenomenon) (18, 19). Dewey divides the human experience into two categories. First, the 'primary experience'

> refers to the immediate qualitative unity of experiencing and experienced that constitutes an empirical whole – a total situation – before we begin to discriminate elements. (18, p. 21)

The 'secondary experience' is a result of human reflexivity, when individuals analyse, try to forecast events, and construct a reality based on the primary experience and specific interests. The secondary experience is culturally contextualised. Dewey sees nature as an open and dynamic process where individual organisms and other elements of the natural world interact and develop relationships; these relationships create all sorts of emergent phenomena seen in the natural world.

Pragmatism in this thesis integrates these elements, in which there are no hard boundaries separating the investigation of the constructed social world and observed natural world phenomena and this can be seen in the analysis of data when two theoretical frameworks are used (see section 2.2 Theoretical framework). These elements are seen as interconnected and complementary and are in line with examining the intersection of public involvement, HTA, and government health funding decision processes. A mixed-methods strategy was explicitly developed to operationalise the pragmatic position adopted and facilitate integration between the knowledge obtained through constructivist-based and positivist-related methods (20, 21).

The primary theoretical drive of this thesis is inductive (22), and the main case study employs qualitative methods, as the idea is to understand stakeholders' points of view and how they influence the outcome of public involvement processes in HTA. However, this thesis also incorporates a supplementary deductive, quantitative strategy to examine reasons for the perceived need to involve the public in policy development and for understanding HTA methods.

2.2 Theoretical framework

Systems Thinking is an umbrella term that encompasses various theories and methodologies that examine different phenomena as a system (23-25):

> (…) Systems Thinkers often contend that complex systems such as the immune system or the global economy cannot fully be understood by simply analysing their constituents. Rather, they argue the importance of incorporating the study of often non-linear and dynamic relationships between networks of 'agents' and the environment surrounding a conceptual Complex Adaptive System (CAS) (Mitchell 2009). Through the collective self-organization, adaptation and co-evolution of these networks of agents, Systems Thinkers propose that whole-system characteristics distinctly 'emerge' which cannot be understood solely by studying the agents themselves (Gu et al. 2009). (23)

These principles characterise systems which can be explained as:

> an adaptive whole, an entity having emergent properties, a layered structure, and processes of communication and control that allow adaptation in a changing environment. (26)

The study of systems has spread through various disciplines and, currently, there are many different definitions of such types of systems in the literature, depending on which particular branch of Systems Thinking one adopts (23).

2.2.1 Hard and soft systems

Complex systems have been described as existing in a continuum from 'hard' to 'soft' systems (27). Hard systems treat agents as objects, which can be manipulated, and use formal modelling language to describe the system in precise terms. Alternatively, soft systems define agents as subjects with 'tangible' and 'intangible' properties, that can only be measured to a certain extent, as the intangible nature of agents cannot be computed (28, 29). The management field also named systems approaches as 'hard systems' or 'soft systems', which is relevant in this project as the system being examined here involves government policy development.

2.2.2 Complex Adaptive Systems (CAS)

A particular kind of system is a Complex Adaptive System. Mitchell (30) defines a Complex Adaptive System (CAS) as:

> a system in which large networks of components with no central control and simple rules of operation give rise to complex collective behavior, sophisticated information processing, and adaptation via learning or evolution.

The term 'components' cited above is more commonly referred to as 'agents' and, in CAS, a system is composed of agents that interact with one another, can adapt to changes in their surrounding environment and the actions of other agents, and have the capacity to learn and use their experiences in adaptive behaviour (31, 32). CAS can be seen as a 'hard' or a 'soft' system, depending on how a research design integrates CAS elements. The interaction of agents creates systems that are complex and adaptive, and these types of systems have some characteristics such as emergent patterns, self-organisation, non-linear dynamics, and diversity. Emergence has been defined as a macro-level property of the system that is the result of agents' interactions at a micro-level; emergent patterns are new phenomena that do not exist at the individual agent-level, only at the system-level (33). Self-organisation refers to the actions of agents that, acting independently and without any external force directing them, result in organised systems (33). Non-linear dynamics refer to how changes in the initial condition of a system can lead to unpredictable outcomes because of agents' adaptive behaviour, which is continuously changing. Finally, the diversity of agents can increase the complexity of a system. Such diversity can be present in different ways: 'variation' (a difference in some characteristics of individual agents), diversity of types of agents (different types or groups of agents), and 'configuration' (how the same agents or connections between agents can be rearranged in different ways) (34). Pype and colleagues (35) examine healthcare teams as complex adaptive systems and, based on this example, the previous concepts are illustrated. In Pype et al.'s research, healthcare teams were composed of individuals (agents) that used their own judgements (micro-level actions) to provide concerted healthcare treatment for patients (emergent pattern). Non-linearity, in this example, was demonstrated by the way communication within the team took place: a GP requested the assistance of nurse for procedure outside a pre-established protocol and the nurse refused to attend, which resulted in the GP terminating the team collaboration. In contrast, other teams dealt with similar conflicts in different ways that did not necessarily cease their collaborative efforts. In this example, diversity is illustrated by the different individuals with the same role, such as two nurses, that composed the healthcare team (variation); the different types of professionals that made up those teams, such as GPs, nurses, and allied health professionals (diversity of types of agents); and how teams were organised depending on the type of care needed to be provided to the patient (configuration).

2.2.3 Soft Systems Methodology (SSM)

In the Soft Systems Methodology (SSM) developed by Checkland (36), people are the actors that perceive a situation to be problematic and act with purpose ('purposeful action') to 'improve' such situation; different people will have different perceptions of the problem, and those perceptions are called 'worldviews' (p. 25). Another relevant feature of this methodology is that SSM is also systemic, that is, the methodology itself also exhibits the similar characteristics to a system (emergent properties, layered structure, and processes resulting in adaptation to environment).

Public involvement is being examined as a change in the HTA system and a situation that is seen as 'problematic' by the stakeholders. The stakeholders included in the conceptualisation of the project were: HTA practitioners (i.e., health technology evaluators writing HTA reports), government staff requesting and using HTA reports, and those involved in providing information to the HTA process (researchers, clinicians, patients, representatives of patient organisations, members of the public when present, and representatives of the health industry).

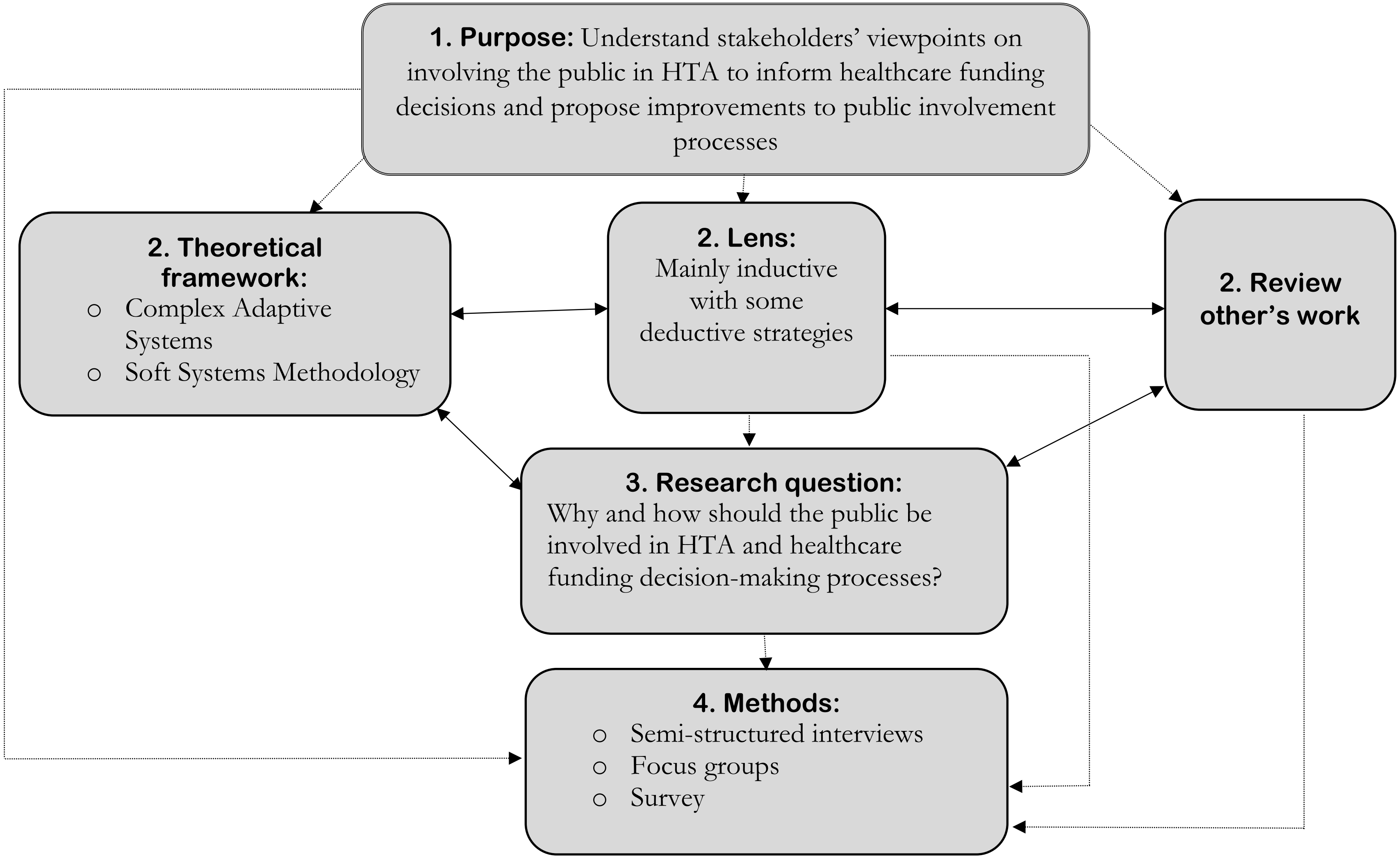
2.2.4 Combining CAS and SSM

Despite using CAS to describe the various elements of the system, the main epistemological underpinnings guiding this project are more aligned with a soft systems approach. In most conceptualisations of CAS, a system is taken to exist independently of individuals' perspectives, which is not entirely appropriate to describe the social phenomenon investigated in this project. There are some exceptions, as emergent CAS theories argue for its use in understanding the complex behaviour of individuals through the employment of applied qualitative research (37). However, the predominant trend with CAS-related projects is to adopt the 'hard systems' approach to systems. Therefore, the SSM approach was adopted to overcome this limitation (36) by including individuals' worldviews as a key element in examining a social system. Some characteristics of SSM and CAS are similar, which facilitates the integration of these two approaches in the same project. For example, the notion that agents act independently resulting in a system (CAS) is similar to the idea that individuals act based on their unique worldviews in social systems (SSM).

In this project, the HTA process is conceptualised as a system, and the nomenclature of CAS was adopted in the project design by shaping: sample selection (agents), questions for interviews and focus groups (questions related to relationships and interactions), and data analysis (the structure of the results sections of Chapters 6, 7, and 8). A soft systems approach was used in the data analysis and the writing up of the discussion of some chapters (namely, 6, 8, and 9). Chapters 6 and 8 have more detailed information on how stakeholders' and researchers' worldviews were made explicit in this project.

2.3 Study design

The project employed mainly inductive reasoning by using Soft Systems Methodology (36, 38, 39) and, as a supplementary strategy, a deductive approach by using Complex Adaptive Systems (31, 32, 40). The pragmatic approach adopted here aligns with the typology of research purposes proposed by Tashakkori and Teddlie (17), used below to illustrate how the aim of this research lead to decisions regarding methods (see Figure 2.1).



a Figure 2.1 Study rationale

2.4 Research questions

Main research question: Why and how should the public be involved in HTA and healthcare funding decision-making processes?

Sub-questions:

1) Why involve the 'public' in healthcare funding decisions?

2) How can the 'public' be defined in HTA?

3) How should the public be involved in HTA? Part 1. What does HTA look like when figured as a complex and adaptive system composed of individuals with diverse worldviews?

4) How should the public be involved in HTA? Part 2. What do HTA stakeholders and the public think about the rationale and design of public involvement in HTA and related funding decisions?

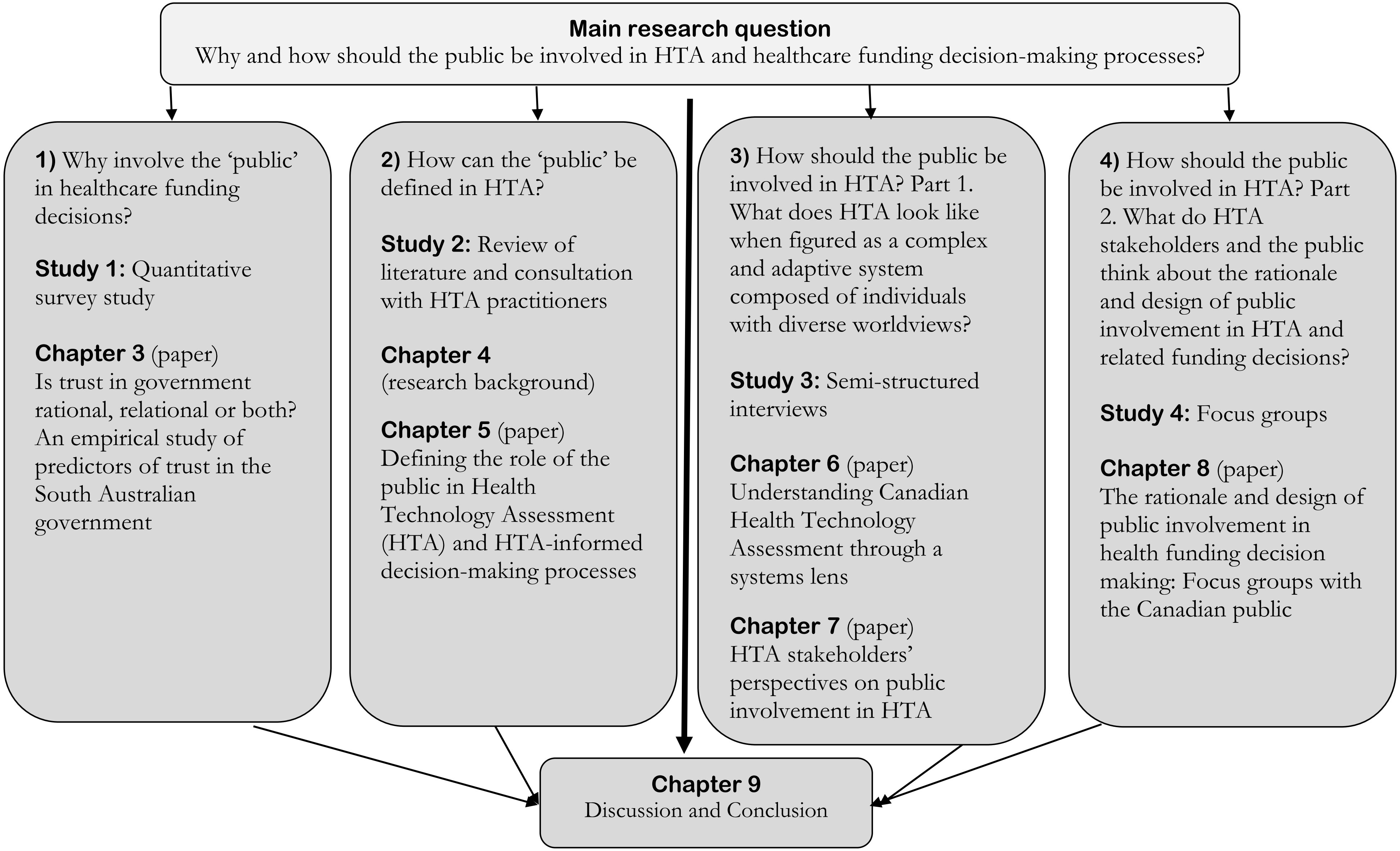
The first sub-question explores the reasons for public involvement in policy decisions and relates to the 'why' of the main research question. Chapter 3 will discuss the reasons why policymakers involve the public in government policy development and decision making. This study includes a brief review of the literature and a survey undertaken as part of a government initiative to engage the public in policy decisions in Australia. The aim of this empirical study was to demonstrate whether the theoretical arguments for public involvement are consistent with the public's actual views of their involvement.

The second sub-question addresses one of the main issues with involving the public in HTA, which is whether the 'public' is different from 'patients' and relates to the 'why' of the main research question. This question is at the centre of the debate on whether there should be specific methods to involve the public as a separate group from patients. The second sub-question will be answered by Chapters 4 and 5. Chapter 4 presents the current challenges in involving the public in HTA. Chapter 5 presents a proposal on how to define who can be considered 'public' in HTA (as opposed to other types of stakeholders, such as patients, for example). Chapter 5 does this based on both a literature review of terms and consultation with experts from two international HTA peak bodies.

Chapters 6 and 7 will answer the third sub-question. This sub-question relates to the 'how' of the main research question, and it will be answered from the perspectives of the research participants, in line with the integration of CAS and SSM approaches adopted in this thesis. This will be accomplished through the results of semi-structured interviews conducted with policymakers, health industry representatives, patient organisation representatives, clinicians, HTA staff representatives, and public and patient members of HTA expert review committees. Chapter 6 presents a case study in Canada, where HTA is examined as a system from a Systems Thinking theoretical framework. It helps to understand how the stakeholders involved in HTA see the process and its relationship to healthcare funding decisions. Chapter 7 presents HTA stakeholders' views regarding public involvement in HTA.

Chapter 8 answers the fourth sub-question, which also relates to the 'how' of the main research question. This study presents the views of the public about being involved in HTA and healthcare funding decisions as identified through focus groups of members of the public in Canada. The overarching research question is answered in Chapter 9, which integrates the findings from all studies and presents their major implications. The study settings for this research were Australia and Canada, two developed countries with similarly decentralised and publicly funded healthcare systems that use HTA to inform government reimbursement decisions related to health technologies.

See Figure 2.2 below for a visual representation of the thesis structure.



Main research question
Why and how should the public be involved in HTA and healthcare funding decision-making processes?

1) Why involve the 'public' in healthcare funding decisions?

Study 1: Quantitative survey study

Chapter 3 (paper)
Is trust in government rational, relational or both? An empirical study of predictors of trust in the South Australian government

2) How can the 'public' be defined in HTA?

Study 2: Review of literature and consultation with HTA practitioners

Chapter 4
(research background)

Chapter 5 (paper)
Defining the role of the public in Health Technology Assessment (HTA) and HTA-informed decision-making processes

3) How should the public be involved in HTA? Part 1. What does HTA look like when figured as a complex and adaptive system composed of individuals with diverse worldviews?

Study 3: Semi-structured interviews

Chapter 6 (paper)
Understanding Canadian Health Technology Assessment through a systems lens

Chapter 7 (paper)
HTA stakeholders' perspectives on public involvement in HTA

4) How should the public be involved in HTA? Part 2. What do HTA stakeholders and the public think about the rationale and design of public involvement in HTA and related funding decisions?

Study 4: Focus groups

Chapter 8 (paper)
The rationale and design of public involvement in health funding decision making: Focus groups with the Canadian public

Chapter 9
Discussion and Conclusion

b Figure 2.2 Thesis overview

2.5 Reflexivity

The idea of this PhD research project was partially born from the previous work I had conducted in my Master's degree on patient involvement in HTA and partly as a collaboration with my supervisors, who are also interested in this topic and had completed some research in the area of public involvement in this field. At the beginning of my PhD degree, I had decided to use Systems Thinking theories to guide the research based on contact with these theories during the previous Master’s research. Because I adopted Soft Systems Methodology (SSM) as a theoretical framework, it was important to pay attention to how my perspectives and those of my supervisors were shaping this project as the research developed.

In conceptualising the research project, I thought that one of the issues worth investigating was related to how different people are involved and interact in HTA. Frameworks that dichotomised people’s viewpoints, such as the power relations framework that I used previously (41, 42), can be informative but can also oversimplify how human relationships take place and influence processes, structures, and organisations. Going through the research process using SSM and trying to keep a reflective attitude showed me that I was looking at public involvement in HTA as a 'problematical situation':

> The aim of the work which led to the development of Soft Systems Methodology (SSM) was to find a better way of dealing with a kind of situation we continually find ourselves facing in everyday life: a situation about which we have the feeling that 'something needs to be done about this'. We call such situations' problematical' rather than describing them as

> 'problem situations', since they may not present a well-defined 'problem' to be 'solved' out of existence… (43)

This realisation caused me to reflect on how I would go about conducting this research. I recognised that I would have to maintain constant attention to how my own values were playing a role in how I formulated questions and interpreted the answers given by stakeholders and I tried to keep this awareness throughout the research process (44). In particular, I had to think about what my position was in relation to public involvement in government policy, which I describe below.

I was as a journalist in Brazil, where I worked for organisations that promoted the involvement of the public in policy through a diversity of participatory mechanisms before I decided to become a researcher. Through my work, I became familiar with some of the rationales for public involvement, and these experiences have influenced my views on different types of participatory tools. Another influence, in my (new) research career, relates to being guided by supervisors who are also involved in HTA, albeit each with a different role and areas of interest. This has impacted on how I see such processes. All these perspectives were important for the design and development of the research presented here.

I kept a reflective journal while conducting this research, where I wrote my own observations about how I felt about particular topics, responses, research processes, personal reflections and discussions with supervisors. On re-reading some of my notes, it is clear that the project itself has changed and developed over time with the ideas from

SSM but also Complex Adaptive Systems feeding into the next stage of planning in an actual 'process of learning'.

Besides the work with HTA processes, I conducted part of the research in partnership with a South Australian government agency. Doing research with non-research partners can add some challenges to the research process, as the dynamics with government departments are different, particularly in terms of time and changes to work priorities that can affect research outcomes. Staff from the government also contributed to the development of the project, which added another set of values to be considered. I found that their participation enriched the research process, adding some concepts that were not included initially but that are relevant from their perspective and the viewpoint of other stakeholders. The exploration of 'trust' concepts, for example, which became an essential point of analysis in the whole project, was a reflection of the partnership with the staff from the government agency.

The research process did not always go smoothly; there were roadblocks throughout the way. My personal circumstances changed, as I became a mother during this process, which impacted my time availability and changed my perspectives concerning the project. I also lived in Canada for four months to do part of the research. On the one hand, it was a great professional development experience working with a different research group and learning about different practices. On the other hand, it added some complications as cultural differences and my lack of experience with focus group research affected data collection in Canada. Differences of opinions and changes in the relationship with the supervisory panel during the research process made navigating the degree intricate (45). I see this is part of my development as a researcher and part of the progression of a research project that spans five years. Maintaining a reflective practice, revisiting initial understandings and keeping an iterative approach that allowed for the incorporation of evolving themes when necessary revealed to be a fruitful approach to the research, in which the outcomes were grounded in the data collected and informed by the worldviews of participants.

This account is based on my own reflections as a PhD candidate for the duration of the project. However, as I stated earlier, this project is a collaborative effort of many people, in particular of my supervisors, and their own reflections about this process may be very different from what I presented here. It is positive to note that, despite our different worldviews and purposes for this research, we were able to find accommodations to move forward with this project and achieve its end with positive outcomes for all involved. This is what we propose at the end of this thesis: this can be an achievable goal when involving the public in HTA and healthcare funding decisions, despite the different perspectives of different stakeholders.

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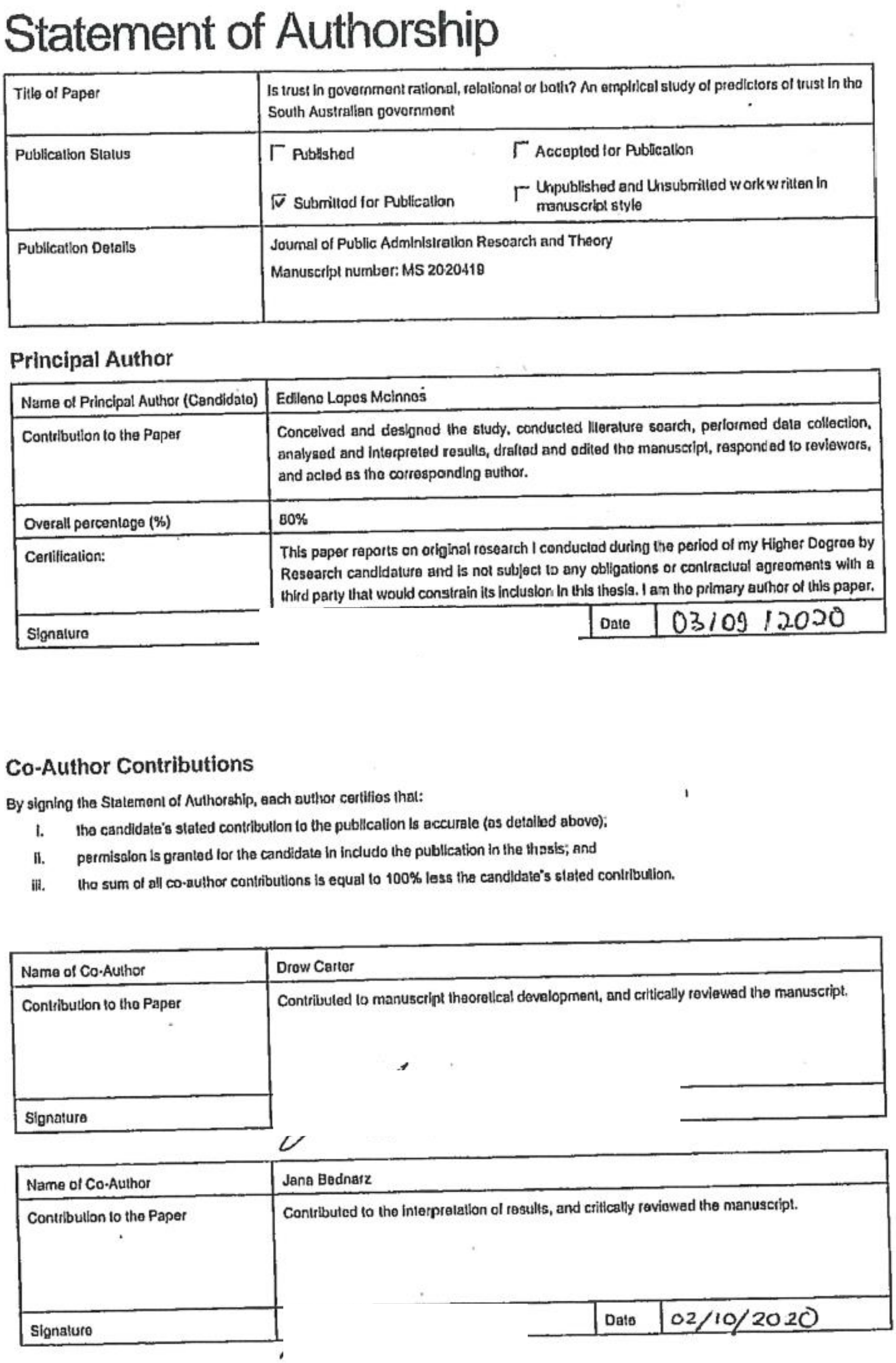
Chapter 3: Why involve the public in policy decisions?

In Chapter 2, an outline of the thesis and the main research question (Why and how should the public be involved in HTA and healthcare funding decision-making processes?) were presented. This chapter explores the rationales for public involvement in government policy development. HTA is used around the world to support government policy development when it comes to healthcare funding. It is important to understand how introducing public involvement in HTA processes impacts HTA's usefulness to policymakers.

Chapter 3 describes the existing literature on public involvement in government decisions with an emphasis on how this involvement can increase trust in government. This chapter also reports the findings of a survey on whether participation in engagement processes is associated with higher public trust in government. This relates to the first sub-question this thesis attempts to answer (why involve the 'public' in healthcare funding decisions?) and the first part of the main research question (Why and how should the public be involved in HTA and healthcare funding decision-making processes?)

This study was undertaken in South Australia and analysed the views of members of the public in a state-wide initiative to involve them in policy decisions. The initiative described here was a programme with a range of online and face-to-face government engagement processes, which were centralised under the YourSAy website (https://yoursay.sa.gov.au/) used by all South Australian Government departments to engage with the public. The YourSAy initiative was created by the Labor party Premier from 2011 to 2018. In 2018, with the election of a Liberal party Premier to the state government, the engagement program was significantly reduced, and the scope and types of involvement processes conducted also changed. However, the fact that this programme, a hallmark from the previous administration, was maintained lends support to the idea that governments feel the need to create channels to interact directly with the public.

3.1 Statement of authorship



Statement of Authorship

Title of Paper	Is trust in government rational, relational or both? An empirical study of predictors of trust in the South Australian government
Publication Status	☐ Published ☐ Accepted for Publication ☑ Submitted for Publication ☐ Unpublished and Unsubmitted work written in manuscript style
Publication Details	Journal of Public Administration Research and Theory Manuscript number: MS 2020419

Principal Author

Name of Principal Author (Candidate)	Edilene Lopes McInnes
Contribution to the Paper	Conceived and designed the study, conducted literature search, performed data collection, analysed and interpreted results, drafted and edited the manuscript, responded to reviewers, and acted as the corresponding author.
Overall percentage (%)	80%
Certification:	This paper reports on original research I conducted during the period of my Higher Degree by Research candidature and is not subject to any obligations or contractual agreements with a third party that would constrain its inclusion in this thesis. I am the primary author of this paper.
Signature	Date 03/09/2020

Co-Author Contributions

By signing the Statement of Authorship, each author certifies that:

i. the candidate's stated contribution to the publication is accurate (as detailed above);
ii. permission is granted for the candidate in include the publication in the thesis; and
iii. the sum of all co-author contributions is equal to 100% less the candidate's stated contribution.

Name of Co-Author	Drew Carter
Contribution to the Paper	Contributed to manuscript theoretical development, and critically reviewed the manuscript.
Signature	

Name of Co-Author	Jana Bednarz
Contribution to the Paper	Contributed to the interpretation of results, and critically reviewed the manuscript.
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Contribution to the Paper	Contributed to manuscript theoretical development, and critically reviewed the manuscript.		
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Name of Co-Author	Tracy Merlin		
Contribution to the Paper	Contributed to the design of the study, interpretation of results, provided guidance in manuscript theoretical development, and critically reviewed the manuscript.		
Signature		Date	30/9/2020.

3.2 Abstract

Article title: Is trust in government rational, relational or both? An empirical study of predictors of trust in the South Australian government

Background: Gathering support from the public can be a challenge to governments of all levels and can affect the implementation of policies. Despite the adoption of diverse strategies to involve the public in policy development and decision making, public discontent with government persists. The concept of trust lies at the heart of discussions about this.

Objective: To investigate whether positive evaluation of public involvement processes is associated with higher trust in government and whether rational, relational trust-building theories explain this phenomenon.

Design: Data was collected through a cross-sectional survey with members of the public from South Australia who took part in online public involvement processes organised by the state government. The analysis consisted of a Principal Components Factor Analysis (PCFA) to reduce the number of variables for multivariable regression modelling. The linear regression modelling examined the associations between the various sub-concepts of trust, evaluation of the engagement processes, and trust in state government.

Results: The regression model showed a positive association between trust in state government and positive evaluation of government public engagement exercises. The

results also demonstrated that elements of rational trust-building and one element of relational trust-building theories were positively associated with trust in state government. These elements were: perceived transparency of policy decision making, perceived citizen influence on decisions, and trust in organisations such as the federal government, respectively.

Conclusion: Our research shows that rational trust theories are mostly able to account for trust in state government, whereas relational trust theories make a limited contribution. Public engagement processes can help foster closer links between the public and the state government by allowing the public to view the government as transparent and by allowing the public to view itself as able to influence policy development and decision making.

3.3 Paper

Introduction

Governments of all levels face challenges gathering support from stakeholders when making policy decisions. This can affect the implementation of policies and perceptions of government performance. In the 1970s, scholars spoke of this in terms of a 'crisis of governability', defining governability as the 'relative efficacy of government in meeting economic, social, and political challenges' (1). Under this definition, governments were responsible for maintaining a functioning society. However, their perceived ability to succeed at this diminished, particularly after the global economic crisis of 2008 (2), which left governments around the world struggling to rebuild relationships between different sectors of society. The concept of governability was also supplanted by the concept of governance, which is understood in terms of 'the organizational form and practices through which collective action occurs' (3). Some governance theories postulate that power is managed by a network of social actors, which includes government, other organisations (both for-profit and not-for-profit), and individuals (4). Therefore, practitioners and scholars of government are now greatly concerned with strengthening relationships between diverse stakeholders in society, rather than focusing merely on the success of governments as the dominant social actor. This has led to a search for more inclusive governance methods and, as a result, direct public engagement has increased in government departments, including departments governing the environment, healthcare, and education (3, 5-7).

But, despite governments adopting diverse strategies to involve the public and other social actors in decision making over many years, the public's discontent with government actions has persisted (8-13). Moreover, researchers disagree about whether increasing social involvement in decision making has managed to improve interactions between governments and the public (14-16). The concept of trust lies at the heart of these discussions.

There is some support for the idea that a lack of trust on the part of citizens tends to erode voluntary compliance with law and regulations, engagement with government activities, and pro-social behaviours that would benefit other social actors (11). Some scholars argue that people who trust the government would be the ones to participate more than others in government-led initiatives (17), whereas other scholars argue that, on the contrary, it is the people who distrust their government who would be the ones most willing to engage, namely to keep their government in check (18). These divergent views on the implications of a lack of trust in government may partly stem from the diverse definitions of trust that are offered in the literature (19-22).

In this study, we focused on an Australian state government initiative to engage its citizens in policy decisions. In this context, we asked the following research question: which elements of relational and rational trust-building theories affect trust in an intermediate government institution such as a state government? We analysed participants' evaluation of engagement processes they participated in and whether their evaluation affected their level of trust in government. Our approach is innovative because it carefully examines which elements of trust are most relevant to people's views of government. Moreover, it examines whether those elements relate primarily to personal experiences and upbringing (as per social or relational theories of trust) or personal evaluations of government performance (as per rational theories of trust). Uncovering which types of trust are related to state government will help policymakers improve their interactions with the public when devising their governance strategies.

3.4 Theory and hypotheses

3.4.1 Trust-building theories

Studies on trust in government have been conceptualised as examining political trust, which has been given various definitions. Government has been identified with political regimes at international and national levels (23), elected officials, and the institutions that make up governmental structures (24). Levi and Stoker (25) recommend that these different conceptions of government need to be disentangled since trust in political incumbents (elected officials) tends to be more transient than trust in governmental institutions or political regimes (22). When examining trust in government within a country, Newton et al. (26) explain that there are differences in how people evaluate different types of institutions (e.g., federal, state, and municipal institutions). Accordingly, they recommend that survey questions specify what types of political institutions are being examined.

We adopted the following definition of political trust: 'the generalisation of trust to include government, its organisations, and systems' (20). We looked at governmental organisations within a country (Australia) at three different levels: local (public institutions that people deal directly with, such as the police department), intermediate (the state government executive department), and remote (public institutions that people deal with only indirectly, such as the federal Parliament).

Some trust-building theories state that a person's biological make-up and personality influence their level of trust in others (19). Other theories contend that social influences play a role (26), and this is generally referred to as 'social trust'. Another approach is to understand trust from the perspective of rational-choice theories, which assume that people make conscious decisions and evaluate the costs and benefits of their actions to achieve their goals (27).

Job (20) examines several sources of trust, from both rational-choice perspectives and social-psychological perspectives (Job also calls the latter relational perspectives). From rational-choice perspectives, individuals trust governments if they evaluate their performance positively, believe that governments are not corrupt, and decisions are seen to be transparent and take public perspectives into account (28-30). By contrast, relational trust-building theories contend that trust starts in a person's inner social circles of family and friends and is then generalised to other people and to institutions. For instance, growing up in an environment that fosters low levels of trust can reduce someone's trust in other people and institutions, and this may not be ameliorated by positive social experiences or good government performance. The inverse is also possible, with institutional actions affecting trust in other institutions, other people, and even inner social circles (26) (see Table 4.1).

a. Table 3.1 Trust-building theories

Trust-building theories	Elements influencing this type of trust
Social-psychological (relational)	o Psychological and personality traits o Trust in family and friends o Trust in wider social circles
Rational-choice	o Government performance o Lack of corruption o Transparency of decision making o Public can influence decisions

According to Job, both rational-choice and relational theories should be used to understand trust in institutions as both theories have been shown to contribute to building trust empirically. In this study, we examine elements of both theories, as follows.

3.4.2 Relational perspective

Uslaner (31) argues that there are two types of social trust: 'strategic trust' (where people trust others to do something for them in specific circumstances) and 'moralistic trust' (trust with a moral foundation that makes people presume that they can trust others). Strategic trust results from personal experience and manifests in 'particularised trust' (trust we have in people we know and who resemble us). Moralistic trust, on the other hand, is learnt from a young age from our immediate family and is fostered by a sense of optimism and control over our lives. Moralistic trust manifests in 'generalised trust' (trust in people we do not know and who differ from us). In Job's empirical work (20), the levels of trust were found to move in descending order with higher levels of trust in the family, which decreased at each level down to remote institutions. In this study, we examine how both familial (particularised) and social (generalised) trust relate to trust in an intermediate institution (state government). In this research, familial trust refers only to trust in the family. Specifically, we hypothesise the following.

Hypothesis 1: Familial trust (trust in family) and social trust will be positively associated with political trust in an intermediate institution.

We also examine how trust in state government relates to trust in other governmental institutions at local and remote levels, hypothesising the following.

Hypothesis 2: Political trust in local government institutions will be positively associated with political trust in an intermediate institution.

Hypothesis 3: Political trust in remote government institutions will be positively associated with political trust in an intermediate institution.

3.4.3 Rational perspective

Rational trust-building theories posit that trust in an institution is influenced by one's evaluation of its service provision (30, 32). From a rational perspective, trust in an institution is also affected by one's perception of the complexity (29) and transparency (28) of its decision making. Cook and Santana (27) contend that 'trust as rational action assumes that the trustor calculates, or predicts, the trustees' level of trustworthiness.' Individuals talk about institutions in terms of trust, and this goes beyond the contractual and formal assurances that they already have. This view, however, is criticised by Job (20) as conflating 'trust' with the concepts of 'dependability':

> Trust as confidence in the other's reliability is problematic because reliability may be just a façade (Hardy, Phillips and Lawrence 1998:67) promoted by ritualistic processes that convey sameness. (20).

In our study, we examine how perceived government performance relates to trust in a state government, by including measures of the perceived 'quality' and 'integrity' of government performance (20). In this research, quality refers to the engagement process conducted by the government and one's perception of the transparency of policy decision making. We hypothesised the following:

Hypothesis 4: There will be a positive association between evaluation of government public engagement processes and political trust in an intermediate institution.

Hypothesis 5: There will be a positive association between perceived transparency of government policy decision making and political trust in an intermediate institution.

Political trust also involves views on the government's integrity. Integrity encompasses how corrupt or honest a government is (33) and whether citizens feel they have a say in government decisions (20). Based on these elements of rational trust, we formulated the following hypotheses.

Hypothesis 6: There will be a negative association between the perceived level of corruption and political trust in an intermediate institution.

Hypothesis 7: There will be a positive association between perceived level of citizen power and political trust in an intermediate institution.

3.5 Methods

3.5.1 Study design

This project utilised data collected from a cross-sectional survey that we designed to gauge participants' views of the state government when they took part in an online community engagement process. We designed the survey to collect information on demographic characteristics and relational and rational aspects of trust-building.

3.5.2 Survey concepts

We included two measures of social trust. The first, based on Rosenberg's research (34), is a single-item scale. It asks the following question, answered on a four-point Likert-type scale: 'Generally speaking, would you say that most people can be trusted, or that you can't be too careful in dealing with people?' While this measure is commonly used in surveys, it has been criticised (35-37). Critics argue that the scale measures trustworthiness rather than trust. However, given its widespread historical use, we included this scale to facilitate comparison with existing literature. To help address criticism of the scale, we also included an additional measure of social trust, composed of items that contextualise trust in various situations (see Table 4.3 for details).

We sub-divided political trust into trust in local, intermediate, and remote institutions. The objective was to provide context to the trust measures and disentangle the differences between trust in micro-(local), meso-(intermediate), and macro-(remote) level institutions, as per the advice of Newton et al. (26). As we are interested in trust in the state government, which can be considered a meso-level institution, the distinction between the types of institutions is important.

To apply a rational trust perspective, we used measures based on Job's work, which studied the perceived 'quality' and 'integrity' of government performance (20). We measured 'quality' by including questions about the online engagement process, the complexity and transparency of government policy decision making, and the types of input (expert or public) that ought to guide government decision making. We based the questions about the online engagement process on Rowe and Frewer's framework (38), which defines nine criteria for evaluating public participation methods: representativeness, independence, early involvement, influence, transparency, resource accessibility, task definition, structured decision making, and cost-effectiveness. We measured 'integrity' by including questions on corruption and honesty in Australian governments (see Table 4.2).

b . Table 3.2 Survey sub-concepts

Sub-concepts	
Relational trust	Relational trust
	Social trust (single-item)
	Social trust (multi-item)
	Political trust (local institutions)
	Political trust (intermediate institutions)
	Political trust (remote institutions)
Rational trust	Rational trust
	Perception of corruption
	Perception of citizen power or lack of power
	Perception of complexity of policy decision making
	Perception of transparency of policy decision making
	Exclusive expert input in policy decision making
	Public input in policy decision making

3.5.3 Sample and data collection

Three online public engagement exercises, in the YourSAy initiative (https://yoursay.sa.gov.au/), were posted on a web portal administered by the Government of South Australia. The engagement exercises were open to South Australian residents from April to May 2017. Participants could take part in one, two, or three engagement processes. After taking part in at least one, participants were emailed the online survey. The online survey questionnaire was developed in five stages comprising face validity, cognitive interviewing with members of the public, 'skirmish' process for checking question validity, and pilot testing using an online engagement process (see Web supplement for complete questionnaire) (See the Appendices section in this thesis).

The survey was hosted by Survey Monkey for the same period of time that the engagement processes ran. The state government agency sent out the emails, received and collated the results, and provided de-identified answers to the researchers. A total of 234 responses were obtained in Excel format. Human Research Ethics Approval was provided by The University of Adelaide (Project number H-2016-200).

3.5.4 Outcome and predictors

The outcome that we sought to predict was the level of political trust in state government, considered as a meso-level organisation or an intermediate institution, that is, an institution that people only deal directly with in particular circumstances (for example, when taking part in an online engagement exercise such as the participatory budgeting exercise that we studied). We investigated factors pertaining to relational and rational trust-building theories for their association with political trust in state government. The relational and rational sub-concepts are listed in Table 2. Data were transformed and scaled to a consistent five-point or seven-point Likert scale, ranging from negatively to positively scaled values. A table in the web supplement indicates the factors used in the regression analysis and the scaling underpinning each concept (See the Appendices section in this thesis).

3.6 Analysis

The analysis consisted of two major parts. First, we used Principal Components Factor Analysis (PCFA) to reduce the number of variables (survey questions) for multivariable regression modelling. Summary measures for latent constructs (dimensions) of trust were generated as linear composites of questionnaire items identified a priori as measuring the same dimension or sub-concept of trust. Each pre-determined set of similar survey items was assessed for unidimensionality based on the number of eigenvalues greater than one. If more than one latent factor was indicated, variables with lower loadings were systematically removed until unidimensionality was indicated for each sub-concept. Factors with loadings greater than 0.40 were retained and a summary score for each latent construct was created based on the regression method (39).

Summary measures of the following sub-concepts were constructed using the above method: level of political trust in state government (political trust in intermediate institutions), level of social trust (multi-item), level of political trust (local institutions), level of political trust (remote institutions), evaluation of engagement exercise, and perceived level of citizen power or lack of power. We assessed the internal consistency (reliability) of these summary measures by calculating the average inter-item correlation and Cronbach's alpha. Correlations from 0.2 to 0.5 and a Cronbach's alpha of 0.60 or higher were considered acceptable (40, 41). The sub-concepts of familial trust, transparency of policy decision making, perception of corruption in Australian federal government, complexity of policy decision making, and exclusive expert input in policy decision making were represented by single survey questions.

Second, linear regression modelling was conducted to examine the associations between the various sub-concepts of trust and the outcome of interest, namely trust in state government considered as an intermediate institution. The model with the sub-concepts of relational trust as predictors was compared to the model with the sub-concepts of rational trust as predictors. Then, all sub-concepts were entered into the model simultaneously to assess the joint effects of both relational and rational trust on the outcome.

A sensitivity analysis was conducted on the joint model, which involved identifying any disproportionately influential observations and the effect of their removal on the regression results. A leverage-versus-squared-residual plot was assessed to identify any unusual or outlying data points. The model was re-run with these observations omitted, and results were compared with the original model. We also tested for non-linearity using Augmented Component-Plus-Residual (ACPR) plots and assessed the assumptions of normality and homoscedasticity of residuals by visual inspection of a Kernel density plot and a residual-versus-fitted plot, respectively. Variance Inflation Factors (VIFs) were obtained to identify multicollinearity, and a test for model specification (link test) was conducted.

Finally, two exploratory analyses were conducted. First, the joint model was adjusted according to whether demographic data was provided by the participant or withheld, because we thought that this could potentially reflect a participant's level of trust in state government. Second, the joint model was adjusted for the effects of select demographic variables (age, gender, marital status, work status, and level of social disadvantage and advantage) to explore their association with trust among those participants who did provide demographic data.

All statistical analyses were carried out using Stata (version 15, StataCorp, College Station, Texas). The level of statistical significance was set to 0.05.

3.7 Results

3.7.1 Participants' characteristics

Our sample was drawn from participants of a state government engagement process. Comparison between the survey sample and the underlying state population demonstrated some significant differences between these two groups. Survey participants were mostly female and older, more educated, and more socio-economically advantaged than the population average (see Web supplement) (See the Appendices section in this thesis).

