The International Network of Agencies for Health Technology Assessment

HTA Impact Assessment Study

Part II: Factors that Enable or Inhibit HTA Impact Assessment Activities in HTA Agencies

February 2020

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Executive Summary

The field of health technology assessment (HTA) research is still early in its understanding of how policymakers use HTA information to make decisions about investments in (or disinvestments from) technologies in healthcare.[1,2] Insights into the conditions under which healthcare decision makers use HTA information can promote transparency of the decision-making process and enable HTA producers to better align the evidence they provide to the needs of their requestors[2] Assessing the impact of HTA reports can also aid the understanding of the quality of the HTA process, including the degree to which the HTA's objectives have been met. It can bring to light any difficulties with the use of the HTA recommendations in the decision-making process thereby allowing the opportunity to strengthen the usefulness of HTA for health system decision making.

Producing HTA reports is typically the core activity of HTA agencies, however, this occurs in a context where they are faced with many competing demands on their time. Assessing the impact of their HTA reports is often an additional task that HTA producers may or may not be able to easily accommodate in their core business work flows. Nevertheless, agencies still are interested to understand the impact or influence of their HTAs on decision making or other outcomes, and this is important for quality assurance and program improvement. Moreover, impact assessment (IA) can be viewed as part of the purpose of HTA, which is to improve the use of health resources and positively impacting health outcomes.

This is the first study to apply a theoretical framework to examine underlying social cognitions of senior staff of INAHTA member agencies for the implementation of IA strategies. The application of the social cognitions lens by investigating the concepts of *attitude* and *social support* towards IA while also looking at *perceived barriers* and *self-efficacy* to overcome barriers allowed for a refined investigation into the factors that support or inhibit an HTA agency to conduct a program to assess the impact of their HTA reports. In the Attitude-Social Support-Self-efficacy (ASE-Model)[3], it is understood that an agency is likely to perform IA where there is support from key referent others to do so, where stakeholders have the conviction to overcome barriers to IA, and where IA is positively valued as a result of understanding the advantages and positive consequences of IA. In