3.7.2 Principal Components Factor Analysis

Table 4.3 provides an overview of the items and factor loadings that were combined to form distinct concepts. These combinations were initially developed on theoretical grounds and then further refined on the basis of the Principal Components Factor Analysis (PCFA) results.

c. Table 3.3 Principal Components Factor Analysis results

Variable	Factors retained	Items and factor loadings	Eigenvalue*	Explained Variance	Average inter-item correlation	Cronbach's alpha
Political trust (intermediate institution)	1	Perception of corruption in state government (-0.50) Trust in state government (0.85) State government trusts people to do the right thing (0.67) Trust in state government decision making process (0.88)	2.21	55%	0.39	0.72
Social trust (multi-item)	1	Trust in people in the neighbourhood (0.70) Trust in people in sports clubs and social activities (0.74) Trust in people in stores (0.82) Trust in people in the same city/region (0.78)	2.34	58%	0.44	0.76
Political trust (local institutions)	1	Trust in local police station (0.64) Trust in local fire station (0.64)	2.22	44%	0.29	0.67

		Trust in local schools (0.70)				
		Trust in local council (0.62)				
		Trust in local hospitals (0.70)				
Political trust (remote institutions)	2	Trust in newspapers (0.72)	2.44 1.12	48% 22%	0.35	0.72
		Trust in television channels (0.76)				
		Trust in federal government (0.68)				
		Trust in the Parliament (0.67)				
		Trust in the courts (0.63)				
Evaluation of engagement exercise	1	Have enough information to participate (0.65)	1.99	39%	0.24	0.61
		Able to express opinion (0.56)				
		Online methods are best to participate (0.71)				
		Results will be used in decisions (0.53)				
		Anyone can take part in online process (0.67)				
Perception of citizen power or lack of power	2	People in power try to exploit others (0.68)	3.21 1.04	45% 14%	0.35	0.79

		Governments are not concerned with me (0.79)				
		Most people try to take advantage (0.52)				
		Governments only benefit special interest groups (0.41)				
		I feel left out of community (0.64)				
		I have no say in state decisions (0.80)				
		I have no say in federal decisions (0.77)				

*Eigenvalues above 1 were retained.

3.7.3 Effect of relational trust on the level of political trust in an intermediate institution

Linear regression was used to predict the effect of relational trust on the level of political trust in an intermediate institution. We compared the multivariable models obtained using the alternate parameterisations of the social trust sub-concept (with Model 1 using the single-item measure and Model 2 using the multi-item measure – see Table 4.4).

The results suggest that, overall, relational trust elements have little influence on the level of political trust in an intermediate institution. In both Models 1 and 2 only political trust in remote institutions is a significant predictor, with higher levels of political trust in remote institutions being associated with higher levels of political trust in an intermediate institution. The point estimates and confidence intervals for the effect of familial trust, political trust (local institutions) and political trust (remote institutions) are similar between models, suggesting that the alternative parameterisations of social trust have little impact on overall results. The proportion of variance in the outcome explained by the model is also similar between Models 1 and 2, with adjusted R-squared values of 0.25 and 0.22, respectively.

d. Table 3.4 Regression models for relational trust and political trust in an intermediate institution – Models 1 and 2

Predictor	Model 1 social trust (single-item)				Model 2 social trust (multi-item)			
	Coefficient	Std. Error	95%CI[†]	p-value	Coefficient	Std. Error	95%CI[†]	p-value
Familial trust	0.02	0.21	-0.40, 0.44	0.921	0.07	0.21	-0.34, 0.49	0.712
Social trust (single-item)	0.09	0.07	-0.05, 0.25	0.194	---	---	---	--
Social trust (multi-item)	---	---	---	---	-0.04	0.09	-0.22, 0.13	0.629
Political trust (local institutions)	-0.04	0.13	-0.30, 0.21	0.733	-0.05	0.14	-0.34, 0.22	0.687
Political trust (remote institutions)	0.51	0.07	0.37, 0.65	p<0.000	0.54	0.07	0.38, 0.70	p<0.000
Adjusted R-squared	0.25				0.22			

[†]CI-Confidence Interval

3.7.4 Effect of rational trust on the level of political trust in an intermediate institution

The results suggest that perception of citizen power or lack of power, perception of transparency of policy decision making, and evaluation of the engagement exercise were all positively associated with the level of political trust in an intermediate institution. This means that a higher level of political trust in state government was predicted by a belief in citizen influence on government decisions, a positive assessment of the online process and higher perceived transparency of policy decision making. The effects of other rational trust predictors were smaller and not statistically significant (see Table 4.5 for details).

e. Table 3.5 Regression model for rational trust and political trust in an intermediate institution – Model 3

Predictor	Coefficient	Std. Error	95%CI†	p-value
Perception of citizen power or lack of power	0.38	0.07	0.24, 0.51	p<0.000
Perception of transparency of policy decision making	0.31	0.08	0.14, 0.48	p<0.000
Evaluation of engagement exercise	0.15	0.05	0.04, 0.27	0.007
Perception of corruption in Australian government	-0.08	0.04	-0.16, 0.00	0.060
Public input in policy decision making	-0.09	0.07	-0.24, 0.04	0.178
Perception of complexity of policy decision making	-0.02	0.07	-0.17, 0.11	0.683
Exclusive expert input in policy decision making	-0.07	0.05	-0.18, 0.02	0.142
Adjusted R-squared	0.36			

†CI-Confidence Interval

3.7.5 Hierarchical model of relational and rational trust-building theories

We then compared the relative influence of each set of trust-building elements (relational and rational) using a hierarchical regression technique. The base model (Model 2) included the relational trust-building elements only, with the multi-item measure of social trust. Next, rational trust elements were added (Model 3). The addition of these elements increased the adjusted R-squared from 0.22 to 0.36. After adjusting for the effects of all predictors in the model, there were significant associations between the outcome and both the relational sub-concept of level of political trust in remote institutions and the rational sub-concepts of level of perceived citizen power, level of perceived transparency of policy decision making, and evaluation of the engagement exercise (see Table 4.6).

f. Table 3.6 Regression model combining elements of relational and rational trust – Model 4

Sub-concept	Coefficient	Std. Error	95%CI†	p-value
Relational trust				
Familial trust	0.01	0.17	-0.32, 0.35	0.927
Social trust (multi-item)	-0.08	0.09	-0.27, 0.09	0.345
Political trust (local institutions)	-0.08	0.13	-0.34, 0.18	0.537
Political trust (remote institutions)	0.36	0.08	0.20, 0.52	p<0.000
Rational trust				
Perception of citizen power or lack of power	0.32	0.07	0.16, 0.48	p<0.000
Perception of transparency of policy decision making	0.34	0.10	0.14, 0.54	p<0.000
Evaluation of engagement exercise	0.19	0.06	0.05, 0.33	0.005
Perception of corruption in Australian government	-0.03	0.05	-0.13, 0.07	0.518
Public input in policy decision making	0.01	0.08	-0.16, 0.18	0.889
Perception of complexity of policy decision making	0.00	0.08	-0.17, 0.17	0.974
Exclusive expert input in policy decision making	-0.09	0.06	-0.22, 0.02	0.122
Adjusted R-squared	0.44			

†CI-Confidence Interval

3.7.6 Sensitivity analysis and model assessment

We graphed a leverage-versus-squared-residual plot to examine Model 4 for unusual data and disproportionally influential observations. We conducted a sensitivity analysis which found that the removal of three influential observations did not materially alter the effect estimates or p-values, indicating that the model was relatively robust. We assessed the assumption of linearity between predictors and the outcome using Augmented Component-Plus-Residual plots. There was no evidence to suggest any non-linear relationships. Inspection of kernel density plots showed that residuals were approximately normally distributed. Visual inspection of residual plots indicated little evidence against the assumption of homoscedasticity of errors. The mean Variance Inflation Factor (VIF) was 1.35, which suggested no concerning collinearity among the predictor variables. Finally, there was no evidence from a link test for model specification that the model had been incorrectly specified.

3.7.7 Examining the role of personal characteristics

In our sample, around a third of the participants (75/234=32.05%) did not answer demographic questions. We examined whether providing demographic data was associated with the outcome or was potentially confounding any of the other observed associations. We defined ‘providing demographic data’ as having answered at least four of the eight demographic questions in the original questionnaire. There was little change in the effect estimates from the joint model (Model 4) when ‘demographic data status’ was added to the model (data not shown).

3.7.8 Exploratory analysis with the addition of demographic data

We also examined the effect of particular demographic characteristics among those who provided demographic data. In this model (Model 6), we included the following demographic items: gender (male/female), age (young/middle-aged/older-aged), marital status (partner/no partner), work status (working/not working), and socio-economic status (from most disadvantaged (1) to most advantaged (10)). The addition of the demographic variables significantly improved the variance in the level of political trust in an intermediate institution outcome explained by the model (F (17, 78)=7.76, $p< 0.000$, Adj. R^2 0.51, Root MSE 0.77, 96 observations). In addition to perception of citizen power or lack of power, perception of transparency of policy decision making, evaluation of engagement exercise, and political trust in remote political institution another variable showed a significant association: exclusive input from experts (see Table 4.7 for a comparison between Models 2, 4, and 6). Because the number of observations for the group providing demographic data is almost one third smaller than for the main regression model, these results should be interpreted cautiously.

g. Table 3.7 Relational and rational trust-building elements with the addition of demographic data

Predictor	Model 2				Model 4				Model 6			
	B	SE B	95%CI†	p-value	B	SE B	95%CI†	p-value	B	SE B	95%CI†	p-value
Familial trust	0.07	0.21	-0.34, 0.49	0.712	0.01	0.17	-0.32, 0.35	0.927	0.07	0.20	-0.32, 0.47	0.721
Social trust (multi-item)	-0.04	0.09	-0.22, 0.13	0.629	-0.08	0.09	-0.27, 0.09	0.345	-0.02	0.12	-0.28, 0.22	0.834
Political trust (local institutions)	-0.05	0.14	-0.34, 0.22	0.687	-0.08	0.13	-0.34, 0.18	0.537	-0.17	0.15	-0.48, 0.13	0.271
Political trust (remote institutions)	0.54	0.07	0.38, 0.70	<.0001	0.36	0.08	0.20, 0.52	<.0001	0.35	0.11	0.12, 0.58	0.003
Perception of citizen power or lack of power					0.32	0.07	0.16, 0.48	<.0001	0.33	0.10	0.12, 0.54	0.002
Perception of transparency of policy decision making					0.34	0.10	0.14, 0.54	0.001	0.42	0.12	0.18, 0.66	0.001
Evaluation of engagement exercise					0.19	0.06	0.05, 0.33	0.005	0.18	0.07	0.03, 0.34	0.019
Perception of corruption in Australian government					-0.03	0.05	-0.13, 0.07	0.518	-0.03	0.09	-0.21, 0.14	0.729
Public input in policy decision making					0.01	0.08	-0.16, 0.18	0.889	-0.06	0.10	-0.28, 0.15	0.556
Perception of complexity of policy decision making					0.00	0.08	-0.17, 0.17	0.974	0.08	0.09	-0.11, 0.27	0.406

Exclusive expert input in policy decision making					-0.09	0.06	-0.22, 0.02	0.122	-0.22	0.06	-0.35, -0.08	0.002
Gender: male*									-0.13	0.17	-0.48, 0.20	0.432
Age: middle*									0.22	0.19	-0.16, 0.61	0.251
Age: old*									0.57	0.35	-0.13, 1.29	0.112
Marital: partner*									0.19	0.21	-0.23, 0.61	0.367
Work: not working*									-0.74	0.26	-1.27, -0.20	0.007
IRSAD: most advantaged*									0.04	0.19	-0.33 0.42	0.803
Adjusted R-squared	0.2227				0.4492				0.5195			

†CI-Confidence Interval, *Demographic data referent levels: Gender: female, Age: young, Marital: no partner, Work: working, IRSAD: most disadvantaged.

3.8 Discussion

The regression model that included relational and rational trust-building elements delivered some important results. In particular, it revealed a number of potential predictors for political trust in an intermediate institution like the state government. Specifically, it provided empirical support for hypotheses 3, 4, 5, and 7. This means that there is a positive association between each of the following and the level of political trust in an intermediate institution like the state government:

- level of political trust in remote institutions like the federal government;
- evaluation of government public engagement exercise;
- perceived level of transparency of government policy decision making; and
- perceived level of citizen power.

Cook et al. (28) have highlighted the role of transparency in processes in increasing confidence in institutions, and our regression model supported this idea. The more our participants perceived that they could influence decisions, and the more they perceived decision-making processes as transparent, the higher was their level of trust in the state government. In particular, evaluating the engagement exercise positively was associated with a higher level of trust. However, from our data, we cannot infer that there was a causal relationship between any of the predictors in our model. State government decisions impact directly on the day-to-day dealings of citizens. When citizens understand the rationale for state government decisions and feel that they are a part of policymaking, their level of trust in the state government tends to increase.

Our model revealed that some factors did not appear to predict political trust in an intermediate institution. Specifically, it did not provide support for hypotheses 1, 2, or 6. This means that there was little evidence to suggest an association between any of the following factors and political trust in an intermediate institution like the state government:

- level of familial or social trust;
- level of political trust in local government institutions; or
- perceived level of corruption.

Half of the participants in our study perceived the Australian government to be honest, and the other half perceived it to be corrupt. These results made it difficult to ascertain whether the perceived level of corruption influenced trust in an intermediate institution. Trust in one's immediate family and social trust were not significantly associated with trust in the state government. Indeed, the only relational factor associated with trust in the state government was trust in remote political institutions like the federal government. Therefore, our results provided little support for the relational trust-building theory that trust in other people can influence trust in institutions. Instead, our results provided substantial empirical support for the rational trust-building theory that trust is the result of the public evaluating the government positively in terms of its transparency and their involvement in decision making. This finding has significant implications for conceptualising, measuring and, in particular, building political trust in intermediate political institutions like the state government. These types of institutions need to focus on performing well with respect to being transparent and seek to meaningfully involve the public in decision making to increase public trust.

Although we did not detect any strong effects of relational elements on the level of trust in state government, our findings are consistent with more general aspects of relational trust-building theories. We found that trust in intermediate institutions like the state government can, and therefore should, be examined as a separate sub-concept from federal and local governments, in line with calls from Levi and Stoker (25), who suggest that there may be differences in trust between diverse government levels. We found that the public <u>does</u> distinguish the state government from the federal government. However, trust in the state government rises and falls with trust in the federal government, probably because both levels of government are experienced as similarly remote or distal from one's everyday activities. Our analysis of social trust (multi-item) suggests that measures of social trust should be contextualised. For example, our study showed that trust in people at one's church or place of worship might not be a helpful item to be included in Australian surveys due to the low response rate. According to data from the Australian Bureau of Statistics (42), around 25% of Australian residents do not report any religious affiliation, and there is a downward trend in people identifying with specific institutionalised religions.

The literature contains a mix of results concerning the influence of demographic characteristics on trust (31, 43). We have canvassed that literature and compared it to our results. Based on an empirical study, Jennings and Stoker (44) propose that social trust varies with age, and changes throughout a person's life: trust was found to decline as people transition from adolescence into young adulthood but then rise again as people age. This pattern of change also finds support in the theorising of Uslaner (31). However, Jennings and Stoker (44) warn that socioeconomic status may either independently influence or confound the relationship between trust and age. Socioeconomic factors have been found to influence social trust. In particular, income inequality has been shown to have a significant effect on trust in cross-national studies (45): the greater the inequality in income, the lower the level of social trust. When proposing government policies that could increase trust, Knack and Zak (46) suggest these should focus on reducing economic inequality. There is conflicting evidence regarding the influence of gender on social trust. In a study using trust games to investigate gender differences in adolescents, Derks, Lee, and Krabbendam (47) found males to be more trusting than females. However, Job used a survey instrument and found that females have a higher level of social trust relative to males (20). Meanwhile, other studies using survey measures did not find gender to be a significant predictor of social trust (31, 48). Finally, with respect to marital status, Lindström (49) found that unmarried and divorced men and unmarried women had lower levels of generalised trust than married or widowed men and women and divorced women. However, results from a second study have not found this same relationship (48).

In the present study, we did not detect significant associations between age, gender, socioeconomic status or marital status and political trust. Only work status was found to be associated with political trust: people who are not working have a lower level of trust in government compared to those who are in the workforce. However, this result was based on only a subset of our study participants, as almost one-third of respondents did not provide demographic data. Findings regarding the effects of demographic characteristics should be interpreted with caution and may not be readily generalised to either the whole survey sample or the wider population.

3.8.1 Study limitations

Our study was a cross-sectional survey, and there are limitations with respect to the measurement of trust through such an instrument since there are time-variant and confounding factors that cannot be captured. We suggest that surveys regarding meso-level institutions, in particular state governments, could be conducted using longitudinal designs, thereby minimising the effect of potentially confounding factors such as the current economic climate and the influence of public opinion on elected officials. Our survey participants took part in a state government public engagement process, which may have affected their base level of trust in state government. These participants also had direct contact with state government via the engagement process, while most of the broader population would not have such contact in their day-to-day interactions. Our familial trust measure was treated as a single item in the regression model, whereas the typical familial trust measure includes multiple specific inner social circles (e.g., work colleagues), and these differences may have influenced the results regarding the effects of familial trust.

3.9 Conclusion

It has been argued that trust in government is a multi-factorial concept (22). Our research shows that rational trust theories are largely able to account for trust in state government. Political trust in an intermediate institution like the state government is associated with positive evaluation of government public engagement exercises, perception of transparency of government policy decision, and the perception of citizen power over government decisions. However, political trust in the state government does not seem to be associated with perception of government corruption.

Alongside rational trust theories, relational trust theories do help explain variation in political trust, but only a little. Specifically, relational trust theories help to account for the association between trust in state government and trust in remote institutions like the federal government. Political trust in an intermediate institution like the state government is positively associated with political trust in remote institutions like the federal government, but it is not associated with familial or social trust or political trust in local government institutions. We found evidence that our sample does tend to view the state government as a separate institution from the federal government. However, the public may experience both levels of government as similarly remote or distal from its everyday activities.

These findings commend more public involvement in policymaking on the part of intermediate institutions like the state government (50). Our research highlights that such engagement may help to increase public trust by allowing the public to view the government as performing well in terms of being transparent and meaningfully involving the public in its decision making. Engagement processes cannot afford to be trivial or tokenistic in the eyes of the public. They need to be conducted in a way that participants evaluate positively because this evaluation influences trust in government. Governments may also enhance public trust by developing policies that increase the transparency of decision making in general. Our research has produced empirical evidence to support these ideas.

3.9.1 Future directions for research

We examined trust in state government and how it relates to the involvement of the public in policy decisions. We included some measures of trust related to participants' evaluation of the government decision-making process. However, policy decision making is a complex concept, and the development and validation of a scale to measure the public's perception of government decision processes would be valuable in future trust studies.

We also used some specific measures of social trust and trust in state government. Development of country-specific multi-item social trust measures would also assist in the further development of trust-building theories.

3.10 Acknowledgements

EL was part-funded by a scholarship from the Government of South Australia and by the Australian Department of Education, Employment, and Skills. The authors would like to acknowledge the advice provided by Dr Stuart Howell at an earlier stage of the project.

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Chapter 4: Public involvement in the healthcare sector and HTA

In Chapter 3, one of the challenges identified in the public involvement field was the absence of clear justification for engaging the public in government policy decisions. This chapter explores the drivers for the engagement of external stakeholders in healthcare systems, presents some of the ways in which public involvement has been conceptualised, and describes the core challenges in this field.

The central debates around public involvement in healthcare and the specific topics that informed the conceptualisation of this PhD research project are explained below. Specifically, this chapter addresses some of the determining factors for public involvement (related to the 'why' of the main research question) and the problems in the implementation of such initiatives (related to the 'how' of the main research question). These two topics are presented first in the context of broad healthcare policy development (sections 4.1 to 4.4) and then specifically in relation to HTA (sections 4.5 and 4.6).

4.1 Patient and public involvement in policy

In this chapter, public involvement is considered a separate concept from patient involvement. This will be discussed in more depth in Chapter 5, where a taxonomy for the involvement of different groups in HTA will be presented.

Countries around the world struggle with the administration of the health sector as there is a constant tension between, on one side, increasing costs and scarcity of resources (financial and human) and, on the other, rising demand for treatments and services. Governments have implemented various governance policies to assist in the management of healthcare systems to try to align the needs of those working within them and of those expected to use health services. Some administrators have tried to implement new governance structures, such as shared governance (1) or clinical governance (2), to help solve these problems. The principal problem with these approaches is their exclusive focus on attending to the needs of internal stakeholders within the health sector. However, various factors have pressured governments to increase the involvement of external stakeholders in healthcare decisions, particularly patients and the public.

4.2 Patient involvement in healthcare

In the late 1970s, the World Health Organisation's Declaration of Alma Ata (3) stated:

> The people have the right and duty to participate individually and collectively in the planning and implementation of their health care. (3)

The Alma-Ata Declaration was one of the first official calls for the increased involvement of patients in their treatment and in the development of healthcare policies. The Declaration was followed by a range of actions by governments globally to increase the involvement of patients in decisions, which focused mainly on patient satisfaction as a measure of healthcare quality (4-6). This emphasis on patients as customers and patient satisfaction, however, has been shown to be problematic, and Barnes (7) and Williams (8) describe this approach to patient involvement as paternalistic (9), since it does not take into account the will of patients. Reducing the role of patients in healthcare decisions to that of consumers exacerbates the existing power differentials between those who provide care and those who receive care (10).

4.3 Public involvement in healthcare

A seminal work by Arnstein (11) guided much of the initial discussion in defining the nature of public involvement processes. Arnstein developed a typology of citizen participation based on how much control over decisions the powerful shared with the powerless (in her work, the latter was represented by citizens). Some public involvement strategies were classified as forms of 'non-participation' (called by Arnstein Manipulation and Therapy), others were classified as tokenistic (Informing, Consultation, and Placation), and some forms were classified as allowing citizens to have control and power to influence decisions (Partnership, Delegated Power, and Citizen Control). Arnstein's work was developed during the 1960s, when the social movements for public input in government policy and demands for power-sharing were high, which explains the uncompromising tone of this work (12).

Some researchers have built on Arnstein's idea, in which the level of public involvement is examined only from the public or citizen perspective (13). However, others have criticised this approach. Bishop and Davis (14) suggest that public involvement processes should not be considered as being on a continuum from non-participation to full-participation; rather they should be seen as discontinuous, with different strategies being used in diverse circumstances. For example, consultations can be a useful instrument at times to 'gauge community reaction to a proposal and invite feedback' (p. 27) or a referendum could be used to 'hand control of an issue to the electorate' (p. 27). On this view, one form of public involvement is not inherently better than another.

The differences between types of involvement processes are still being discussed in the literature of a variety of fields (e.g., environment, health). These debates highlight the diverse ideological and theoretical underpinnings of the methods proposed, many of which have their origins in contrasting democratic theories, particularly theoretical frameworks concerning representative and participatory democracy (15, 16). In representative democratic theories, the public elects their government representatives, whom they entrust to run the government and make decisions on their behalf. Candidates represent the points of views of various segments of the population, and public influence in decisions and policy development happens indirectly (15). Theories of representative democracy suggest that direct public involvement is unnecessary. By contrast, participatory democracy theories purport that, alongside electing representatives to look after their interests, members of the population should also be directly engaged in specific decisions and policies to fulfil democratic aspirations (16).

Public involvement processes that are akin to representative democratic practices tend to follow pragmatic considerations of obtaining relevant information to solve specific policy problems (17). The information gathered can be used, in conjunction with other considerations, by the elected representatives and their delegates to make decisions. Alternatively, processes that follow a participatory approach are concerned with the public's ability to influence decisions, and the direct input from the affected publics is considered necessary to support well-informed and legitimate decision making (17). In the healthcare literature, these contrasting approaches are known as technocratic versus democratic. Technocratic processes are concerned with objective and evidence-based information to be included in decision making, whereas democratic processes are concerned with inclusiveness and place great value on who takes part in policy decisions and how they are involved (17, 18).

4.4 Challenges in involving the public in healthcare settings

At the same time as there was an increased push for patient involvement in health care, social movements also demanded more 'public involvement' in government policy development more generally. In response to the increased calls for public involvement in healthcare, governments made changes to their governance structures and started to develop mechanisms to involve the public (as discussed in Chapter 3). In the United States, in the 1970s, regulations requiring the involvement of the public in decentralised health care planning units, known as Health Systems Agencies (HSAs), spread across the country (19, 20). Canada, the United Kingdom and Australia followed suit by developing a range of methods for involving the public in the health sector (21-23). Public participation has gradually increased over the years, and programmes to facilitate further engagement are still high on most government agendas (24). However, the action has often lagged behind the rhetoric and, in some cases, public involvement has not been maintained.

The extant literature on public involvement in health policy has claimed positive outcomes for public involvement initiatives (22, 25): increasing accountability to the population on how resources have been allocated, providing policymakers with information that can assist in problem-solving during the development of new policies, fostering trust, and reducing conflicts.

Some writers, however, have pointed to potential drawbacks related to involving the public in policy decisions (26), such as increasing the time for decisions to be made, increasing costs for governments, the difficulty of changing decisions once they have public approval, and possibly decreasing trust in government (26, 27).

In some instances, encouraging results have been found after some public involvement processes have been implemented (28). Most recent research has stated that there is a need for the development of robust methods for evaluating public involvement processes (29), as their impact in healthcare policy is difficult to assess due to a lack of standard definitions for what public involvement is and who is being involved (who the ‘public’ is). Additionally, the objectives for involvement are not well developed, and which involvement approaches should be adopted is not always clear (29, 30).

One of the challenges in this area starts with definitions for public involvement processes. The scholarly literature lacks definitions for terms such as involvement, engagement, and participation but it also conflates the terms public and patient. In this thesis, 'involvement' has been used as an umbrella term to include a variety of processes independent of their conceptual underpinnings (10, 28). The public here is defined as per the taxonomy presented in Chapter 5: 'A community member who holds the public interest and has no commercial, personal, or professional interest in the HTA process.' (31).

4.5 Healthcare management and HTA

The major concerns for those managing healthcare systems are regulatory and financial issues, particularly those related to ensuring the safety and quality of services (32) and long-term sustainability (33). HTA can help health system managers assess health technologies to be introduced or removed from healthcare systems (34, 35). Health technologies include a range of medical interventions such as medical services, surgery, medicines, vaccines, health programs, and the actual delivery of health care (36). According to Health Technology Assessment international Glossary, HTA can be defined as:

> A multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle. The purpose is to inform decision-making in order to promote an equitable, efficient, and high-quality health system.
> Note 1: Definition of health technology.
> Note 2: The process is formal, systematic and transparent, and uses state-of-the-art methods to consider the best available evidence.
> Note 3: The dimensions of value for a health technology may be assessed by examining the intended and unintended consequences of using a health technology compared to existing alternatives. These dimensions often

> include clinical effectiveness, safety, costs and economic implications, ethical, social, cultural and legal issues, organisational and environmental aspects, as well as wider implications for the patient, relatives, caregivers, and the population. The overall value may vary depending on the perspective taken, the stakeholders involved, and the decision context.
> Note 4: HTA can be applied at different points in the lifecycle of a health technology, i.e., pre-market, during market approval, post-market, through to the disinvestment of a health technology. (37)

Policymakers from several developed and developing nations use HTA reports to assist them in making healthcare funding decisions (38-42). Publicly funded systems, such as in Australia, use HTA to inform reimbursement decisions (41), and in privately funded systems, such as in the United States, insurers use HTA to select which items to cover (43).

4.6 Involving the public and patients in HTA

In HTA processes, evidence on what can impact the introduction of a health technology in a healthcare system is collected and analysed, and medical, economic, social, and ethical concerns are considered. Patients and the public can provide, respectively, information that is relevant to the medical aspects and to social and ethical aspects of health technologies (44). It has been argued that the public can specifically help with issues related to the broader social value of funding health technologies (45). In this thesis, social, societal or public value refers to the concept of ‘terminal value’ as defined by Shams et al. (46), which includes some characteristics such as being able to affect one’s choices, being more resistant to change over time than other types of beliefs, being able to motivate people to sacrifice their individual interests, being trans-situational. Terminal values are related to results of policymaking, according to Shams et al. (46), which makes them appropriate to the investigation of stakeholders' values in healthcare funding policy decisions. When participants present their views as arising from their broader beliefs and as not related to their (or their stakeholder group) immediate benefit, for example, these views are assessed as terminal values.

Patient involvement in HTA has enjoyed growing acceptance in HTA circles (47). However, there is evidence that HTA agencies themselves are not comfortable with adding 'public involvement' to their processes as these organisations already have stretched resources meeting the rigorous demands of the HTA process (48). The lack of clear taxonomies of processes (49) and their effectiveness (50) have also been pointed out as reasons for resistance in adopting public involvement processes in HTA.

Despite all these challenges and due to government pressure, several methods have been employed to involve the public in HTA (50). This has brought to light questions that are commonly found in other areas of healthcare, such as why involve the public and whether it differs from involving patients (51, 52). Because the rationale for involving different types of stakeholders is not established, it has been unclear which type of group (patient or the public) can contribute to healthcare funding decisions and how. The next chapter will discuss the rationale for public involvement in HTA (Chapter 5).

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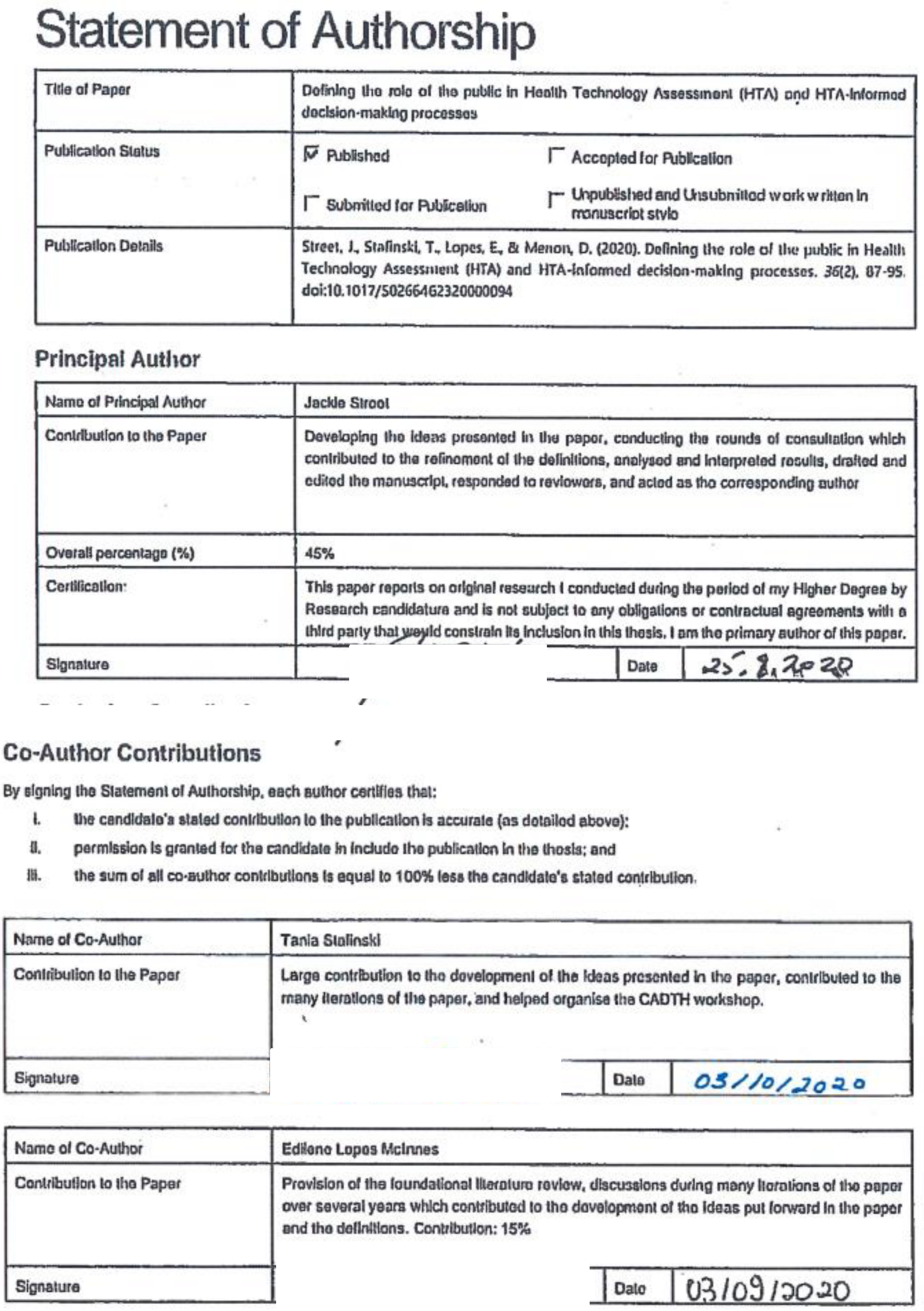
Chapter 5: Definitions of the public and patients in the literature

In Chapter 4, background literature on patient and public involvement in the healthcare s presented. The present chapter will focus on public involvement in Health Technology Assessment (HTA), and it will tackle one of the main issues in this area: how to define who the 'public' is in comparison to other healthcare system stakeholders (such as patients and caregivers).

Chapter 5 explores the types of groups that can be involved in HTA and healthcare funding decisions and highlights the research gap related to the rationale of public involvement in HTA discussed in the previous chapter. The paper presented here proposes a taxonomy for defining the 'public' as a different group from patients and presents a rationale for public and patient involvement in HTA based on scholarly literature and the views of HTA practitioners. The results of this study relate to the first and second sub-questions of this thesis: Why involve the 'public' in healthcare funding decisions? How can the 'public' be defined in HTA? It also helps answer the main research question (Why and how should the public be involved in HTA and healthcare funding decision-making processes?).

This article provides the first step in the discussion of public involvement specifically in HTA, and it will be followed by an in-depth examination of a case study in Canada, which will be discussed in Chapters 6, 7, and 8.

5.1 Statement of authorship



Statement of Authorship

Title of Paper	Defining the role of the public in Health Technology Assessment (HTA) and HTA-informed decision-making processes
Publication Status	☑ Published ☐ Accepted for Publication ☐ Submitted for Publication ☐ Unpublished and Unsubmitted work written in manuscript style
Publication Details	Street, J., Stafinski, T., Lopes, E., & Menon, D. (2020). Defining the role of the public in Health Technology Assessment (HTA) and HTA-informed decision-making processes. 36(2), 87-95. doi:10.1017/S0266462320000094

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Contribution to the Paper	Developing the ideas presented in the paper, conducting the rounds of consultation which contributed to the refinement of the definitions, analysed and interpreted results, drafted and edited the manuscript, responded to reviewers, and acted as the corresponding author		
Overall percentage (%)	45%		
Certification:	This paper reports on original research I conducted during the period of my Higher Degree by Research candidature and is not subject to any obligations or contractual agreements with a third party that would constrain its inclusion in this thesis. I am the primary author of this paper.		
Signature		Date	25.8.2020

Co-Author Contributions

By signing the Statement of Authorship, each author certifies that:

i. the candidate's stated contribution to the publication is accurate (as detailed above);
ii. permission is granted for the candidate in include the publication in the thesis; and
iii. the sum of all co-author contributions is equal to 100% less the candidate's stated contribution.

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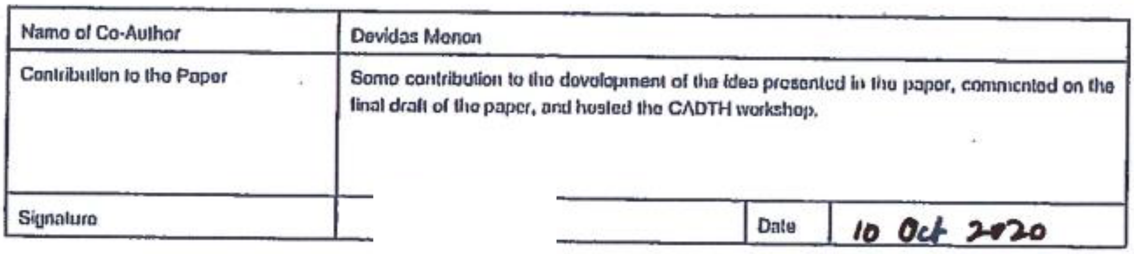
Contribution to the Paper	Large contribution to the development of the ideas presented in the paper, contributed to the many iterations of the paper, and helped organise the CADTH workshop.		
Signature		Date	03/10/2020

Name of Co-Author	Edilene Lopes McInnes		
Contribution to the Paper	Provision of the foundational literature review, discussions during many iterations of the paper over several years which contributed to the development of the ideas put forward in the paper and the definitions. Contribution: 15%		
Signature		Date	03/09/2020



Name of Co-Author	Devidas Menon		
Contribution to the Paper	Some contribution to the development of the idea presented in the paper, commented on the final draft of the paper, and hosted the CADTH workshop.		
Signature	[redacted]	Date	10 Oct 2020

5.2 Abstract

Article title: Defining the role of the public in Health Technology Assessment (HTA) and HTA-informed decision-making processes

Objectives: The terminology used to describe community participation in Health Technology Assessment (HTA) is contested and frequently confusing. The terms patients, consumers, public, lay members, customers, users, citizens, and others have been variously used, sometimes interchangeably. Clarity in the use of terms and goals for including the different groups is needed to mitigate existing inconsistencies in the application of Patient and Public Involvement (PPI) across HTA processes around the world.

Methods: We drew from a range of literature sources in order to conceptualise (i) an operational definition for the 'public' and other stakeholders in the context of HTA and (ii) possible goals for their involvement. Draft definitions were tested and refined in an iterative consensus-building process with stakeholders from around the world.

Results: The goals, terminology, interests, and roles for PPI in HTA processes were clarified. The research provides rationales for why the role of the public should be distinguished from that of patients, their families, and caregivers. A definition for the public in the context of HTA was developed: a community member who holds the public interest and has no commercial, personal, or professional interest in the HTA process.

Conclusions: There are two distinct aspects to the interests held by the public which should be explicitly included in the HTA process: the first lies in ensuring democratic accountability and the second in recognising the importance of including public values in decision making.

5.3 Paper

International Journal of Technology Assessment in Health Care

cambridge.org/thc

Method

Defining the role of the public in Health Technology Assessment (HTA) and HTA-informed decision-making processes

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Objectives. The terminology used to describe community participation in Health Technology Assessment (HTA) is contested and frequently confusing. The terms patients, consumers, public, lay members, customers, users, citizens, and others have been variously used, sometimes interchangeably. Clarity in the use of terms and goals for including the different groups is needed to mitigate existing inconsistencies in the application of patient and public involvement (PPI) across HTA processes around the world.
Methods. We drew from a range of literature sources in order to conceptualize (i) an operational definition for the "public" and other stakeholders in the context of HTA and (ii) possible goals for their involvement. Draft definitions were tested and refined in an iterative consensus-building process with stakeholders from around the world.
Results. The goals, terminology, interests, and roles for PPI in HTA processes were clarified. The research provides rationales for why the role of the public should be distinguished from that of patients, their families, and caregivers. A definition for the public in the context of HTA was developed: A community member who holds the public interest and has no commercial, personal, or professional interest in the HTA process
Conclusions. There are two distinct aspects to the interests held by the public which should be explicitly included in the HTA process: the first lies in ensuring democratic accountability and the second in recognising the importance of including public values in decision making.

Cite this article: Street J, Stafinski T, Lopes E, Menon D (2020). Defining the role of the public in Health Technology Assessment (HTA) and HTA-informed decision-making processes. *International Journal of Technology Assessment in Health Care* **36**, 87–95. https://doi.org/10.1017/S0266462320000094

Received: 1 August 2019
Revised: 10 December 2019
Accepted: 31 January 2020
First published online: 10 March 2020

Key words:
Health technology assessment; Methodology; Community participation; Patient participation

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It has been 50 years since Arnstein published her seminal paper, "A ladder of citizen participation" (1). It aimed to distinguish between *citizen control* and empowerment and *citizen consultation* and levels of "tokenism." Some 40 years later, Tritter and McCallum (2) published a critique of Arnstein's model, suggesting that her emphasis on power undermined the potential of involvement processes. Tritter and McCallum explored the involvement of users of health care in healthcare decision making, focusing on the aspects of effective involvement that Arnstein's model did not consider (Arnstein's "missing rungs" (2, p.161)).

From "citizens" to "users," Tritter and McCallum's paper reflected a neoliberal shift in citizen involvement to that of "future service users" and "potential patients" (2, p.160). The shift emerged from the notion that markets could improve health service provision by "giving [patients] purchasing power—i.e. making them *customers* of primary care services" (emphasis in the original text) (3, p.95). The term "user" employed by Tritter and McCallum (2) is consistent with "consumer," the term preferred in Australian government circles.

The debate over terminology continued. Coulter suggested that it was "easy to stumble into semantic minefields when writing about patient engagement" (4, p.8), and rejected the use of alternative terms to "patient." However, in many countries, the term fell out of use in a context which saw service delivery as operating within a market. The term "citizen," on the other hand, suggests a reciprocal arrangement with the state in which individuals have both rights and responsibilities. It also carries notions of nationality and may be seen to exclude noncitizen residents. While the term "citizen" includes patients, in recent years "public and patient" or simply "public" involvement has mostly engaged those presenting patient and/or carer perspectives. (5)

Public and patient involvement in Health Technology Assessment (HTA) and HTA-informed decision making, at least initially, appears to have been undertaken with relatively little attention to the roles these groups might play. Boothe suggests that, without any clear goals, the inclusion of public members in the Canadian Drug Expert Committee was a response to demands by patients' groups "and a reluctance on the part of experts in agencies responsible to involve patients directly on the committee" (6, p.639). She also documents how our iterative engagement (7), described in this paper, sparked intense reflection and debate amongst researchers, agencies, and patient communities (6) with one ministry official commenting, “they’re working on trying to make a conceptual distinction between patient and public…I find that really hard to draw, except at the extreme case” (6, p.640). As of November 2019, there is no definition of “public” provided in the glossary of Health Technology Assessment international (HTAi) (8) or HTAGlossary.net although there are definitions of patient, consumer, user, advocate, and patient representative (see Table 1). In the main, the definitions describe the type of individual involved and not the interests that they represent. To date, in many cases, the distinction between “public” and “patient” or “consumer” has failed to penetrate the working processes of HTA and HTA decision making. A summary of public and patient involvement across countries is provided in Supplementary Table 1.

Implications for Health Technology Assessment

The lack of clarity in the use of these terms has resulted in their inconsistent application across HTA processes around the world. HTA is a multidisciplinary process through which governments compare new health technologies with existing publicly funded medicines, services, and devices. It is based on a systematic evaluation of safety, effectiveness, cost-effectiveness, and social, ethical, and legal factors. It supports decisions on which technologies to fund and, in some cases, which ones not to fund (9;10).

The past 10 years have seen increasing demand for patient and public involvement (PPI) in HTA and HTA-informed policy decision making (11;12). This has stemmed from a broader move toward patient-centered care in all health systems, a focus on patient empowerment and the associated collectivization of patient voices in patient organizations and lobby groups (12). Also, a desire to address a “democratic deficit” in representative democracies has emerged. Democratic deficit refers to a point at which the public becomes disaffected with governments and political matters because they are not aligned with public aspirations (13). In general, stakeholders, including clinicians, industry, HTA agencies, and government departments, have responded favorably to patient involvement in HTA processes. Patient involvement supports a broad panel of objectives, including improved practice, transparency, legitimacy, and comprehensiveness through the incorporation of valuable information about the “lived experience” of patients and carers (12). However, concern remains that a focus on patient interests may increase pressure to publicly fund particular services, drugs, and devices outside the usual funding criteria. Consideration of public interests—namely appropriate use of limited resources and preservation of a well-functioning health service—can act to mitigate these concerns.

Currently, most HTA decision-making processes are based on systematic reviews of safety and effectiveness and an economic evaluation that generates a cost per quality-adjusted life years (QALYs) and an incremental cost-effectiveness ratio (ICER). If the process reflects the values held by society, the use of QALYs assumes that the public and patients highly value population health maximization. In most countries, however, there has been little empirical work on what the public values in terms of health technologies or what constitutes the public interest. Where this research has occurred, the public prioritized funding of technologies based on other criteria, namely, equitable distribution of resources, life-saving treatments, prevention, and interventions for children (14;15).

In Australia, the Consumer Consultative Council is designed to reflect consumer rather than public interests. The Pharmaceutical Benefits Advisory Committee (PBAC) and Medical Services Advisory Committee (MSAC) processes allow and invite public input but the process primarily attracts submissions from patients, carers, and patient advocacy groups (16). In 2006, the Canadian Drug Expert Committee added two public members and the Ontario Committee to Evaluate Drugs added two patient representatives but the role of both is to collect, interpret, and present information from patient groups (6).

In the UK, through input from the Citizens Council, NICE has included a public perspective on broad moral and ethical issues in public healthcare policy sometimes at odds with economic imperatives (17). Recommendations from the Citizens Council are not directly incorporated into NICE guidance but are included in Social Value Judgement documents with which decisions are expected to align. The Citizens Council has examined trade-offs between equity and efficiency (14), and departures from the recommended ICER threshold (15). Whilst this has provided important community input into specific moral and ethical issues surrounding health funding decisions, it does not provide public input in the same way that clinician, health economist, and consumer advocate input is currently provided. In addition, it is unclear whether the general value statements are interpreted such that the final decisions would align with technology-specific recommendations if they were made directly by a public panel.

Despite the involvement of patients and the public in HTA processes for more than a decade, standardized methods are underdeveloped. This has resulted in the use of the terms “patient” and “public” interchangeably in many HTA organizations. (5;6). The lack of guidance around the use of terms is at odds with the traditionally rigorous standards employed in HTA to assess the safety, effectiveness, and cost-effectiveness of health technologies (18;19). It also contributes to the potential for “mismatched expectations” (5, p.96) in decision making, leaving PPI in the HTA process open to criticism. In addition, where this conflation occurs, public interests may not be explicitly included in HTA decision making but rather they are considered in an *ad hoc* manner dependent on the inclination of those involved.

This paper clarifies the goals, terminology, interests, and roles for public involvement in HTA processes and provides a rationale for why the role of the public should be distinguished from that of patients, their families, and caregivers.

Methods

The term HTA was used as defined in HTAGlossary.net (accessed November 2019), an official collaboration between the peak HTA bodies including HTAi and International Network of Agencies for HTA. This definition excludes “decision making” from HTA. The decision-making step is an important point for the incorporation of public values in funding decisions and therefore we included the consideration of HTA-informed decision making in this work. To conceptualize an operational definition for the “public” in the context of HTA and possible goals for their involvement, we drew from (i) the literature reviews we had previously conducted on the use of deliberative methods in HTA (see 23 and 24 in Table 2), (ii) our own primary research on the inclusion of patient and public voices in HTA (see 16–19, 21, 22, 26, and 28 in Table 2), and (iii) additional relevant key scholarly papers identified primarily through a literature review conducted for the doctoral thesis of author EL and with a small number of

Table 1. Definitions in Common Usage in HTA

	Definition provided by HTAGlossary.net[a]	Definition provided by Glossary for Consumers and Patients, HTAi Patient and Citizen Involvement Interest Group[a]
Public	No definition provided	No definition provided
Patient	A person, presenting with clinical signs or not, who consults a physician. See consumer	See consumer
Consumer	A person who uses, is affected by, is entitled to or is compelled to use a health service. **Note:** In the health care field, the term *consumer* is used mainly in the United States, where there is no universal health insurance system. Elsewhere "patient" is often used, but since this word should be applied only to persons who consult a physician, terms such as *user*, *recipient* and *client* are used in the Canadian health system. **Syn.:** patient, user, recipient, client	A person who is the ultimate user of the health care resource. A consumer may or may not have a specific health issue, condition or disease. A patient is someone with a specific health condition. All patients are consumers, but not all consumers are patients
User	See consumer and patient	No definition provided
Carer/care giver	(1) A duly trained and paid person who provides a person with a disease or disability with care. (2) A person (often a family member or friend), paid or unpaid, who regularly provides a person with a disease or disability with any form of care.	A person who looks after family, partners or friends in need of help because they are ill, frail or have a disability. The care they provide is unpaid.
Lay	No definition provided	No definition provided
Stakeholder	No definition provided	No definition provided
Consumer representative	A person or organisation who/that is actively involved with others and presents the perspectives and concerns of a group of patients. **Syn.:** patient representative.	No definition provided
Consumer advocate	No definition provided	See advocate: Advocate: Someone who speaks on behalf of themself or another person. In health, an advocate is usually a person who speaks on behalf of a health care consumer or patient, or a group of consumers or patients. An example of an advocate is a person who is closely involved with consumers or patients or a consumer support group, and is able to voice any concerns and views of a consumer or patient group
Patient representative	See consumer advocate	See consumer advocate
Public/patient/ consumer member	No definition provided	No definition provided

[a] Accessed November 2019.

papers offered by participants in the consultation process described below (see 1–15, 20, 25, and 27 in Table 2).

We applied an iterative process with stakeholders over several years. Draft definitions were refined in consultation with academic researchers and practitioners of PPI processes in HTA, including members of the HTAi Patient and Citizen Involvement Group (PCIG) (http://www.htai.org/interest-groups/patient-and-citizen-involvement.html). We note that initially, the distinction between patient and public was highly contentious as some argued that all stakeholders, including patients and craft groups, were members of the public. A version of the document was released for a consultation to the PCIG/HTAi working groups during the period from July to September 2016. The feedback received was then used to refine the list of goals for involvement and develop a nomenclature for different types of public in the HTA process. Subsequently, the definition and goals were refined at a workshop involving individuals from different stakeholder groups at the 2017 Canadian Agency for Drugs and Technologies in Health (CADTH) Conference in Ottawa (7). A revised document was released to the PCIG, the workshop participants and the Australian public and patient engagement advocacy group, Health Technology Assessment—Australia (HTA-Aus), for a second round of consultation early in 2018. The final description was presented at the 2018 HTAi conference.

Findings

Participants in the consulted groups agreed that clearer definitions of PPI were needed. The rationale for patient involvement was seen as relatively well defined (12), namely to reflect the patient experience of diseases and technologies used in their treatment, to ensure that patient priorities were considered and to support the inclusion of the views of those stakeholders who would be most impacted by the decisions. Clearly, patients are consumers (or users) of technology but consumers may also be healthy individuals who undergo screening or use vaccines or other preventive technologies. The role of consumers in HTA is very similar to those of patients, namely to reflect the consumer experience with these technologies and to support the inclusion of consumer views in decision making. Goals for public involvement, which constitutes the public, the nature of public interests, and the lines of separation between public and patient and

Table 2. Literature Used to Support the Development of an Operational Definition for the "public" in the Context of HTA and Possible Goals for their Involvement

#	Reference	Contribution to concept development
1	Abels (32)	Describes the normative claims for citizen participation. Distinguishes between the scientific assessment of new technologies and the normative evaluation of their impact. Critiques and explores the functions, goals, and models of participatory technology assessment.
2	Abelson et al. (33)	Explores questions of which publics to involve and the goals of public engagement in health technology assessment. In particular, distinguishes between process-oriented goals and instrumental goals for this involvement.
3	Abelson et al. (34)	Collates the international HTA practice of patient and public involvement (PPI) in HTA agencies extracting the goals and rationales for PPI. Distinguishes between patients, the public, and other stakeholders, advocates the establishment of a *common language* to support PPI, and suggests the different groups should be involved at different stages in the HTA process.
4	Anderson et al. (35)	A case study of the development of public involvement structures in six UK primary health care organizations and in particular the meaningful inclusion of public voices in decision-making. Includes the value and goals of public involvement and some of the issues encountered in developing participatory processes. Critiques *Arnstein's Ladder* as a framework.
5	Barham (36)	Describes and critiques the involvement of patients and public members in NICE processes.
6	Bombard et al. (37)	Describes a Canadian empirical deliberative process eliciting the ethical and social values which should be considered in every assessment of a technology
7	Degeling et al. (38)	Distinguishes between different publics, particularly citizens, consumers and advocates, their roles, and the strengths that each bring to the process of public deliberation.
8	Degeling et al. (39)	Discusses the ways in which the public is framed in public deliberation, critiques claims of representativeness, and the value of public deliberation in policy decision making.
9	Fredriksson and Tritter (5)	Distinguishes between patients and citizens in community involvement in health care decisions and describes the slippage in the way in which the terms have been used. Highlights the interests of patients vs. citizens and the different perspectives, goals, and benefits each brings to decision making.
10	Gagnon et al. (40)	Systematic review of studies reporting participation of patient and public in the HTA process and the limited roles that they fulfil.
11	Gauvin et al. (41)	Conceptualizes public involvement in the context of HTA. Examines how *public involvement* is constructed in HTA and how the rationale for public involvement may conflict with HTA narrowly defined (i.e., a focus on effectiveness, safety, and cost-effectiveness).
12	Gauvin et al. (42)	Defines patients, the public, and stakeholders and describes the theorized goals of public and patient engagement in HTA.
13	Guttman (43)	Discusses the theoretical and pragmatic issues involving *ordinary* citizens in public deliberation on policy issues. Defines the goals and benefits of public deliberation and normative concerns in public participation initiatives. Explores the potential clash between normative and instrumental goals in public deliberation.
14	Jorgensen and Bozeman (44)	This paper attempts to elicit the boundaries and meanings of public values and the public interest from relevant literature primarily drawn from the area of public administration.
15	Lehoux et al. (45)	Challenges the notion of the "ordinary" citizen. Explores the complexity and richness of the contribution of four individual citizens within a public deliberation process.
16	Lopes et al. (46)	Examines beliefs about the role of patients and public in HTA and hence what Australian Advisory Committee members consider to be reliable information to inform the HTA process.
17	Lopes et al. (47)	Explores the idea of representativeness in HTA and the inadequate explication of the role (task) of patients and patient input in HTA processes in Australia at the time.
18	Menon and Stafinski (48)	Sets out potential roles for patients and the public in HTA. Distinguishes between the roles that patients and the public can fulfil and suggests that they are considered separately when they are involved in HTA.
19	Merlin et al. (49)	Using social media extracts public and patient views on the use of selected health technologies. This process demonstrated the different functions these two groups bring to HTA.
20	Nabatchi (50)	Explores the nature of public values and provides a framework of goals for public participation corresponding to a spectrum of participation.
21	Ploug-Hansen and Street (51)	Discusses the interests held by patients including patients as a group across the disease spectrum. Sets out the terms used to describe patients in HTA and how these terms define the type of participant included in the process and the goals (implicit, explicit, or indefinite) which underpin their inclusion/exclusion.
22	Stafinski and Menon (52)	Uses citizens juries (Canadian) to generate social value statements demonstrating consistency in the findings across juries.
23	Street et al. (53)	Examines the ways in which publics have been selected for citizens juries for health policy decision-making. Critiques the use of the term citizen in juries and how well juries support "active" citizenship.

(*Continued*)

Table 2. (*Continued.*)

#	Reference	Contribution to concept development
24	Street and Lopes (54)	Examines the nature of deliberation in HTA and those factors which contribute to good deliberation. Distinguishes between patients and the public. Maps current potential stakeholders in HTA deliberations and the interest that they hold.
25	Whitty (55)	Documents international practice in public and patient engagement in HTA organizations.
26	Wortley et al. (56) 24.	Describes the factors—and hence the underpinning goals—which determine the choice of public engagement in HTA organizations. Distinguishes between different types of public.
27	Wortley et al. (57)	Provides community views on public and patient engagement in HTA in Australia. The findings indicate potential goals for the inclusion of publics including patients or consumers.
28	Young et al. (58)	Explores the role of patients with rare diseases in the orphan drug lifecycle.

consumer interests were seen as much less well defined. Participants described six possible goals for public involvement in HTA.

The Goals and Rationale for "public" Involvement

The goals for including the public are shown in Table 3.

The rationale for these goals is as follows:

(1) To improve the comprehensiveness of evidence underpinning the decision making for individual health technologies

The public may offer important insights into the value proposition of specific public health-related technologies, such as vaccines or health promotion and screening programs. They may also help to ensure that technologies which elicit strongly held social and cultural values, such as contraceptives or assisted reproductive technologies (20) or those being considered for disinvestment (21), are assessed as holistically as possible.

(2) To increase the legitimacy of the process for the assessment of preventive technologies, thereby ensuring public uptake of the findings

The public utilize preventive technologies; vaccines are an important aspect of public health, which is threatened by concerns about their safety. Similarly, doubts about the effectiveness of some screening programs impact their uptake (22). Greater public involvement in HTA processes, with associated improved public understanding, may increase legitimacy, allay community fears, and improve uptake.

(3) To increase the capacity of the public to engage in their own health care

Health literacy and public understanding of the assessment of new technologies may be improved by making the process of HTA more accessible to the public and more transparent. A more "health literate" public is a public more likely to become informed about their own health care: this is an essential plank for improving population health and building support for public health measures.

(4) To improve the involvement of members of the public in the democratic process

Table 3. Goals for Public Involvement in HTA

1. To improve the comprehensiveness of evidence underpinning the decision making for individual health technologies
2. To increase the legitimacy of the process for the assessment of preventive technologies, thereby ensuring public uptake of the findings
3. To increase the capacity of the public to engage in their own health care
4. To improve the involvement of members of the public in the democratic process
5. To ensure that the HTA process aligns with public values and that the interests of the public are included in the HTA process values
6. To assist in explaining to the public the rationale for difficult decisions which deny funding for potentially life-saving or life-altering health technologies

Over the past 20–30 years, there has been a demand for a more devolved participatory democracy in developed nations. The drivers for this demand include increased availability of evidence to all (23), the rise of social media with national and global public discussion of policies (24), falling trust in governments (25), and the recognized "weaknesses in traditional representative structures" (26, p.22). Loss of trust in governments and representative democracy is particularly evident in younger voters (27). Public participation in policy development and decision-making processes has high levels of support amongst younger voters and could be seen as a mechanism for overcoming some of the weaknesses in a representative democracy, where voting is usually around a "limited set of choices with little depth of involvement" (26, p.22). Some governments are now including deliberative informed public involvement processes in specific cases where decision making is contentious (e.g., 28).

(5) To ensure that the HTA process aligns with public values and that the interests of the public are included in the HTA process

Values are intangible standards or principles which guide our choices and behavioral responses and provide meaning to our lives. These might include personal Kantian virtues such as good will and moral duty. At the societal level, such virtues underpin public values of fairness, accountability, and integrity. Public values are typically elicited through empirical research (e.g., citizens' juries).

Interests embody the trade-offs we are willing to make in the execution of those values. For example, many people believe autonomy and respect for personal privacy should be underpinning values guiding government processes and decision making. The public interest therefore lies in ensuring that the HTA processes and the subsequent decision making reflect respect for persons. This invariably requires trade-offs with other values. For example, the high public value placed on health and wellbeing and effective health services may require some loss of privacy and autonomy due to sharing of health data. How trade-offs should play out in HTA processes is difficult to decide if we do not understand the range of values held by the public and the weightings the public would make in trading one against the other.

In deliberations determining public values and interests or in the representation of those interests, individuals should come to the deliberation as free as possible from other interests. Although others involved in the HTA process are also members of the public, they represent specific interests, including those of patients, healthcare providers, health administrators, industry, and public services. They are often appointed to committees because of their affiliation with those groups through their work, professional role, and qualifications. The inclusion of members of the public, without particular financial, work, or personal interests in the outcome, in these committees ensures broader representation in decision making and explicit consideration of public interests. In some cases, active inclusion of the public interest may act as a bulwark against powerful vested interests wishing to undermine the rigor, impartiality, and independence of the HTA process.

(6) To assist in explaining to the public the rationale for difficult decisions which deny funding for potentially life-saving or life-altering health technologies

Funding for contentious health technologies which loom large in the public imagination but fail to measure up in the assessment processes is an ongoing issue for governments (e.g., see 29). In acting as independent advocates for the public interest, public panels or public members present the public interest argument for denying or approving public funding for technologies which are considered overly expensive relative to the public benefit or for which evidence of benefit is equivocal. This is an extension of goals 5 and 6 in that, under these circumstances, PPI acts as a conduit for public education and informed debate but also as a process for formal input on public interests and values.

Defining Terminology for "the public" in HTA and HTA-Informed Decision-Making

In Table 4, we define terms which have been loosely defined and often used interchangeably in the HTA community. These terms were developed from scholarly literature and in consultation with a broad group of members of the HTAi community, but we suggest that there is no right or wrong definition. The actual term used is less important than achieving consensus from the HTA community about what the terms mean. In other areas of HTA, there is a clearly understood shared language.

In the consultation process, our original definition of *public*, drawn from the literature, was expanded to describe particular exclusions such as those individuals representing commercial industries manufacturing drugs and devices, the HTA industry, and individuals who work or who have previously worked in the healthcare industry. In addition, we excluded individuals with personal interests from this term, including patients and carers, so as to be consistent about the inclusion of the public interest. Other definitions were also refined in response to feedback. For example, our original definition described a patient as someone "with a diagnosed disease or disorder." As a result of the consultation, the word "diagnosed" was dropped as being too narrow and the sentence: "An individual with the lived experience of a disease or disorder who can provide information pertinent to that disease or disorder" added in order to describe the contribution such a person might bring to the HTA process. The term "representative" was removed and the word "represent" used carefully since the capacity or remit for a person to "represent" patients or the public was seen as problematic. Therefore, the word was only used to describe individuals who were consumer or patient advocates and thus specifically asked to represent the views of others. Finally, we recommend against the use of the term "lay." Although considered a neutral term by some (30), in the context of HTA decision making, where we are making the case for public and patient expertise, it is damaging: for example, current common dictionary synonyms for the term include amateur, inexpert, unqualified, and dilettante.

Discussion

Fifty years after Arnstein's ladder of citizen participation (1) and 13 years after Tritter and McCallum's work on user involvement (2), the conceptualization of public involvement in public decision making has shifted. Arnstein's ladder reflected the paternalistic and rigid processes of the sixties and the contemporary push for more participatory processes and "citizen power." Tritter and McCallum's reformulation reflected the rise of patient-centered care, the empowered patient and advocacy for patient involvement in those decisions which affected them. By 2007, it was clearly problematic to ask patients to manage their own care while denying them any input into the very decisions which affected the range of health technologies to which they had access. The latest iteration in this debate, which we describe in this paper, is the recognition that patients and the public hold very different interests and both sets of interests should be systematically incorporated into public decision making.

It is difficult to comment on differences between the public and patient populations in terms of their held values since there is little empirical evidence drawing this comparison. There is some evidence that even where values are shared they may be differently weighted, for example, some studies suggest that patients have a higher tolerance of risk than the public (31). However, as the findings from this article and Boothe (6) suggest, the interests of patients, patient advocates, and patient members lie primarily in advocating for specific medicines or treatments which will benefit a particular patient group, whereas the interests of the public will always rest not only in ensuring equitable distribution of scarce resources amongst all patient groups but also in supporting a well-functioning society which sustains the wellbeing of all. Further, the goals of PPI described in this paper go well beyond the instrumental goals which might be met through observing changed recommendations from an advisory committee or an altered final funding decision as a result of PPI (6). This narrow understanding of the potential impact of PPI neglects the benefits of a more transparent and inclusive process particularly in democratic accountability and in maintaining and rebuilding public trust in government decision making (6). More empirical research

Table 4. Definitions of Terms for Use in Public and Patient Involvement in the Context of Health Technology Assessment and HTA Decision Making

Term	Definition and rationale
Public	**A community member who holds the public interest and has no commercial, personal, or professional interest in the HTA process** Rationale: Public is an umbrella term which, in the context of the HTA process, incorporates all nonpatient, noncommercial, and nonprofessional stakeholders within the health sector. This would exclude patients and carers and representatives from patient and consumer organizations since in the context of HTA they will invariably hold different interests to those of the society at large and it is important that these perspectives are kept separate. It will also exclude representatives from commercial vendors of drugs and devices and organizations offering paid health services; individuals engaged in the Health Technology Assessment industry; and individuals who work or who have worked in the healthcare industry. These individuals are excluded from the term because they have a potential conflict of interest and already have a defined role in the HTA process. The term “public” would include individuals with professional or commercial interests outside these areas, e.g., a physicist or a lawyer.
Patient	**An individual with a disease or disorder who is using some aspect(s) of the healthcare system because of this disease or disorder.** Rationale: Patients are individuals with the lived experience of a disease or disorder who can provide information in the HTA process pertinent to that disease or disorder.
Consumer/user	**An individual who uses, has used, or intends to use a particular health technology or service.** Rationale: A consumer may be a patient but may also be a user of a preventive health technology, e.g., screening or vaccination. The word consumer might also be seen to include health workers and professional and nonprofessional caregivers since all of these use technologies and therefore are consumers with the capacity to inform the HTA process. However, in the context of the HTA process, we would exclude professional consumers from this category since they are represented in the process in their capacity as clinical stakeholders. We note that there is often conflation between the term consumer and patient in healthcare settings in that a healthy person using a vaccine, e.g., will be termed a “patient.” In HTA we recommend that these terms be differentiated.
Carer/caregiver	**An individual who is the unpaid informal primary or secondary caregiver for a patient.** Rationale: A carer or caregiver is usually recognized as holding the interests of the patient(s) in their care but may have additional needs and interests. In the context of the HTA process, unless otherwise specified, the carer is assumed to be nonprofessional.
Lay	**An individual who has no professional healthcare qualifications or expert healthcare knowledge.** Rationale: Since all individuals have expert knowledge of their own lived experience, we suggest that this term should not be used to describe the patient or the public in the HTA process. In addition, we recognize that many individuals who act as a patient or public members have professional qualifications in other fields.
Stakeholder	**An individual with an interest in the outcome of the HTA process final decision.** Rationale: A stakeholder is someone who will be impacted (i) through a change in health or lifestyle, (ii) financially, or (iii) in some other way, by the decision to exclude or include a technology from public support. Potential stakeholders in Health Technology Assessment include patients, consumers, carers, industry representatives, healthcare providers, employers, health insurers, and other payers who are impacted by decisions made in response to the assessment. Members of the public and taxpayers may also be considered to be distal stakeholders in the HTA process because of their interest in a viable effective health system and the judicious use of public funds.
Patient advocate	**An individual who represents and advocates for the interests of a particular group of patients on a committee, e.g., patients with breast cancer.** Rationale: We have distinguished a patient advocate from a patient member since a patient advocate is directly charged with representing the interests of a particular patient organization or group.
Public member	**An individual who has been selected to support the inclusion of the interests of the society at large on a decision-making committee in HTA.** Rationale: We recognize that society has an interest in maintaining an efficient, effective, and equitable health service which, as far as possible, meets the needs of all individuals in society including balancing the range of needs of patients using the system. The use of the word “partner,” e.g., a public partner, suggests the member holds more power than is usually the case. We suggest the term “public partner” should be avoided. The public member may sit on a cross-disciplinary panel of HTA stakeholders (e.g., industry sponsors and clinical stakeholders) or may be one of several sitting on a public or community panel.
Patient member	**An individual who has been selected to support the inclusion of the interests of patients in Health Technology Assessment processes on a committee.** Rationale: We recognize that patients have unique information relevant to inform the HTA process. Representation of this information on decision making committees is important. This individual may be a patient or an unpaid caregiver and may collate the experiences of patients relevant to particular technologies considered by the committee.
Consumer member	**An individual who has been selected to support the inclusion of the interests of consumers on a committee.** Rationale: we have included this term since it is used in some HTA jurisdictions, e.g., Australia and, based on the definition of consumer, we see the remit of the member as wider than the remit of a patient member.

is needed to explore whether increased public and patient involvement increases public trust in the HTA process.

The ways in which Australia, Canada, and the UK conceptualise public and patient engagement in HTA processes, described in the introduction to this paper, exemplify one way of differentiating the roles of patients/consumers and the public. This was identified by Fredriksson (5) as patient and consumer views drawing on “experiential knowledge generated from being a service user” and public views, exemplified by the UK NICE Citizens Council, as “collective perspectives generated from diversity” (5, p.97). Our work points to a different interpretation: the terms describing patient and public in HTA should not describe who the people are but rather the interests and values they are tasked to present in the HTA process or at the decision-making table.

Arising from the public involvement goals described in this paper, our work suggests that there are two distinct aspects to the interests held by the public which should be explicitly included in the HTA process. The first lies in ensuring democratic accountability in the process, namely that it includes comprehensive, high-quality evidence, good deliberation, and is free of bias from special interests. In this role, public members act as independent auditors for the process, building legitimacy and public trust for the process. The second ensures the inclusion of public values. These values would need to be delineated in diverse informed deliberative fora. The role of a deliberative public council might be to develop a generic set of values similar to the operation of the NICE Citizens Council with explicit inclusion of these values in the process. For example, individuals from the council might sit on any decision-making body or be embedded in the HTA process. Alternatively, contentious decisions in HTA could be directly considered by a public council. The ways in which the public values and interests are explicitly included in HTA and the HTA decision-making process will need to be developed within each jurisdiction to reflect the particular policy context. Potentially, public representation could act as a broker between the broader public and the decision-making committee, assisting in the dissemination of the rationale for decisions and increasing public understanding of the HTA process.

Conclusion

Including the public and patients in HTA and HTA-informed policy decisions has become imperative in many jurisdictions using HTA as the basis for government healthcare provision. However, their inclusion has been compromised by the lack of clarity around goals and the roles of the public and patients. This paper provides definitions of those goals and roles drawn from the literature and shaped in a consensus building process. The definitions provided here are particular to the HTA context, but may also be useful in other areas where patients and the public are included in decision making. The next step is a broader discussion across all HTA stakeholders in order to provide an industrywide understanding of the distinct roles and interests of the patient and public members in the HTA process.

Supplementary material. The supplementary material for this article can be found at https://doi.org/10.1017/S0266462320000094

Acknowledgments. The authors gratefully acknowledge the contribution of the members of the HTAi/PCIG, HTA-AUS group, and the CADTH workshop and other HTAi members in engaging in robust discussion, providing feedback, and refining the nomenclature.

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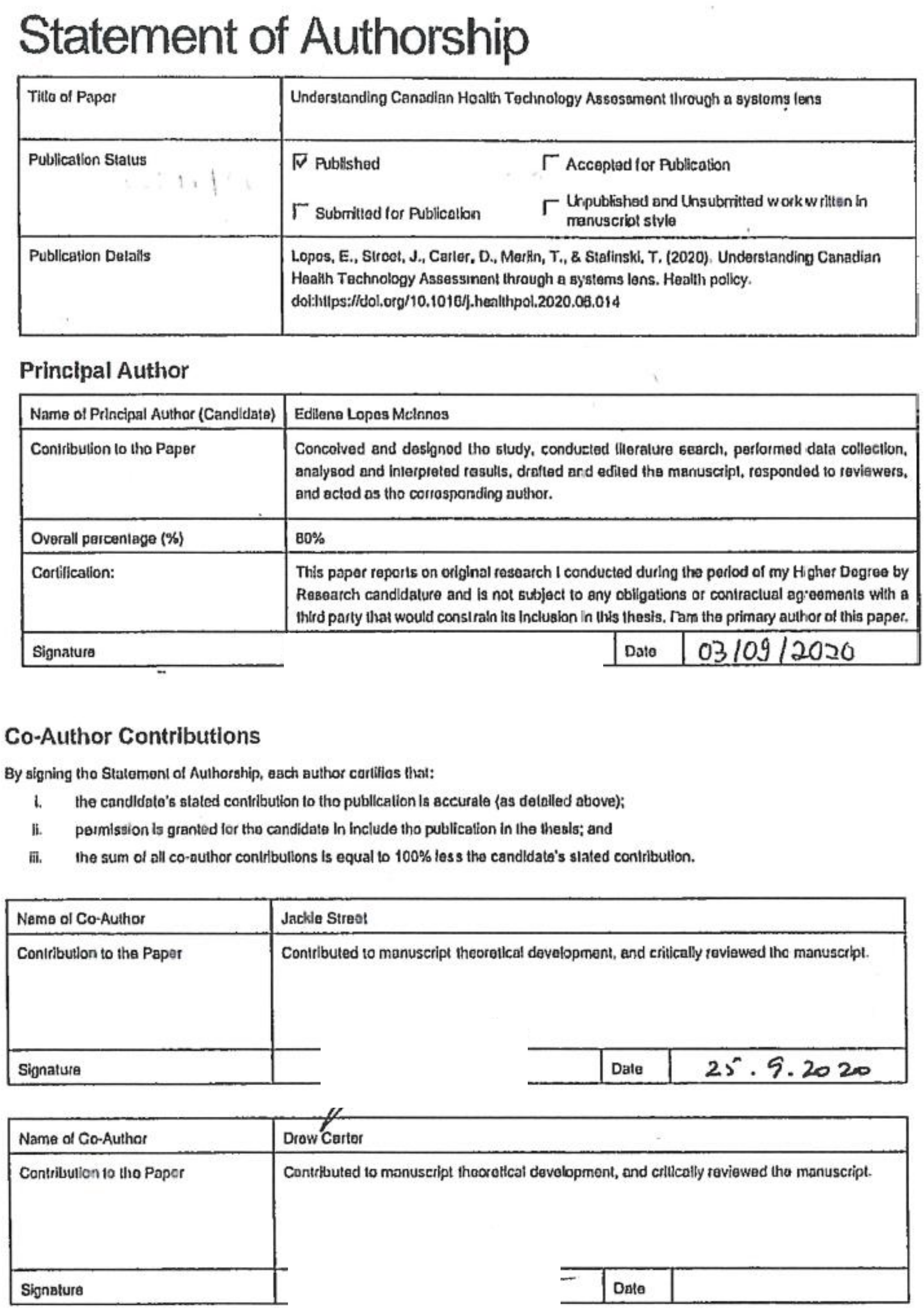
Chapter 6: Characterising Canadian HTA as a system

In Chapter 5, the goals for public involvement proposed by HTA practitioners and academic researchers involved in PPI were to: improve the comprehensiveness of evidence for decision making related to individual health technologies, increase legitimacy for processes regarding preventive technologies, increase the public's ability to engage in their own healthcare and be involved in democratic processes, ensure that HTA processes align with public values and interests, and explain the rationale for decisions denying life-saving or life-altering health technologies. A member of the public was defined as 'a community member who holds the public interest and has no commercial, personal, or professional interest in the HTA process.'

In Chapter 6, the Canadian HTA at both national and provincial levels is examined as a Complex Adaptive System. This chapter will discuss the Canadian HTA system, and make the first step in this thesis in trying to understand how changes to the system, such as the introduction of public involvement, are viewed by a range of HTA stakeholders, whose perspectives should be considered when designing engagement strategies. This chapter relates to the third sub-question of the thesis: what does HTA look like when figured as a complex and adaptive system composed of individuals with diverse worldviews? It also helps to answer the second part of the main research question: Why and how should the public be involved in HTA and healthcare funding decision-making processes?

This work was conducted in Canada, which is a country with a decentralised, publicly funded healthcare system, where individual provinces use HTA reports to make decisions regarding the reimbursement of health technologies. Canada's use of HTA is not dissimilar to other developed nations and is particularly relevant to comparable countries such as Australia, where this thesis has been written. This article sets the scene for the discussion of the introduction of public involvement to HTA, as it describes how changes are usually dealt with in the context of HTA processes.

6.1 Statement of authorship



Statement of Authorship

Title of Paper	Understanding Canadian Health Technology Assessment through a systems lens
Publication Status	☑ Published ☐ Accepted for Publication ☐ Submitted for Publication ☐ Unpublished and Unsubmitted work written in manuscript style
Publication Details	Lopes, E., Street, J., Carter, D., Merlin, T., & Stafinski, T. (2020). Understanding Canadian Health Technology Assessment through a systems lens. Health policy. doi:https://doi.org/10.1016/j.healthpol.2020.08.014

Principal Author

Name of Principal Author (Candidate)	Edilene Lopes McInnes		
Contribution to the Paper	Conceived and designed the study, conducted literature search, performed data collection, analysed and interpreted results, drafted and edited the manuscript, responded to reviewers, and acted as the corresponding author.		
Overall percentage (%)	80%		
Certification:	This paper reports on original research I conducted during the period of my Higher Degree by Research candidature and is not subject to any obligations or contractual agreements with a third party that would constrain its inclusion in this thesis. I am the primary author of this paper.		
Signature		Date	03/09/2020

Co-Author Contributions

By signing the Statement of Authorship, each author certifies that:

i. the candidate's stated contribution to the publication is accurate (as detailed above);

ii. permission is granted for the candidate in include the publication in the thesis; and

iii. the sum of all co-author contributions is equal to 100% less the candidate's stated contribution.

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Name of Co-Author	Drew Carter		
Contribution to the Paper	Contributed to manuscript theoretical development, and critically reviewed the manuscript.		
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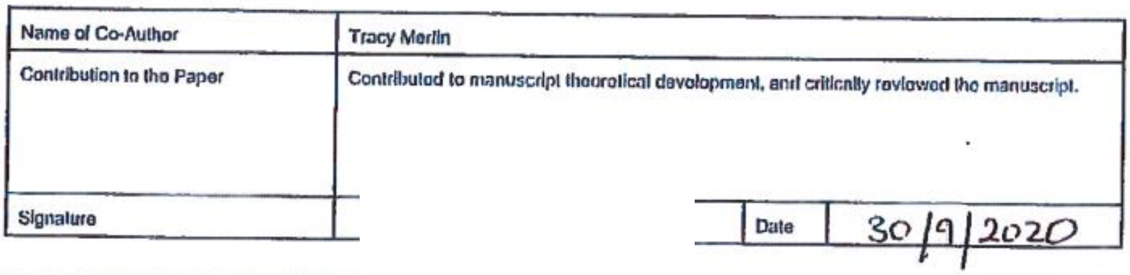
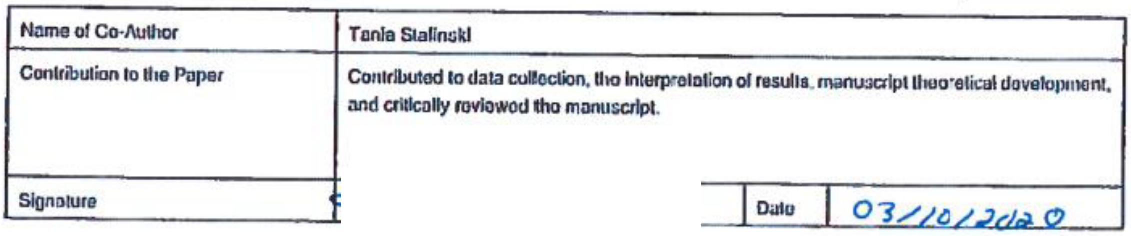


Name of Co-Author	Tracy Merlin		
Contribution to the Paper	Contributed to manuscript theoretical development, and critically reviewed the manuscript.		
Signature		Date	30/9/2020



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Contribution to the Paper	Contributed to data collection, the interpretation of results, manuscript theoretical development, and critically reviewed the manuscript.		
Signature		Date	03/10/2020

6.2 Abstract

Article title: Understanding Canadian Health Technology Assessment through a systems lens

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 HTA in Canada at a national or provincial level. We conducted 22 semi-structured interviews in September-December 2016. Data were analysed using NVivo 10 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 contextual factors. Stakeholders' worldviews include individuals and group values and they affect the exchange of information, and the interpretation of events. Factors external to the system, such as changes to government structures, also affect the system.

Conclusion: Most stakeholder groups are supportive of the HTA system. However, participants identified a need for change, though the exact changes being commended 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).

6.3 Paper

G Model
HEAP-4296; No. of Pages 7
ARTICLE IN PRESS

Health Policy xxx (2020) xxx–xxx

Contents lists available at ScienceDirect

Health Policy

journal homepage: www.elsevier.com/locate/healthpol

Understanding Canadian Health Technology Assessment through a systems lens

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ARTICLE INFO

Article history:
Received 21 August 2019
Received in revised form 12 February 2020
Accepted 24 June 2020

Keywords:
Health Technology Assessment
Soft systems methodology
Complex adaptive systems
Healthcare funding
Healthcare decision making
Health policy

ABSTRACT

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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).

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-

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https://doi.org/10.1016/j.healthpol.2020.06.014
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Please cite this article in press as: Lopes E, et al. Understanding Canadian Health Technology Assessment through a systems lens. Health Policy (2020), https://doi.org/10.1016/j.healthpol.2020.06.014

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 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.

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.

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.

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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)

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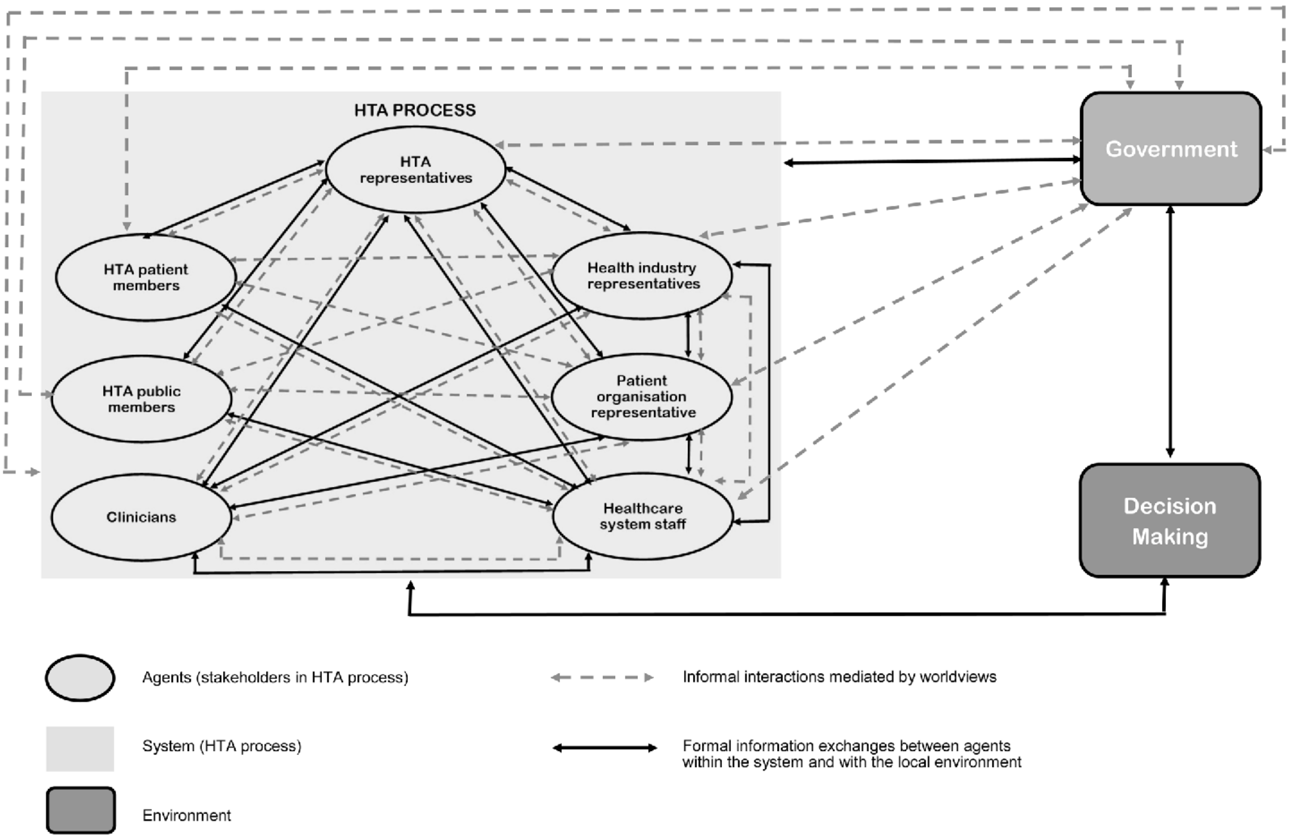

Fig. 1. Canadian HTA as a system – concept map.

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)*

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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

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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

This project was undertaken as part of EL's PhD project. EL received funding from the Australian Department of Education and Training (Endeavour Fellowship) and had some travel costs covered by The University of Alberta (Canada). JS, DC, and TM declare that

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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.

Acknowledgments

The authors acknowledge the contribution of Prof Devidas Menon in recruiting, refining the interview schedule, and providing ongoing support for this research project; and of Andrea Young and Lynne Lacombe for administrative support.

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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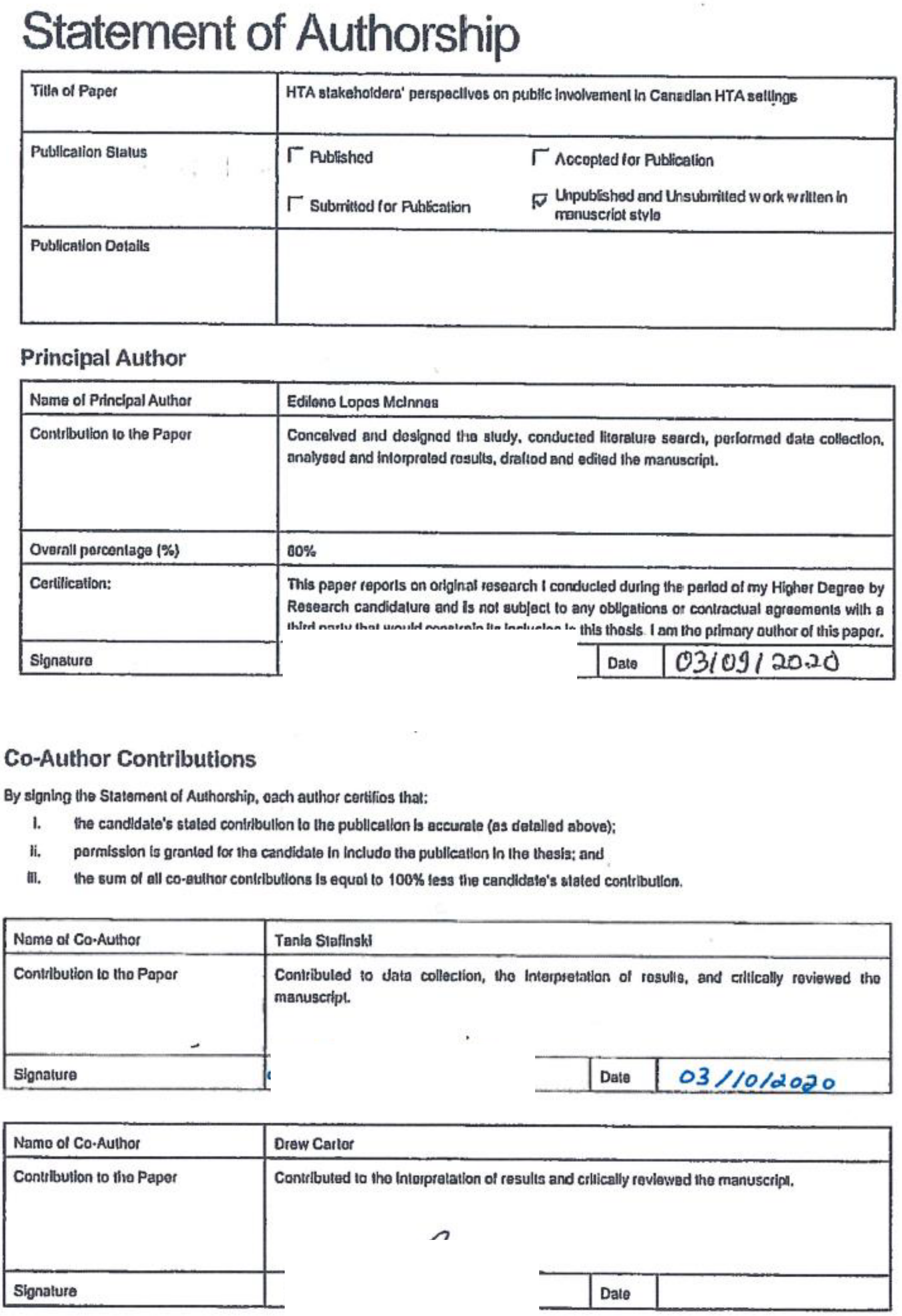
Chapter 7: HTA stakeholders' perspectives on public involvement in HTA

In Chapter 6, HTA was characterised as a Complex Adaptive System, in which HTA stakeholders were considered the most influential factor. HTA stakeholders were influenced by their personal and group worldviews and values and their interactions centred on exchanging information about HTA (the system) and its environment. Most study participants were supportive of HTA as a tool to be used in government decision making, but many changes to the HTA process were suggested. The lack of agreement between stakeholders can make changes to the system difficult to implement and may result in other non-expected consequences depending on how those who are part of the system see those changes.

The present study explores HTA stakeholders' views of public involvement processes in HTA settings in Canada. It presents further empirical support for the notion that confusion between the roles of the public and patients in HTA is common and it presents the second part of the findings of the semi-structured interviews with HTA stakeholders. This study relates to the fourth sub-question of this thesis: what do HTA stakeholders and the public think about the rationale and design of public involvement in HTA and related funding decisions? It also relates to the second part of the main research question: Why and how should the public be involved in HTA and healthcare funding decision-making processes?

7.1 Statement of authorship



Statement of Authorship

Title of Paper	HTA stakeholders' perspectives on public involvement in Canadian HTA settings	
Publication Status	☐ Published ☐ Submitted for Publication	☐ Accepted for Publication ☑ Unpublished and Unsubmitted work written in manuscript style
Publication Details		

Principal Author

Name of Principal Author	Edilene Lopes McInnes
Contribution to the Paper	Conceived and designed the study, conducted literature search, performed data collection, analysed and interpreted results, drafted and edited the manuscript.
Overall percentage (%)	80%
Certification:	This paper reports on original research I conducted during the period of my Higher Degree by Research candidature and is not subject to any obligations or contractual agreements with a third party that would constrain its inclusion in this thesis. I am the primary author of this paper.
Signature	Date 03/09/2020

Co-Author Contributions

By signing the Statement of Authorship, each author certifies that:

- i. the candidate's stated contribution to the publication is accurate (as detailed above);
- ii. permission is granted for the candidate in include the publication in the thesis; and
- iii. the sum of all co-author contributions is equal to 100% less the candidate's stated contribution.

Name of Co-Author	Tania Stafinski
Contribution to the Paper	Contributed to data collection, the interpretation of results, and critically reviewed the manuscript.
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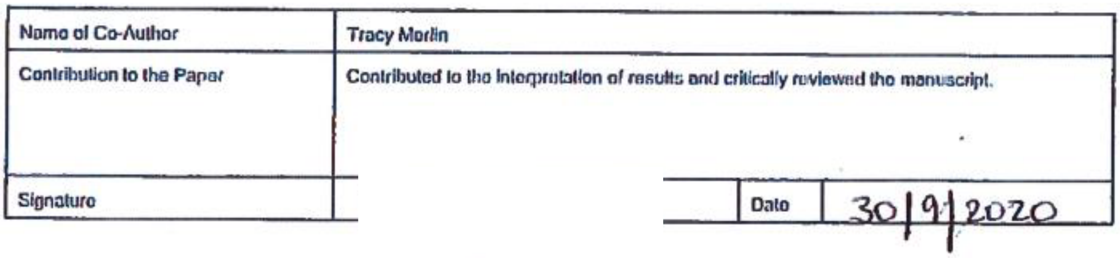
Contribution to the Paper	Contributed to the interpretation of results and critically reviewed the manuscript.
Signature	Date



Name of Co-Author	Tracy Merlin		
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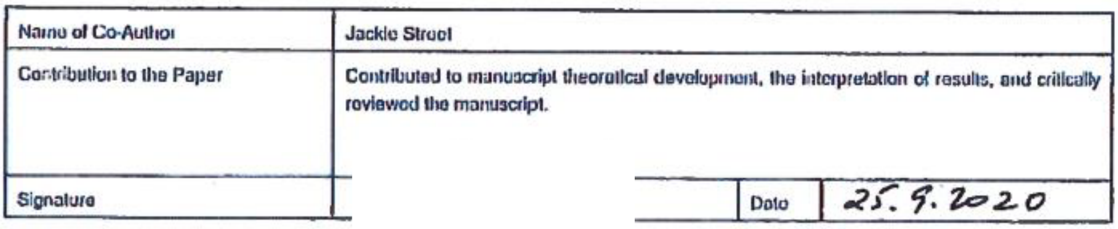
Signature		Date	30/9/2020



Name of Co-Author	Jackie Street		
Contribution to the Paper	Contributed to manuscript theoretical development, the interpretation of results, and critically reviewed the manuscript.		
Signature		Date	25.9.2020

7.2 Abstract

Article title: HTA stakeholders' perspectives on public involvement in Canadian HTA.

Background: Health Technology Assessment (HTA) has been adopted by many countries to optimise health sector expenditure and to select health technologies to include in their healthcare systems. Currently, numerous processes are being employed in HTA to involve the public. However, there are problems related to how to define the public and what rationales can be used to foster public involvement in HTA.

Objective: To understand the perspectives of HTA stakeholders regarding the involvement of the public in HTA.

Design: A purposive sample of HTA stakeholders involved in Canadian HTA processes was selected. We conducted 22 semi-structured interviews from September to December 2016. Data were analysed using an inductive and deductive approach under the theoretical framework of Systems Thinking.

Results: HTA stakeholders do not have a clear definition of who the public is in HTA settings or the rationales to involve them. Participants were able to differentiate the public and the patient perspectives in HTA and suggested that public involvement processes could be used before or after HTA processes take place, but not during the assessment of health technologies.

Discussion and Conclusion: Our study found that HTA stakeholders see public involvement in HTA as useful. Research participants propose that the stages at which public involvement should occur are different from current calls for public involvement in HTA in the scholarly literature. Consideration of the views of stakeholders is important to understand the challenges in increasing public participation in HTA.

7.3 Paper

Introduction

Health Technology Assessment (HTA) has been adopted by many countries to optimise health sector expenditure and to select health technologies to include in their healthcare systems (1). In HTA, health technologies encompass medicines, medical devices, vaccines, diverse types of medical tests, and health programs (2). HTA assesses new health technologies in terms of their safety, cost-effectiveness, and ethical and social impacts.

There is evidence that HTA can assist managers in reducing costs and improving healthcare system outcomes (3-5). However, some critics argue that HTA could examine ethical and social issues in more depth (6-11). Involvement of the public in HTA has been considered as one way of incorporating this type of information and social values into the evaluation process (12).

Currently, a range of processes are used in HTA to involve the public (13). However, definitions of who the public is have only emerged very recently (14). This paper investigates the views of HTA stakeholders regarding public involvement processes in Canada. It answers the following research question: How do HTA stakeholders view the rationale and design of public involvement in HTA and related funding decisions?

7.3.1 Canadian HTA

This paper focuses on the Canadian HTA process at the national level and in one province (which is not named to protect the anonymity of participants). At the national level, Canada has a pan-Canadian HTA agency, which assesses health technologies that are classified into three categories: cancer drugs, non-cancer drugs and non-drug medical interventions and services. The national agency has expert review committees for each of the categories mentioned; the membership of these committees includes patient members (for the committee reviewing cancer drugs) or public members (for the other committees). The national HTA agency has specific definitions for 'patient' and 'public' in these contexts (15). At the provincial level, the design of the HTA processes varies across the provinces. Some provinces have stand-alone HTA organisations, whereas others have HTA processes within their Ministries of Health or only use the pan-Canadian HTA agency processes.

7.4 Methods

7.4.1 Theoretical framework

This paper employs two Systems Thinking approaches to the project design, data collection, and analysis, namely Complex Adaptive Systems (CAS) (16-18) and Soft Systems Methodology (SSM) (19). This article is part of more extensive research using these two methodologies. In CAS, phenomena of interest are considered systems, which have agents that interact with one another, learn, and adapt to their environment. In this way, the HTA process is regarded as a system, and HTA stakeholders are examined as system agents (See Table 7.1). The Canadian government processes at the provincial and national levels are taken to be the system's surrounding environment.

SSM has been adopted as another theoretical framework because the system investigated here is a social system, in which people (HTA stakeholders) interact. In SSM, specific situations are constructed as problematic by the people involved. The people involved in a problematical situation are deemed to have individual worldviews that influence their actions and their interactions with others. In the present study, the introduction of public involvement processes into HTA is conceptualised as a 'problematical situation' (19). In this sense, SSM has informed the analysis of the interactions between HTA stakeholders and their worldviews as described by participants in their interviews.

7.4.2 Data collection and analysis

Participants were recruited using a Maximum Variation Sampling strategy (20) to select HTA stakeholders who could provide diverse perspectives related to the HTA process in one Canadian province and the pan-Canadian HTA process. We selected 22 participants and conducted interviews from September to December 2016. Some interviews were conducted face-to-face and some via telephone, depending on the availability and location of participants. The name of the province and other organisations cited in the interviews are omitted to protect the privacy of participants. Recordings from interviews were transcribed and analysed using NVivo 10 qualitative software. Transcripts were coded using an inductive and deductive strategy (21, 22);

based on the theoretical framework, a list of initial codes was created, and open coding was also used. ELM and JS coded three interviews separately and then discussed the results to achieve an agreed coding strategy. ELM coded the remaining interviews. This process resulted in 306 codes (30 initial codes and 276 emerging codes). These codes were first aggregated into first-order themes (based on the content of codes) and then organised under theoretically informed second-order themes (based on CAS and SSM). (See the Appendices section in this thesis). Findings reported here relate to participants' views of public involvement processes in the Canadian HTA at national and provincial levels. Results are presented under the following sub-headings: 'Definition of public', 'Differences between public and patient involvement in HTA', 'Current methods used to involve the public', 'Public involvement in HTA processes', and 'Public involvement in healthcare funding decisions'.

h. Table 7.1 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 a company) Three from pharmaceutical organisations (two from the same umbrella organisation and one from a company)

Patient 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 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)

7.5 Findings

7.5.1 Definition of public

Participants did not clearly distinguish the public from patients, arguing that patients are also citizens and members of the public. Some participants, such as a policy-related healthcare system staff member and a health industry staff member (medical devices), used the terms interchangeably, considering both patients and the public as external stakeholders to HTA and government processes. Other participants attributed the difficulty of defining who the public is in HTA processes to how the public is conceptualised:

> …[T]here isn't an organised public, right?.... I would really like to see what that public role would be, who is considered to be the public, and how that might actually contribute to a better quality HTA (Patient organisation representative)

Despite this, many participants were able to express differences between patient and public perspectives or interests in HTA, stating that the public perspective or interest would be concerned with a societal viewpoint related to how government money is spent and the overall impact that the introduction of a health technology has in the healthcare system. This contrasts with the patient perspective or interest, which was seen as narrowly related to specific health conditions and health technologies to treat them. However, participants did not agree on which type of stakeholder could represent the public perspective or interest, and various suggestions were put forward: citizens, public members in HTA expert review committees, the provincial drug plans, or the provincial department of health.

> I think [Name of the provincial health department] is already taking the public standpoint because they have to look at sort of facilitating budgets for all different types of diseases, so they probably do play that role already. I don't know how much more beneficial a public representative is on that group (Clinician 1)

7.5.2 Differences between public and patient involvement in HTA

Patient involvement in HTA was seen as a means to understand the impact of health technologies on patients. By contrast, public involvement was seen to mainly provide legitimacy to HTA processes by explicitly including a tax-payer perspective in relation to the costs and value of health technologies. Accounts of the relevance, importance and influence of patient involvement were more consistent among participants than was the case for public involvement. Most participants were able to elaborate on the differences between patient and public involvement in HTA by mainly focusing on what patient involvement entails:

> I think individuals with specific diseases are good if you are going to reflect only within the environment or the space for the treatment of that particular disease, but if you are going to reflect social values I think you actually have to have the perspective of citizens who are in fact the custodians of those social values… (Health industry representative 2)

Some participants believed that there is not a role for the public to add helpful new information to the HTA process. However, they acknowledge that it is necessary to have public involvement processes in place to make the committees and HTA processes simply look legitimate in the eyes of the population:

> They are doing it for optics, and for political reasons. If someone asks the question, scratch beneath the surface… what impact does that input actually make, I don't know. (HTA representative 1)

7.5.3 Current methods used to involve the public

The majority of participants were aware of the public member role in HTA expert advisory committees in Canada and talked about this involvement method. Committee members representing the public perspective were seen as beneficial by some participants and problematic by others. The role of public members was seen positively when they were seen to counterbalance other stakeholders' interests:

> I think it might be helpful to gain a non-vested, external point of view. I think it could be more useful than having the patient perspective because you have lots of vested interests. (Healthcare system staff 1)

Most of the problems related to the role of the public member were linked to the involvement model utilised in Canada, in which the public member presents the information provided by patients and patient organisations. Participants thought that public members were not as knowledgeable as patients regarding health conditions and patient issues:

> the [Name of committee] public members allocate everything from diabetes drugs to Parkinson's… I don't know what else they do, rare diseases… I would find it challenging to try to really look at all of those very diverse issues. It's hard to understand the conditions. (Patient member 2)

Participants also commented on advisory committees composed of members of the public, another method used in some provinces. One of the challenges related to how the public involvement process was operationalised and whether the information gathered could be incorporated into HTA.

> I think [Name of committee] can be more structured and more scientific for sure. But then it's going to be a balance between rigour and what additional value that's going to come out… I find that you get the comment [from the advisory committee] and it makes sense, but I don't know what to do with that…(HTA staff representative 1)

7.5.4 Public involvement in HTA processes

Most participants suggested that the public was able to contribute to determining broader societal values to be considered by HTA practitioners when assessing specific health technologies rather than contributing to specific assessments:

> I think there could be some form of a consultation and a deliberative process by which one might try to clarify what societal values are. I think that might be useful… How that would be done, and how it could be done I think is something that is more than just an HTA. (Patient organisation representative)

Two participants commented on two ways of gathering information from the public: the use of online consultations and citizen's panels. Both initiatives were considered to be appropriate for the involvement of the public in the decision-making processes happening before or after HTA, but not for the HTA assessment and report writing. According to these participants, these methods are to be used for broader issues rather than the assessment of specific health technologies:

> When it comes to big wholesale policy changes, we do need to put consultation processes out there. When it comes to the little onesies and twosies, the little widgets… How much public engagement can the public put up with, after a while it just gets to be so routine…How do you make sure that you are engaging them when it matters? (Healthcare system staff 2)

Some participants believed that there could be an opportunity for public input in the final report produced by HTA agencies and units. However, various issues were raised in relation to the difficulty of receiving information from the public at this stage due to the type of knowledge required to read these reports:

> If you try to find regular people and put them onto a technical process, I don't think that serves the intent very well at all, and if you find regular people who actually are technically capable then they are not regular people (Health industry representative 2)

Increase in the time and cost of HTA processes were also raised as barriers to public involvement in HTA.

> It already takes such a long time to build these reports that adding more layers and adding time periods to allow for all the feedback from the public or from patients and then incorporating that into the report it slows down the process. (Clinician 1)

7.5.5 Public involvement in healthcare funding decisions

Participants had mixed responses in relation to involving the public in priority setting. Some were supportive because the public could counterbalance the interests of other stakeholders, such as the health industry and researchers, and the public could help set the parameters for selection of health technologies. Others were concerned that the public could be swayed by other stakeholders with vested interests because their access to accurate information about health technologies is limited.

> You may have fundraising groups that raise money for technologies to go into hospitals or foundations, and they [the public] may be highly influenced by informal conversations with clinicians. I don't know that that's a good basis for buying a technology and introducing it as much as a broader understanding of what the technology purported to do and the impact that that could have on patient care and patient outcomes. (Healthcare system staff 3)

Other issues related to which mechanisms would be used to elicit information and whether the prioritisation process would be systematic and repeatable, as the public may weigh factors related to healthcare technologies differently at different times.

Some participants did not think that the public should be involved in the HTA recommendation committees because committees have elected government representatives with a mandate to make decisions on the public's behalf. Other participants believed that members of the public should take part in committees, but feared that the current model of involvement is not appropriate.

> I think we have to make sure that when we say committees, we don't have a committee of 10 clinicians, and we put one member of the public on it. I am not sure that's effective… One voice in a room of white lab coats might be intimidating or it might be a very technical discussion that's not conducive to public input. (Healthcare system staff 3)

Some participants highlighted that being at the table does not necessarily mean that the public perspective is going to be incorporated into the committee recommendation.

> The strength of personality and the credibility they are bringing with them before they even get on that committee mean an awful lot about how that's going to work out and what they are able to bring to it. So, there is a little bit of uncertainty about under what conditions they're going to influence the decision or have any sort of impact. (HTA representative 3)

7.6 Discussion

Participants reflected on a range of different rationales for involving the public and involving patients in HTA. However, there was disagreement about who and how the public perspective or interest might be presented, and some participants doubted the feasibility of implementing public involvement processes in HTA. This has been identified as a common problem in public involvement in other healthcare settings and can be understood under the broader issue of the lack of agreed standards for the objectives, processes and evaluation of public involvement (23).

Because participants typically lacked a clear definition of public in HTA, the rationale for public involvement was also vague. Some participants believed that the composition of committees needs to appear legitimate, even if the public involvement does not have a real impact on the outcomes of discussions. Some proposed reasons for public involvement included the increasing accountability of healthcare spending to tax-payers (represented by the public) and gaining more public advice on the social value of the health technologies under consideration. Recently, Street et al. (14) proposed goals for the involvement of the public in HTA drawing on academic researchers and HTA practitioners' perspectives, which is a step forward in trying to address the problem of vagueness and ambiguity characterising stakeholders' ideas about the reasons for involving the public in HTA. Incorporating the views of other HTA stakeholders, particularly government staff who request and use HTA reports, may also help to address this problem.

Participants were not able to comment on a wide range of public involvement methods for engaging the public in HTA. They mainly concentrated on critiquing the methods that were well-known to them. Only two participants departed from this with the caveat that other methodologies could be used to involve the public in other stages of healthcare funding decision making but not in HTA. One participant mentioned NICE's citizens' council as an example, but mostly raised the drawbacks of this method. When the perspectives of HTA stakeholders are compared to the views of the public with regards to the methods that can be used (24), it is clear that the public proposed a broader range of possible methods. Involving the public in designing involvement processes could assist HTA staff and governments to develop novel methods that are appropriate for health funding decision-making processes.

In general, participants did not believe that the public could usefully take part in HTA processes directly. Some participants commented on the possibility of social values from the public informing HTA; such information, however, would be collected externally to HTA processes and then used by HTA practitioners to incorporate public perspectives. Stages immediately prior to or following assessments (e.g., priority setting or recommendation committees) were seen as the ideal places for public involvement. Experiences in other countries, such as the UK, have demonstrated that it is feasible to involve the public at different HTA research stages (25). The stance adopted by HTA stakeholders regarding public involvement is in stark contrast with the opinions of the public (24) and with research findings which suggest that there is a need to involve the public in HTA (6). The problem seems to relate to the difficulty of integrating different types of information (e.g., ethical considerations). For example, cost-effectiveness analysis represents a method for integrating different types of information (on costs, effects on survival and health-related quality of life), but there are still other types of information yet unable (or not readily able) to be included in this, such as whether the assumptions regarding health-related quality of life reflect the values of the public.

In 2011, Gauvin et al. (26) reported some 'resistance' in the HTA community to increased public involvement in HTA; nine years later, our research finds similar results. This indicates that, despite all the promotion of the idea of public involvement in HTA, the move towards greater participation is slow. However, research within HTA settings (27) continues to highlight avenues forward.

7.7 Conclusion

Our research found that stakeholders involved in the pan-Canadian and one provincial HTA processes did not have a clear definition of who the public is in HTA settings or a clear idea of the rationales that ought to underpin initiatives to involve them. Participants were able to differentiate the public and the patient perspectives in HTA; however, the roles of patient and public members in expert advisory committees were conflated.

Public involvement processes currently in use in Canadian HTA processes usually take place after the HTA report has been produced. HTA stakeholders suggest that public involvement processes could be developed to identify social values to be considered during the HTA process, but direct participation of the public is not warranted. Consideration of the views of stakeholders is important to understand the challenges in increasing public involvement in HTA.

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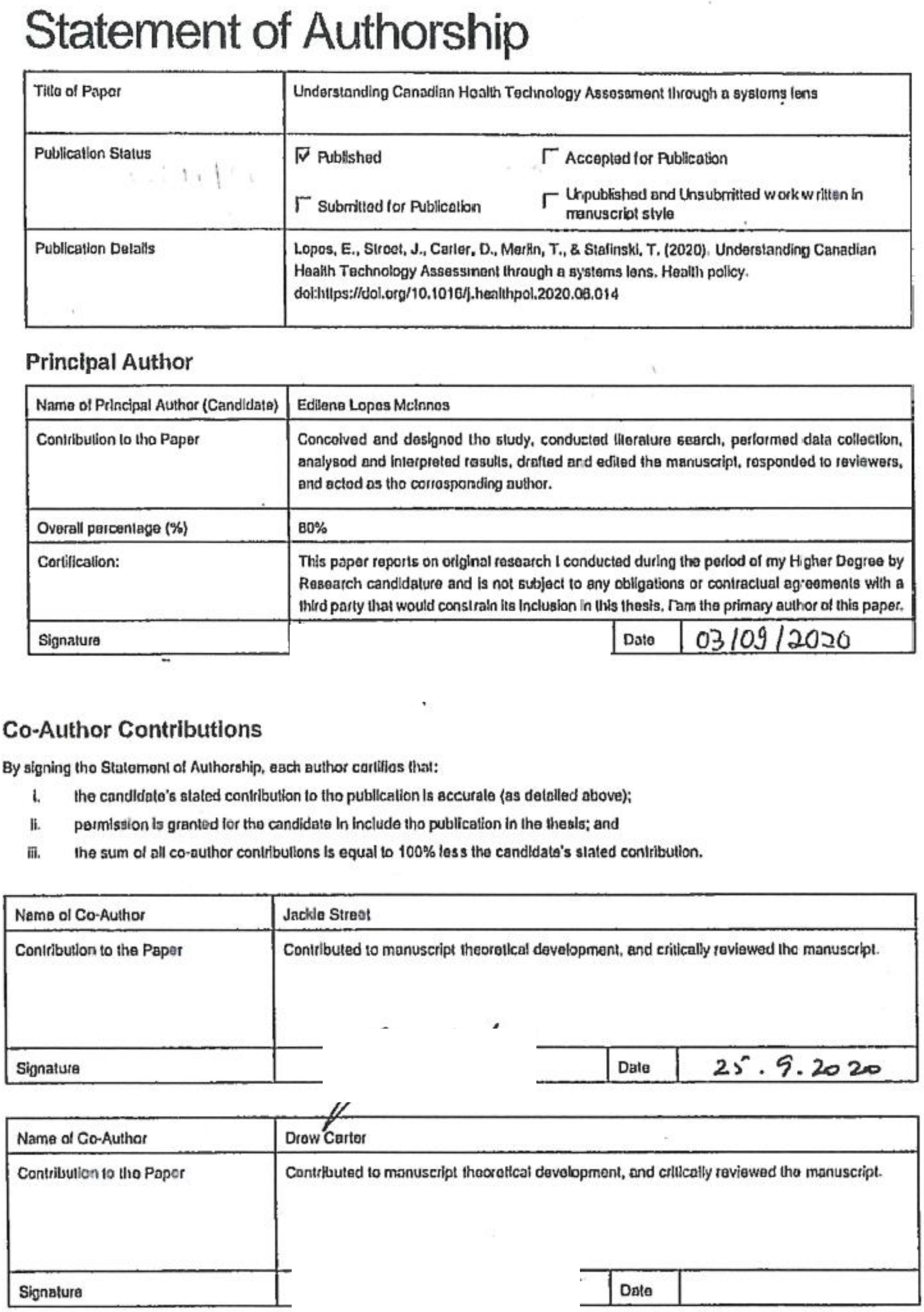
Chapter 8: Public involvement in Canadian HTA through a systems lens

In Chapter 7, the perspectives of the HTA stakeholders concerning public involvement processes were examined, and the study found that, despite the use of some public involvement processes in Canada, HTA stakeholders did not have a clear definition of who the public is in HTA settings nor of the precise objectives for involvement. The roles of patient and public members in expert advisory committees were conflated. This finding echoes the findings of Chapter 5, which looked at HTA practitioners' perspectives. Chapter 7 also demonstrated that HTA stakeholders do not think the public can take part in the HTA process itself but believe that the public perspective can be useful before an assessment starts (e.g., in priority setting concerning which health technologies ought to be assessed) or after an HTA report is produced (e.g., when HTA committees deliberate and make their funding recommendation).

The present study reveals the perspectives of the public – conceptualised as an external stakeholder – about the HTA system and their potential role in it. This is the last empirical study presented in this thesis and it examines the views of members of the public in a Canadian province. This study relates to the fourth sub-question of this thesis: What do HTA stakeholders and the public think about the rationale and design of public involvement in HTA and related funding decisions? It also relates to the second part of the main research question: Why and how should the public be involved in HTA and healthcare funding decision-making processes?

8.1 Statement of authorship



Statement of Authorship

Title of Paper	Understanding Canadian Health Technology Assessment through a systems lens
Publication Status	☑ Published ☐ Accepted for Publication ☐ Submitted for Publication ☐ Unpublished and Unsubmitted work written in manuscript style
Publication Details	Lopes, E., Street, J., Carter, D., Merlin, T., & Stafinski, T. (2020). Understanding Canadian Health Technology Assessment through a systems lens. Health policy. doi:https://doi.org/10.1016/j.healthpol.2020.08.014

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Contribution to the Paper	Conceived and designed the study, conducted literature search, performed data collection, analysed and interpreted results, drafted and edited the manuscript, responded to reviewers, and acted as the corresponding author.		
Overall percentage (%)	80%		
Certification:	This paper reports on original research I conducted during the period of my Higher Degree by Research candidature and is not subject to any obligations or contractual agreements with a third party that would constrain its inclusion in this thesis. I am the primary author of this paper.		
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Co-Author Contributions

By signing the Statement of Authorship, each author certifies that:

i. the candidate's stated contribution to the publication is accurate (as detailed above);

ii. permission is granted for the candidate in include the publication in the thesis; and

iii. the sum of all co-author contributions is equal to 100% less the candidate's stated contribution.

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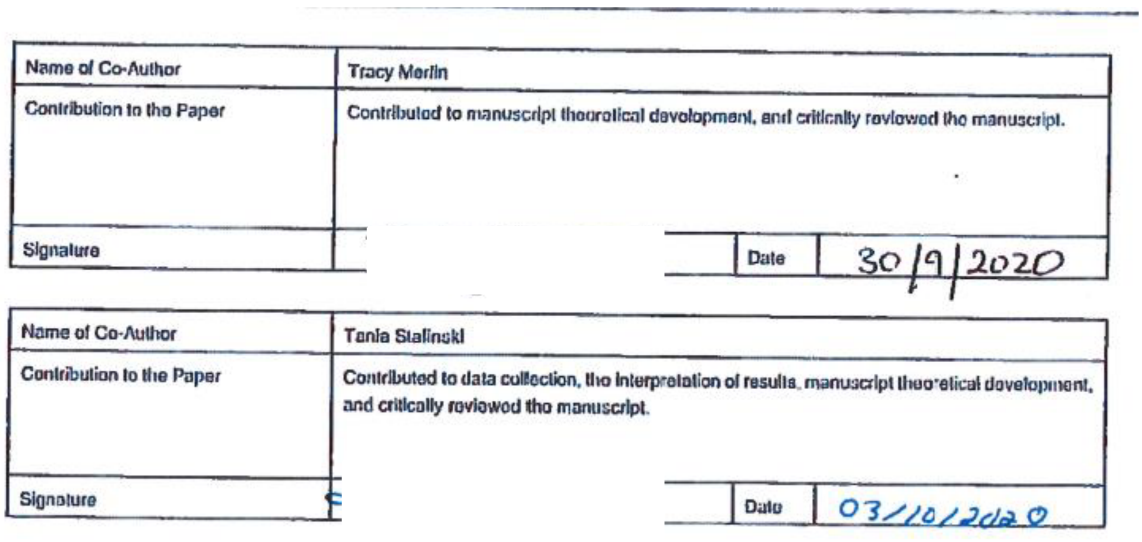

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8.2 Abstract

Article title: The rationale and design of public involvement in health funding decision making: Focus groups with the Canadian public

Background: Worldwide, governments employ Health Technology Assessment (HTA) in healthcare funding decision making. Requests to include public perspectives in this process are increasing, with the idea being that the public can identify social values to guide policy development and increase the transparency and accountability of government decision making.

Objective: To understand the perspectives of the Canadian public on the rationale and design of public involvement in HTA.

Design: A demographically representative sample of residents of a Canadian province was selected to take part in two sets of two focus groups (16 people for the first set and 20 for the second set).

Results: Participants were suspicious of the interests driving various stakeholders involved in HTA. They saw the public as uniquely impartial though also lacking knowledge about health technologies. Participants were also suspicious of personal biases and commended mechanisms to reduce their impact. Participants suggested various involvement methods, such as focus groups, citizens' juries and surveys, noting advantages and disadvantages belonging to each and commending a combination.

Discussion and Conclusion: We identified a lack of public understanding of how decisions are made and distrust concerning whose interests and values are being considered. Public involvement was seen as a way of providing information to the public and ascertaining their views and values. Participants suggested that public involvement should employ a mixed-methods strategy to support informed debate and the participation of a large number of people.

8.3 Paper

International Journal of Technology Assessment in Health Care

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Policy

The rationale and design of public involvement in health-funding decision making: focus groups with the Canadian public

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Cite this article: Lopes E, Street J, Stafinski T, Merlin T, Carter D (2020). The rationale and design of public involvement in health-funding decision making: focus groups with the Canadian public. *International Journal of Technology Assessment in Health Care* 1–7. https://doi.org/10.1017/S0266462320000537

Received: 19 February 2020
Revised: 19 June 2020
Accepted: 27 June 2020

Key words:
Public involvement; Health technology assessment; Soft systems methodology; Complex adaptive system; Focus groups

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Background. Worldwide, governments employ health technology assessment (HTA) in healthcare funding decision making. Requests to include public perspectives in this are increasing, with the idea being that the public can identify social values to guide policy development, increasing the transparency and accountability of government decision making.

Objective. To understand the perspectives of the Canadian public on the rationale and design of public involvement in HTA.

Design. A demographically representative sample of residents of a Canadian province was selected to take part in two sets of two focus groups (sixteen people for the first set and twenty for the second set).

Results. Participants were suspicious of the interests driving various stakeholders involved in HTA. They saw the public as uniquely impartial though also lacking knowledge about health technologies. Participants were also suspicious of personal biases and commended mechanisms to reduce their impact. Participants suggested various involvement methods, such as focus groups, citizens' juries and surveys, noting advantages and disadvantages belonging to each and commending a combination.

Discussion and conclusions. We identified a lack of public understanding of how decisions are made and distrust concerning whose interests and values are being considered. Public involvement was seen as a way of providing information to the public and ascertaining their views and values. Participants suggested that public involvement should employ a mixed-methods strategy to support informed debate and participation of a large number of people.

Governments around the world employ health technology assessment (HTA) to assist them in making healthcare funding decisions. HTA processes evaluate health technologies (medical treatments, medical devices, drugs, and healthcare programs) in terms of their safety, effectiveness, cost-effectiveness, and broader implications for society (1).

Governments have increasingly involved the public in health-funding policy development, and calls for patient and public involvement have been particularly influential in publicly funded healthcare systems (2). Some authors argue that patient and public perspectives should be included when a range of different values need to be considered or when more information on social or psychological experiences of living with a disease is warranted (3). Multiple involvement methods have been used by HTA agencies and government bodies (4), but more advances have been made in the involvement of patients than the general public (5). Patient experiences can provide additional information on health outcomes during an HTA (6). Some purposes for public involvement include identifying when particular social values are worth emphasizing in policy development, increasing the transparency of decisions, and the accountability of government spending (7).

There are methodological challenges in involving the public in HTA (8); for example, it is not clear which processes are more appropriate for involving a representative sample of the public. Nonetheless, this has not stopped some countries from trialing diverse public involvement processes in HTA (9). There are also criticisms of how both patients and the public have been involved in healthcare funding decisions (2). Stakeholders often fail to appreciate the different roles that patients and the public can play in HTA (8) and what meaningful involvement constitutes in the eyes of patients and the public (9).

Public Involvement in Canadian HTA

Canada has a primarily public healthcare system, with a federal level responsible for defining the provision of healthcare services (10) for the whole country and a provincial level, which is

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responsible for the administration of health services. Canada also has a pan-Canadian HTA agency that assesses cancer and non-cancer medicines and some non-drug health technologies. Some Canadian provinces have their own HTA processes that support their provincial healthcare system. Both the pan-Canadian HTA agency and some provincial HTA processes have patient and public members in their review or recommendation committees (11).

In this paper, we answer the following research question: "What do members of the Canadian public think about the rationale and design of public involvement in HTA and related funding decision making?" We do this by reporting the views of members of the Canadian public on public involvement in HTA.

Methods

A Systems Thinking Approach

This paper is part of a more comprehensive project that uses Complex Adaptive Systems (CAS) (12) and Soft Systems Methodology (SSM) (13) to examine patient and public involvement in HTA. CAS proponents treat all manner of phenomena as systems composed of diverse, independent, and interacting agents. In SSM, challenges in a system are constructed through the interplay of stakeholders' perspectives or "worldviews" (13). In this project, HTA stakeholders and we, as researchers utilizing SSM, have constructed public involvement in HTA and healthcare funding decisions as a challenging situation (13). The HTA process is considered a system and its stakeholders are agents (healthcare system staff, HTA staff, health industry staff, patient organizations, and public members, patients, and clinicians). The general public is conceptualized as a distal agent, currently acting at the periphery of the system.

We describe findings from two sets of two focus groups conducted with members of the Canadian public to elicit their views on being involved in HTA and healthcare system funding decisions. The first set was exploratory, took place in December 2016 and, after a presentation about provincial healthcare funding decision making and HTA in Canada, participants discussed their potential participation in such processes, including whether the public could participate, at which stages, and through which involvement methods. The second set of focus groups took place in January 2008 and featured the same topics in addition to participants' views on reasons for public involvement. Overall, this approach served to bring out a significant number of ideas (first set of focus groups), which were later explored in more depth (second set of focus groups).

Sampling and Data Collection

We recruited participants via postal invitation. We sent out letters to 500 residents living in a single province in Canada, asking them to answer screening questionnaires online or over-the-phone to determine their willingness and eligibility to participate. We decline to name the province to maintain participants' anonymity. We selected a demographically representative sample of residents to take part in four focus groups (sixteen people for the first set of focus groups and twenty for the second set). We excluded individuals who were members of patient organizations or who had worked (or had relatives who had worked) for health industry companies, government health departments, or healthcare delivery organizations (see the Appendix for details).

Data Analysis

Focus group sessions were audio-recorded and then transcribed. Transcripts were coded using a combination of inductive and deductive coding. Five initial codes were developed based on elements of CAS and SSM: "HTA process," "Public involvement," "Patient involvement," "Relationships," and "Other stakeholders" and open coding generated a further 178 codes. Codes were collapsed into first-order themes, which numbered eighteen. Codes and first-order themes were then combined into second-order themes based on the theoretical framework, which resulted in five themes: "System," "Environment," "Agents," "Interactions," and "PPI processes." Only these themes are reported under broader headings: "Stakeholders," "Decision Making," and "Public Involvement Processes" (see the Appendix for details).

Findings

Stakeholders

Participants in all focus groups talked about their lack of trust in various stakeholders involved in HTA and healthcare funding processes. Some participants were concerned that governments' political biases influence decisions. Governments would only benefit groups that would vote for or fund them. Other participants felt that ministers are chosen based on being media-savvy and the ability to win elections leading to poor decision making. Some participants believed that pharmaceutical and health insurance companies have vested interests in the reimbursement of health technologies and that they disproportionately profit from government funding.

> *… our private health insurance* [companies] *find themselves somewhat responsible for a few of these drugs… [T]hey have a vested interest in this. We are paying these huge sums of money that goes to a great big pot instead of the government having to take all these responsibilities. (Focus Group Three, participant K)*

Many participants believed that pharmaceutical companies pressure governments to reimburse them. Some participants indicated a lack of trust in HTA processes and stated that trust in HTA organizations would have to be built over time. Some participants believed that media outlets might inaccurately report government actions and information from pharmaceutical companies due to their own vested interests.

> *I feel that you…we have a situation where we get information through the media that may not necessarily be what's going on behind those doors in that decision making, and so that distorts the public view… (Focus Group Three, participant D)*

In general, participants held the view that the public is a stakeholder in healthcare-related decisions because they fund the system through their taxes. However, participants also recognized that public participation might increase the complexity and costs of HTA and funding processes. Some participants discussed the difficulty of defining the public as this would depend on how people are selected to take part (e.g., an open invitation to an online survey or selection based on demographic criteria).

Advantages and disadvantages of the public being more closely involved in HTA processes were discussed. Advantages included: the public is unbiased, has no vested interests in comparison with other stakeholders, and has a broader perspective based on their life experiences. However, disadvantages included: the public can base their views only on their preferences (here, "preference" is used in its quotidian meaning as in something that is liked "best"), neglecting other relevant factors, and are not knowledgeable about health technologies, medical issues, or government processes.

Most participants described groups and individuals differently. For example, the public was regarded as impartial when considered as a collective, however individual members were seen as potentially biased toward benefiting themselves, their family, or friends. Similarly, governments were seen as concerned with balancing budgets and with party ideologies, but individual politicians were seen as biased by their personal desire to be re-elected. In general, when considered as individuals rather than as groups, stakeholders were seen as potentially influenced by a variety of personal factors, such as their own beliefs or relationships.

> *I think whoever heads up a particular ministry or position is trying to form a legacy for themselves. I have sat on so many* [name of the meeting] *where they have open houses and so on and they don't want to hear from you, they are just there for a photo op or something like that. (Focus Group Three, participant K)*

Participants suggested that institutional mechanisms need to be established to avoid individual preferences interfering with population-wide healthcare funding decisions.

Decision Making

Some participants stated that they did not understand the processes employed by the government to make decisions, suggesting that governments should educate, inform, and involve the public in such processes. Local governments were seen as more approachable and trustworthy than the federal government, and participants' trust tended to decrease as the level of government increased. Many participants said that they did not trust governments because they may only consider the interests of special-interest groups, prioritize short-term outcomes, and give too much power to key individuals who can be swayed by their personal or others' vested interests.

The majority of participants believed that the public should be engaged in funding decisions involving HTA; however, there were some dissident voices. Participants in favor of public involvement argued that public values and priorities could counterbalance the values and priorities of other stakeholders. For these participants, there is a need to increase transparency. Factors presented by the public as important should be considered in decision making, leading to greater public acceptance of controversial decisions.

> *I think though that one thing that comes in the public involvement that does make a difference, it's like the social license to make those decisions. Because more and more technologies become available that are very expensive and if they are not available, people are very upset about that because it's a life and death thing. (Focus Group One, participant K)*

The participants who expressed scepticism over involving the public said that committees with no public membership were more knowledgeable of government processes, medical issues and health technologies.

> *I'm happy to leave it* [healthcare funding decisions] *to experts because it's just a lot of education and knowledge that goes behind that assessment with all those different technologies, the cost of it and effectiveness… I don't think the general public understands enough about medical technologies to have valuable input. (Focus Group One, participant G)*

According to these participants, committees could still take into consideration the values of the public, gathered through research. Some of the reasons not to involve the public included potential delays in decisions and increased costs and bureaucracy. Also, members of the public might be unwilling to take part in involvement processes because they might not be interested or might feel that they lack the knowledge to make such decisions.

The majority of participants recognized public values as being relevant to funding decisions, especially when research evidence is not clear on whether the benefits of a health technology outweigh its harms. Public values were seen as appropriate to guide decisions because the public was seen as independent of the HTA and government processes, offering impartial views.

However, ascertaining the values of the public was not seen as straightforward. Some participants argued that some value judgments might change over time and depend on the type of health technology, whereas others may remain the same across different contexts. Regular consultations were proposed to determine the values of the public and to check whether government decisions were in line with public priorities.

Personal values were seen to have the potential to negatively impact decision making, particularly where they supported benefits for some groups to the detriment of others. Some participants argued that the personal values of clinicians, researchers, politicians, and health industry staff might be at odds with public values and priorities.

> *…scientists make their research… they already have a particular idea about what is valuable to research about… you already would have in some sense, thought about disease A if it is eradicated, for example. (…) But, that's a value that the bureaucrats or whoever sets the agenda bring to the table… I think that's problematic because, if they belong to a particular religious group, that might affect the value they place on sickness or the kind of way they think about that… Perhaps that's where public participation is important because the public needs to go and say, "No, that is not the value we want, what we want is this" to prevent the possibility that the bureaucrats will be bringing their own values and take it to be the values of the general Canadians. (Focus Group Three, participant E)*

In this sense, the public values were seen as able to offset the personal and group values of other stakeholders involved in HTA and funding decisions. The public was seen as not having a vested interest in the outcome of a specific healthcare funding decision, whereas all other stakeholder groups were seen as having a distinct stake in the outcome.

Public Involvement Processes

Participants discussed the stages at which public involvement would provide meaningful information to HTA processes and health-funding decisions. Some participants suggested that public perspectives could be included in setting priorities for HTA and establishing criteria for making decisions on whether health technologies should be publicly reimbursed. The underpinning rationale was that these areas especially involve value judgments, and the public can contribute more impartial value judgments than the other stakeholders. Additionally, public involvement was seen as useful at the assessment stage for controversial, value-

Table 1. Involvement processes suggested by participants

Type of involvement process	Appropriate objective	Benefits	Drawbacks
Surveys (online or mail)	Elicit preferences with respect to a list of options (e.g., which technologies should be prioritized for assessment, which values should be considered in a decision)	Online: Allow a greater number of people from anywhere in the province/country to take part Mail: Reach segments of the population with no access to digital resources	Online: Lack of security (digital files can be breached by people with vested interests in decisions) Mail: Many people do not respond to postal surveys Participants may not have enough information about healthcare system issues and may not contribute meaningfully to decisions Participants can be manipulated by those with vested interests
Online video vignettes	Inform the public about the complexity of some choices to increase public understanding of the ethical issues and opportunity costs in health-funding decisions	Transfer knowledge of healthcare funding issues to the public	May exclude segments of the population who do not have access to digital resources Participants may not have enough information about healthcare system issues and may not contribute meaningfully to decisions
Focus groups	Present information about government decision processes to the public Foster discussion between participants to elicit public values	Diverse groups of the population come together to discuss healthcare issues Participants can be selected to reflect the population's demographic characteristics and include a diversity of views Participants receive more in-depth information on complex healthcare system issues from various sources	More costly and time-consuming than surveys or online processes People may not express their genuine views because they want to conform to what the majority of the group thinks (mob mentality) Only a small group of people would take part
Citizens' juries	Inform the public about government decision processes and diverse points of view in healthcare funding Foster discussion between participants to elicit public values	Diverse groups of the population come together to discuss healthcare issues Participants can be selected to reflect the population's demographic characteristics and include a diversity of views Participants can receive more in-depth information on complex healthcare system issues from various sources	More costly and time-consuming than surveys or online processes People may not express their genuine views because they want to conform to what the majority of the group thinks (mob mentality) Only a small group of people would take part
Audit committees	A committee comprising members of the public reviews the decisions made by recommendation committees to check whether they are aligned with public values	Allow the public (as an independent party) to act as a check and balance in relation to government processes Participants can be selected to reflect the population's demographic characteristics and include a diversity of views	May delay decisions No information on what happens when there is a disagreement between the audit committee and the review or recommendation committees

laden health technologies by providing public views on whether these should be publicly reimbursed.

Participants discussed various methods of public involvement with different types of processes considered more appropriate for specific objectives. Face-to-face methods would be most appropriate for value-laden questions or in developing criteria to guide policy makers in priority setting, reimbursement recommendations, and collecting information for the assessment of a health technology. Surveys were seen as appropriate when governments need to elicit public priorities with respect to a pre-determined list of options. Table 1 lists the involvement processes suggested by participants.

Some participants indicated that survey design factors could impact the results (how they are designed, delivered, and reported). Some participants suggested that the selection of participants for face-to-face involvement processes should be demographically based and able to ensure that the public is not influenced by other stakeholders (monetarily or with misinformation). Various participants talked positively about citizens' juries because their structure is similar to that of legal juries, with procedures that they are familiar with and trust. The timing of involvement was seen as important because it could potentially impact on people's trust in the process (e.g., if it occurs too late, the public may perceive it as tokenistic).

In all of the focus groups, information exchange between the public and HTA and funding decision stakeholders was seen as valuable. The public can provide information to HTA and decision-making processes regarding public values, which can improve decisions. In a reciprocal manner, the public can be informed about government processes, health technologies, health conditions and diseases, and the ethical and financial issues regarding some decisions. However, this two-way sharing of knowledge was considered a challenge by some participants. The main problems identified related to cost and issues in effectively and impartially translating technical information for a public audience.

> *…[N]o matter how you set up a board or however you make a decision…, you are going to end up pissing somebody off, right? Something is not going to be covered. Potentially, there is going to be room to learn; there is going to be room to grow. I think the more that communities and governments allow for that room to grow and evolve, the more that can be kind of a comfortable thing to know that you can say: "Ok, well maybe we are not making this decision the best way, let's try something else, instead of being like so rigid about it, I think that makes a difference." (Focus Group Three, participant K)*

Discussion

Our findings highlight that public concerns related to being listened to when it comes to specific funding decisions and a lack of trust in institutions and HTA stakeholders depending on how processes are managed. The main issues identified were a lack of understanding of the rationale for funding decisions, a lack of transparency in decisions processes, and distrust with respect to whose interests and values are being considered. Fostering public involvement was seen as a way of providing information to the public and a way to increase the diversity of social values to be included in decision making. In the scholarly literature (14), trust in government (or political trust) has similarly been linked to the transparency of government processes.

To understand how transparency plays into public trust and the social license that underpins public acceptance of government processes, we can turn to the study of Grimmelikhuijsen et al. (14). It highlights three features of transparency relating to the information made public: completeness (whether people have access to all of the information available); color (whether those releasing the information have reported it positively or negatively depending on their interests); and usability (how easy the information is to understand). Our findings suggest that, when it comes to healthcare funding decision making, at least some members of the Canadian public are dissatisfied in relation to all three elements: information about processes is too incomplete, too colored, and too hard to understand.

Job (15) explains how both "rational" and "relational" trust-building theories may play a role in explaining public trust in government. Job defines political trust as the "attitudes people have towards the future actions of government, government organizations, and the people who administer those abstract systems" (p. 3). Rational trust theories contend that trust is built in response to government performance, whereas some relational theories contend that trust is built on the basis of people's cultural norms, learning experiences and beliefs that are projected onto political institutions. Participants in our study presented reasons for their distrust that were both rational (governments are visibly influenced by others when managing public money) and relational (participants trust the federal government less than provincial and municipal governments because they feel the federal government is more distant from them). Low levels of political trust have been linked to lower levels of law compliance by citizens and potential problems in governability (16). In HTA, for example, people who distrust government healthcare policy-making processes may protest for changes when particular health technologies are not approved for funding.

Participants in our study identified the diverse "worldviews" of stakeholders in HTA and related healthcare funding decisions. "Worldviews" are defined as the assumptions people make about the world based on their experiences, genetics, and contextual influences (13). When a challenge arises, worldviews come into play in how the situation and its implications are seen by stakeholders. Challenging situations cannot be "solved" because the problem is seen differently by diverse stakeholders, but accommodations between the different worldviews can be achieved. Poetz (17) argues for the use of relationship management skills when it comes to public involvement around controversial issues that include technical or scientific information and cautions against striving for consensus in favor of simply finding ways to move forward.

Our findings suggest that the worldviews and interests of diverse stakeholder groups could potentially be at odds with what the public believes would be best for society. Governing political parties can be viewed as focusing on re-election, whereas bureaucrats can be viewed as overly concerned with cost savings at the expense of other public priorities. Health-related companies are seen as trying to increase their profits at the expense of others and undermining public involvement initiatives. Researchers are seen as having interests in specific topics of research that may not align with the views of other stakeholders.

Moe (18) recognizes that the public is indirectly invested in the decision by having an interest in how taxpayer money is used by the government and by having the potential to benefit in future from health technologies. Citizens' interests are "diffuse" (18) compared to the interests of other stakeholders, who receive direct benefits. In our research, participants presented the public interest as diffuse when the public was considered as a group. For this reason, many participants regarded the public as able to provide an outside perspective, in contrast with the government, clinicians, academics, and the health industry. Participants, however, also depicted the public as naïve and at risk of being manipulated because it generally lacked clinical and political expertise. In this context, public values can be understood as (19):

> *(…) providing normative consensus about (a) the rights, benefits, and prerogatives to which citizens should (and should not) be entitled; (b) the obligations of citizens to society, the state, and one another; and (c) the principles on which governments and policies should be based. (…) Citizens can hold a public value that is not the same as their own self-interested private value.*

Our findings indicate that participants looked beyond collective vested interests, pinpointing how individuals' worldviews and interests could affect decision making. To overcome this, participants suggested that decision-making processes needed a "check and balance" procedure and that the design of public involvement processes also needed safeguards against individual interests and values.

Participants in our focus groups reviewed the benefits and drawbacks of diverse methods, as can be seen in Table 1. Based on these considerations, most participants agreed that public involvement processes should employ a mixed-methods strategy to support the participation of a large number of people through surveys as well as informed public debate using deliberative processes. The representative methods (e.g., surveys and online vignettes) allow the views of a large number of people to inform decisions, preventing personal biases becoming prevalent in discussions. Participatory methods (e.g., citizens' juries, focus groups, and community forums) make it possible for members of the public to understand issues in-depth and to contribute more considered views, which may then carry the same weight provided by other well-informed stakeholders. Some challenges can arise relating to each type of democratic rationale when used to underpin involvement processes, according to Bevir (20,21). In a representative democracy, the public would not have access to sufficient information to present considered viewpoints; and in a participatory democracy, only a select group would participate, excluding most people from taking part in decisions. In line with modern democratic theory debates, our research highlights the tension between having direct participation from anyone and public involvement in which some procedures are in place to ensure that people can debate issues in facilitated spaces and present informed and considered views. One possible way forward is to use the mixed-methods strategy suggested by our participants.

Lopes et al. (22) also investigate how public involvement affects a lack of trust in government:

> *Involving the public in policy development and in making decisions can help foster closer links between citizens and governments. Such processes, however, need to be conducted in a way that is seen positively by participants as their view of the process can influence their opinions of government trustworthiness. Governments would also benefit from developing policies that increase the transparency of policy decisions (p. 21).*

Fox (23) explains that social accountability involves citizens monitoring government and private sectors using a series of methods, such as the audit committees suggested by our participants. Social accountability can be divided into two types: tactical (tools are used to give citizens a "voice") and strategic (various mechanisms are used to foster the necessary conditions for that to happen) (23). Strategic social accountability can be achieved when various stakeholders are involved, including the public: explicit consideration of diverse worldviews would enable deliberation on various issues that could affect government and healthcare funding processes. Our study participants argued that public involvement is a desirable feature of healthcare funding decision processes. However, other stakeholders may object to involving the public because they may be unsure about whether it is helpful, cost-effective, or too time-consuming. These concerns were also raised by some participants, who highlighted that the public was not knowledgeable about government or HTA processes. Martin (24) brings a relevant perspective to this debate when discussing the involvement of AIDS activists during drug trials. As members of the public, these activists were able to bring to the attention of health professionals and researchers "human values" that entailed trade-offs between scientific pragmatism (which could help alleviate suffering for some patients) and the scientific purity (keeping on with strict eligibility criteria for trials) that could still move research and care for patients forward (p. 38). There is little evidence in the healthcare literature about the benefits of involving the public in policy development. However, other fields, such as environmental sciences, have a long tradition of conducting and evaluating public engagement initiatives and have ascertained some benefits of these processes to the development of government policy (25).

From an SSM perspective, the views of all stakeholders should be considered when implementing changes to arrive at outcomes more likely to be acceptable to all, while building trust between those involved.

Conclusion

Our study found that members of the public in one Canadian province do not understand government decision-making processes and are suspicious of the interests driving the actions of various stakeholders involved in HTA processes and healthcare funding decisions. These findings demonstrate that governments can be seen as mostly just fighting to remain in power and pharmaceutical and insurance companies as mostly just wanting to turn a profit. The public, however, with its diffuse interest in funding decisions, can be regarded as an independent party that can contribute to HTA decision making with impartiality, notwithstanding our participant's recognition of the public's lack of knowledge about health technologies. Differences in levels of trust were also evident when participants talked about individuals as opposed to stakeholder groups, with individuals being viewed as overwhelmingly swayed by their own personal interests and stakeholder groups as being better able to seek broader benefits. Accordingly, participants reasoned that decision making should include public values to counterbalance the values of other stakeholder groups and mechanisms should be put in place to prevent individuals from making decisions that would unduly benefit themselves.

Members of the public believe that public involvement will help to incorporate public values into HTA decision making, although there are some recognized drawbacks, such as potential delays in decisions or increases in expense and bureaucracy.

Participants suggested various public involvement methods, such as surveys, focus groups, citizens' juries, and audit committees. Independent of which method is used, easy and timely access to relevant information and a rigorous selection process were considered essential to ensure diverse perspectives are included. An ideal strategy would include the collection of public priorities from large numbers of people, together with in-depth discussions from smaller groups of people. Another possibility could be to use the findings from an in-depth participatory method to spark wider public debate with a more representative method, such as a large-scale survey.

Public involvement should be comprehensive (occurring at multiple stages of the funding process) and accessible (reaching a wide range of people, providing reliable information, and an opportunity for deliberation) to be able to deliver valuable input to healthcare decision-making processes. Involving the public as one stakeholder of HTA and related funding decision processes can broaden policy makers' awareness of different values to be considered and potential implications of decisions that are not foreseen by other stakeholders. It will also allow the public to take part in government processes that will affect them. As part of a system, HTA could be used alongside social value judgments at different stages of health technology development, such as at the design of research projects and the real-world use of new technologies.

Supplementary material. The supplementary material for this article can be found at https://doi.org/10.1017/S0266462320000537

Acknowledgments. The authors acknowledge the contribution of Andrea Young for administrative support. EL received funding through an Endeavour Fellowship by the Australian Department of Education and Training, an Australian Post-Graduate Award from the University of Adelaide, and funding from the University of Alberta.

Conflict of interest. Dr. Stafinski reports participation 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. Prof. Merlin reports undertaking commissioned research for the Australian Government Department of Health, outside the submitted work. The Department of Health had no role in the funding, conception, design, analysis, or interpretation of the submitted work. Ms Lopes reports grants from Australian Government (Endeavour Award), non-financial support and other from University of Alberta (Health Technology and Policy Unit), during the conduct of the study. Dr. Carter reports grants from Australian Government (MSAC and PBAC), outside the submitted work. All other authors have nothing to disclose.

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Chapter 9: Discussion and Conclusion

This chapter concludes the thesis and is organised as follows. The overall findings of the research project and how they answer the research question are presented. Then, the main results of the five articles are summarised, the implications of the findings considered together are discussed, and recommendations for practice and further research are presented. The chapter ends with a brief conclusion.

9.1 Discussion

9.1.1 Answering the research question

This thesis set out to examine public involvement in Health Technology Assessment and healthcare funding decision making. Specifically, it set out to propose a rationale for public involvement processes based on an understanding of stakeholders' perspectives. The main research question posed was as follows. Why and how should the public be involved in HTA and healthcare funding decision-making processes?

The major finding of this research was that the diverse values and worldviews of the public and HTA stakeholders shape how they value HTA and how they see the role of public involvement in HTA. In this research, the public and HTA stakeholders provide different rationales to justify the need for public involvement in HTA, which answers the why of the main research question. According to HTA stakeholders, the public can provide information for value-based decisions, help prioritise health technologies for assessment, and learn about government funding decisions by taking part in engagement processes. By contrast, the public is concerned with counterbalancing the biases of HTA stakeholders and are hopeful that their participation will increase transparency and trust in HTA and related government healthcare funding decisions. Ideally, the rationale for public involvement strategies should be conceptualised by considering the perspectives of both the public and HTA stakeholders to accommodate their diverse worldviews. The difficulty in implementing public involvement in HTA owes partly to the different objectives arising from these perspectives. In addition, it is clear that there exists a complicated relationship between the fields of HTA (as a scientific endeavour), public involvement (as a partly democratic aspiration), and policy development processes (as a pragmatic governmental enterprise). These relationships between the fields of HTA, public involvement, and policy development will be discussed in more depth below (in the section: 9.2 Implications of the findings: Interplay between HTA, policy development, and the public involvement areas). Governments are increasingly involving the public in decision-making processes, and an HTA system which does not successfully adapt to incorporate the values of the public in its processes could have a limited future role. In order to the 'problematical situation' investigated here (public involvement in HTA and healthcare funding decisions) to move forward, all stakeholders should be able to reach accommodations, including governments, HTA agencies, and the public.

In terms of how public involvement strategies can be enacted, members of the public suggest the use of mixed-methods with small scale in-depth discussion with a relatively small number of members of the public and large-scale preference-scoping processes that allow the participation of a great number of people. Based on the results of this research, it is important to stress that public involvement methods should be chosen in accordance with the opinions of those organising and taking part in them and it should also consider context-specific factors as this can influence how appropriate these methods will be in the eyes of participants. In Canada, where the case study took place, making use of existing public deliberative fora, adapting them to HTA topics and using other mechanisms such as large-scale surveys, similar to those already used in some provinces, could be a way forward. Countries with similar HTA processes could also benefit from trying such public involvement strategies, taking into account deliberative and large-scale data collection methods already used in the country and consulting with relevant local stakeholders. However, cultural factors and political structures are essential factors to consider when planning public involvement activities, as they will influence stakeholders' interactions, personal worldviews and group values. It is recommended that such factors are formally included in any public involvement strategy.

9.2 A summary of the main results

This thesis began by investigating the reasons for public input into policy development and decision-making. An appraisal of extant research on public participation in government policy development (Chapters 3 and 4) found that one of the reasons to involve the public in policy development is to increase trust in government on the part of the public. As explained in Chapter 3, new governance strategies have been developed by governments to involve diverse social actors in decision making and thereby increase trust. The findings of a survey showed that the views of the public were influenced by how they evaluated public engagement processes, as well as how much they trusted similar political institutions. Two other relevant factors that influenced trust in government were the transparency of government processes and whether citizens had the power to influence decisions. These results support the idea that involving the public in policy development and decision making has a positive effect on the interactions between governments and the public, especially in terms of public trust. HTA intends to support government policy and involving the public in its processes will increase its relevance to policymakers. The adoption of a CAS and soft systems approach to the design of public involvement processes in HTA would be instrumental in improving confidence in healthcare funding decisions from the public's, and possibly other stakeholders', perspective.

According to academic researchers and HTA practitioners (e.g., evaluators who write HTA reports) involved in Patient and Public Involvement (PPI), there are multiple reasons to involve the public in HTA and health funding decisions. In Chapter 5, some of these reasons were made explicit:

- gather information about public values to inform value-based funding decisions,
- increase the legitimacy of HTA and policy processes,
- clarify the grounds of decision-making to the public, and
- increase the public's participation in their own healthcare and in democratic processes.

These are the views on public involvement from HTA practitioners involved in PPI rather than those who would take part (the public) or those wanting to make use of HTA findings (the government).

The introduction of public involvement in HTA processes will depend on the level of support among HTA stakeholders (namely, policymakers, health industry representatives, patients, patient organisation representatives, and potentially the public). HTA processes in Canada were examined through a Systems Thinking lens to uncover HTA stakeholders' perspectives in Chapter 6. It was demonstrated that people's worldviews and values influence HTA and health-funding related decisions. These worldviews affect how individuals process information and interact with one another. Stakeholders' group affiliations (e.g., representing industry or patient groups) also affected the interests and positions taken during decisions. All of these factors alongside contextual influences (e.g., political situation or economic conditions) can affect healthcare funding decision making and the potential for changes to such processes and HTA, including public involvement processes.

In Chapter 7, the viewpoints of the HTA stakeholders are presented. These stakeholders hold a range of views on whether the public should take part in healthcare funding decisions, with some supporting the inclusion of a public perspective and others finding it redundant given the role of elected officials and government staff. The majority of stakeholders did not see a role for the public in the HTA process per se, only prior or following the HTA process (e.g., prioritisation of health technologies to be assessed or HTA recommendation committees).

Chapter 8 shows that members of the public see their involvement in HTA as a counterbalance to the undue influence of values and interests of individual and stakeholder groups in HTA-related decision making. Members of the public described the various interests that they saw at play: governments with political biases, pharmaceutical and health insurance companies with financial interests in the reimbursement of health technologies, and the media with popular or sensationalist stories to spur readership and thereby profit. Trust in HTA organisations would have to be built over time, according to participants, who proposed a mixed-methods strategy to involve the public in HTA, including surveys, focus groups, deliberative fora, and audit committees. These findings are in line with and extend the results of Chapter 3, which highlighted the relevance of trust-building between the public and government. Participants also indicated that engagement should occur at different stages of HTA, including a broad range of members of the public, trustworthy information, and opportunity for discussion to satisfy their expectations. Participants suggested that the need for trust-building activities should also be widened to include other HTA stakeholders.

9.3 Implications of the findings: the interplay between HTA, policy development and public involvement areas

Considering HTA as a Complex Adaptive System brings an original perspective to the data collected from the interviews with HTA stakeholders and focus groups with members of the public. These two groups have contrasting views of the objectives for public involvement in HTA, as outlined above. This is, however, only the most superficial layer in the conflicting worldviews held by these two groups. As presented in Chapter 2, three different fields emerged as areas of focus in this body of research when investigating public involvement in HTA: engagement of the public in areas involving technical and scientific knowledge, government policy development, and HTA (as a healthcare system evaluation method). The underlying ideologies of each field play a role in how the engagement of the public in the HTA process is conceptualised by different stakeholders.

9.3.1 HTA and public involvement

The first of these areas of focus, public involvement in HTA has similar challenges to public involvement in health and other scientific disciplines. These challenges include the belief that the public does not have the skills and understanding to contribute to areas of scientific endeavour and that any attempts to engage the public may contaminate and corrupt the scientific process. These concerns are addressed by the 'Public Understanding of Science' (PUS), an area of transdisciplinary research and practice that examines the relationship between scientists and the public (1). Bauer's proposition of three main PUS paradigms, namely 'scientific literacy', 'public understanding', and 'science-in-society' (2), is useful to understand the main issues in this area and how they apply to HTA. The first two paradigms are based on a 'deficit model of public understanding of science' (3), in which it is believed that increasing scientific literacy results in both increased public understanding of, and positive attitudes towards, science and technology. The third paradigm, science-in-society, is an inversion of the deficit model and proposes that scientific experts are the ones who do not have knowledge or understanding of public aspirations.

According to the scientific literacy paradigm, the problem with engaging members of the public in science is their lack of knowledge about scientific facts, methods, appreciation of outcomes, and their belief in non-evidence-based knowledge (called 'superstition') (2). The objective of involving the public would then be to educate them, which resonates with some of the findings from Chapters 5 and 6. HTA stakeholders and some members of the public expressed concern over the lack of scientific knowledge and the need to educate the public. This has also been an argument cited in the literature as the purpose of public involvement processes in HTA (4).

In the public understanding of science paradigm, the positive aspects of technological development are highlighted to foster positive public attitudes towards science. The objective here goes beyond educating the public; the public should endorse scientific endeavours. Two strategies are devised to help change the public's attitudes: a) provision of information to and training of the public, and b) the promotion of scientific advances as positive and desirable (2). Chapter 5 shows that academic researchers and HTA practitioners involved in PPI believe that public involvement can help the public accept the rationale for difficult decisions related to health technologies, and this was endorsed by other HTA stakeholders. According to this argument, more knowledge about processes will result in goodwill towards HTA and health funding decisions. Support for this view can be found in the literature about public involvement in HTA (5).

In the science-in-society paradigm, the public is in a 'crisis of confidence' regarding scientific initiatives (2), which becomes explicit in areas where scientific knowledge guides policymaking. There is a rise in efforts to involve the public in the makings of the research or in policy processes to restore trust. Such initiatives are supposed to allow the public voice to emerge, and deliberative methods of participation are chosen for this objective (e.g., citizens' juries, consensus conferences, hearings, deliberative fora). This crisis of confidence can be seen clearly in the lack of trust in HTA stakeholders expressed by focus group participants in Chapter 8. These participants were not suspicious of the research knowledge per se but were distrustful of the attitudes and values of those involved in the process. Focus groups participants emphasised the relevance of deliberative methods in public involvement processes (together with other methodologies) to help counteract what they saw as problematic biases on the part of government and industry.

These three PUS paradigms help to place some of the challenges in public involvement in HTA in perspective, since they relate to the conceptualisation of knowledge and its utility by different social groups, particularly those producing and using science and the general public. Definition of knowledge in healthcare can be affected by the values of the different social groups. This issue has been discussed by Lopes and colleagues (6). Traditionally, public involvement processes in health have been trying to increase the public's knowledge of healthcare issues, as demonstrated earlier in this section. However, under the science-in-society paradigm, for example, these ventures are not likely to work from the public's perspective as the issue of a lack of trust would not be addressed. It is necessary to change the way public involvement processes are thought about and, instead of attempting to only upskill members of the public, there is a need to upskill researchers and policymakers in understanding the knowledge and values held by the public and their trust-building aspirations and incorporating these aspirations into policy development. All three PUS paradigms help explain the issues related to public involvement in HTA and can provide steps forward on how to achieve accommodations between HTA stakeholders and the public.

In HTA, patient involvement processes have progressed over time in line with the progression of PUS paradigms: initially, information was collected from patients to inform processes, but this was not deemed enough by patients (7). The next step was to involve patients in research and policy processes by educating and training them, which is currently the predominant model of involvement (4). However, the emergent trend is to involve patients in designing research and defining policy questions (8, 9). Public involvement in HTA and health policy decisions follows similar trends but at a much slower pace. The idea of the public as a different entity or stakeholder to patients is relatively new, and the debates around how to involve the public are still at the stage where there is a focus on gathering information, educating, and training members of the public. However, the findings of the focus group research presented here show that the public is willing to be part of priority setting processes and wants to help shape policy alongside other social actors. Members of the public believe that they can provide social values and priorities that should be taken into account in policy decisions. This is in line with the science-in-society paradigm, which reflects some of the more contemporary issues in this area.

9.3.2 HTA and government policy development

The second area of focus, government policy development, has been defined as: 'an "arena", or a space, in which a range of political actors, all recognized as having a legitimate place at the table (stakeholders), interact to produce policy' (10). However, government policymaking can also have an 'authoritative' role as governments take purposive action to solve problems (10, 11). On both these accounts, governments have to interact with other social actors to fulfil their role. Kooiman (12) has proposed a recent governance theory, based on Systems Thinking. Kooiman coined the term 'interactive governance' to define governance as a system, which is continuously evolving due to the actions and interactions of different social actors:

> [interactive governance is] the whole of interactions taken to solve societal problems and to create societal opportunities; including the formulation and application of principles guiding those interactions and care for institutions that enable and control them (12).

As discussed in Chapters 3 and 4, governments have been employing several tools to engage the public in policy development in various departments, including healthcare systems and HTA-informed decision making. HTA agencies can either be independent entities that provide services to the government or be part of governmental structures (13). Whether they are internal or external to government, HTA agencies occupy a particular space in which they interact with different stakeholders and provide expert knowledge to inform government policy but are essentially independent from both stakeholders and government. As such, HTA agencies have been conceptualised as 'boundary organisations' (14).

According to Guston (15), boundary organisations are part of an evolution of the relationship between the social worlds of science and politics. Boundary organisations act as bridges between two different areas: in the case of HTA, the organisations bridge the scholarly work produced in the health sciences and the political application of such knowledge. However, the production and transfer of knowledge in the health area brings its own difficulties to HTA's role as a boundary organisation. Jones (11), for example, presents three paradigms in the scholarly literature about knowledge transfer into the political domain that helps to understand the challenges HTA agencies face. The first paradigm is named 'rational' (in which knowledge guides policy development), the second is 'pluralism or opportunism' (in which the uptake of knowledge is pragmatic and opportunistic, depending on efforts from various social actors), and the third is 'politics and legitimisation' (in which the notion of power struggles come into play and knowledge is seen to support power structures and imbalances).

In line with the politics and legitimisation paradigm, Chapter 6 presents HTA stakeholders' descriptions of their interactions as a power struggle, in which the influence of different social actors varies depending on the context. Uptake of or disregard for scientific knowledge in healthcare settings can also follow the rational paradigm (when HTA-based recommendations are followed) or the pluralism or opportunism paradigm (as was the case with the Herceptin story presented in Chapter 1). An example of an opportunism paradigm is when the value of the knowledge provided by HTA is questioned by some stakeholders who suggest that the HTA process is not appropriate for some specific health technologies, or that the process may not include all the relevant information necessary for decision making. In this scenario, HTA/government structures are under pressure to be changed and to attend to the needs of the various social actors involved in the development of policy. As a Complex Adaptive System, HTA adapts by expanding its reach to involving other stakeholders: in this case, patients and, increasingly, the public. Currently, depending on the jurisdiction, the staff at some HTA organisations develop formal and informal relationships with other stakeholders (such as the health industry and patient organisations), and develop processes to interact with patients and the public.

The findings of this project have provided evidence that public involvement in HTA and healthcare funding decisions can best be understood by two different research paradigms: 1) 'science-in-society' from the Public Understanding of Science and 2) 'politics and legitimisation' from knowledge transfer to the political domain. Research in these two areas can also present some additional resources to be utilised in planning public involvement strategies for HTA. For challenges related to 'science-in-society' paradigm, Bauer and Falade (2) suggest that knowledge about the impact of public involvement processes can be built over time by collecting data via longitudinal designs (including quantitative and qualitative studies). In relation to 'politics and legitimisation' paradigm, Jones (11) suggests the use of different strategies namely: translation of knowledge, communication, interaction and exchange of information, and use of intermediaries with social influence to facilitate the transfer of scientific knowledge to political areas. These ideas can help planning strategies for the development of public involvement processes. In the next section, some guidelines for planning public involvement processes are presented.

9.4 Recommendations for practice

The findings of this research have implications for practice. For governments, involving the public in policy development and decision making should be beneficial in:

1) increasing public trust in government, particularly for remote institutions, such as state and federal or national governments,

2) increasing the types of information available to understand policy challenges and understanding of the nature of the underpinning values held by the public relevant to policy development and decision making, and

3) broadening of the range of possible solutions to policy topics by involving the public.

Strategies for public involvement, to be successful, should be designed with the input of those who are to be involved, those organising the exercise, and any other stakeholder affected by the outcome. These research findings suggest that interactions between stakeholders happen independently of formal processes; however, formal fora for discussion were still highlighted by participants as useful to understanding the issues and the range of viewpoints from all stakeholders. In addition, formal fora introduce additional options for potential ways forward. Some research participants suggested the use of a mixed-method public involvement strategy with face-to-face methods (to allow the public to provide considered views after in-depth discussion) and online methods (to enable the participation of a large number of people and counterbalance personal biases). Most of the public involvement processes suggested were based on participants' previous experiences with these methods. Development of public involvement strategies should take into account contextual and cultural factors and the values of those to be involved, and it may look different for different countries and for different jurisdictions within a country.

9.5 Recommendations for further research

This research project used Complex Adaptive Systems and Soft Systems Methodology as theoretical frameworks. Future research could benefit from adopting this approach and extending it by using some methodological techniques from Complex Adaptive Systems, such as Social Network Analysis to collect other data on interactions and personal characteristics of stakeholders. This could complement information gathered through interviews in giving an in-depth account of interactions between people within a system. Longitudinal designs would also be useful in understanding how specific systems behave over time, since a complex and adaptive system is a continuous, dynamic entity.

In transdisciplinary research, examining the assumptions and practices of different fields can illuminate the underlying issues that arise from the interaction between these different areas. This changes the focus from the superficial analysis of the causes of problems to the consequences of deep-set values that may be feeding into these problems. To do this, researchers need to examine the theories which inform the practices in the interacting research areas and design projects that take those factors into account, which can result in innovative approaches. In Soft Systems Methodology, the process of inquiry is a loop, in which the answers to the initial research question results in more questions that require other answers, in a continuous process of improvement. Adopting this process-improvement mindset in the development of research can benefit the advancement of the field of public involvement in HTA.

9.6 Limitations

This research has some limitations. The case study was undertaken in Canada, and it relates to the experiences of Canadian HTA stakeholders and the public. Countries with different political regimes and healthcare system structures may have significantly different contextual and cultural factors influencing public participation in HTA, and the applicability of these findings may be limited. Part of this research was conducted in Australia, which has a similarly structured healthcare system and HTA processes. However, Australia has very different patient and public involvement processes, which highlights the relevance of taking into account local experiences when designing strategies to involve the public in healthcare funding decisions.

The examination of Canadian HTA as a Complex Adaptive System through semi-structured interviews and focus groups means that the information available for analysis was limited; the design of the studies did not allow for consideration of other cultural and contextual factors to be included in the analysis.

The research design did not allow the dynamism of a complex adaptive system to be captured in its actual form, and the information about the system included in this research is specific to the time of the data collection, which restricts a more in-depth examination of how the public involvement in HTA evolves over time.

9.7 Conclusion

Examining HTA as a Complex Adaptive System helps us to understand the pressure for change in HTA processes. Individual stakeholders involved in HTA hold particular worldviews and personal and group values which are often shared by those with similar roles in HTA and related decision-making processes. The inclusion of members of the public as part of the system adds another set of individual and group values that may be quite different from the values currently considered in healthcare funding decisions. However, there may be pressure to include the public due to changes in the political environment surrounding HTA, particularly the adoption of new governance models which require broader engagement with a range of social actors. The way public involvement processes are managed can influence their success in the eyes of the public and its consequences for trust in government. Consideration should be given to the public's and other stakeholders' views on how the involvement should occur. Having a new stakeholder embedded in HTA and related policy processes will likely change the dynamics of the system. However, diversifying views and types of information inputted into HTA can also improve the usefulness of HTA to the government.

9.8 Chapter references

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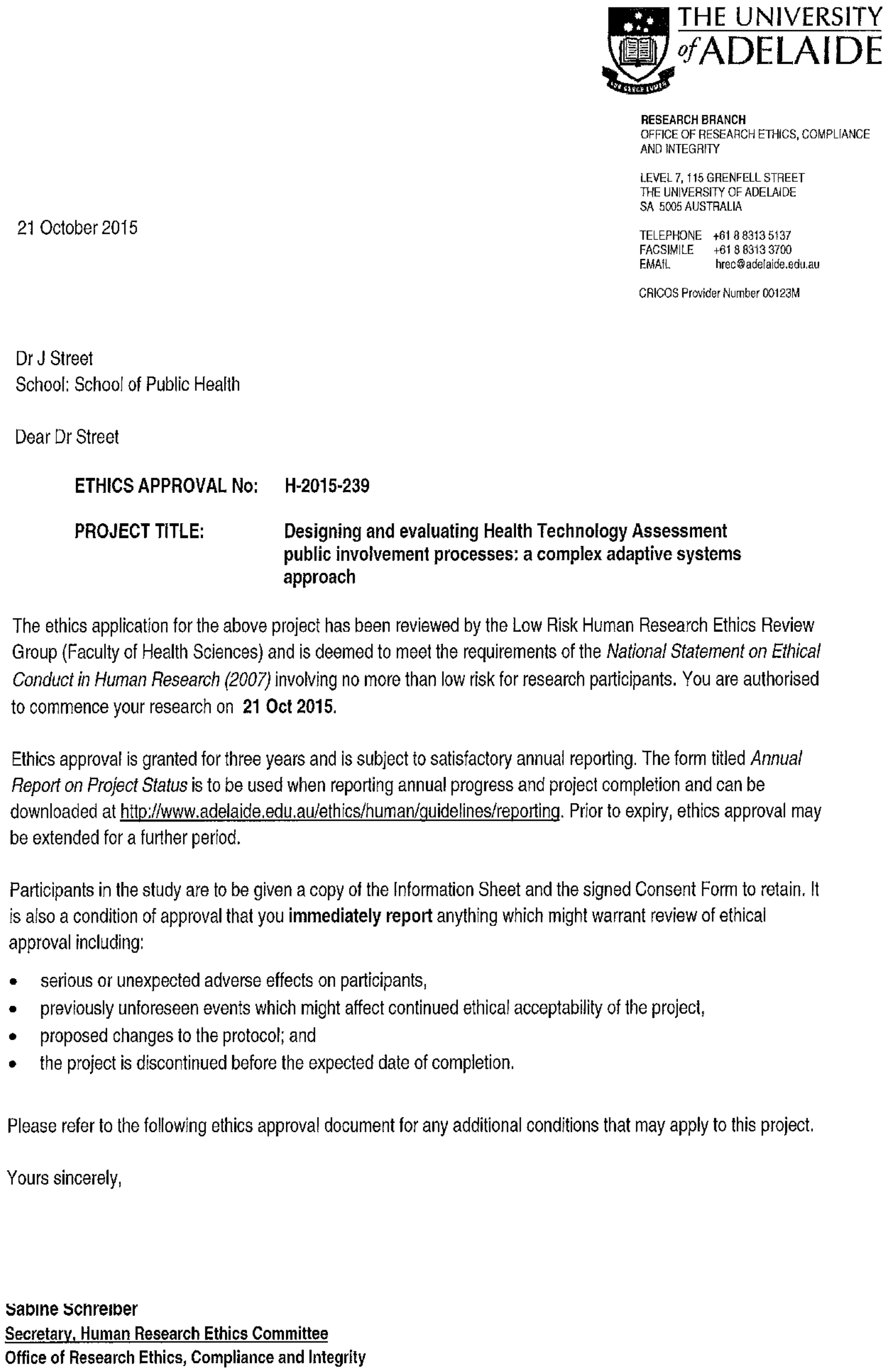
Appendices

This section contains supplementary materials related to Chapters 3, 5, 6, 7, and 8. These materials have also been published as part of a paper (and are available online).

Chapter 3 Appendix

The information contained here is associated with Chapter 3's paper: Is trust in government rational, relational or both? An empirical study of predictors of trust in the South Australian government.

Ethics approval



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21 October 2015

Dr J Street
School: School of Public Health

Dear Dr Street

ETHICS APPROVAL No: **H-2015-239**

PROJECT TITLE: **Designing and evaluating Health Technology Assessment public involvement processes: a complex adaptive systems approach**

The ethics application for the above project has been reviewed by the Low Risk Human Research Ethics Review Group (Faculty of Health Sciences) and is deemed to meet the requirements of the *National Statement on Ethical Conduct in Human Research (2007)* involving no more than low risk for research participants. You are authorised to commence your research on **21 Oct 2015**.

Ethics approval is granted for three years and is subject to satisfactory annual reporting. The form titled *Annual Report on Project Status* is to be used when reporting annual progress and project completion and can be downloaded at http://www.adelaide.edu.au/ethics/human/guidelines/reporting. Prior to expiry, ethics approval may be extended for a further period.

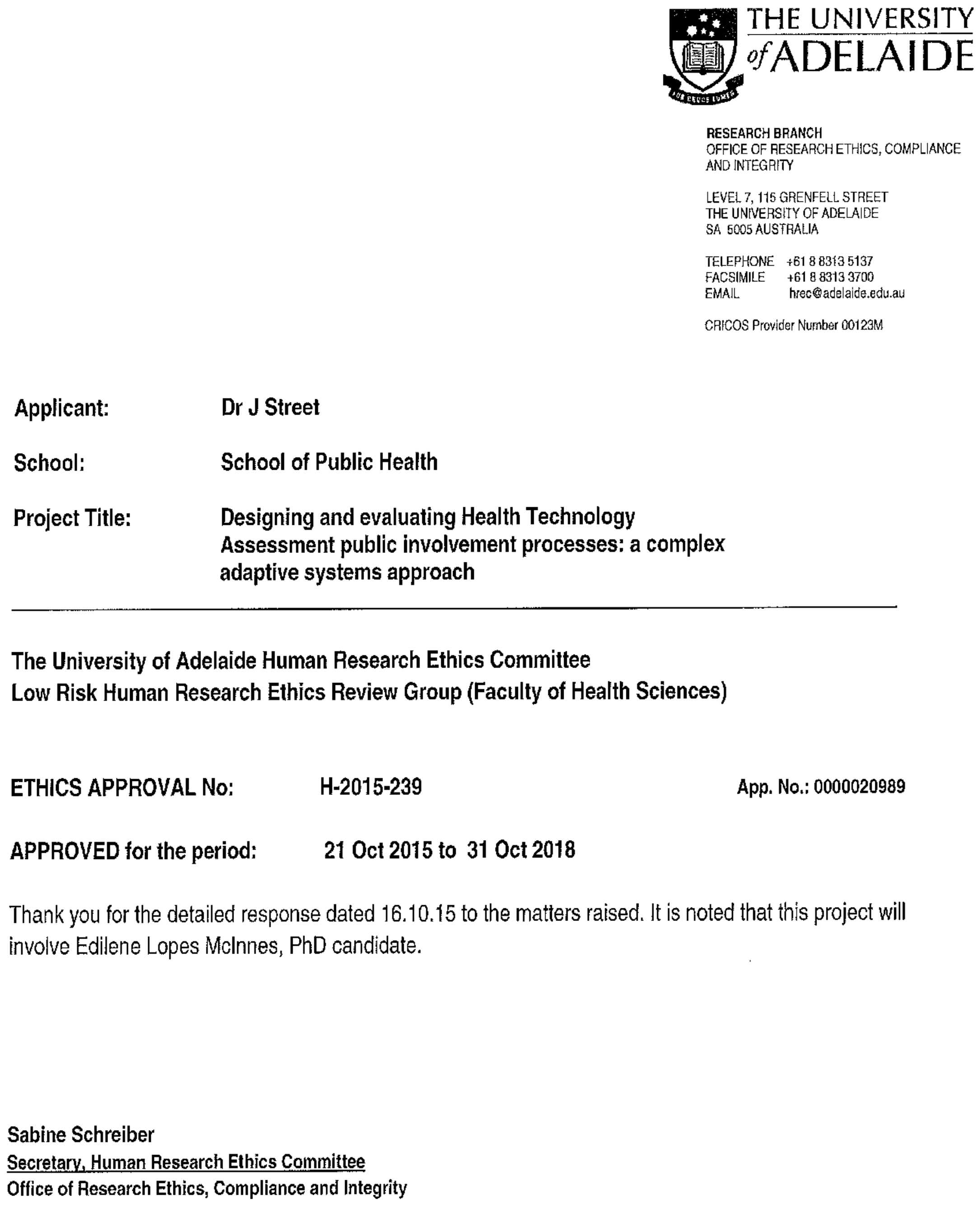
Participants in the study are to be given a copy of the Information Sheet and the signed Consent Form to retain. It is also a condition of approval that you **immediately report** anything which might warrant review of ethical approval including:

- serious or unexpected adverse effects on participants,
- previously unforeseen events which might affect continued ethical acceptability of the project,
- proposed changes to the protocol; and
- the project is discontinued before the expected date of completion.

Please refer to the following ethics approval document for any additional conditions that may apply to this project.

Yours sincerely,

Sabine Schreiber
Secretary, Human Research Ethics Committee
Office of Research Ethics, Compliance and Integrity



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CRICOS Provider Number 00123M

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School:	**School of Public Health**
Project Title:	**Designing and evaluating Health Technology Assessment public involvement processes: a complex adaptive systems approach**

The University of Adelaide Human Research Ethics Committee
Low Risk Human Research Ethics Review Group (Faculty of Health Sciences)

ETHICS APPROVAL No: **H-2015-239** **App. No.: 0000020989**

APPROVED for the period: **21 Oct 2015 to 31 Oct 2018**

Thank you for the detailed response dated 16.10.15 to the matters raised. It is noted that this project will involve Edilene Lopes McInnes, PhD candidate.

Sabine Schreiber
Secretary, Human Research Ethics Committee
Office of Research Ethics, Compliance and Integrity

Privacy policy for the online survey

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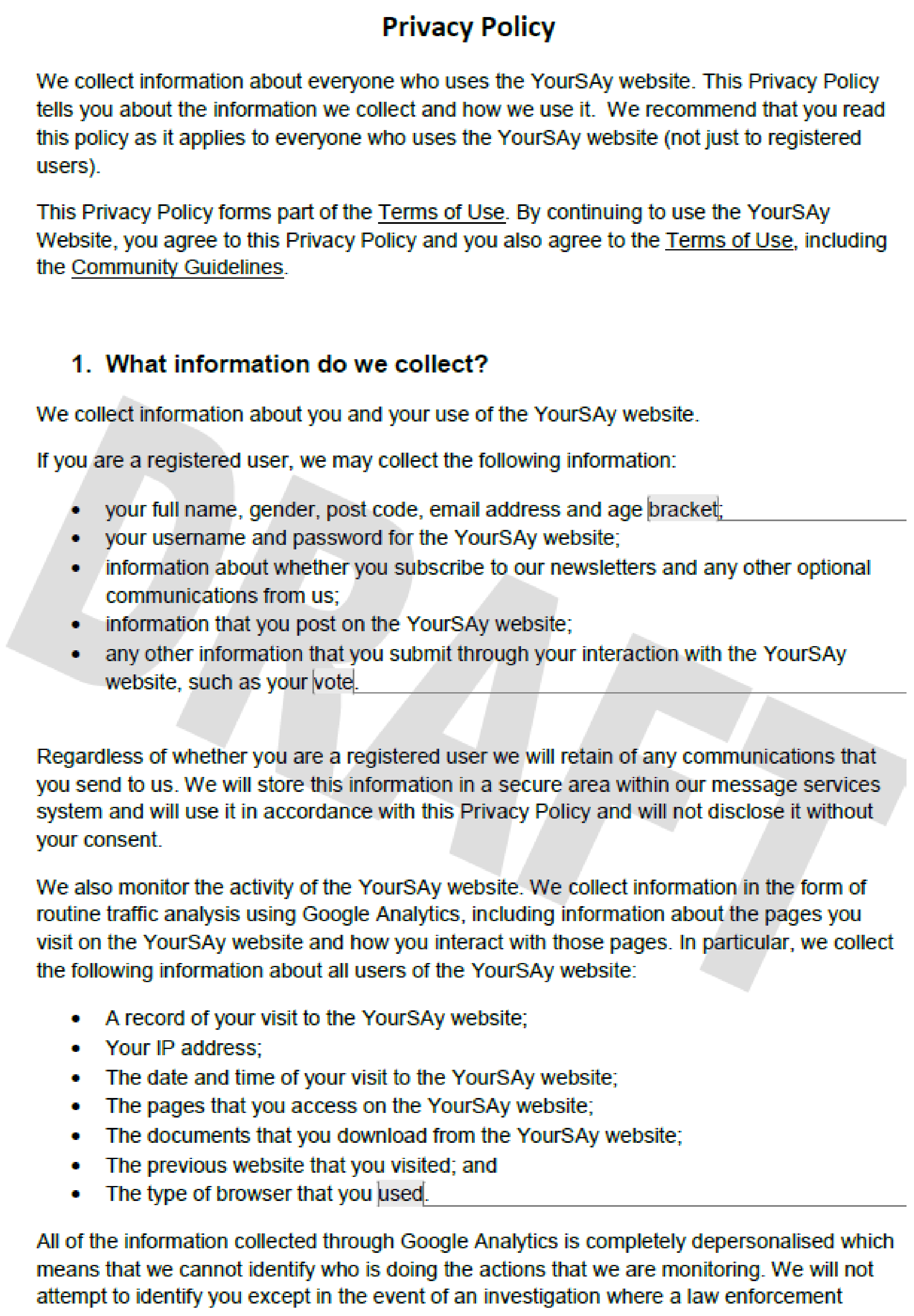

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This Privacy Policy forms part of the Terms of Use. By continuing to use the YourSAy Website, you agree to this Privacy Policy and you also agree to the Terms of Use, including the Community Guidelines.

1. What information do we collect?

We collect information about you and your use of the YourSAy website.

If you are a registered user, we may collect the following information:

- your full name, gender, post code, email address and age bracket;
- your username and password for the YourSAy website;
- information about whether you subscribe to our newsletters and any other optional communications from us;
- information that you post on the YourSAy website;
- any other information that you submit through your interaction with the YourSAy website, such as your vote.

Regardless of whether you are a registered user we will retain of any communications that you send to us. We will store this information in a secure area within our message services system and will use it in accordance with this Privacy Policy and will not disclose it without your consent.

We also monitor the activity of the YourSAy website. We collect information in the form of routine traffic analysis using Google Analytics, including information about the pages you visit on the YourSAy website and how you interact with those pages. In particular, we collect the following information about all users of the YourSAy website:

- A record of your visit to the YourSAy website;
- Your IP address;
- The date and time of your visit to the YourSAy website;
- The pages that you access on the YourSAy website;
- The documents that you download from the YourSAy website;
- The previous website that you visited; and
- The type of browser that you used.

All of the information collected through Google Analytics is completely depersonalised which means that we cannot identify who is doing the actions that we are monitoring. We will not attempt to identify you except in the event of an investigation where a law enforcement agency may exercise a warrant to inspect our service provider's logs or where we are legally compelled to do so.

We intend to use the data that we collect using Google Analytics to be able to inform you and other users of the website about statistics relevant to the website.

We are responsible for the privacy and security of the information while it is collected, stored on or passing through the YourSAy website. The information that we collect may or may not be personal information for the purpose of the State of South Australia's Information Privacy Principles. We operate the YourSAy website in accordance with those principles. A copy of the Information Privacy Principles can be obtained from the South Australian Department of the Premier and Cabinet's website.

2. Is the information that we collect accurate?

We try to ensure that the information that we collect is accurate. However, we need your help with this. If information that you have provided us is no longer accurate, please contact us at bettertogether@sa.gov.au so that we can update our records.

3. What's publically available and what's not?

Not all of the information that you provide us will be able to be viewed by other users of the YourSAy website. Of course, information that you post on the YourSAy website will be able to be viewed by everyone who uses the website. Each post will contain your full name. However, we will not disclose the following to other users:

- Your password for the YourSAy website;
- Your post code, email address and age bracket;
- Communications that you send to bettertogether@sa.gov.au or that you send us through the Contact Us page on the YourSAy website.

We will protect and handle your personal information in accordance with the Information Privacy Principles. If we need to share your personal information with a third-party, then we will ensure that we comply with the Information Privacy Principles.

4. How will we use your personal information?

We will use the information about you:

- to administer the YourSAy website and your account on the YourSAy website;
- to identify when you sign into your account on the YourSAy website;
- to send you newsletters and information about other things that may interest you, but only when you have agreed to us sending you this information;
- to respond to queries that you have contacted us about;
- to attribute content that you post on the YourSAy website to you;

- to analyse the use of the YourSAy website;
- to [insert]; and
- for any other purposes that we may disclose to you when we request your information.

The information is stored in a secure area of the YourSAy website's system.

Regardless of whether the information that we collect is personal information for the purposes of the Information Privacy Principles, by continuing to use the YourSAy website you consent to us collecting and using this information in the ways specified in this Privacy Policy.

5. When will we contact you?

We may send you other emails and announcements from time to time. However, we will try to keep these to a minimum.

You can choose to receive newsletters and other updates from us by email. If you choose this but then change your mind, you can unsubscribe at any time by following the process set out in the emails that we send you.

6. Other matters

There are some other important matters that you should know about:

- You should note that there are inherent risks associated with transmission of information via the internet. You should make your own assessment of the potential risks to the security of your information when making a decision as to whether or not to use the YourSAy website. There are alternative ways to obtain information from, and transact business with, us if you do not wish to use the internet.

- There are links to other websites on the YourSAy website. If you click on one of those links, you will leave the YourSAy website. This Privacy Policy will not apply to the other website.

- We reserve the right to release information about you if we are required to do so by law, or if we believe that such action is necessary to comply with State and Federal laws or to respond to a court order, subpoena or a search warrant.

- We also reserve the right to disclose information about you when we believe, in good faith, that it is appropriate or necessary to enforce our Terms of Use, to take precautions against liability, for us to investigate and defend against any third-party claims or allegations, to assist government enforcement agencies, to protect the security or integrity of the YourSAy website, and to protect the rights, property or personal safety of us, our users or others.

- The information that you submit through the YourSAy website may be transferred to countries other than Australia. We will protect all information that we receive in accordance with this Privacy Policy.

- We may update the content of this Privacy Policy from time to time for any reason. The updated version of the Privacy Policy will apply to you as soon as it is posted on the YourSAy website, so we suggest that each time you return to the YourSAy website you should read the Privacy Policy (and the Terms of Use and Community Guidelines) carefully.

7. Questions

If you have any questions, please contact us at bettertogether@sa.gov.au.

Questionnaire development process

Stage 1: Developing concepts to be tested

Concept 1: Government Performance

- Engagement evaluation: Question 2
- Government evaluation: Question 10
- Citizen power or lack of power: Question 7
- Perception of corruption: Questions 5 and 6
- Government policy decision making: Question 3

Concept 2: Trust

Familiar trust: Question 8, items: a, c, and d

- Social trust (general): Question 4
- Social trust (different situations): Question 8, items: b, e, f, g, and h
- Political trust (local): Question 9, items: a, b, c, and g
- Political trust (remote): Question 9: items: d, e, f, h and i
- Institutional trust (local): Question 11

Concept 3: Social Demographic characteristics

- Age
- Gender
- Marital status
- Children
- Country of birth
- Aboriginal or Torres Strait Islander origin
- Language
- Education
- Employment status
- Postcode

Stage 2: Developing questions

Engagement evaluation questions were developed based on Rowe and Frewer's framework. Some performance questions and all of the trust questions were based on Job's research.

Stage 3: First review of questions by research supervisors (JS and DC). Changes made to some questions: Question 3, item 'b' (wording), Question 4 (wording), Question 8, item 'h' (wording), Question 11, item 'a' (wording).

Stage 4: Second review of questions by DPC staff (RL). Changes made to some questions: Question 1 (open ended) removed, Question 3, items 'a', 'c', 'd' (wording), Question 4, items 'b', 'c' (wording), Question 6 (wording), Question 8, items 'e', 'h' (wording), Question 9, items 'a', 'e', 'f', 'g' (wording), Question 10, item 'd' (wording), Question 11, item 'a' (wording), added Questions 12 and 13.

Stage 5: Cognitive interviewing with nine people from different backgrounds and diverse South Australian regions. Significant changes made to questionnaire, including order of the questions, wording, and removal of some questions. Changes were made based on the outcomes of cognitive interviewing. After the cognitive interviews were conducted and the answers reviewed by ELM and JS, changes were made to the questionnaire. The following questions/sub-items were modified based on the cognitive interviews: Question 2, items ‘c’, ‘f’, Question 3 (heading), items ‘a’, ‘b’, Question 4, items ‘a’, ‘b’, ‘c’, ‘d’, ‘e’, ‘f’, Question 5 (heading), Question 8 (all items), Question 9 (heading), and Question 10, items ‘a’, ‘b’, and ‘c’.

Stage 6: Testing with 8 respondents (skirmish) to check validity of questions, and how much time, on average, it took people to answer the questionnaire. The following questions/items were modified or considered for further analysis at the pilot test stage: Question 3, item ‘d’, Question 7, item ‘a’, Question 8, items ‘a’, ‘e’, Question 9, items ‘d’, ‘f’, ‘i’, Question 10, items ‘c’, ‘d’, and Question 11, item ‘b’.

Stage 7: Pilot test using an online engagement process conducted by DPC.

Stage 8: Addition of demographic questions.

Stage 9: Review of survey in the host software (‘Survey Monkey’).

Stage 10: Review of questions before releasing the survey.

Cognitive interviews (Stage 5)

Some of the criteria used in cognitive interviewing:
Meaning: ensure that respondents understand the meaning of the question and that you understand their answer.
Analysis of item non-response rates and response distribution: identify questions that respondents do not want to answer. Analysis of response distributions could indicate that other changes may be necessary.
Number of people interviewed: 9

Characteristics:

- Participant 1 (P1) - Female, 36 years old, employed, University degree, married with an adult child who lives with her, lives West of the city, migrant living in Australia for over 5 years.
- Participant 2 (P2) - Female, 30 years old, PhD student, married, pregnant, lives South of the city, Australian.
- Participant 3 (P3) - Male, 34 years old, tradesman, apprenticeship, married with no kids, lives North of the city, Australian.
- Participant 4 (P4) - Female, 62 years old, retired for a long time, no University degree, married with adult children who don’t live with her, lives in the country, Australian.
- Participant 5 (P5) - Female, 28 years old, Diploma, employed, married with three young children, lives in the country, Australian.
- Participant 6 (P6) - Male, 36 years old, University degree, professional job, single, live in Adelaide city, from South Africa but grew up in Australia.

- Participant 7 (P7) - Male, 69 years old, recently retired, no University degree, married with adult children who don't live with him, lives South of the city, Australian.
- Participant 8 (P8) - Male, 28 years old, PhD student, married with no children, lives in the city, international student living in Adelaide for 10 months.
- Participant 9 (P9) - Female, 21 years old, University student with two casual jobs, single with no children, lives West of the city, migrant, living in Adelaide for four years.

Skirmish (stage 8)

Some of the criteria used in skirmish:
Analysis of item non-response rates and response distributions: identification of questions that respondents are unwilling to answer. Analysis of response distributions assists in assessing whether there is need for changes to the question wording or the classifications used.
Variation: if most people give similar answers to a question, it will be of little use in later analysis and we should assess whether the question should be kept in the final questionnaire.
Redundancy: If two questions measure the same thing, only one is needed in the final questionnaire.
Non-response: the refusal of a large number of people to answer a particular question produces difficulty at the data analysis stage and can lead to serious reductions in sample size.
Timing: how long it takes for participants to answer the questionnaire.
Number of people who answered the whole questionnaire: 8

Participants' characteristics:

- Participant 1 (P1) - Female, 37 years old, employed, University degree, married with a young child, lives in the city, Australian.
- Participant 2 (P2) - Male, 36 years old, employed, University degree, married, no children, lives Northwest of the city, Australian.
- Participant 3 (P3) - Female, 28 years old, PhD student, single, lives Northwest of the city, Australian.
- Participant 4 (P4) - Male, 65 years old, retired, Australian.
- Participant 5 (P5) - Female, 60 years old, Diploma, employed, married with two adult children who don't live with her, lives South of the city, Australian.
- Participant 6 (P6) - Male, 30 years old, no University degree, unemployed, married, lives North of the city, Australian.
- Participant 7 (P7) - Female, 34 years old, University degree, unemployed, single, lives South of the city, Australian.
- Participant 8 (P8) - Female, 28 years old, PhD student, single, lives in the city, international student living in Adelaide for 5 years.

Pilot testing (stage 7)

Pilot testing was conducted from February to early April. An email with a link to the online survey questionnaire was sent to participants who took part in one of YourSAy online engagement processes that took place in 2016/2017. We received 48 responses for analysis. Statistical support was sourced from the School of Public Health at the University of Adelaide. No changes were made to the questionnaire. Demographic questions had to be added to the questionnaire after pilot testing was done because we were unable to use the information already collected by the DPC.

Some of the criteria used in pilot testing the questionnaire:
Analysis of item non-response rates and response distributions: identification of questions that respondents are unwilling to answer due to their sensitivity. Analysis of response distributions provides indication
Variation: if most people give similar answers to a question, it will be of little use in later analysis.
Redundancy: If two questions measure the same thing, one can be removed. If two items are designed to measure the same concept and are highly correlated, one of the items can be dropped.
Non-response: assess the need to remove a question if a large number of people decide to not answer it.

Research project questionnaire

1. Have you taken part in any of the following programs?

QUESTION ITEMS	SCALE	
	Yes	No
a) Fund My Community 2017	1	2
b) Fund My Idea	1	2
c) Fund My Project – Riverine Recovery	1	2

2. Below are some statements about the online process in which you have just participated. Please indicate how much you agree or disagree with each statement by choosing the number that is closest to your own view.

QUESTION ITEMS	SCALE				
	Strongly disagree	Disagree	Neither	Agree	Strongly agree
a) I was able to access enough information about the topic	1	2	3	4	5

b) I was able to express my opinion about the topic	1	2	3	4	5
c) Thinking about topics that interest me, online methods are the best way for me to provide my views to the State Government	1	2	3	4	5
d) I believe that the State Government will take the results of online methods into account when making a decision	1	2	3	4	5
e) I believe that anyone would be able to take part in this type of online process	1	2	3	4	5

3. This question relates to policy decisions that governments need to make. Please indicate how much you agree or disagree with each statement by choosing the number that is closest to your own view.

QUESTION ITEMS	SCALE				
	Strongly disagree	Disagree	Neither	Agree	Strongly agree
a) I believe the way governments make policy decisions is complex	1	2	3	4	5
b) I believe the way governments make decisions is transparent	1	2	3	4	5
c) I believe policy decisions are best made exclusively by experts or professionals with knowledge in the particular area/topic	1	2	3	4	5
d) I believe policy decisions are best made with input from the general public	1	2	3	4	5

The next three questions relate to general trust. Please indicate your answer by choosing the number that is closest to your own view. Note that we are using different scales.

4. Generally speaking, would you say that most people can be trusted or cannot be trusted?

SCALE						
Most people cannot be trusted 1	2	3	Neutral 4	5	6	Most people can be trusted 7

5. Generally speaking, would you say that politics in South Australia is:

SCALE						
Honest 1	2	3	Neutral 4	5	6	Corrupt 7

6. And how would you describe politics in Australia?

SCALE						
Honest 1	2	3	Neutral 4	5	6	Corrupt 7

The next questions relate to trust in other people, trust in institutions, and trust in government. Read on and follow the instructions given in each question.

7. Below are some statements about how people relate to each other. Please indicate how much you agree or disagree with each statement by choosing the number that is closest to your own view.

QUESTION ITEMS	**SCALE**				
	Strongly disagree	**Disagree**	**Neither**	**Agree**	**Strongly agree**
a) Most people in positions of power in society try to exploit me	1	2	3	4	5
b) Governments are not really concerned with what happens to me	1	2	3	4	5
c) Most people in my day to day dealings try to be fair with me	1	2	3	4	5
d) Most people in my day to day dealings would try to take advantage of me if they got the chance	1	2	3	4	5
e) Governments act to benefit groups with financial, ideological, or other special interests in government decisions	1	2	3	4	5
f) I feel left out of what is happening around me, for example in my community	1	2	3	4	5
g) People like me don't have any say about what the State Government does	1	2	3	4	5
h) People like me don't have any say about what the Federal Government does	1	2	3	4	5

8. The following asks your opinion about trusting other people. Would you please indicate how much you feel you can trust these different groups of people? Choose the number that is closest to how you feel.

QUESTION ITEMS	SCALE					
	Not trust them at all	Trust them very little	Neither	Trust them a fair bit	Trust them a lot	Not applicable
a) People in your immediate family	1	2	3	4	5	N/A
b) People in your neighbourhood	1	2	3	4	5	N/A
c) Your boss or supervisor	1	2	3	4	5	N/A
d) People you work with	1	2	3	4	5	N/A
e) People at your church or place of worship	1	2	3	4	5	N/A
f) People in the same sporting clubs or social activities as you	1	2	3	4	5	N/A
g) People who work in the stores where you shop regularly	1	2	3	4	5	N/A
h) People you encounter in the city/region in which you live	1	2	3	4	5	N/A

9. The following is a list of different institutions or organisations. For each one would you please indicate how much you can trust them by choosing a number that is closest to how you feel. By trust, we mean the trust you have in their ability to meet community needs and expectations.

QUESTION ITEMS	SCALE					
	Not trust them at all	Trust them very little	Neither	Trust them a fair bit	Trust them a lot	Not applicable
a) The police station in your area	1	2	3	4	5	N/A
b) The fire station in your area	1	2	3	4	5	N/A
c) The public schools in your area	1	2	3	4	5	N/A
d) Your local council	1	2	3	4	5	N/A
e) The newspapers you read	1	2	3	4	5	N/A
f) The television news channels you watch	1	2	3	4	5	N/A
g) The hospitals in your city/region	1	2	3	4	5	N/A
h) The State Government	1	2	3	4	5	N/A
i) The Federal Government	1	2	3	4	5	N/A

10. Would you please think now about the State Government? Below are some statements that describe ways people see the state government. Please indicate how much you agree or disagree with each statement by choosing the number that is closest to your own view.

QUESTION ITEMS	SCALE				
	Strongly disagree	Disagree	Neither	Agree	Strongly agree
a) I believe the State Government trusts people to do the right thing	1	2	3	4	5
b) I believe the State Government considers the concerns of average citizens when making decisions	1	2	3	4	5
c) I believe the State Government cares about its citizens	1	2	3	4	5
d) I believe the State Government tries to be fair when making their decisions	1	2	3	4	5

11. How much do you personally trust each of the following:

QUESTION ITEMS	SCALE				
	No trust at all	No trust	Neither	Trust	Complete trust
a) I trust the way the State Government makes decisions in South Australia	1	2	3	4	5
b) I trust South Australia's Parliament	1	2	3	4	5
c) I trust South Australia's legal system, for example the courts	1	2	3	4	5

We would now like to know a little about your background. We ask these questions just so we can get an idea of the perspectives of different groups of people, such as men and women, and city people and country people.

12. How old are you?

18-29	30-39	40-49	50-59	60-69	70-79	80+

13. Are you male or female?

Male	Female	Other

14. What is your current formal marital status? Are you...

Married	De Facto	Widowed	Separated but not divorced	Divorced	Never married

15. How many people living in the household are children under 16 years of age?
____________ people in household

16. In which country were you born?

Australia	Other. Please specify:

17. Are you of Aboriginal or Torres Strait Islander origin?

Aboriginal	Torres Strait	Aboriginal and Torres Strait Islander origin	Not Aboriginal or Torres Strait Islander origin

18. Do you usually speak a language other than English at home?

No	Yes. Please specify:

19. What was the highest level of school education you completed?

No schooling
Completed School Certificate/ Intermediate/ Year 10/ 4th Form
Completed High Secondary School/ Leaving/Year 12/ 6th Form
Trade Certificate/Diploma
University/Tertiary degree or higher
Other. Please specify:

20. Which of the following best describes your current work status?

Full-time	Part-time /casual	Self-employed	Unemployed	Retired	Other. Please specify:

21. Could you please tell me your postcode?
________________ (postcode)

i. Appendix: Distribution of demographic characteristics of participants in this study and the state population†

Characteristic	Sample group* (%)	State population† (%)
Sex		
Female	72.33	50.70

Characteristic	Sample group* (%)	State population† (%)
Male	27.67	49.30
Aboriginal and/or Torres Strait Islander		
Yes	3.55	2.00
Age group		
18-29 years old (survey sample) 20-29 years old (state population)	6.29	12.80
30-39 years old	12.58	12.70
40-49 years old	26.42	13.20
50-59 years old	27.04	13.50
60-69 years old	20.75	11.80
70-79 years old	6.29	7.50
80+ years old	0.63	5.00
Marital status		
Never married	15.82	33.90
De Facto	13.92	--
Married	58.86	47.70
Separated	3.16	3.20
Divorced	7.59	9.20
Widowed	0.63	6.00
Country of birth - top responses		
Australia	79.11	71.10
England	6.33	5.80
Highest educational attainment		
Tertiary degree or higher	72.96	18.50
Trade Certificate/Diploma	16.98	18.79
Year 12	5.66	15.50

Characteristic	Sample group* (%)	State population† (%)
Year 11	0.63	9.30
Year 10	2.52	10.00
Year 9 or below	1.26	8.60
No schooling	---	0.80
Current work status		
Full-time	42.77	53.90
Part-time/casual	25.16	33.50
Self-employed	6.29	--
Unemployed	3.14	7.50
Retired	18.87	--
Away from work	3.78	5.00
Index of Relative Socio-economic Advantage and Disadvantage (IRSAD) decile		
1	3.25	14.70
2 to 9	74.67	82.40
10	22.08	2.30

† Australian Bureau of Statistics (137), Australian Bureau of Statistics (248), Australian Bureau of Statistics (249) * n= 234 †The total for this table is 99.4% as 0.6% of the population was excluded from Statistical Areas 1 (SA1s).

How scores were calculated

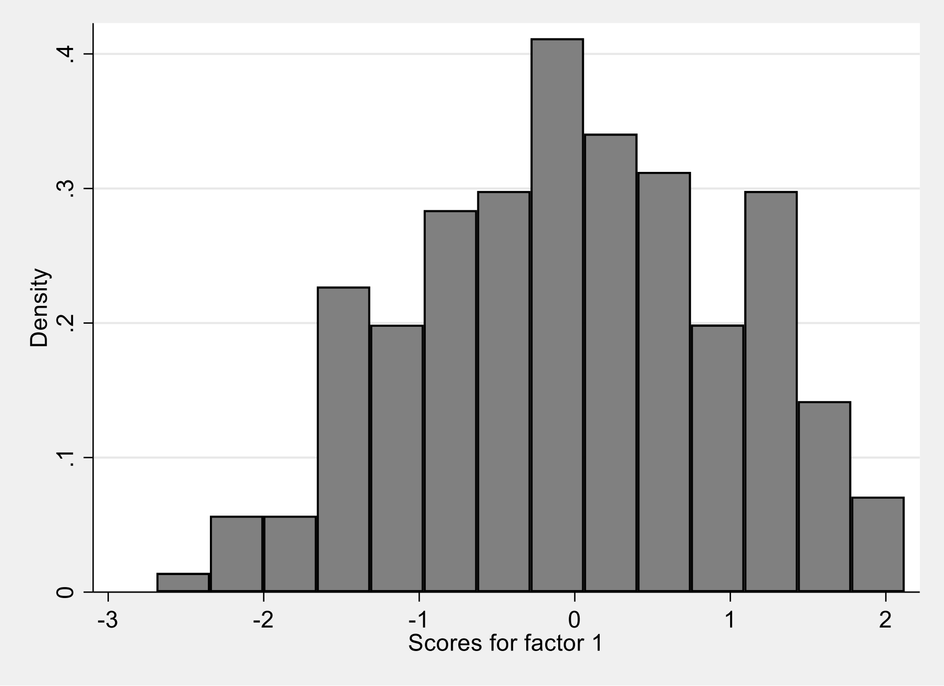
We used Principal-Components Factor Analysis (PCFA) to produce the scores for all summary measures (level of political trust in state government, level of social trust (multi-item), level of political trust in local institutions, level of political trust in remote institutions, evaluation of engagement exercise, and perceived level of citizen power).

These summary measures will be continuous measures. Therefore, we first transformed survey responses answered on a Likert-type scale to numeric scores. Then, a summary score based on the relevant items for each sub-concept was obtained following PCFA using the regression method. All Likert-type scales were assigned numeric values, see the table below for an example:

j. Appendix: Score transformation for evaluation of engagement process

Response on Likert-type scale	Numeric value
Strongly disagree	-2
Disagree	-1
Neutral	0
Agree	1
Strongly agree	2

Outcome. Four items in the questionnaire were thought to be related to political trust (intermediate institutions). For each item, numeric values were assigned to the five-point or seven-point Likert-type scale (as per example above). Political trust (intermediate institutions) has a mean score of approximately zero and standard deviation (SD) of 1. Scores ranged from -2.68 to 2.12. Negative values represent lower levels of trust, positive values represent higher levels of trust, and a value of 0 represents neutrality. Scores were approximately normally distributed (See figure below).



c Appendix: Distribution of values for political trust in an intermediate institution

Sub-concepts. For these three summary measures, negative scores indicated a lower level of trust and positive scores indicated higher trust levels. In the questionnaire, items for social trust (multi-item), political trust (local institutions), and political trust (remote institutions) were measured on a five-point Likert-type scale from 'Not trust them at all' to 'Trust them a lot' and each category response was assigned a numeric value as stated earlier. Social trust (multi-item) had a mean score of approximately zero (SD=1) and scores ranging from -3.42 to 2.09. Political trust (local institutions) had a mean score of approximately zero (SD=1) and scores ranging from -5.86 to 1.50. Political trust (remote institutions) had a mean score of approximately zero (SD=1) and scores ranging from -2.36 to 2.60.

For evaluation of engagement process and perception of citizen power or lack of power, original questionnaire items were measured on a five-point Likert-type scale from 'Strongly disagree' to 'Strongly agree'. After PCFA, evaluation of engagement process had a mean score of approximately zero (SD=1) and scores ranging from -2.83 to 2.23 with negative scores indicating negative evaluation of engagement processes and positive scores indicating positive evaluation. Perception of citizen power had a mean score of approximately zero (SD=1) and scores from -2.88 to 2.89. Positive scores for perception of citizen power relate to higher perceptions of being able to influence government decisions and more control over one's life, whereas negative scores indicate perception of a lack of citizen power.

Single items. These measures were assigned numeric values and treated as continuous in the regression model, as they are an ordinal approximation of a continuous variable and they all have more than four categories[1]. See table below for scores.

k. Appendix: Single-item scores

Sub-concept	Response on Likert-type scale	Numeric value
Perception of transparency of decision making Perception of complexity of decision making Public input in decision making Exclusive expert input in decision making	Strongly disagree	1
	Disagree	2
	Neutral	3
	Agree	4
	Strongly agree	5
Perception of corruption in Australian government	Honest	1, 2, 3
	Neutral	4
	Corrupt	5, 6, 7

Perception of transparency of decision making, perception of complexity of decision making, public input in decision making, and exclusive expert input in decision making were all measured in a five-point Likert-type scale from 'Strongly disagree' to 'Strongly agree'. Higher scores for transparency indicate the perception that decisions are made transparently. However, a stronger level of agreement for complexity indicates that decision-making processes are perceived as difficult to understand and opaque. Higher

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[1] See Johnson DR, Creech JC. Ordinal measures in multiple indicator models: A simulation study of categorization error. Am Sociol Rev. 1983;48(3):398-407 and Norman G. Likert scales, levels of measurement and the "laws" of statistics. Adv Health Sci Educ. 2010;15(5):625-32.

scores for exclusive expert input relate to relying on opinions of experts in government decisions and higher scores for public input relates to looking favourably on having public participation in decisions. Perception of corruption in Australian government was measured in a seven-point Likert-type scale from 'Honest' to 'Corrupt' and scores were reversed in the regression model. Higher scores indicate that the government is perceived as corrupt and lower scores indicate that government is perceived as honest.

I. Appendix: Regression model combining elements of relational and rational trust and missing demographics – Model 5

Sub-concepts	Coefficients	Std. Error	95%CI†	p-value
Relational trust				
Familial trust	0.01	0.17	-0.32, 0.35	0.924
Social trust (multi-item)	-0.09	0.09	-0.27, 0.09	0.344
Political trust (local institutions)	-0.08	0.13	-0.34, 0.18	0.537
Political trust (remote institutions)	0.36	0.08	0.20, 0.52	<0.001
Rational trust				
Perception of citizen power or lack of power	0.32	0.08	0.15, 0.49	<0.001
Perception of transparency of decision making	0.34	0.10	0.14, 0.55	0.001
Evaluation of engagement process	0.19	0.06	0.05, 0.33	0.006
Perception of corruption in Australian government	-0.03	0.06	-0.15, 0.09	0.625
Public input in decision making	0.01	0.09	-0.16, 0.19	0.868

Perception of complexity of decision making	0.00	0.08	-0.17, 0.16	0.965
Exclusive expert input in decision making	-0.09	0.06	-0.22, 0.02	0.124
Demographic information missing: Yes	0.03	0.19	-0.34,0.41	0.846

Chapter 5 Appendix

The information contained here is associated with Chapter 5: Defining the role of the public in Health Technology Assessment (HTA) and HTA-informed decision-making processes.

m. Appendix: Supplementary table 1 - Public and patient involvement in HTA and HTA decision making

Country	Organization	Specifications of the decision problem	Information inputs into the decision-making process	The decision-making process	Public accountability and decision implementation considerations
Australia	Pharmaceutical Benefits Advisory Committee	Refer technology for consideration: anyone	Part of sub-committee who provides advice during evaluation: patients	Membership on advisory committee: patient representative	No role identified
Australia	Medical Services Advisory Committee	Refer technology for consideration: anyone	Part of advisory panel who defines scope of appraisal: patients	Membership on advisory committee: patient representative	No role identified
Belgium	Drug Reimbursement Committee	No role identified	No role identified	No role identified	No role identified
Canada	Canadian Agency for Drugs and Technologies in Health	No role identified	Submit information to group preparing evaluation report: patients and patient organizations	Membership on advisory committee: two patient representatives (pan-Canadian Oncology Review); public	No role identified

				representative: two "public" representatives (Canadian Drug Expert Committee)	
Denmark	Danish Medicines Agency	No role identified	No role identified	No role identified	No role identified
France	French National Authority for Health	Refer technology for consideration: patients and patient organisations	o Participate in defining scope of the appraisal: patients o Participate in consultations during evaluation: patients	Membership on advisory committee: patient representative (HAS Interdisciplinary Economic Evaluation and Public Health Committee (CEESP))	No role identified
Germany	Federal Joint Committee (G-BA)	No role identified	o Participate in defining scope of the appraisal: patients o Comment on draft protocol for evaluation: anyone o Submit information to	Membership on advisory committee: patient representative	No role identified

			group preparing evaluation report: anyone		
Italy	Italian Medicines Agency	No role identified	No role identified	No role identified	No role identified
Japan	Drug Pricing Organization	No role identified	No role identified	No role identified	No role identified
New Zealand	Pharmaceutical Management Agency of New Zealand (PHARMAC)	Refer technology for consideration: patients and patient organisations	Submit information to group preparing evaluation report: anyone	No role identified	No role identified
Norway	Norwegian Medicines Agency	No role identified	No role identified	No role identified	No role identified
Scotland	Scottish Medicines Consortium	No role identified	No role identified	○ Membership on advisory committee: patient representative	No role identified

				○ Submit written testimonials: patient organisations	
Singapore	Singapore Ministry of Health Drug Advisory Committee	No role identified	No role identified	No role identified	No role identified
Spain	Ministry of Health (Directorate General of Pharmacy and Health Products)	No role identified	No role identified	No role identified	No role identified
Spain	National Health System Inter-territorial Council	No role identified	No role identified	No role identified	No role identified
Sweden	Dental and Pharmaceutical Benefits Board (TLV)	No role identified	No role identified	Membership on advisory committee: two patient representatives	No role identified

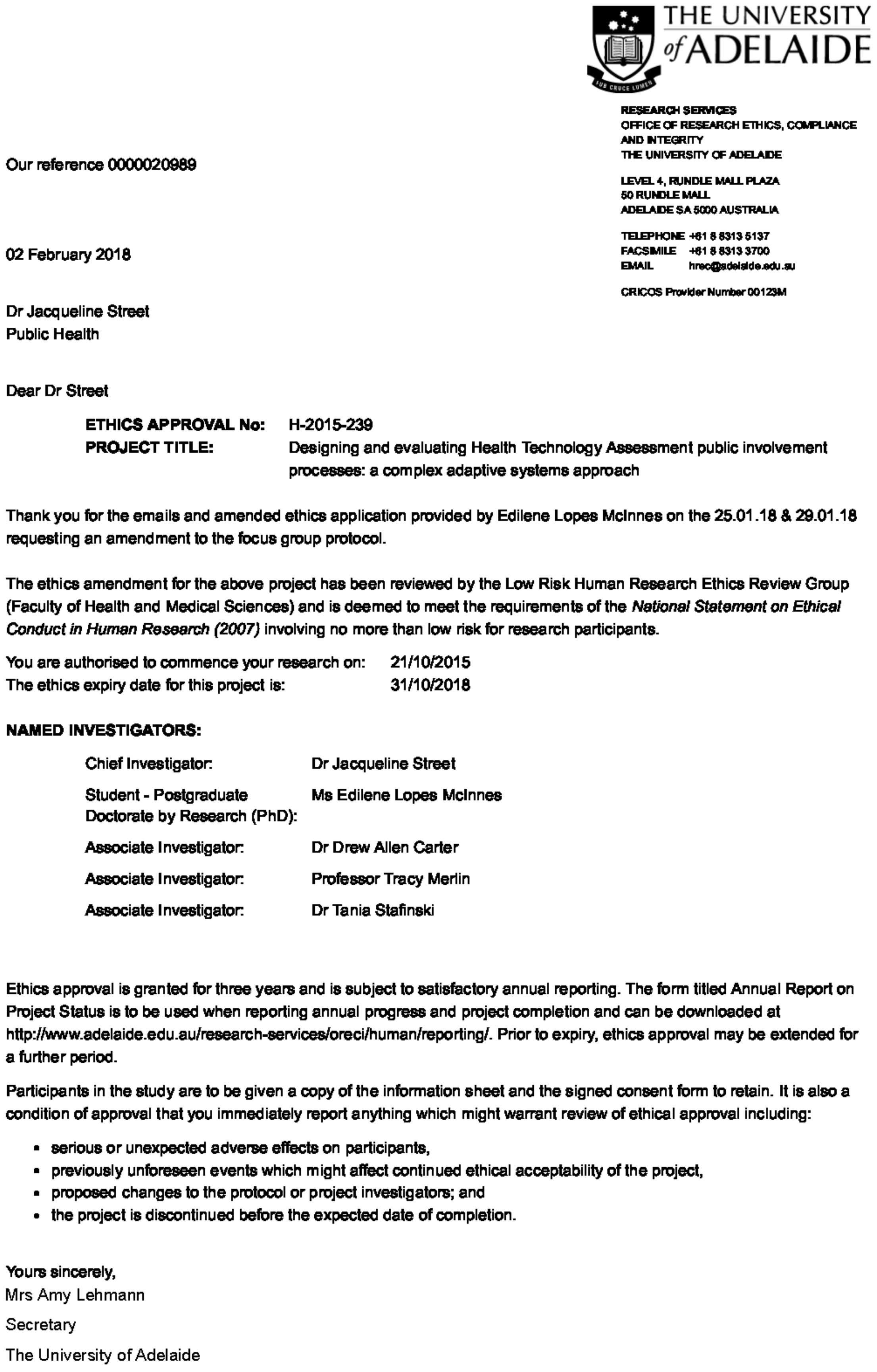
The Netherlands	Dutch Health Care Insurance Board (CVZ)	Refer technology for consideration: patients	No role identified	No role identified	No role identified
United Kingdom	National Institute for Health and Clinical Excellence (NICE)	Refer technology for consideration: patients and the general public	o Participate in defining scope of the appraisal: patient organisations o Submit information to group preparing evaluation report: patient organisations	o Membership on advisory committee: two patient representatives o Submit written testimonials: patient organisations o Comment on draft recommendations: public and patients	Appeal recommendations: patient organisations
United States	Centres for Medicare and Medicaid Services (CMS)	Refer technology for consideration: patients	Submit information to group preparing evaluation report: anyone	o Membership on advisory committee: patient representative o Submit additional information: anyone	Appeal recommendations: anyone

				○ Present to advisory committee: anyone	
Wales	All Wales Medicines Strategy Group	No information found	No information found	○ Membership on advisory committee: patient representative ○ Attend committee meeting: public and patients	

Chapters 6 and 7 Appendices

The information contained here is associated with Chapter 6: Understanding Canadian Health Technology Assessment through a systems lens and Chapter 7: HTA stakeholders' perspectives on public involvement in Canadian HTA.

Ethics approval
(This ethics approval also includes the study conducted in Chapter 8)



THE UNIVERSITY of ADELAIDE

RESEARCH SERVICES
OFFICE OF RESEARCH ETHICS, COMPLIANCE AND INTEGRITY
THE UNIVERSITY OF ADELAIDE

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CRICOS Provider Number 00123M

Our reference 0000020989

02 February 2018

Dr Jacqueline Street
Public Health

Dear Dr Street

ETHICS APPROVAL No: H-2015-239
PROJECT TITLE: Designing and evaluating Health Technology Assessment public involvement processes: a complex adaptive systems approach

Thank you for the emails and amended ethics application provided by Edilene Lopes McInnes on the 25.01.18 & 29.01.18 requesting an amendment to the focus group protocol.

The ethics amendment for the above project has been reviewed by the Low Risk Human Research Ethics Review Group (Faculty of Health and Medical Sciences) and is deemed to meet the requirements of the *National Statement on Ethical Conduct in Human Research (2007)* involving no more than low risk for research participants.

You are authorised to commence your research on: 21/10/2015
The ethics expiry date for this project is: 31/10/2018

NAMED INVESTIGATORS:

Chief Investigator:	Dr Jacqueline Street
Student - Postgraduate Doctorate by Research (PhD):	Ms Edilene Lopes McInnes
Associate Investigator:	Dr Drew Allen Carter
Associate Investigator:	Professor Tracy Merlin
Associate Investigator:	Dr Tania Stafinski

Ethics approval is granted for three years and is subject to satisfactory annual reporting. The form titled Annual Report on Project Status is to be used when reporting annual progress and project completion and can be downloaded at http://www.adelaide.edu.au/research-services/oreci/human/reporting/. Prior to expiry, ethics approval may be extended for a further period.

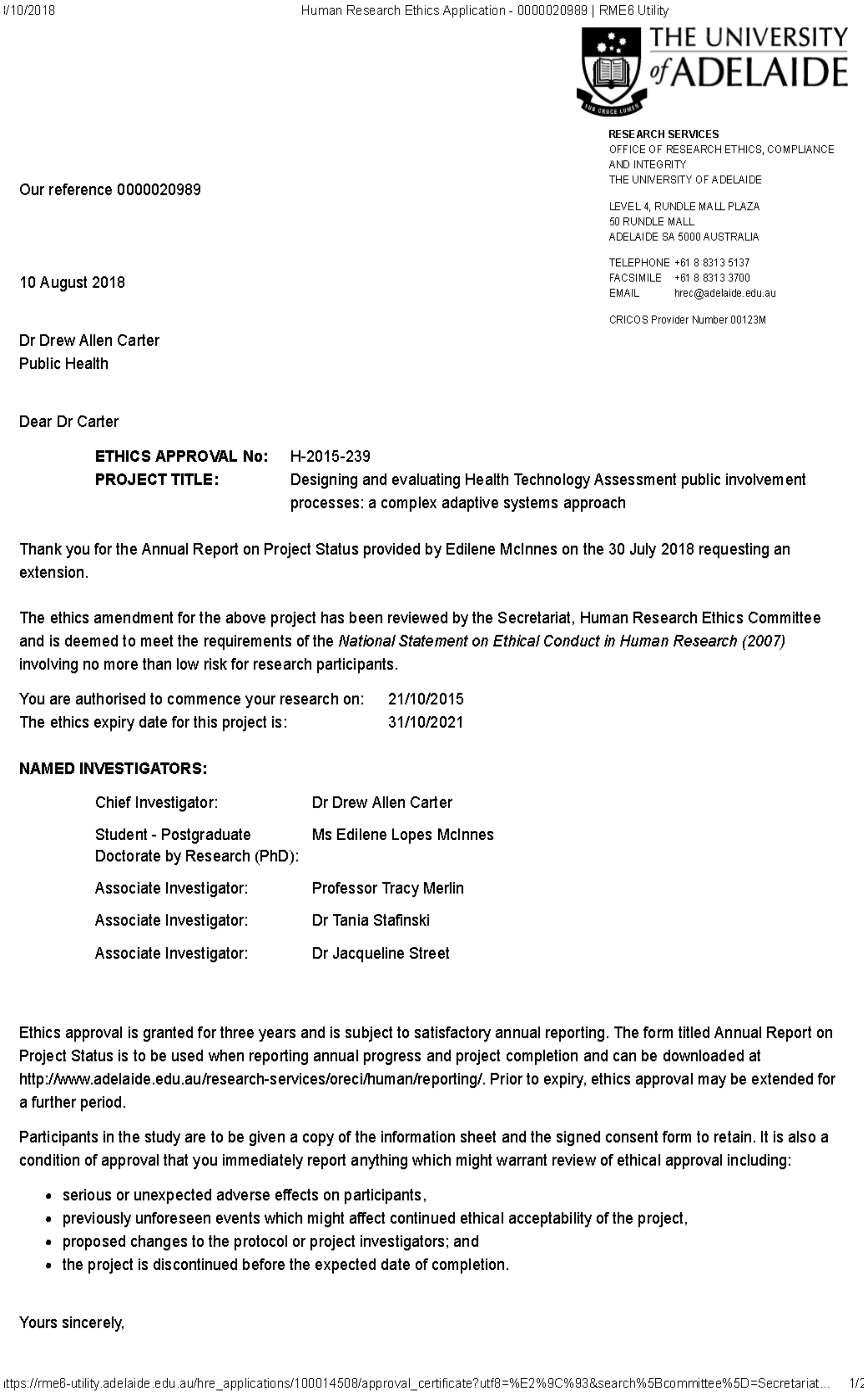
Participants in the study are to be given a copy of the information sheet and the signed consent form to retain. It is also a condition of approval that you immediately report anything which might warrant review of ethical approval including:

- serious or unexpected adverse effects on participants,
- previously unforeseen events which might affect continued ethical acceptability of the project,
- proposed changes to the protocol or project investigators; and
- the project is discontinued before the expected date of completion.

Yours sincerely,
Mrs Amy Lehmann

Secretary

The University of Adelaide



/10/2018 Human Research Ethics Application - 0000020989 | RME6 Utility

THE UNIVERSITY of ADELAIDE

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CRICOS Provider Number 00123M

Our reference 0000020989

10 August 2018

Dr Drew Allen Carter
Public Health

Dear Dr Carter

ETHICS APPROVAL No: H-2015-239
PROJECT TITLE: Designing and evaluating Health Technology Assessment public involvement processes: a complex adaptive systems approach

Thank you for the Annual Report on Project Status provided by Edilene McInnes on the 30 July 2018 requesting an extension.

The ethics amendment for the above project has been reviewed by the Secretariat, Human Research Ethics Committee and is deemed to meet the requirements of the *National Statement on Ethical Conduct in Human Research (2007)* involving no more than low risk for research participants.

You are authorised to commence your research on: 21/10/2015
The ethics expiry date for this project is: 31/10/2021

NAMED INVESTIGATORS:

Chief Investigator:	Dr Drew Allen Carter
Student - Postgraduate Doctorate by Research (PhD):	Ms Edilene Lopes McInnes
Associate Investigator:	Professor Tracy Merlin
Associate Investigator:	Dr Tania Stafinski
Associate Investigator:	Dr Jacqueline Street

Ethics approval is granted for three years and is subject to satisfactory annual reporting. The form titled Annual Report on Project Status is to be used when reporting annual progress and project completion and can be downloaded at http://www.adelaide.edu.au/research-services/oreci/human/reporting/. Prior to expiry, ethics approval may be extended for a further period.

Participants in the study are to be given a copy of the information sheet and the signed consent form to retain. It is also a condition of approval that you immediately report anything which might warrant review of ethical approval including:

- serious or unexpected adverse effects on participants,
- previously unforeseen events which might affect continued ethical acceptability of the project,
- proposed changes to the protocol or project investigators; and
- the project is discontinued before the expected date of completion.

Yours sincerely,

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Participant information sheet and consent form

PARTICIPANT INFORMATION SHEET

Title of Study: Involving the public in health policy decision making
Principal Investigator: Dr Jackie Street
Research/Study Coordinators: Mrs Edilene Lopes McInnes and Dr Tania Stafinski

Why am I being asked to take part in this research study?
This project will provide guidance on how public involvement processes should to be designed and evaluated in Health Technology Assessment (HTA). HTA is a system for assessing whether particular medicines and medical devices should be government funded based on their costs and benefits. Public involvement processes are methods used to engage the public and patients in such decisions. We will establish how to design and evaluate public involvement processes by conducting a systematic review of literature along with semi-structured interviews and focus groups with policy makers, members of the public, and representatives from HTA agencies, patient organisations and medicine and device manufacturers.

What is the reason for doing the study?
The objective is to use this information to improve how governments and HTA agencies design processes to engage with the public and then evaluate those processes. This research will form the basis for Edilene's degree of Doctor of Philosophy at the University of Adelaide (Australia) under the supervision of Dr Jackie Street, Dr Drew Carter, Dr Tania Stafinski, and Associate Professor Tracy Merlin.

What will I be asked to do?
You will be asked to participate in an interview of approximately one hour. The interview will be conducted face to face, at a mutually agreed place, or over the phone, depending on which is more convenient for you. If you accept the invitation to participate in this project, you will be asked to sign a consent form and return it on the day of the interview or by a reply prepaid envelope that we will send to you.

What are the risks and discomforts?
Talking about the availability of funding for life-changing or life-saving drugs may be distressing for some people. It is possible that talking about your experiences in this area may cause some discomfort. If you become uncomfortable during the interview, our conversation will be immediately paused or stopped and you will be able to take a moment. In such cases, you will receive a telephone call later from the Senior Researcher, Dr Tania Stafinski, to discuss any matters you think relevant. It is not possible to know all of the risks that may happen in a study, but the researchers have taken all reasonable safeguards to minimize any known risks to a study participant.

What are the benefits to me?
You are not expected to get any benefit from being in this research study. This project aims at making recommendations on how governments and HTA agencies can improve the design and evaluation of processes that involve the public in decision

making. While this project may facilitate participation in the processes by a wider range of people, making the processes more democratic, and your involvement may not be of any direct benefit to you.

Do I have to take part in the study?
Being in this study is your choice. If you decide to be in the study, you can change your mind and stop being in the study at any time before or during the interview. You may also refuse to answer any questions during the interview.

Will I be paid to be in the research?
No, but we will cover any expenses incurred through your participation in the study.

Will my information be kept private?
During the study we will be collecting data about your opinions. We will do everything we can to make sure that this data is kept private. No data relating to this study that includes your name will be released outside of the researcher's office or published by the researchers. Sometimes, by law, we may have to release your information with your name so we cannot guarantee absolute privacy. However, we will make every legal effort to make sure that your information is kept private.

The project results will be published as part of a PhD thesis that will be freely available at the University of Adelaide library (in Australia) in hard copy and online. We will publish articles in scientific journals and present findings at national and international health-related conferences. If you wish, we can send you a copy of all outputs from the research project. The information we obtain from you will be dealt with confidentially. You will not be identified in any publications or presentations. If we use a quote from your interview, we will not identify you but instead use a code, such as a number.

What if I have questions?
If you have any questions about the research now or later, please contact Dr Tania Stafinski at (1) 780-492-4791. If you have any questions regarding your rights as a research participant, you may contact the Health Research Ethics Board at (1) 780-492-2615. This office has no affiliation with the study investigators.

The study has been approved by the Human Research Ethics Committee at the University of Adelaide (Australia) (approval number H-2015-239). If you have questions or problems associated with the practical aspects of your participation in the project, or wish to raise a concern or complaint about the project, then you should consult the Principal Investigator (Dr Jackie Street). Contact the Human Research Ethics Committee's Secretariat on phone +61 8 8313 6028 or by email to hrec@adelaide.edu.au if you wish to speak with an independent person regarding concerns or a complaint, the University's policy on research involving human participants, or your rights as a participant. Any complaint or concern will be treated in confidence and fully investigated. You will be informed of the outcome.

The study is being conducted by the University of Adelaide (Australia) in collaboration with the University of Alberta. Mrs Lopes McInnes is supported by a post-graduate scholarship funded by the Australian Government. You are entitled to request any details concerning the financial support for this project from the Principal Investigator (Dr Jackie Street) or the Research/Study Coordinators (Dr Tania Stafinski and Mrs Edilene Lopes McInnes).

CONSENT FORM

Title of Study: Involving the public in health policy decision making
Principal Investigator: Dr Jackie Street
Study Coordinator: Dr Tania Stafinski and Mrs Edilene Lopes McInnes
Phone Number: (1) 780-492-4791

	Yes	No
Do you understand that you have been asked to be in a research study?	☐	☐
Have you read and received a copy of the attached Information Sheet?	☐	☐
Do you understand the benefits and risks involved in taking part in this research study?	☐	☐
Have you had an opportunity to ask questions and discuss this study?	☐	☐
Do you understand that you are free to leave the study at any time, without having to give a reason and without penalty?	☐	☐
Has the issue of confidentiality been explained to you?	☐	☐
Do you understand who will have access to your study records?	☐	☐
I agree to the interview being audio recorded.	☐	☐
Who explained this study to you? ______________________________		
I agree to take part in this study: Signature of Research Participant: ______________________________		
I believe that the person signing this form understands what is involved in the study and voluntarily agrees to participate.		
Signature of Investigator or Designee: ______________________________		
Date: ______________________________		
The information sheet must be attached to this consent form and a copy given to the research participant		

Data analysis

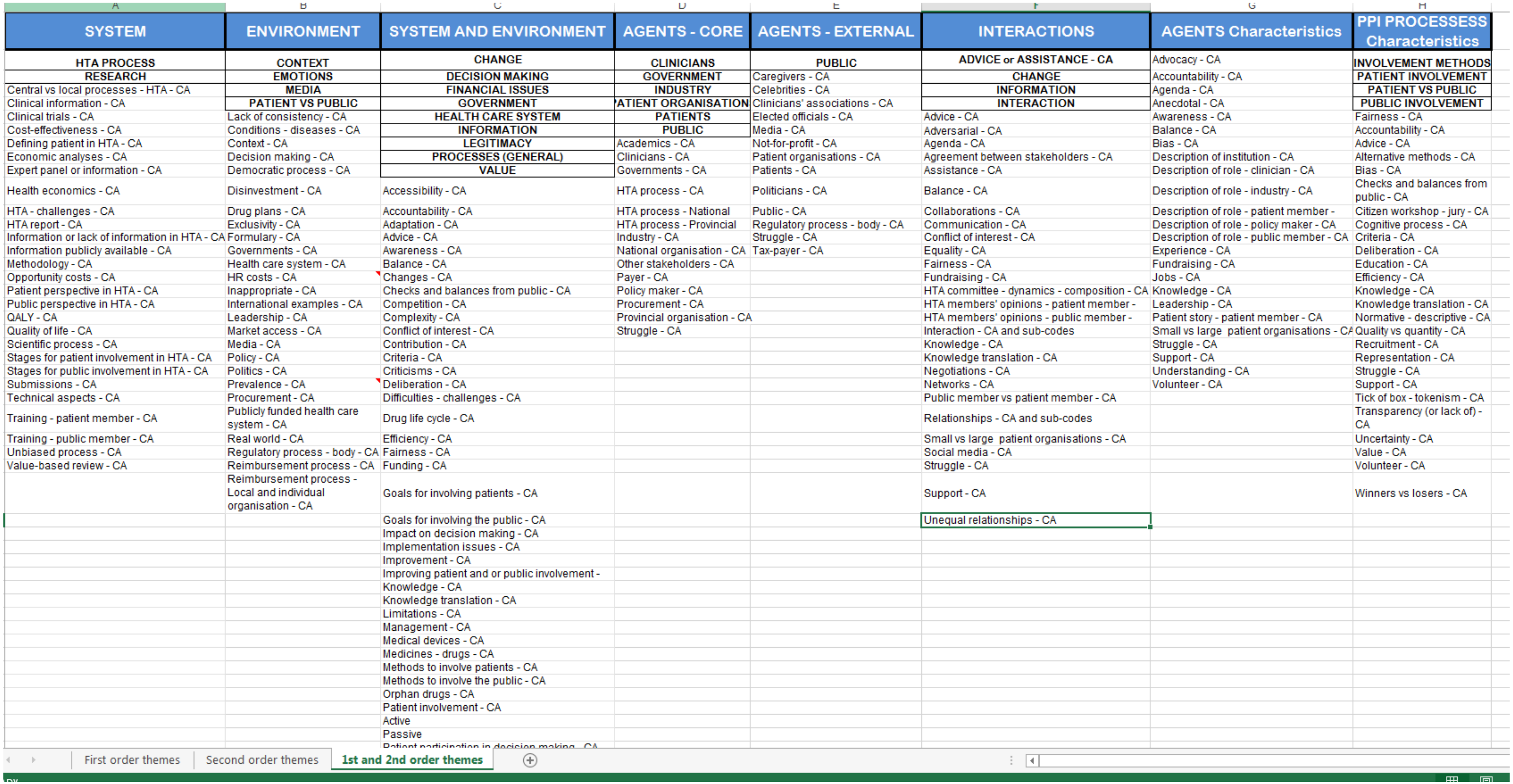
Coding

We coded interviews using NVivo 10 with a pre-coded list based on elements of the CAS nomenclature (e.g., agents, environment) and open coding. 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 were developed, all interviews were re-coded. This process resulted in 306 codes (30 initial codes and 276 codes from the re-coding iterative process).

We collapsed codes into first (26) and second (ten) order themes using Excel 2013. For example, the first-order theme 'Areas of Care' included codes related to interviewees' descriptions or examples of diseases and health conditions or preventative measures related to HTA processes. Specifically, 'Areas of Care' combined the codes: Conditions and diseases, Lung, Newborn screening, Oncology, and Rare Diseases. In some cases, the same codes could be included under different themes as it was the case with the code 'Conflict of interest', which was included under the themes 'Government processes', 'Industry', and 'Patient organisations'.

We generated second-order themes and sub-themes using SSM and CAS theoretical frameworks. Second-order themes encompassed first order themes and single codes. For instance, the theme 'Agents' was divided into three sub-themes: 'Core Agents'; 'External Agents'; 'Agents' characteristics'. The sub-theme 'Core Agents' included the codes Academics; Clinicians; Payer; Policymaker; Procurement staff; HTA staff; as well as first-order themes: 'Government'; 'Industry'; 'Clinicians'; 'HTA Process'. Organising codes into first- and second-order themes preserved the richness of the data and allowed for the thick description of particular aspects of the HTA system.

First-order themes, second-order themes and codes



SYSTEM	ENVIRONMENT	SYSTEM AND ENVIRONMENT	AGENTS - CORE	AGENTS - EXTERNAL	INTERACTIONS	AGENTS Characteristics	PPI PROCESSESS Characteristics
HTA PROCESS	**CONTEXT**	**CHANGE**	**CLINICIANS**	**PUBLIC**	**ADVICE or ASSISTANCE - CA**	Advocacy - CA	**INVOLVEMENT METHODS**
RESEARCH	**EMOTIONS**	**DECISION MAKING**	**GOVERNMENT**	Caregivers - CA	**CHANGE**	Accountability - CA	**PATIENT INVOLVEMENT**
Central vs local processes - HTA - CA	**MEDIA**	**FINANCIAL ISSUES**	**INDUSTRY**	Celebrities - CA	**INFORMATION**	Agenda - CA	**PATIENT VS PUBLIC**
Clinical information - CA	**PATIENT VS PUBLIC**	**GOVERNMENT**	**ATIENT ORGANISATION**	Clinicians' associations - CA	**INTERACTION**	Anecdotal - CA	**PUBLIC INVOLVEMENT**
Clinical trials - CA	Lack of consistency - CA	**HEALTH CARE SYSTEM**	**PATIENTS**	Elected officials - CA	Advice - CA	Awareness - CA	Fairness - CA
Cost-effectiveness - CA	Conditions - diseases - CA	**INFORMATION**	**PUBLIC**	Media - CA	Adversarial - CA	Balance - CA	Accountability - CA
Defining patient in HTA - CA	Context - CA	**LEGITIMACY**	Academics - CA	Not-for-profit - CA	Agenda - CA	Bias - CA	Advice - CA
Economic analyses - CA	Decision making - CA	**PROCESSES (GENERAL)**	Clinicians - CA	Patient organisations - CA	Agreement between stakeholders - CA	Description of institution - CA	Alternative methods - CA
Expert panel or information - CA	Democratic process - CA	**VALUE**	Governments - CA	Patients - CA	Assistance - CA	Description of role - clinician - CA	Bias - CA
Health economics - CA	Disinvestment - CA	Accessibility - CA	HTA process - CA	Politicians - CA	Balance - CA	Description of role - industry - CA	Checks and balances from public - CA
HTA - challenges - CA	Drug plans - CA	Accountability - CA	HTA process - National	Public - CA	Collaborations - CA	Description of role - patient member -	Citizen workshop - jury - CA
HTA report - CA	Exclusivity - CA	Adaptation - CA	HTA process - Provincial	Regulatory process - body - CA	Communication - CA	Description of role - policy maker - CA	Cognitive process - CA
Information or lack of information in HTA - CA	Formulary - CA	Advice - CA	Industry - CA	Struggle - CA	Conflict of interest - CA	Description of role - public member - CA	Criteria - CA
Information publicly available - CA	Governments - CA	Awareness - CA	National organisation - CA	Tax-payer - CA	Equality - CA	Experience - CA	Deliberation - CA
Methodology - CA	Health care system - CA	Balance - CA	Other stakeholders - CA		Fairness - CA	Fundraising - CA	Education - CA
Opportunity costs - CA	HR costs - CA	Changes - CA	Payer - CA		Fundraising - CA	Jobs - CA	Efficiency - CA
Patient perspective in HTA - CA	Inappropriate - CA	Checks and balances from public - CA	Policy maker - CA		HTA committee - dynamics - composition - CA	Knowledge - CA	Knowledge - CA
Public perspective in HTA - CA	International examples - CA	Competition - CA	Procurement - CA		HTA members' opinions - patient member -	Leadership - CA	Knowledge translation - CA
QALY - CA	Leadership - CA	Complexity - CA	Provincial organisation - CA		HTA members' opinions - public member -	Patient story - patient member - CA	Normative - descriptive - CA
Quality of life - CA	Market access - CA	Conflict of interest - CA	Struggle - CA		Interaction - CA and sub-codes	Small vs large patient organisations - CA	Quality vs quantity - CA
Scientific process - CA	Media - CA	Contribution - CA			Knowledge - CA	Struggle - CA	Recruitment - CA
Stages for patient involvement in HTA - CA	Policy - CA	Criteria - CA			Knowledge translation - CA	Support - CA	Representation - CA
Stages for public involvement in HTA - CA	Politics - CA	Criticisms - CA			Negotiations - CA	Understanding - CA	Struggle - CA
Submissions - CA	Prevalence - CA	Deliberation - CA			Networks - CA	Volunteer - CA	Support - CA
Technical aspects - CA	Procurement - CA	Difficulties - challenges - CA			Public member vs patient member - CA		Tick of box - tokenism - CA
Training - patient member - CA	Publicly funded health care system - CA	Drug life cycle - CA			Relationships - CA and sub-codes		Transparency (or lack of) - CA
Training - public member - CA	Real world - CA	Efficiency - CA			Small vs large patient organisations - CA		Uncertainty - CA
Unbiased process - CA	Regulatory process - body - CA	Fairness - CA			Social media - CA		Value - CA
Value-based review - CA	Reimbursement process - CA	Funding - CA			Struggle - CA		Volunteer - CA
	Reimbursement process - Local and individual organisation - CA	Goals for involving patients - CA			Support - CA		Winners vs losers - CA
		Goals for involving the public - CA			Unequal relationships - CA		
		Impact on decision making - CA					
		Implementation issues - CA					
		Improvement - CA					
		Improving patient and or public involvement -					
		Knowledge - CA					
		Knowledge translation - CA					
		Limitations - CA					
		Management - CA					
		Medical devices - CA					
		Medicines - drugs - CA					
		Methods to involve patients - CA					
		Methods to involve the public - CA					
		Orphan drugs - CA					
		Patient involvement - CA					
		Active					
		Passive					
		Patient participation in decision making - CA					

Interview schedules

Here, we present the interview schedules adapted for each specific type of stakeholder.

Schedule 1 – Government representative

- Could you start talking about your role in the government?
- Can you briefly explain what your department's objectives are in using HTA processes?
- What is your opinion about the HTA agency application process?

Prompts: What is the most useful aspect?
What is the least useful aspect?
What type of information do you need and what type of information do you receive (are there any gaps)?

- What is your opinion about involving the public in HTA?

Prompts: Objective of having such processes
How these processes could affect the outcome of reimbursement processes
How these processes could affect the final decision by government agencies/departments
How do you think this should be done?

- How do you think your department would use the outcomes of a public involvement process?
- How do you think patient organisations would see such a process?
- How do you think manufacturers would see such a process?
- Do you have direct contact with representatives of patient organisations or members of the public concerning HTA results that your department is considering? Why/Why not?
- Do you have direct contact with manufacturers about HTA results that your department is considering? Why/Why not?
- How do you think HTA agencies relate to manufacturers? And to patient organisations?

What is your opinion about manufacturers' relationship with patient organisations?

How do you think public involvement would affect patient involvement?

Comments about the research project

- Any issues would like to raise that have not been asked during the interview
- Any comments on the way the interview was conducted
- Any questions about the research project or anything you would like to add

Schedule 2 – HTA representative

- Could we start by talking about your organisation?
- What is your role in this organisation?
- Can you briefly explain how the Health Technology Assessment process happens in your agency?

Prompts: Stages and explanation of the application process
Opinion about the application process:

- what type of information the agency needs
- how the information has to be provided (format)
- information received from various stakeholders
- application process timelines
- human resources available
- access to other sources of information
- financial issues

- Do you have patient involvement in your agency's HTA process?

Yes: Can you explain how do you involve patients?
Prompts:

  - what types of involvement processes this agency employs
  - if there is more than one, explanation of each type of involvement
  - what type of information from patients does the agency need
  - how the information needs to be provided (format)
  - application process timelines
  - human resources available
  - access to other sources of information
  - financial issues

No: What is your opinion on having patients taking part in this type of assessment?

- Do you have public involvement in your agency's Health Technology Assessment process?

Yes: Can you explain how do you involve the public?
Prompts:

- what types of involvement processes this agency employs
- if there is more than one, explanation of each type of involvement
- what type of information from patients does the agency need
- how the information needs to be provided (format)
- application process timelines
- human resources available
- access to other sources of information
- financial issues

No: What is your opinion on having the public taking part in this type of assessment?

- We can involve patients and the public at different stages of HTA. I will give you a few examples of how this could be potentially done and then ask your opinion about them…

Case 1 – Before the assessment starts:
If a committee/unit receives ten health technologies for assessment but can assess only three of them, should patients have a say in choosing which health technologies should be assessed? (Why/ Why not) Should the public (ordinary citizens) have a say in choosing which health technologies the wider community would prefer to have assessed? (Why/ Why not)

Case 2 – Protocol stage:
When the assessment protocol is being designed, should patients have a say in suggesting which measurement outcomes should be used? (Why/ Why not) Should the public (ordinary citizens) have a say in defining which social values should be incorporated in the assessment of health technology? (Why/ Why not)

Case 3 – Assessment stage:
When information is being collected for the assessment of a particular health technology, should patients provide information related to their experience with a condition/disease and using different treatments or drugs? (Why/ Why not) Should the public (ordinary citizens) have a say in providing information on social values related to trade-offs in quality of life or costs being considered? (Why/ Why not)

Case 4 – Report:
Once the draft report has been completed, should patients be able to make suggestions or add comments to the final report? (Why/ Why not) Should citizens be able to make suggestions or add comments to the final report? (Why/ Why not)

Case 5 – Recommendations:
Should patients be part of committees making the decision to recommend a particular health technology to be funded? (Why/ Why not) Should the public (ordinary citizens) be part of committees making the decision to recommend a particular health technology to be funded? (Why/ Why not)

- How do you think the government would use the outcomes of a public involvement process?
- How do you think patient organisations would see such a process?
- How do you think government departments’ relate to manufacturers? And to patient organisations?

What is your opinion about manufacturers’ relationship with patient organisations?

- How do you think public involvement would affect patient involvement?

Comments about the research project

- Any issues would like to raise that have not been asked during the interview
- Any comments on the way the interview was conducted
- Any questions about the research project or anything you would like to add

Schedule 3 – Manufacturer representative (pharmaceuticals)

- Could we start by talking about your organisation?
- What is your role in this organisation?
- Can you talk me through your organisation's participation in a Health Technology Assessment processes?

Prompts: Decision or reasons to submit an application
Step-by-step application submission
Opinion about the application process

- questions asked
- how the information has to be provided (format)
- information received from agency or unit
- application process timelines
- human resources available
- access to other sources of information
- financial issues
- transparency of the process
- the outcome of the process

- Are you aware of calls for public involvement in HTA?

If the answer is no: Some people consider it relevant to have public input in HTA, rather than patients when trade-offs and value-decisions are involved. The idea is that the government would be able to take into consideration what the community/society as a whole thinks needs to be funded when making decisions that will affect health department budgets.

- What is your opinion about public involvement in HTA?

Prompts: Objective of having such processes
How do you think this should be done?
Would patient organisations have a role in such processes?
Would manufacturers have a role in the process?

- How do you think the government would use the outcomes of a public involvement process?
- How do you think patient organisations would see such a process?
- How do you think HTA committees/agencies relate to government departments? And to manufacturers?

- What is your opinion about government departments' relationship with patient organisations?
- How do you think public involvement would affect patient involvement?

Comments about the research project

- Any issues you would like to raise that have not been asked during the interview
- Any comments on the way the interview was conducted
- Any questions about the research project or anything you would like to add

Schedule 4 – Manufacturer representative (medical devices)

- Could we start by talking about your organisation?
- What is your role in this organisation?
- How does your organisation seek to include an item in the government listing for reimbursement?

Prompts: Reasons for applying
How applications are submitted (step by step)
Opinion about the application process: questions asked

- how the information has to be provided (format)
- information received from agency or unit
- application process timelines
- human resources available
- access to other sources of information
- financial issues
- transparency of the process
- the outcome of the process

- Are you aware of calls for public involvement in devices (or other health technologies) reimbursement?

If the answer is no: Some people consider it relevant to have public input in HTA, rather than patients, when trade-offs and value-decisions are involved. The idea is that the government would be able to take into consideration what the community/society as a whole thinks needs to be funded when making decisions that will affect health department budgets.

- What is your opinion about public involvement in this scenario?

Prompts: Objective of having such processes / How could this process affect the outcome of reimbursement processes? / How do you think this should be done? / Would patient organisations have a role in such processes? / Would manufacturers have a role in the process?

- How do you think the government would use the outcomes of a public involvement process?
- How do you think patient organisations would see such a process?
- How do you think HTA committees/agencies relate to government departments? And to manufacturers?

- What is your opinion about government departments' relationship with patient organisations?

- How do you think public involvement would affect patient involvement?

Comments about the research project

- Any issues you would like to raise that have not been asked during the interview
- Any comments on the way the interview was conducted
- Any questions about the research project or anything you would like to add

Schedule 5 – HTA patient representative or public member

- Can you explain to me your role as a patient representative / public member?
- How do you see your role?
- How do you think the other members of the agency/committee see your role?
- What are your specific activities as a patient representative / public member?
- How do the assessment meetings happen? What happens during (before or after) the meetings?

Prompts: Opinion about their participation in the advisory committee's assessment/evaluation process

- The information available about the process they need to analyse (access/language/source)
- Position of other stakeholders (during meetings or when providing feedback)
- Access to other sources of information
- Transparency
- Financial issues

- Are you aware of calls for public involvement in HTA?

If the answer is no: Some people consider it relevant to have public input in HTA, rather than patients when trade-offs and value-decisions are involved. The idea is that the government would be able to take into consideration what the community/society as a whole thinks needs to be funded when making decisions that will affect health department budgets.

- What is your opinion about public involvement in HTA?

Prompts: Objective of having such processes
How do you think this should be done?
Would patient organisations have a role in such processes?
Would manufacturers have a role in the process?

- How do you think the government would use the outcomes of a public involvement process?
- How do you think HTA committees/agencies relate to government departments? And to manufacturers?
- What is your opinion about the government departments' relationship with manufacturers?

Comments about the research project

- Any issues you would like to raise that have not been asked during the interview
- Any comments on the way the interview was conducted
- Any questions about the research project or anything you would like to add

Schedule 6 – Patient organisation representative

- Could we start by talking about your organisation?
- What is your role in this organisation?
- What is your opinion about patient involvement in HTA?
- Why would your organisation take part in HTA processes?
- Can you explain to me what types of processes your organisation has taken part in?

- What is your opinion about the process you have taken part in?

Prompts: Background information received from agency or unit

- Access to other sources of information
- Time to answer the questions
- Human resources
- Financial issues

- Do you think the information you provided was taken into consideration? Why/ Why not?
- At what stage should patient involvement happen in HTA?
- What types of patient organisations should take part in HTA in your opinion? Why?
- What is your opinion about the transparency of the process?
- What is your opinion about the decision-making process that HTA informs?

Are you aware of calls for public involvement in HTA?

If the answer is no: Some people consider it relevant to have public input in HTA, rather than patients when trade-offs and value-decisions are involved. The idea is that the government would be able to take into consideration what the community/society as a whole thinks needs to be funded when making decisions that will affect health department budgets.

- What is your opinion about public involvement in HTA?

- How do you think the government would use the outcomes of a public involvement process?
- How do you think HTA committees/agencies relate to government departments? And to manufacturers?
- What is your opinion about the government departments' relationship with manufacturers?

Comments about the research project

- Any issues you would like to raise that have not been asked during the interview
- Any comments on the way the interview was conducted
- Any questions about the research project or anything you would like to add

Chapter 8 Appendix

The information contained here is associated with Chapter 8: The rationale and design of public involvement in health funding decision making: Focus groups with the Canadian public.

Participant Information sheet

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

Title of Study: Designing and evaluating HTA public involvement processes: a complex adaptive systems approach
Principal Investigator: Dr Jackie Street
Research/Study Coordinators: Dr Tania Stafinski and Mrs Edilene Lopes McInnes

Why am I being asked to take part in this research study?
We would like to understand the opinion of members of the public in relation to processes used to engage and involve the population in decisions that may affect health policy. We are also going to hear from experts in the field of Health Technology Assessment, members of the government, representatives of patient organisations and representatives of the health industry. The objective is to use this information to create guidelines for the design and evaluation of public involvement processes in HTA and to inform government decision about using such processes. Before you decide whether to participate, one of the researchers will go over this form with you. You are encouraged to ask questions if you feel that anything needs to be made clearer. You will be given a copy of this form to keep.

What is the reason for doing the study?
The objective is to use this information to improve how governments and HTA agencies design processes to engage with the public and then evaluate those processes. This research will form the basis for Edilene's degree of Doctor of Philosophy at the University of Adelaide (Australia) under the supervision of Dr Jackie Street, Dr Drew Carter, Dr Tania Stafinski, and Associate Professor Tracy Merlin.

What will I be asked to do?
We will conduct a focus group, which is a discussion group with a maximum of ten people, to debate public involvement processes. We just want to gather your opinions about these processes and we would like you to have a conversation with other nine people about these processes. The discussion will last for 90 minutes and will happen at the University of Alberta. Two researchers will be present: one will provide topics for discussion and ask questions and the other one will take notes. We will also be audio recording the discussion, so we can analyse the data later.

What are the risks and discomforts?
We anticipate that the only risk for your participation is possible inconvenience for giving up your time and taking part in a group discussion. If you or someone else in the group becomes upset during the focus group, the discussion will be paused or stopped and the participant counselled to take a moment. If necessary, we will recommend the participant to seek support from their doctor. In such cases, the participant will receive a telephone call later from the Senior Researcher, Dr Tania Stafinski, to discuss the matter with them.

What are the benefits to me?
You are not expected to get any benefit from being in this research study. However, this project aims at making recommendations on how governments and HTA agencies can improve the design and evaluation of processes that involve the public in decision making. We believe that having such recommendations in place will facilitate participation in the processes by a wider range of the public, making these processes and the decisions based on the outcomes of these processes more democratic. This study may help other people in the future.

Do I have to take part in the study?
Being in this study is your choice. If you decide to be in the study, you can change your mind and stop being in the study at any time leading up to the end of the focus group session. You can also refuse to answer any questions during the focus group.

Will I be paid to be in the research?
We will provide you with an honorarium of CAD$40 in order to cover expenses such as travel, parking and child-minding incurred through your participation in the study, and as a partial recompense for your time. You will receive this honorarium at the end of the session.

Will my information be kept private?
During the study we will be collecting data about you. We will do everything we can to make sure that this data is kept private. No data relating to this study that includes your name will be released outside of the researcher's office or published by the researchers. Sometimes, by law, we may have to release your information with your name so we cannot guarantee absolute privacy. However, we will make every legal effort to make sure that your information is kept private.

The project results will be published as part of a PhD thesis that will be freely available at the University of Adelaide library (in Australia) in hard copy and online. We also expect to publish articles in scientific journals and present the results at national and international health-related conferences. If you wish, we can send you a copy of every outcome of this research project. The information we obtain from you will be dealt with confidentially. Participants will not be identified in any publications or presentations and information will be published as aggregated data. If we use a quote from a focus group participant, we will not identify the person but use a code (which is likely to be a number).

What if I have questions?
If you have any questions about the research now or later, please contact Dr Tania Stafinski at (1) 780-492-4791. If you have any questions regarding your rights as a research participant, you may contact the Health Research Ethics Board at (1) 780-492-2615. This office has no affiliation with the study investigators. The study is being conducted by the University of Adelaide (Australia) in collaboration with the University of Alberta. Mrs Lopes McInnes is supported by a post-graduate scholarship funded by the Australian Government. You are entitled to request any details concerning the financial support for this project from the Principal Investigator (Dr Jackie Street) or the Research/Study Coordinator (Dr Tania Stafinski and Edilene Lopes McInnes).

CONSENT FORM

Title of Study: Designing and evaluating HTA public involvement processes: a complex adaptive systems approach
Principal Investigator(s): Dr Jackie Street
Study Coordinators: Dr Tania Stafinski and Mrs Edilene Lopes McInnes
Phone Number: (1) 780-492-4791

	Yes	No
Do you understand that you have been asked to be in a research study?	☐	☐
Have you read and received a copy of the attached Information Sheet?	☐	☐
Do you understand the benefits and risks involved in taking part in this research study?	☐	☐
Have you had an opportunity to ask questions and discuss this study?	☐	☐
Do you understand that you are free to leave the study at any time, without having to give a reason and without penalty?	☐	☐
Has the issue of confidentiality been explained to you?	☐	☐
Do you understand who will have access to your study records?	☐	☐
Who explained this study to you? ________________________________		
I agree to take part in this study: Signature of Research Participant: ________________________________		
I believe that the person signing this form understands what is involved in the study and voluntarily agrees to participate.		
Signature of Investigator or Designee: ______________________________		
Date: ________________________________		
The information sheet must be attached to this consent form and a copy given to the research participant		

Focus groups selection strategy

Screening questionnaire

SCREENING QUESTIONNAIRE
Interviewer: My name is "----" and I am calling to follow-up on a consent form we received indicating that you would like to be considered for a focus group on Health Technology Assessment. You will take part in a research study that is looking at how the public is involved in Health Technology Assessment decisions that may affect them. First, I would like to thank you for your interest in the project and ask you if you have any questions so far. Please feel free to stop me at any time if you are unclear about something or would like to ask a question. Interviewer: As explained in the information letter, we are trying to select people who represent (province of origin) living in or around the (province) region. This means that we need a mix of males and females, and people from different age groups, income levels, educational backgrounds, and professions. We also need people who are unlikely to voice their views otherwise. Your answers to the questions that I will be asking you will help to make sure that we get things right! Please be aware that you do not have to answer any questions that you do not want to and you may stop the interview at any time. If it's alright with you, I would like to begin now.

Questions	Answer
1. First of all, are you still willing and able to take part in the focus group, which will take place on (date, time, and local)?	If yes, proceed to question 2. If no, stop the interview.
2. Please state your postal code.	
3. How long have you lived at your current address?	
4. Are you male or female?	
5. Please tell me which one of the following age categories you fall into? (check off one of the boxes)	☐ 18 – 24 ☐ 25 – 34 ☐ 35 – 44 ☐ 45 – 54 ☐ 55 – 64 ☐ 65 – 74 ☐ > 75

6. What do you consider to be your ethnic background (e.g., Asian, First Nations, etc.)?	
7. What is the highest level of education you have completed? (check off one of the following boxes)	☐ Less than high school ☐ High school ☐ Post-secondary diploma ☐ University degree ☐ Graduate degree ☐ Other. Please specify:
8. Are you currently working for pay or for profit? Yes / No	If yes, go to question 10. If no, skip to question 13.
9. Which of the following best describes your work status? (check off one or more of the boxes)	☐ Full-time ☐ Part-time ☐ Seasonal ☐ Self-employed ☐ On contract ☐ In a salaried position
10. To which of the following household income categories do you belong, before taxes and deductions: (check off one of the boxes)	☐ < $20,000 ☐ $20,000 to $40,000 ☐ $40,000 to $60,000 ☐ $60,000 to $80,000 ☐ > $80,000
11. Is your current paid employment in the health care system (e.g., health care professional, administrator, support staff, etc.)?	Yes / No
12. Does any immediate member of your family work in health care?	Yes / No
13. Have you ever been associated with or a member of any patient group or society?	Yes / No
14. Do you work for a medical product or health care company?	Yes / No
Thank you for taking the time to answer these questions. When we have finished all of our interviews and selected the 10 participants, we will send you a letter stating whether or not we were able to include you. We plan to have these letters sent out within the next two weeks. In the meantime, if you have any questions or concerns, please feel free to contact me [insert telephone number].	

Data analysis

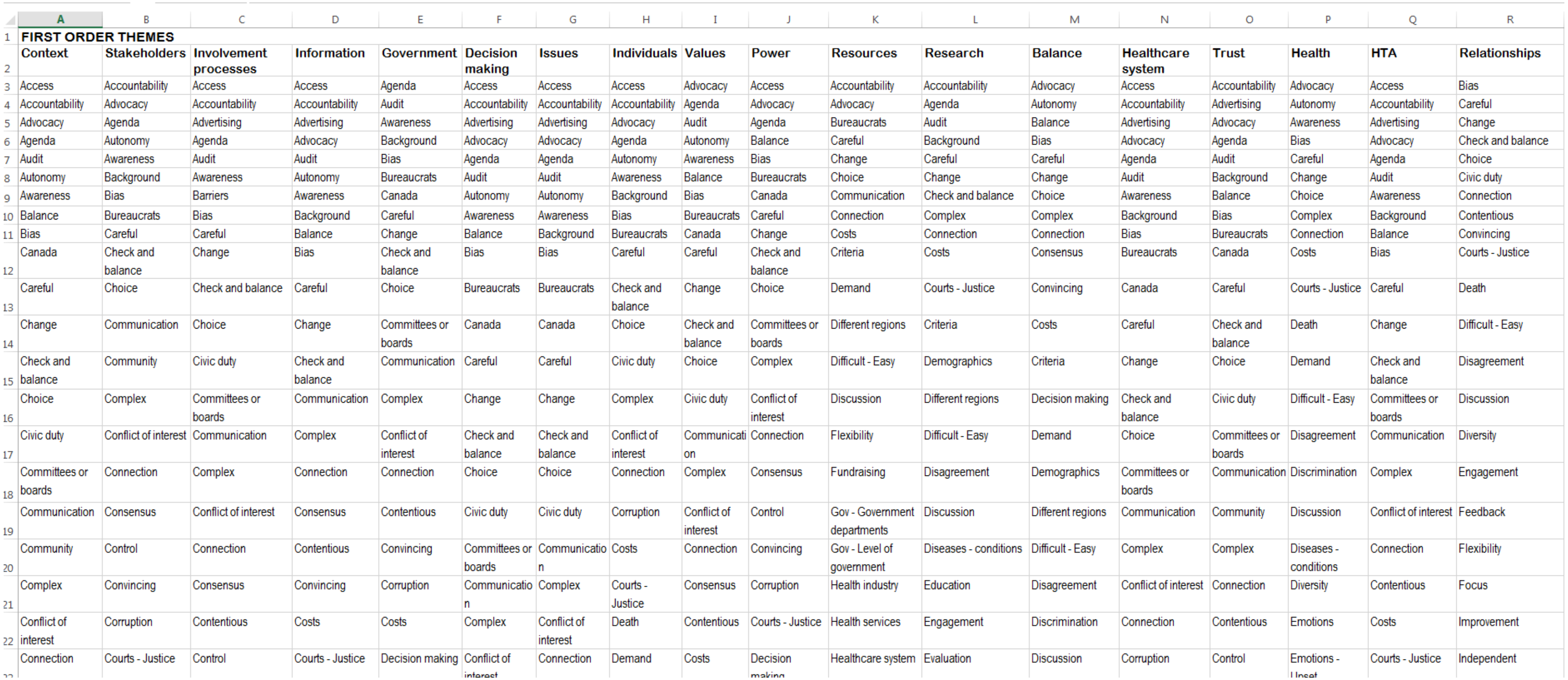
Codes

Access	4	72
Accountability	3	28
Advertising	4	9
Advocacy	4	9
Agenda	4	37
Audit	4	17
Autonomy	3	6
Awareness	4	38
Background	4	26
Balance	4	50
Bias	4	48
Bureaucrats	4	24
Canada	2	9
Careful	4	108
Change	4	48
Check and balance	4	15
Choice	4	49
Civic duty	2	3
Committees or boards	4	41
Communication	4	40
Community	4	104
Complex	4	33
Conflict of interest	4	30
Connection	3	20
Consensus	3	8
Contentious	4	25
Context	4	170
Control	4	20
Convincing	2	3
Corruption	4	9
Costs	4	59
Courts - Justice	3	22
Criteria	4	30
Death	3	3
Decision making	4	118
Demand	2	2
Democracy	3	10
Demographics	4	8
Different regions	3	10
Difficult - Easy	4	93
Disagreement	4	25
Discrimination	3	7
Discussion	4	38
Diseases - conditions	4	35
Distortion	4	65
Diversity	4	39
Doubts	4	113
Education	4	47
Effort	4	63
Emotions	4	30
Engagement	4	83
Ethics	3	6
Evaluation	4	19
Experience	4	67
Experts	4	39
Feedback	4	95

Flexibility	4	30
Focus	4	13
Fundraising	1	1
Government	4	54
Group mentality	2	8
Health	4	39
Health industry	4	19
Health services	3	27
Healthcare professionals	4	30
Healthcare system	4	46
HTA process	3	33
Humanitarian	3	3
Important	4	104
Improvement	4	84
Inclusion - exclusion	4	75
Independent	4	27
Individuals	4	72
Influence	4	68
Information	4	128
Innovation	4	13
Input	4	132
Intention	4	49
Interests	4	92
Internet	4	19
Knowledge	4	78
Leadership	3	8
Learning process	4	16
Limits	4	30
Listened or not listened to	4	23
Lobby group	3	12
Media	3	8
Medical devices	4	18
Medicines	4	29
Middle ground	3	7
Missing something	4	31
Money	4	70
Monitoring	2	9
Objective - subjective	4	62
Older people	4	10
Opportunity	4	64
Other countries	4	20
Other stakeholders	0	0
Patient involvement	4	13
Patient organizations	1	2
Patients	4	32
Perceptions	4	110
Policies	2	8
Politics	3	19
Priorities	4	92
Private health insurance	1	2
Privatization	2	3
Proactive - reactive	4	10
Problematic	4	118
Processes	4	122
Professional	4	17
Promotion	4	19
Provinces	4	15
Public	4	166
Public involvement	4	156
Quality of life	3	12

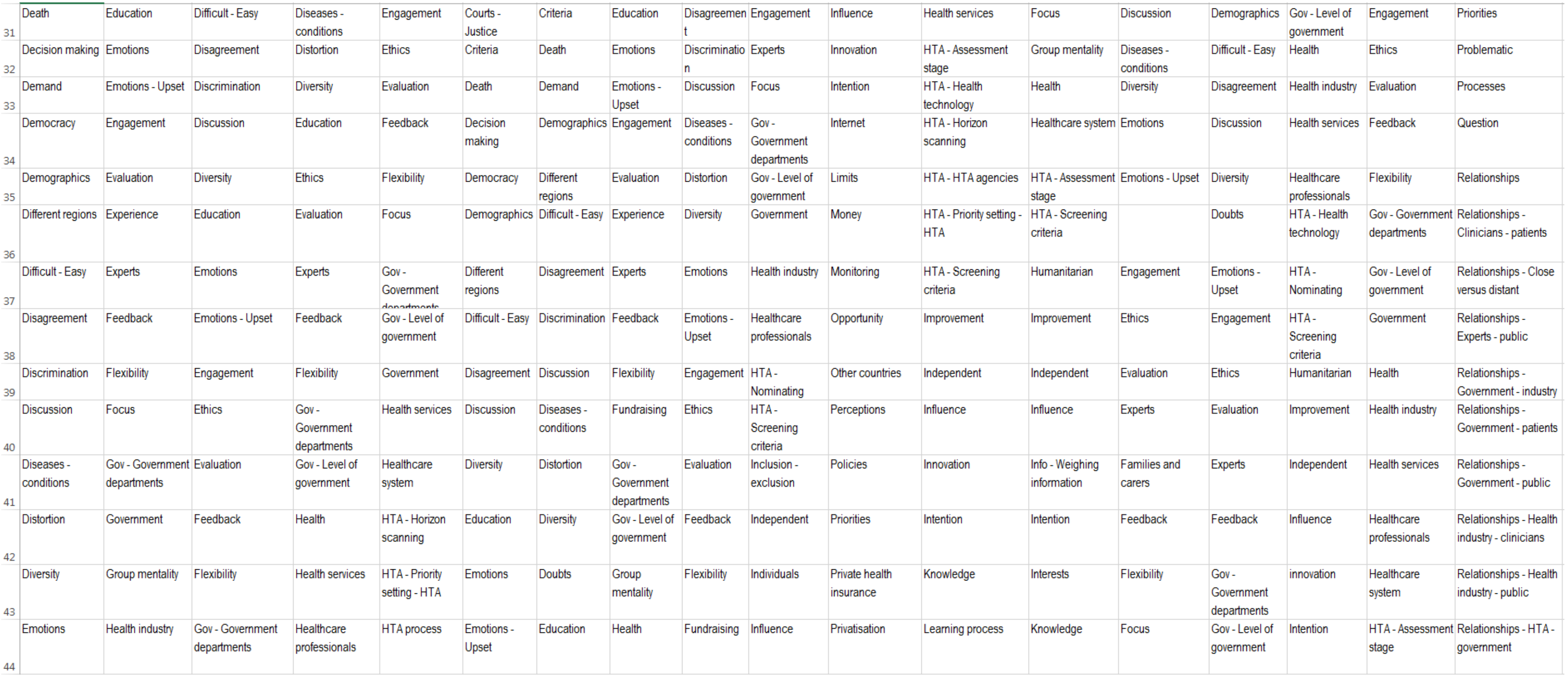
Question	4	72
Random	3	13
Red tape	3	10
Relationships	2	3
Religion	2	3
Report	4	12
Representation	4	32
Research issues	4	54
Researchers	4	17
Responsibility	4	37
Results - outcomes	4	31
Rights	4	17
Saving lives	4	9
Security	2	3
Seriousness	2	5
Skills	4	8
Slowdown	3	5
Small versus large	4	24
Social media	3	5
Stages	2	12
Statistics	3	9
Strategy	4	83
Taxes	4	8
Technology	3	11
Third party	3	4
Time	4	40
Timelines	4	13
Transparency	4	8
Treatment (medical)	4	34
Trust	4	42
Uncertainty	4	85
Understand	4	102
Utilitarianism	3	9
Values	4	83
Variation	4	135
Volunteer	4	5
Waste	4	16
Work	4	13
Young people	3	7

First-order themes

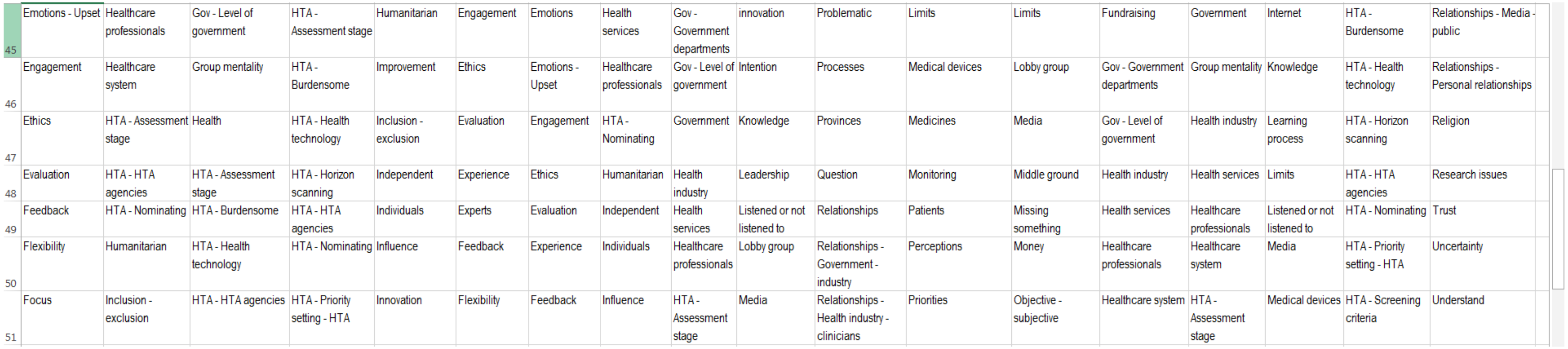


	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R
1	**FIRST ORDER THEMES**																	
2	**Context**	**Stakeholders**	**Involvement processes**	**Information**	**Government**	**Decision making**	**Issues**	**Individuals**	**Values**	**Power**	**Resources**	**Research**	**Balance**	**Healthcare system**	**Trust**	**Health**	**HTA**	**Relationships**
3	Access	Accountability	Access	Access	Agenda	Access	Access	Access	Advocacy	Access	Accountability	Accountability	Advocacy	Access	Accountability	Advocacy	Access	Bias
4	Accountability	Advocacy	Accountability	Accountability	Audit	Accountability	Accountability	Accountability	Agenda	Advocacy	Advocacy	Agenda	Autonomy	Accountability	Advertising	Autonomy	Accountability	Careful
5	Advocacy	Agenda	Advertising	Advertising	Awareness	Advertising	Advertising	Advocacy	Audit	Agenda	Bureaucrats	Audit	Balance	Advertising	Advocacy	Awareness	Advertising	Change
6	Agenda	Autonomy	Agenda	Advocacy	Background	Advocacy	Advocacy	Agenda	Autonomy	Balance	Careful	Background	Bias	Advocacy	Agenda	Bias	Advocacy	Check and balance
7	Audit	Awareness	Audit	Audit	Bias	Agenda	Agenda	Autonomy	Awareness	Bias	Change	Careful	Careful	Agenda	Audit	Careful	Agenda	Choice
8	Autonomy	Background	Awareness	Autonomy	Bureaucrats	Audit	Audit	Awareness	Balance	Bureaucrats	Choice	Change	Change	Audit	Background	Change	Audit	Civic duty
9	Awareness	Bias	Barriers	Awareness	Canada	Autonomy	Autonomy	Background	Bias	Canada	Communication	Check and balance	Choice	Awareness	Balance	Choice	Awareness	Connection
10	Balance	Bureaucrats	Bias	Background	Careful	Awareness	Awareness	Bias	Bureaucrats	Careful	Connection	Complex	Complex	Background	Bias	Complex	Background	Contentious
11	Bias	Careful	Careful	Balance	Change	Balance	Background	Bureaucrats	Canada	Change	Costs	Connection	Connection	Bias	Bureaucrats	Connection	Balance	Convincing
12	Canada	Check and balance	Change	Bias	Check and balance	Bias	Bias	Careful	Careful	Check and balance	Criteria	Costs	Consensus	Bureaucrats	Canada	Costs	Bias	Courts - Justice
13	Careful	Choice	Check and balance	Careful	Choice	Bureaucrats	Bureaucrats	Check and balance	Change	Choice	Demand	Courts - Justice	Convincing	Canada	Careful	Courts - Justice	Careful	Death
14	Change	Communication	Choice	Change	Committees or boards	Canada	Canada	Choice	Check and balance	Committees or boards	Different regions	Criteria	Costs	Careful	Check and balance	Death	Change	Difficult - Easy
15	Check and balance	Community	Civic duty	Check and balance	Communication	Careful	Careful	Civic duty	Choice	Complex	Difficult - Easy	Demographics	Criteria	Change	Choice	Demand	Check and balance	Disagreement
16	Choice	Complex	Committees or boards	Communication	Complex	Change	Change	Complex	Civic duty	Conflict of interest	Discussion	Different regions	Decision making	Check and balance	Civic duty	Difficult - Easy	Committees or boards	Discussion
17	Civic duty	Conflict of interest	Communication	Complex	Conflict of interest	Check and balance	Check and balance	Conflict of interest	Communication	Connection	Flexibility	Difficult - Easy	Demand	Choice	Committees or boards	Disagreement	Communication	Diversity
18	Committees or boards	Connection	Complex	Connection	Connection	Choice	Choice	Connection	Complex	Consensus	Fundraising	Disagreement	Demographics	Committees or boards	Communication	Discrimination	Complex	Engagement
19	Communication	Consensus	Conflict of interest	Consensus	Contentious	Civic duty	Civic duty	Corruption	Conflict of interest	Control	Gov - Government departments	Discussion	Different regions	Communication	Community	Discussion	Conflict of interest	Feedback
20	Community	Control	Connection	Contentious	Convincing	Committees or boards	Communication	Costs	Connection	Convincing	Gov - Level of government	Diseases - conditions	Difficult - Easy	Complex	Complex	Diseases - conditions	Connection	Flexibility
21	Complex	Convincing	Consensus	Convincing	Corruption	Communication	Complex	Courts - Justice	Consensus	Corruption	Health industry	Education	Disagreement	Conflict of interest	Connection	Diversity	Contentious	Focus
22	Conflict of interest	Corruption	Contentious	Costs	Costs	Complex	Conflict of interest	Death	Contentious	Courts - Justice	Health services	Engagement	Discrimination	Connection	Contentious	Emotions	Costs	Improvement
	Connection	Courts - Justice	Control	Courts - Justice	Decision making	Conflict of	Connection	Demand	Costs	Decision	Healthcare system	Evaluation	Discussion	Corruption	Control	Emotions -	Courts - Justice	Independent

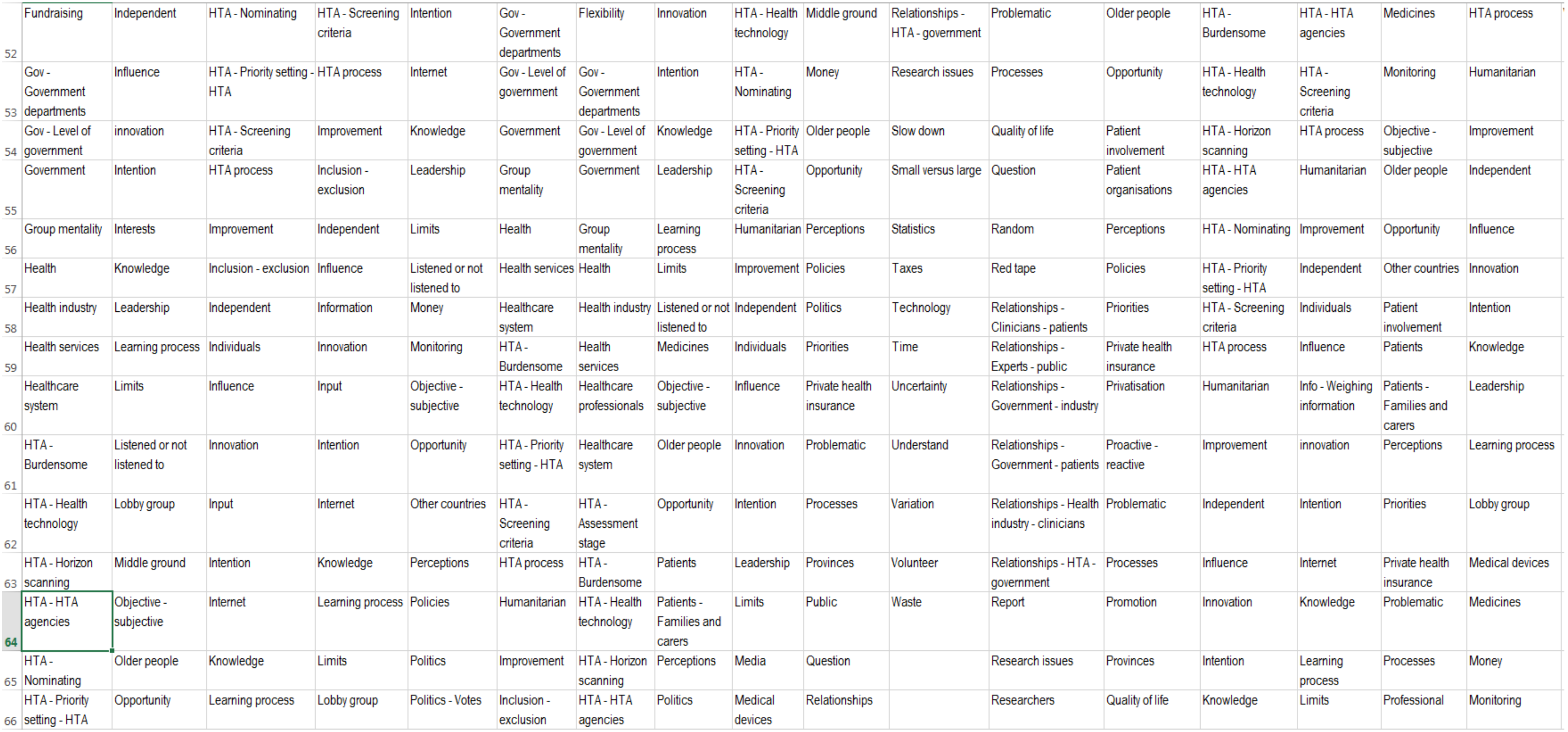
Consensus	Demand	Corruption	Criteria	Democracy	Connection	Consensus	Demographics	Courts - Justice	Democracy	HTA - Burdensome	Experts	Diversity	Costs	Convincing	Engagement	Criteria	Influence
Contentious	Demographics	Costs	Democracy	Different regions	Consensus	Contentious	Difficult - Easy	Criteria	Different regions	HTA - Health technology	Feedback	Emotions - Upset	Courts - Justice	Corruption	Ethics	Different regions	Intention
Control	Different regions	Courts - Justice	Different regions	Difficult - Easy	Contentious	Control	Disagreement	Death	Difficult - Easy	HTA - HTA agencies	Flexibility	Engagement	Demand	Courts - Justice	Evaluation	Difficult - Easy	Knowledge
Convincing	Difficult - Easy	Criteria	Difficult - Easy	Disagreement	Control	Convincing	Discrimination	Democracy	Disagreement	HTA - Priority setting - HTA	Gov - Government departments	Ethics	Different regions	Criteria	Feedback	Disagreement	Objective - subjective
Corruption	Disagreement	Democracy	Disagreement	Discussion	Convincing	Corruption	Discussion	Demographics	Discrimination	HTA process	Gov - Level of government	Experience	Difficult - Easy	Death	Flexibility	Discussion	Opportunity
Costs	Discussion	Demographics	Discrimination	Diversity	Corruption	Costs	Diseases - conditions	Different regions	Discussion	Improvement	Health	Feedback	Disagreement	Decision making	Fundraising	Diseases - conditions	Patient organisations
Courts - Justice	Diversity	Different regions	Discussion	Emotions - Upset	Costs	Courts - Justice	Diversity	Difficult - Easy	Distortion	Independent	Health industry	Flexibility	Discrimination	Democracy	Gov - Government departments	Diversity	Perceptions



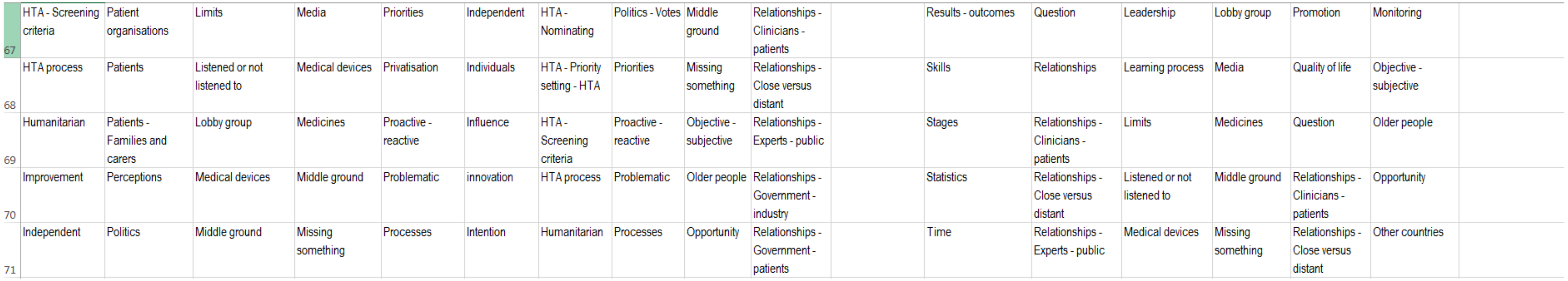
31	Death	Education	Difficult - Easy	Diseases - conditions	Engagement	Courts - Justice	Criteria	Education	Disagreement	Engagement	Influence	Health services	Focus	Discussion	Demographics	Gov - Level of government	Engagement	Priorities
32	Decision making	Emotions	Disagreement	Distortion	Ethics	Criteria	Death	Emotions	Discrimination	Experts	Innovation	HTA - Assessment stage	Group mentality	Diseases - conditions	Difficult - Easy	Health	Ethics	Problematic
33	Demand	Emotions - Upset	Discrimination	Diversity	Evaluation	Death	Demand	Emotions - Upset	Discussion	Focus	Intention	HTA - Health technology	Health	Diversity	Disagreement	Health industry	Evaluation	Processes
34	Democracy	Engagement	Discussion	Education	Feedback	Decision making	Demographics	Engagement	Diseases - conditions	Gov - Government departments	Internet	HTA - Horizon scanning	Healthcare system	Emotions	Discussion	Health services	Feedback	Question
35	Demographics	Evaluation	Diversity	Ethics	Flexibility	Democracy	Different regions	Evaluation	Distortion	Gov - Level of government	Limits	HTA - HTA agencies	HTA - Assessment stage	Emotions - Upset	Diversity	Healthcare professionals	Flexibility	Relationships
36	Different regions	Experience	Education	Evaluation	Focus	Demographics	Difficult - Easy	Experience	Diversity	Government	Money	HTA - Priority setting - HTA	HTA - Screening criteria		Doubts	HTA - Health technology	Gov - Government departments	Relationships - Clinicians - patients
37	Difficult - Easy	Experts	Emotions	Experts	Gov - Government departments	Different regions	Disagreement	Experts	Emotions	Health industry	Monitoring	HTA - Screening criteria	Humanitarian	Engagement	Emotions - Upset	HTA - Nominating	Gov - Level of government	Relationships - Close versus distant
38	Disagreement	Feedback	Emotions - Upset	Feedback	Gov - Level of government	Difficult - Easy	Discrimination	Feedback	Emotions - Upset	Healthcare professionals	Opportunity	Improvement	Improvement	Ethics	Engagement	HTA - Screening criteria	Government	Relationships - Experts - public
39	Discrimination	Flexibility	Engagement	Flexibility	Government	Disagreement	Discussion	Flexibility	Engagement	HTA - Nominating	Other countries	Independent	Independent	Evaluation	Ethics	Humanitarian	Health	Relationships - Government - industry
40	Discussion	Focus	Ethics	Gov - Government departments	Health services	Discussion	Diseases - conditions	Fundraising	Ethics	HTA - Screening criteria	Perceptions	Influence	Influence	Experts	Evaluation	Improvement	Health industry	Relationships - Government - patients
41	Diseases - conditions	Gov - Government departments	Evaluation	Gov - Level of government	Healthcare system	Diversity	Distortion	Gov - Government departments	Evaluation	Inclusion - exclusion	Policies	Innovation	Info - Weighing information	Families and carers	Experts	Independent	Health services	Relationships - Government - public
42	Distortion	Government	Feedback	Health	HTA - Horizon scanning	Education	Diversity	Gov - Level of government	Feedback	Independent	Priorities	Intention	Intention	Feedback	Feedback	Influence	Healthcare professionals	Relationships - Health industry - clinicians
43	Diversity	Group mentality	Flexibility	Health services	HTA - Priority setting - HTA	Emotions	Doubts	Group mentality	Flexibility	Individuals	Private health insurance	Knowledge	Interests	Flexibility	Gov - Government departments	innovation	Healthcare system	Relationships - Health industry - public
44	Emotions	Health industry	Gov - Government departments	Healthcare professionals	HTA process	Emotions - Upset	Education	Health	Fundraising	Influence	Privatisation	Learning process	Knowledge	Focus	Gov - Level of government	Intention	HTA - Assessment stage	Relationships - HTA - government



45	Emotions - Upset	Healthcare professionals	Gov - Level of government	HTA - Assessment stage	Humanitarian	Engagement	Emotions	Health services	Gov - Government departments	innovation	Problematic	Limits	Limits	Fundraising	Government	Internet	HTA - Burdensome	Relationships - Media - public
46	Engagement	Healthcare system	Group mentality	HTA - Burdensome	Improvement	Ethics	Emotions - Upset	Healthcare professionals	Gov - Level of government	Intention	Processes	Medical devices	Lobby group	Gov - Government departments	Group mentality	Knowledge	HTA - Health technology	Relationships - Personal relationships
47	Ethics	HTA - Assessment stage	Health	HTA - Health technology	Inclusion - exclusion	Evaluation	Engagement	HTA - Nominating	Government	Knowledge	Provinces	Medicines	Media	Gov - Level of government	Health industry	Learning process	HTA - Horizon scanning	Religion
48	Evaluation	HTA - HTA agencies	HTA - Assessment stage	HTA - Horizon scanning	Independent	Experience	Ethics	Humanitarian	Health industry	Leadership	Question	Monitoring	Middle ground	Health industry	Health services	Limits	HTA - HTA agencies	Research issues
49	Feedback	HTA - Nominating	HTA - Burdensome	HTA - HTA agencies	Individuals	Experts	Evaluation	Independent	Health services	Listened or not listened to	Relationships	Patients	Missing something	Health services	Healthcare professionals	Listened or not listened to	HTA - Nominating	Trust
50	Flexibility	Humanitarian	HTA - Health technology	HTA - Nominating	Influence	Feedback	Experience	Individuals	Healthcare professionals	Lobby group	Relationships - Government - industry	Perceptions	Money	Healthcare professionals	Healthcare system	Media	HTA - Priority setting - HTA	Uncertainty
51	Focus	Inclusion - exclusion	HTA - HTA agencies	HTA - Priority setting - HTA	Innovation	Flexibility	Feedback	Influence	HTA - Assessment stage	Media	Relationships - Health industry - clinicians	Priorities	Objective - subjective	Healthcare system	HTA - Assessment stage	Medical devices	HTA - Screening criteria	Understand



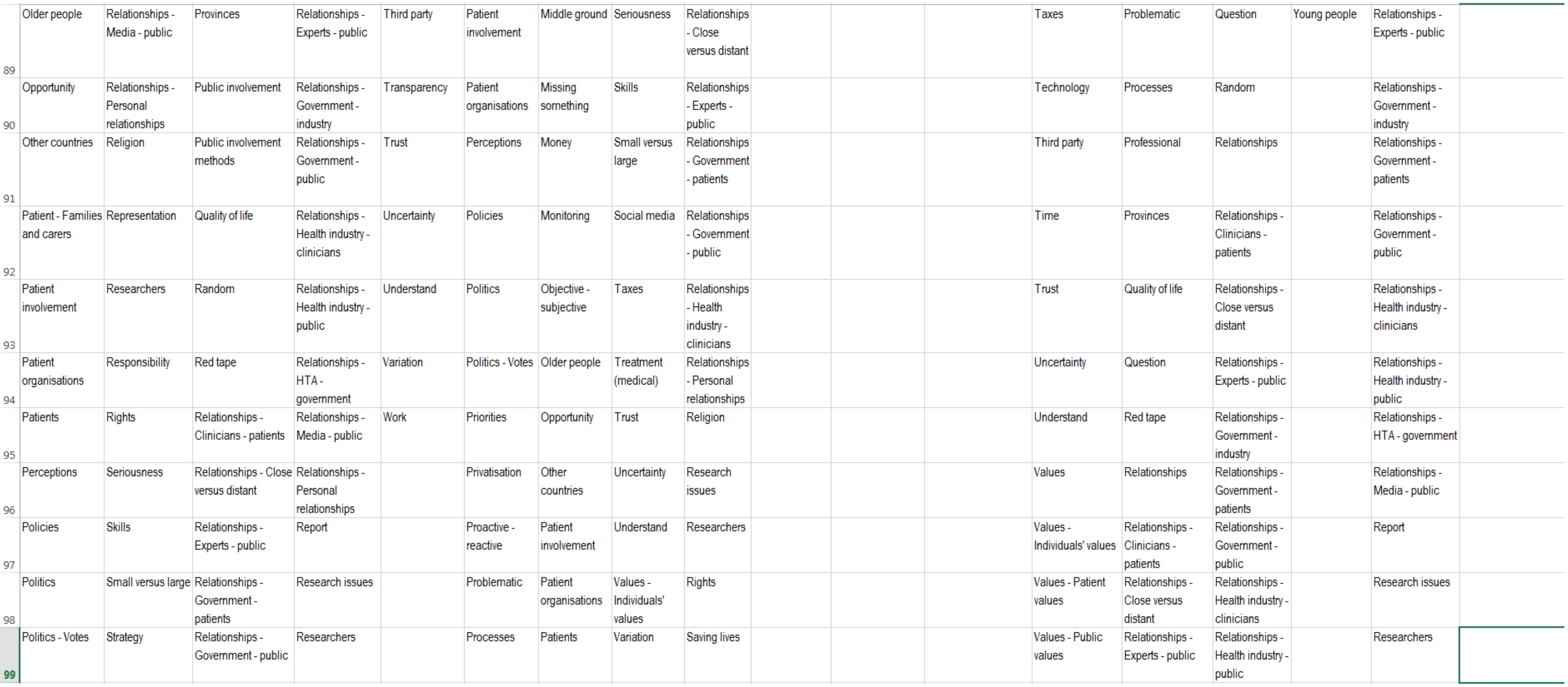
52	Fundraising	Independent	HTA - Nominating	HTA - Screening criteria	Intention	Gov - Government departments	Flexibility	Innovation	HTA - Health technology	Middle ground	Relationships - HTA - government	Problematic	Older people	HTA - Burdensome	HTA - HTA agencies	Medicines	HTA process
53	Gov - Government departments	Influence	HTA - Priority setting - HTA	HTA process	Internet	Gov - Level of government	Gov - Government departments	Intention	HTA - Nominating	Money	Research issues	Processes	Opportunity	HTA - Health technology	HTA - Screening criteria	Monitoring	Humanitarian
54	Gov - Level of government	innovation	HTA - Screening criteria	Improvement	Knowledge	Government	Gov - Level of government	Knowledge	HTA - Priority setting - HTA	Older people	Slow down	Quality of life	Patient involvement	HTA - Horizon scanning	HTA process	Objective - subjective	Improvement
55	Government	Intention	HTA process	Inclusion - exclusion	Leadership	Group mentality	Government	Leadership	HTA - Screening criteria	Opportunity	Small versus large	Question	Patient organisations	HTA - HTA agencies	Humanitarian	Older people	Independent
56	Group mentality	Interests	Improvement	Independent	Limits	Health	Group mentality	Learning process	Humanitarian	Perceptions	Statistics	Random	Perceptions	HTA - Nominating	Improvement	Opportunity	Influence
57	Health	Knowledge	Inclusion - exclusion	Influence	Listened or not listened to	Health services	Health	Limits	Improvement	Policies	Taxes	Red tape	Policies	HTA - Priority setting - HTA	Independent	Other countries	Innovation
58	Health industry	Leadership	Independent	Information	Money	Healthcare system	Health industry	Listened or not listened to	Independent	Politics	Technology	Relationships - Clinicians - patients	Priorities	HTA - Screening criteria	Individuals	Patient involvement	Intention
59	Health services	Learning process	Individuals	Innovation	Monitoring	HTA - Burdensome	Health services	Medicines	Individuals	Priorities	Time	Relationships - Experts - public	Private health insurance	HTA process	Influence	Patients	Knowledge
60	Healthcare system	Limits	Influence	Input	Objective - subjective	HTA - Health technology	Healthcare professionals	Objective - subjective	Influence	Private health insurance	Uncertainty	Relationships - Government - industry	Privatisation	Humanitarian	Info - Weighing information	Patients - Families and carers	Leadership
61	HTA - Burdensome	Listened or not listened to	Innovation	Intention	Opportunity	HTA - Priority setting - HTA	Healthcare system	Older people	Innovation	Problematic	Understand	Relationships - Government - patients	Proactive - reactive	Improvement	innovation	Perceptions	Learning process
62	HTA - Health technology	Lobby group	Input	Internet	Other countries	HTA - Screening criteria	HTA - Assessment stage	Opportunity	Intention	Processes	Variation	Relationships - Health industry - clinicians	Problematic	Independent	Intention	Priorities	Lobby group
63	HTA - Horizon scanning	Middle ground	Intention	Knowledge	Perceptions	HTA process	HTA - Burdensome	Patients	Leadership	Provinces	Volunteer	Relationships - HTA - government	Processes	Influence	Internet	Private health insurance	Medical devices
64	HTA - HTA agencies	Objective - subjective	Internet	Learning process	Policies	Humanitarian	HTA - Health technology	Patients - Families and carers	Limits	Public	Waste	Report	Promotion	Innovation	Knowledge	Problematic	Medicines
65	HTA - Nominating	Older people	Knowledge	Limits	Politics	Improvement	HTA - Horizon scanning	Perceptions	Media	Question		Research issues	Provinces	Intention	Learning process	Processes	Money
66	HTA - Priority setting - HTA	Opportunity	Learning process	Lobby group	Politics - Votes	Inclusion - exclusion	HTA - HTA agencies	Politics	Medical devices	Relationships		Researchers	Quality of life	Knowledge	Limits	Professional	Monitoring



67	HTA - Screening criteria	Patient organisations	Limits	Media	Priorities	Independent	HTA - Nominating	Politics - Votes	Middle ground	Relationships - Clinicians - patients		Results - outcomes	Question	Leadership	Lobby group	Promotion	Monitoring
68	HTA process	Patients	Listened or not listened to	Medical devices	Privatisation	Individuals	HTA - Priority setting - HTA	Priorities	Missing something	Relationships - Close versus distant		Skills	Relationships	Learning process	Media	Quality of life	Objective - subjective
69	Humanitarian	Patients - Families and carers	Lobby group	Medicines	Proactive - reactive	Influence	HTA - Screening criteria	Proactive - reactive	Objective - subjective	Relationships - Experts - public		Stages	Relationships - Clinicians - patients	Limits	Medicines	Question	Older people
70	Improvement	Perceptions	Medical devices	Middle ground	Problematic	innovation	HTA process	Problematic	Older people	Relationships - Government - industry		Statistics	Relationships - Close versus distant	Listened or not listened to	Middle ground	Relationships - Clinicians - patients	Opportunity
71	Independent	Politics	Middle ground	Missing something	Processes	Intention	Humanitarian	Processes	Opportunity	Relationships - Government - patients		Time	Relationships - Experts - public	Medical devices	Missing something	Relationships - Close versus distant	Other countries

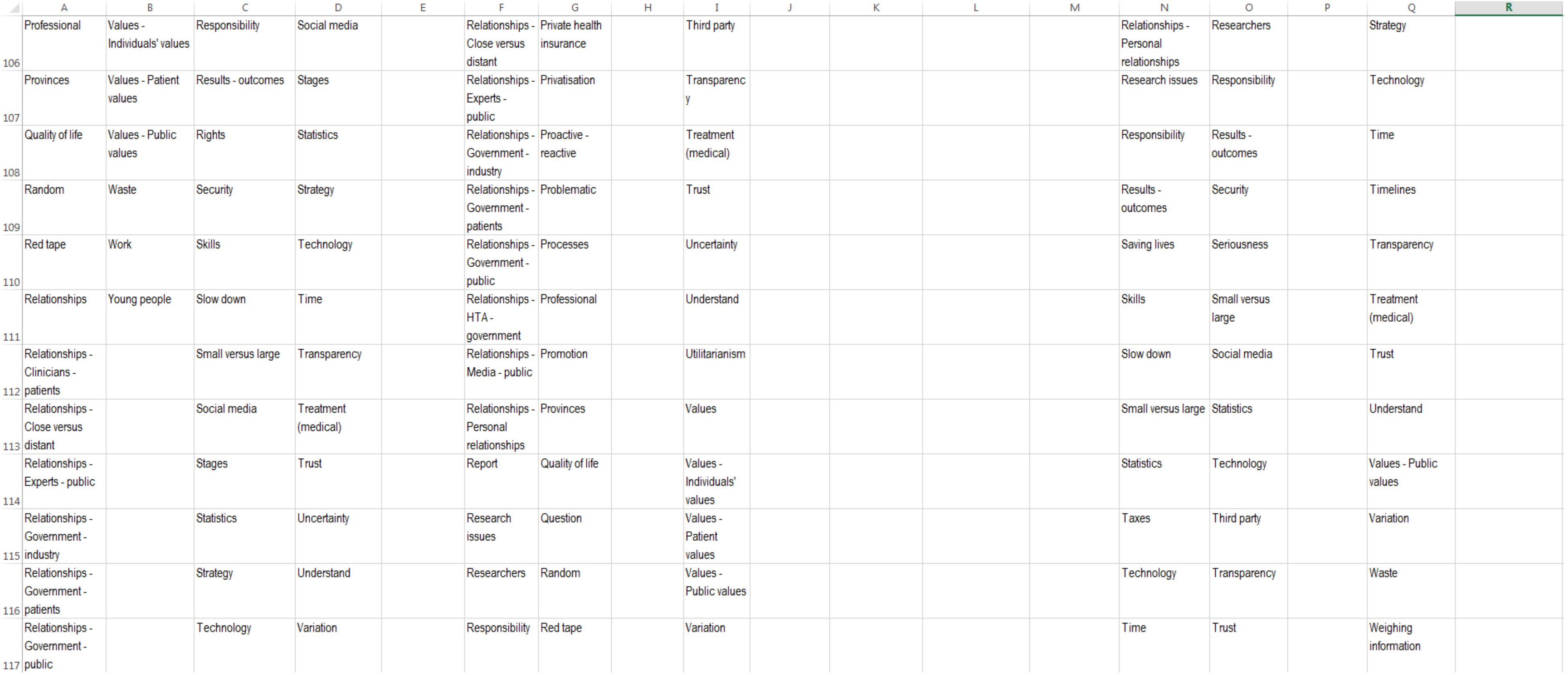
71	Independent	Politics	Middle ground	Missing something	Processes	Intention	Humanitarian	Processes	Opportunity	Relationships - Government - patients		Time	Relationships - Experts - public	Medical devices	Missing something	Relationships - Close versus distant	Other countries	
72	Individuals	Politics - Votes	Missing something	Monitoring	Provinces	Knowledge	Improvement	Professional	Other countries	Relationships - Government - public		Timelines	Relationships - Government - industry	Medicines	Money	Relationships - Experts - public	Patient involvement	
73	Influence	Priorities	Money	Objective - subjective	Question	Leadership	Inclusion - exclusion	Public	Patient involvement	Relationships - Health industry - clinicians		Treatment (medical)	Relationships - Government - patients	Missing something	Monitoring	Relationships - Government - patients	Patients - Families and carers	
74	Info - Weighing information	Problematic	Monitoring	Opportunity	Red tape	Learning process	Independent	Quality of life	Patients - Families and carers	Relationships - Health industry - public		Trust	Relationships - Government - public	Monitoring	Other countries	Relationships - Government - public	Perceptions	
75	Innovation	Processes	Objective - subjective	Other countries	Relationships - Close versus distant	Limits	Influence	Question	Perceptions	Relationships - HTA - government		Understand	Relationships - Health industry - clinicians	Objective - subjective	Patient involvement	Relationships - Health industry - public	Policies	
76	Intention	Professional	Opportunity	Patients - Families and carers	Relationships - Government - industry	Listened or not listened to	Innovation	Random	Policies	Relationships - Media - public		Variation	Relationships - Health industry - public	Older people	Patient organisations	Relationships - Media - public	Priorities	
77	Internet	Public	Other countries	Perceptions	Relationships - Government - patients	Lobby group	Intention	Relationships	Politics	Relationships - Personal relationships		Waste	Relationships - HTA - government	Opportunity	Patients	Relationships - Personal relationships	Proactive - reactive	
78	Knowledge	Random	Patient involvement	Policies	Relationships - Government - public	Media	Interests	Relationships - Clinicians - patients	Politics - Votes	Research issues			Relationships - Media - public	Other countries	Patients - Families and carers	Research issues	Problematic	
79	Learning process	Relationships	Patient organisations	Politics	Relationships - HTA - government	Medical devices	Internet	Relationships - Close versus distant	Priorities	Responsibility			Relationships - Personal relationships	Patient involvement	Perceptions	Responsibility	Processes	
80	Limits	Relationships - Clinicians - patients	Patients	Politics - Votes	Relationships - Personal relationships	Medicines	Knowledge	Relationships - Government - industry	Proactive - reactive	Seriousness			Religion	Patients	Policies	Results - outcomes	Promotion	
81	Listened or not listened to	Relationships - Close versus distant	Patients - Families and carers	Problematic	Report	Middle ground	Leadership	Relationships - Health industry - clinicians	Problematic	Strategy			Representation	Perceptions	Politics	Saving lives	Provinces	
82	Lobby group	Relationships - Experts - public	Perceptions	Processes	Responsibility	Missing something	Learning process	Relationships - Media - public	Processes	Technology			Responsibility	Policies	Politics - Votes	Stages	Public	

83	Media	Relationships - Government - industry	Policies	Professional	Seriousness	Money	Limits	Relationships - Personal relationships	Professional	Trust			Security	Politics	Private health insurance	Technology	Quality of life
84	Medical devices	Relationships - Government - patients	Priorities	Promotion	Small versus large	Monitoring	Listened or not listened to	Religion	Promotion	Uncertainty			Skills	Politics - Votes	Problematic	Treatment (medical)	Question
85	Middle ground	Relationships - Government - public	Proactive - reactive	Quality of life	Statistics	Objective - subjective	Lobby group	Researchers	Provinces	Understand			Slow down	Priorities	Processes	Trust	Red tape
86	Missing something	Relationships - Health industry - clinicians	Problematic	Question	Strategy	Older people	Media	Responsibility	Question	Variation			Social media	Private health insurance	Professional	Uncertainty	Relationships
87	Money	Relationships - Health industry - public	Processes	Red tape	Taxes	Opportunity	Medical devices	Results - outcomes	Random				Stages	Privatisation	Provinces	Understand	Relationships - Clinicians - patients
88	Monitoring	Relationships - HTA - government	Promotion	Relationships - Clinicians - patients	Technology	Other countries	Medicines	Rights	Relationships - Clinicians - patients				Statistics	Proactive - reactive	Public	Variation	Relationships - Close versus distant



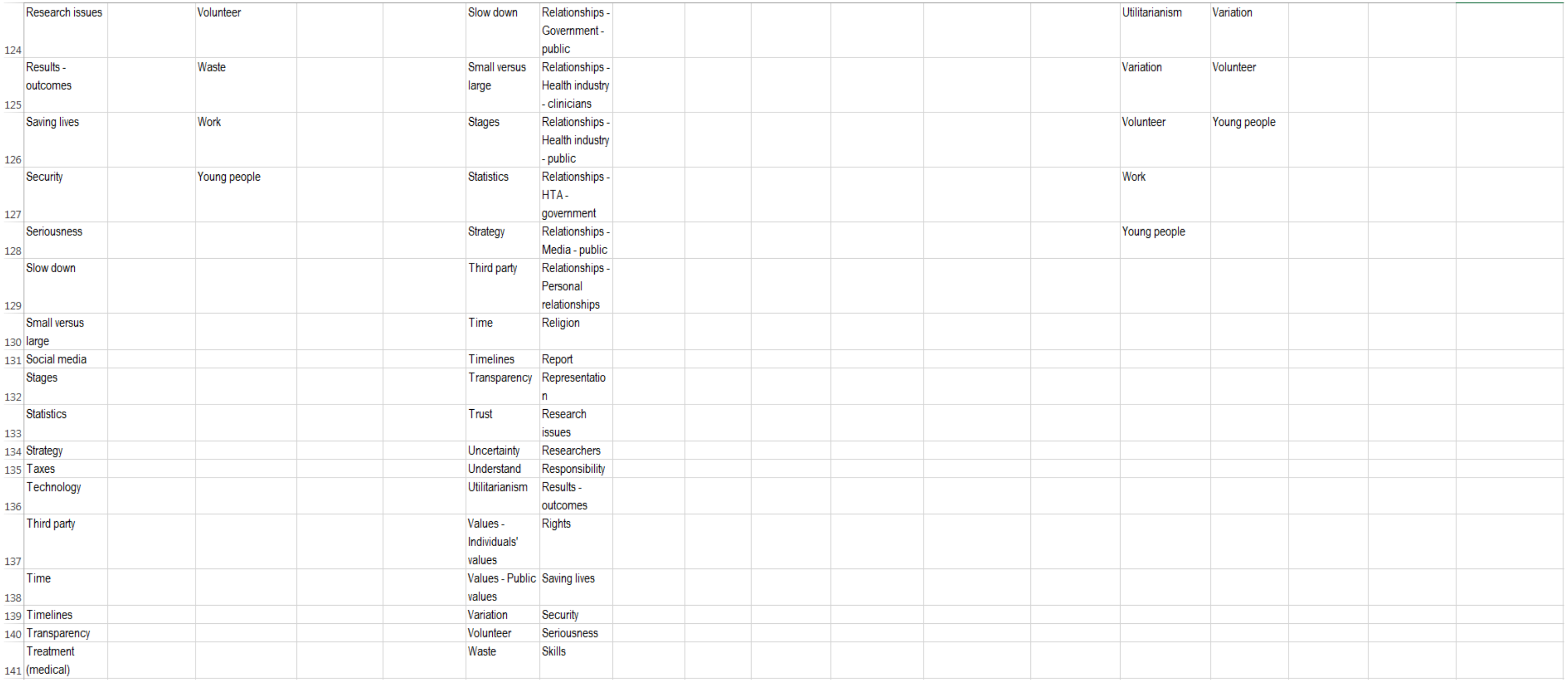
89	Older people	Relationships - Media - public	Provinces	Relationships - Experts - public	Third party	Patient involvement	Middle ground	Seriousness	Relationships - Close versus distant				Taxes	Problematic	Question	Young people	Relationships - Experts - public
90	Opportunity	Relationships - Personal relationships	Public involvement	Relationships - Government - industry	Transparency	Patient organisations	Missing something	Skills	Relationships - Experts - public				Technology	Processes	Random		Relationships - Government - industry
91	Other countries	Religion	Public involvement methods	Relationships - Government - public	Trust	Perceptions	Money	Small versus large	Relationships - Government - patients				Third party	Professional	Relationships		Relationships - Government - patients
92	Patient - Families and carers	Representation	Quality of life	Relationships - Health industry - clinicians	Uncertainty	Policies	Monitoring	Social media	Relationships - Government - public				Time	Provinces	Relationships - Clinicians - patients		Relationships - Government - public
93	Patient involvement	Researchers	Random	Relationships - Health industry - public	Understand	Politics	Objective - subjective	Taxes	Relationships - Health industry - clinicians				Trust	Quality of life	Relationships - Close versus distant		Relationships - Health industry - clinicians
94	Patient organisations	Responsibility	Red tape	Relationships - HTA - government	Variation	Politics - Votes	Older people	Treatment (medical)	Relationships - Personal relationships				Uncertainty	Question	Relationships - Experts - public		Relationships - Health industry - public
95	Patients	Rights	Relationships - Clinicians - patients	Relationships - Media - public	Work	Priorities	Opportunity	Trust	Religion				Understand	Red tape	Relationships - Government - industry		Relationships - HTA - government
96	Perceptions	Seriousness	Relationships - Close versus distant	Relationships - Personal relationships		Privatisation	Other countries	Uncertainty	Research issues				Values	Relationships	Relationships - Government - patients		Relationships - Media - public
97	Policies	Skills	Relationships - Experts - public	Report		Proactive - reactive	Patient involvement	Understand	Researchers				Values - Individuals' values	Relationships - Clinicians - patients	Relationships - Government - public		Report
98	Politics	Small versus large	Relationships - Government - patients	Research issues		Problematic	Patient organisations	Values - Individuals' values	Rights				Values - Patient values	Relationships - Close versus distant	Relationships - Health industry - clinicians		Research issues
99	Politics - Votes	Strategy	Relationships - Government - public	Researchers		Processes	Patients	Variation	Saving lives				Values - Public values	Relationships - Experts - public	Relationships - Health industry - public		Researchers

100	Priorities	Taxes	Relationships - Health industry - public	Responsibility		Professional	Patients - Families and carers	Volunteer	Seriousness				Variation	Relationships - Government - industry	Relationships - HTA - government		Results - outcomes	
101	Private health insurance	Third party	Relationships - Media - public	Rights		Promotion	Perceptions	Waste	Small versus large					Relationships - Government - patients	Relationships - Media - public		Rights	
102	Privatisation	Trust	Report	Saving lives		Provinces	Policies	Work	Social media					Relationships - Government - public	Relationships - Personal relationships		Skills	
103	Proactive - reactive	Uncertainty	Representation	Security		Question	Politics	Young people	Statistics					Relationships - Health industry - clinicians	Religion		Slow down	
104	Problematic	Understand	Research issues	Slow down		Red tape	Politics - Votes		Taxes					Relationships - Health industry - public	Representation		Stages	
105	Processes	Values	Researchers	Small versus large		Relationships	Priorities		Technology					Relationships - HTA - government	Research issues		Statistics	



	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R
106	Professional	Values - Individuals' values	Responsibility	Social media		Relationships - Close versus distant	Private health insurance		Third party					Relationships - Personal relationships	Researchers		Strategy	
107	Provinces	Values - Patient values	Results - outcomes	Stages		Relationships - Experts - public	Privatisation		Transparency					Research issues	Responsibility		Technology	
108	Quality of life	Values - Public values	Rights	Statistics		Relationships - Government - industry	Proactive - reactive		Treatment (medical)					Responsibility	Results - outcomes		Time	
109	Random	Waste	Security	Strategy		Relationships - Government - patients	Problematic		Trust					Results - outcomes	Security		Timelines	
110	Red tape	Work	Skills	Technology		Relationships - Government - public	Processes		Uncertainty					Saving lives	Seriousness		Transparency	
111	Relationships	Young people	Slow down	Time		Relationships - HTA - government	Professional		Understand					Skills	Small versus large		Treatment (medical)	
112	Relationships - Clinicians - patients		Small versus large	Transparency		Relationships - Media - public	Promotion		Utilitarianism					Slow down	Social media		Trust	
113	Relationships - Close versus distant		Social media	Treatment (medical)		Relationships - Personal relationships	Provinces		Values					Small versus large	Statistics		Understand	
114	Relationships - Experts - public		Stages	Trust		Report	Quality of life		Values - Individuals' values					Statistics	Technology		Values - Public values	
115	Relationships - Government - industry		Statistics	Uncertainty		Research issues	Question		Values - Patient values					Taxes	Third party		Variation	
116	Relationships - Government - patients		Strategy	Understand		Researchers	Random		Values - Public values					Technology	Transparency		Waste	
117	Relationships - Government - public		Technology	Variation		Responsibility	Red tape		Variation					Time	Trust		Weighing information	

118	Relationships - Health industry - clinicians		Timelines	Waste		Results - outcomes	Relationships		Volunteer					Timelines	Uncertainty			
119	Relationships - Health industry - public		Transparency	Weighing information		Rights	Relationships - Clinicians - patients		Waste					Transparency	Understand			
120	Relationships - HTA - government		Trust	Young people		Saving lives	Relationships - Close versus distant		Young people					Treatment (medical)	Values			
121	Relationships - Media - public		Uncertainty			Security	Relationships - Experts - public							Trust	Values - Individuals' values			
122	Relationships - Personal relationships		Understand			Seriousness	Relationships - Government - industry							Uncertainty	Values - Patient values			
123	Religion		Variation			Skills	Relationships - Government - patients							Understand	Values - Public values			

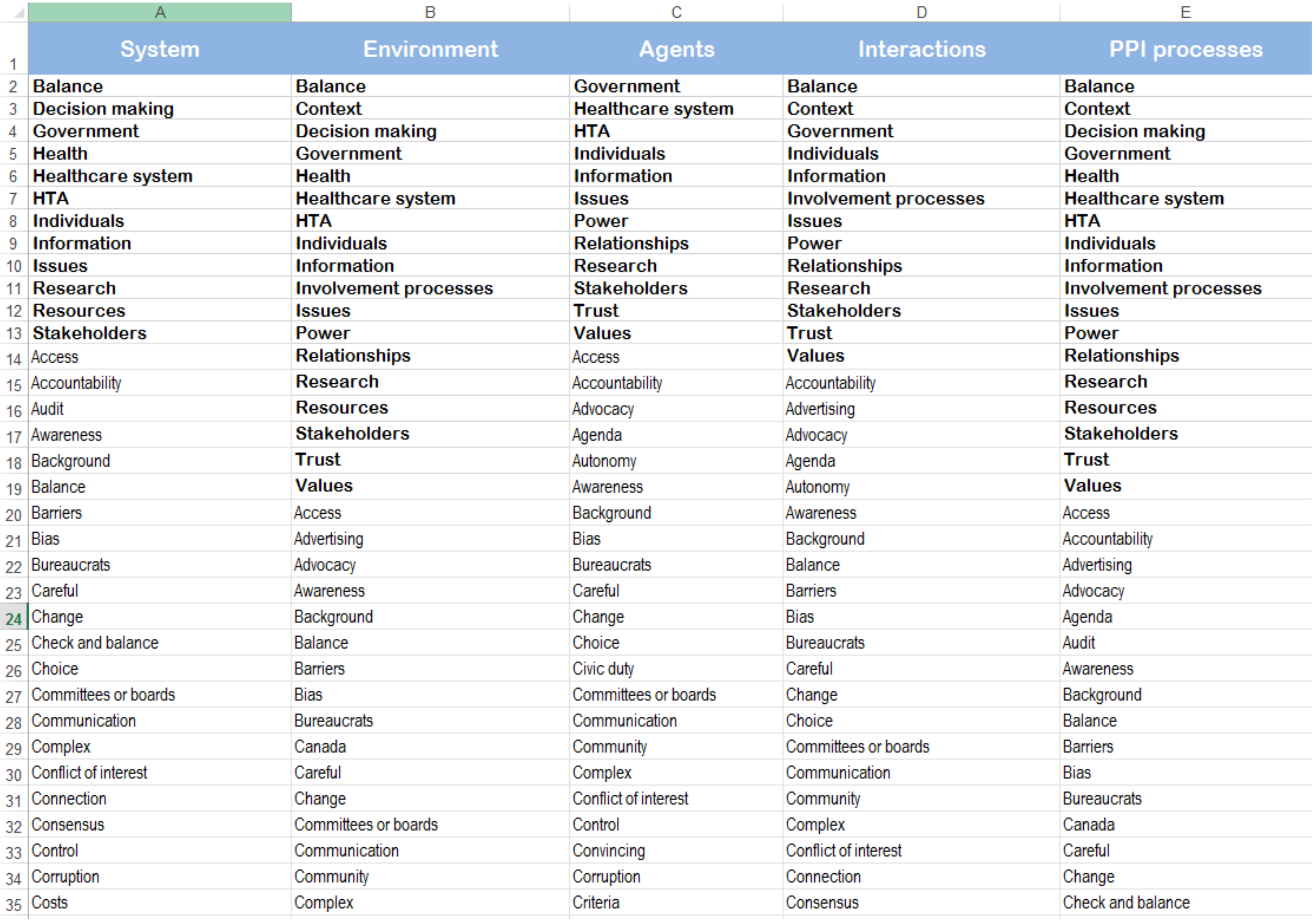


124	Research issues		Volunteer			Slow down	Relationships - Government - public							Utilitarianism	Variation			
125	Results - outcomes		Waste			Small versus large	Relationships - Health industry - clinicians							Variation	Volunteer			
126	Saving lives		Work			Stages	Relationships - Health industry - public							Volunteer	Young people			
127	Security		Young people			Statistics	Relationships - HTA - government							Work				
128	Seriousness					Strategy	Relationships - Media - public							Young people				
129	Slow down					Third party	Relationships - Personal relationships											
130	Small versus large					Time	Religion											
131	Social media					Timelines	Report											
132	Stages					Transparency	Representation											
133	Statistics					Trust	Research issues											
134	Strategy					Uncertainty	Researchers											
135	Taxes					Understand	Responsibility											
136	Technology					Utilitarianism	Results - outcomes											
137	Third party					Values - Individuals' values	Rights											
138	Time					Values - Public values	Saving lives											
139	Timelines					Variation	Security											
140	Transparency					Volunteer	Seriousness											
141	Treatment (medical)					Waste	Skills											

142	Trust					Young people	Slow down
143	Uncertainty						Small versus large
144	Understand						Social media
145	Utilitarianism						Stages
146	Values - Public values						Stages
147	Variation						Statistics
148	Volunteer						Strategy
149	Waste						Taxes
150	Work						Technology
151	Young people						Third party
152							Time
153							Timelines
154							Transparency
155							Treatment (medical)
156							Trust

156							Trust
157							Uncertainty
158							Understand
159							Utilitarianism
160							Values
161							Values - Individuals' values
162							Variation
163							Volunteer
164							Waste
165							Work
166							Young people
167							

Second-order themes

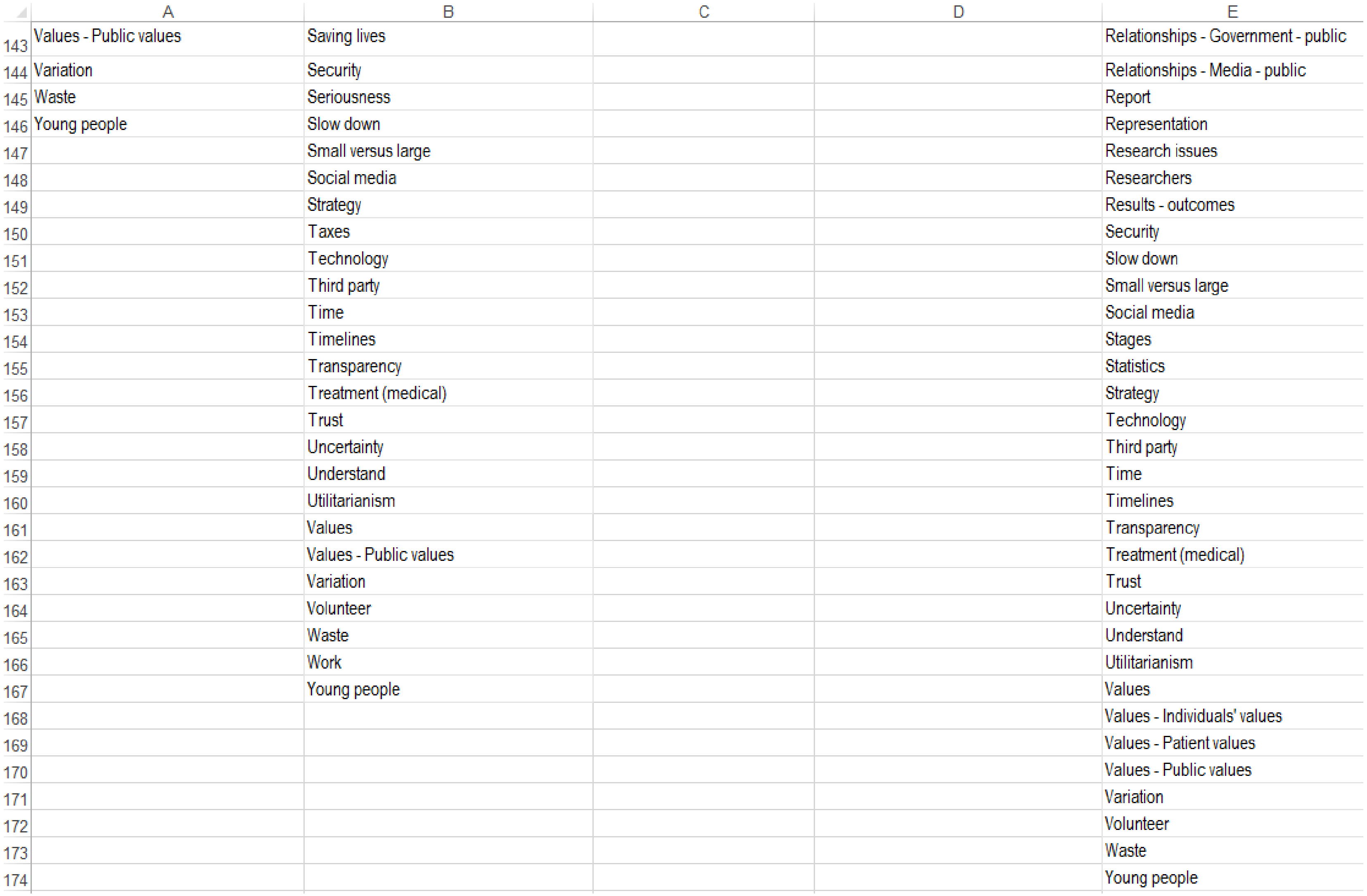


	A	B	C	D	E
1	System	Environment	Agents	Interactions	PPI processes
2	**Balance**	**Balance**	**Government**	**Balance**	**Balance**
3	**Decision making**	**Context**	**Healthcare system**	**Context**	**Context**
4	**Government**	**Decision making**	**HTA**	**Government**	**Decision making**
5	**Health**	**Government**	**Individuals**	**Individuals**	**Government**
6	**Healthcare system**	**Health**	**Information**	**Information**	**Health**
7	**HTA**	**Healthcare system**	**Issues**	**Involvement processes**	**Healthcare system**
8	**Individuals**	**HTA**	**Power**	**Issues**	**HTA**
9	**Information**	**Individuals**	**Relationships**	**Power**	**Individuals**
10	**Issues**	**Information**	**Research**	**Relationships**	**Information**
11	**Research**	**Involvement processes**	**Stakeholders**	**Research**	**Involvement processes**
12	**Resources**	**Issues**	**Trust**	**Stakeholders**	**Issues**
13	**Stakeholders**	**Power**	**Values**	**Trust**	**Power**
14	Access	**Relationships**	Access	**Values**	**Relationships**
15	Accountability	**Research**	Accountability	Accountability	**Research**
16	Audit	**Resources**	Advocacy	Advertising	**Resources**
17	Awareness	**Stakeholders**	Agenda	Advocacy	**Stakeholders**
18	Background	**Trust**	Autonomy	Agenda	**Trust**
19	Balance	**Values**	Awareness	Autonomy	**Values**
20	Barriers	Access	Background	Awareness	Access
21	Bias	Advertising	Bias	Background	Accountability
22	Bureaucrats	Advocacy	Bureaucrats	Balance	Advertising
23	Careful	Awareness	Careful	Barriers	Advocacy
24	Change	Background	Change	Bias	Agenda
25	Check and balance	Balance	Choice	Bureaucrats	Audit
26	Choice	Barriers	Civic duty	Careful	Awareness
27	Committees or boards	Bias	Committees or boards	Change	Background
28	Communication	Bureaucrats	Communication	Choice	Balance
29	Complex	Canada	Community	Committees or boards	Barriers
30	Conflict of interest	Careful	Complex	Communication	Bias
31	Connection	Change	Conflict of interest	Community	Bureaucrats
32	Consensus	Committees or boards	Control	Complex	Canada
33	Control	Communication	Convincing	Conflict of interest	Careful
34	Corruption	Community	Corruption	Connection	Change
35	Costs	Complex	Criteria	Consensus	Check and balance

36	Criteria	Conflict of interest	Death	Contentious	Choice
37	Decision making	Connection	Decision making	Control	Civic duty
38	Difficult - Easy	Consensus	Demand	Convincing	Committees or boards
39	Discussion	Contentious	Demographics	Corruption	Communication
40	Diseases - conditions	Control	Different regions	Courts - Justice	Community
41	Distortion	Convincing	Disagreement	Criteria	Complex
42	Diversity	Corruption	Discrimination	Decision making	Conflict of interest
43	Doubts	Costs	Discussion	Difficult - Easy	Connection
44	Education	Courts - Justice	Diseases - conditions	Disagreement	Consensus
45	Effort	Criteria	Diversity	Discussion	Contentious
46	Emotions	Death	Doubts	Distortion	Control
47	Emotions - Upset	Decision making	Education	Doubts	Corruption
48	Engagement	Demand	Effort	Effort	Costs
49	Ethics	Democracy	Emotions	Engagement	Courts - Justice
50	Evaluation	Different regions	Emotions - Upset	Experience	Criteria
51	Experience	Difficult - Easy	Engagement	Experts	Decision making
52	Experts	Disagreement	Experience	Feedback	Demand
53	Feedback	Discrimination	Experts	Gov - Government departments	Democracy
54	Flexibility	Discussion	Feedback	Gov - Level of government	Demographics
55	Focus	Diseases - conditions	Flexibility	Government	Different regions
56	Fundraising	Distortion	Fundraising	Group mentality	Difficult - Easy
57	Gov - Government departments	Diversity	Gov - Government departments	Health industry	Disagreement
58	Gov - Level of government	Doubts	Gov - Level of government	Healthcare professionals	Discrimination
59	Government	Education	Government	Healthcare system	Discussion
60	Health	Effort	Group mentality	HTA - HTA agencies	Diseases - conditions
61	Health services	Emotions	Health industry	Improvement	Distortion
62	Healthcare professionals	Emotions - Upset	Healthcare professionals	Inclusion - exclusion	Diversity
63	Healthcare system	Engagement	Healthcare system	Individuals	Doubts
64	HTA - Assessment stage	Ethics	HTA - HTA agencies	Influence	Education
65	HTA - Burdensome	Evaluation	Humanitarian	Info - Weighing information	Effort
66	HTA - Health technology	Experience	Inclusion - exclusion	Information	Emotions
67	HTA - Horizon scanning	Experts	Independent	Innovation	Emotions - Upset
68	HTA - HTA agencies	Feedback	Individuals	Intention	Engagement
69	HTA - Nominating	Flexibility	Influence	Interests	Ethics
70	HTA - Priority setting - HTA	Fundraising	Info - Weighing information	Internet	Evaluation
71	HTA - Screening criteria	Gov - Government departments	Information	Knowledge	Experience
72	HTA process	Gov - Level of government	Input	Leadership	Experts

73	Improvement	Government	Intention	Learning process	Feedback
74	Inclusion - exclusion	Group mentality	Interests	Limits	Flexibility
75	Individuals	Health	Internet	Lobby group	Focus
76	Influence	Health industry	Knowledge	Media	Gov - Government departments
77	Info - Weighing information	Health services	Leadership	Middle ground	Gov - Level of government
78	Information	Healthcare professionals	Listened or not listened to	Missing something	Government
79	Innovation	Healthcare system	Lobby group	Money	Group mentality
80	Input	HTA - Health technology	Media	Monitoring	Health
81	Intention	HTA - Horizon scanning	Objective - subjective	Patient	Healthcare professionals
82	Interests	HTA - HTA agencies	Older people	Patient - Families and carers	Healthcare system
83	Internet	HTA - Priority setting - HTA	Opportunity	Patient involvement	HTA - Assessment stage
84	Knowledge	HTA - Screening criteria	Patient	Patient organisations	HTA - HTA agencies
85	Learning process	Improvement	Patient - Families and carers	Perceptions	HTA - Nominating
86	Limits	Inclusion - exclusion	Patient organisations	Politics	HTA - Priority setting - HTA
87	Listened or not listened to	Independent	Perceptions	Priorities	HTA - Screening criteria
88	Lobby group	Individuals	Politics	Private health insurance	HTA process
89	Medical devices	Influence	Politics - Votes	Proactive - reactive	Humanitarian
90	Medicines	Info - Weighing information	Priorities	Problematic	Improvement
91	Middle ground	Information	Private health insurance	Provinces	Inclusion - exclusion
92	Missing something	Innovation	Proactive - reactive	Public	Independent
93	Money	Input	Professional	Public involvement	Individuals
94	Monitoring	Interests	Public	Question	Influence
95	Objective - subjective	Internet	Quality of life	Relationships	Info - Weighing information
96	Older people	Knowledge	Question	Relationships - Clinicians - patients	Information
97	Opportunity	Leadership	Random	Relationships - Close versus distant	Innovation
98	Other countries	Learning process	Religion	Relationships - Experts - public	Input
99	Patient	Listened or not listened to	Representation	Relationships - Government - industry	Intention
100	Patient involvement	Lobby group	Researchers	Relationships - Government - patients	Interests
101	Patient organisations	Media	Responsibility	Relationships - Government - public	Internet
102	Perceptions	Medical devices	Rights	Relationships - Health industry - clinicians	Knowledge
103	Policies	Medicines	Saving lives	Relationships - Health industry - public	Learning process
104	Priorities	Middle ground	Seriousness	Relationships - HTA - government	Limits
105	Proactive - reactive	Missing something	Skills	Relationships - Media - public	Listened or not listened to
106	Problematic	Money	Social media	Relationships - Personal relationships	Lobby group
107	Processes	Objective - subjective	Strategy	Researchers	Media
108	Professional	Older people	Taxes	Responsibility	Medical devices

109	Promotion	Opportunity	Technology	Results - outcomes	Medicines
110	Provinces	Other countries	Trust	Seriousness	Middle ground
111	Public	Patient	Uncertainty	Social media	Missing something
112	Public involvement	Patient involvement	Values	Strategy	Money
113	Quality of life	Patient organisations	Values - Individuals' values	Transparency	Monitoring
114	Question	Perceptions	Values - Patient values	Trust	Objective - subjective
115	Red tape	Policies	Values - Public values	Uncertainty	Older people
116	Relationships - Experts - public	Politics	Variation	Values	Opportunity
117	Relationships - Government - industry	Politics - Votes	Volunteer	Values - Individuals' values	Other countries
118	Relationships - Government - patients	Priorities	Work	Variation	Patient
119	Relationships - Government - public	Private health insurance	Young people		Patient - Families and carers
120	Relationships - HTA - government	Privatisation			Patient involvement
121	Relationships - Personal relationships	Proactive - reactive			Patient organisations
122	Report	Problematic			Perceptions
123	Representation	Processes			Policies
124	Research issues	Promotion			Politics
125	Researchers	Provinces			Politics - Votes
126	Results - outcomes	Public			Priorities
127	Security	Public involvement			Proactive - reactive
128	Slow down	Question			Problematic
129	Stages	Random			Processes
130	Statistics	Red tape			Professional
131	Strategy	Relationships			Promotion
132	Third party	Relationships - Clinicians - patients			Provinces
133	Time	Relationships - Close versus distant			Public
134	Timelines	Relationships - Government - industry			Public involvement
135	Transparency	Relationships - Government - patients			Public involvement methods
136	Treatment (medical)	Relationships - Government - public			Quality of life
137	Trust	Relationships - Health industry - clinicians			Question
138	Uncertainty	Relationships - Health industry - public			Random
139	Understand	Relationships - Media - public			Red tape
140	Utilitarianism	Relationships - Personal relationships			Relationships - Clinicians - patients
141	Values - Individuals' values	Religion			Relationships - Experts - public
142	Values - Patient values	Rights			Relationships - Government - patients



	A	B	C	D	E
143	Values - Public values	Saving lives			Relationships - Government - public
144	Variation	Security			Relationships - Media - public
145	Waste	Seriousness			Report
146	Young people	Slow down			Representation
147		Small versus large			Research issues
148		Social media			Researchers
149		Strategy			Results - outcomes
150		Taxes			Security
151		Technology			Slow down
152		Third party			Small versus large
153		Time			Social media
154		Timelines			Stages
155		Transparency			Statistics
156		Treatment (medical)			Strategy
157		Trust			Technology
158		Uncertainty			Third party
159		Understand			Time
160		Utilitarianism			Timelines
161		Values			Transparency
162		Values - Public values			Treatment (medical)
163		Variation			Trust
164		Volunteer			Uncertainty
165		Waste			Understand
166		Work			Utilitarianism
167		Young people			Values
168					Values - Individuals' values
169					Values - Patient values
170					Values - Public values
171					Variation
172					Volunteer
173					Waste
174					Young people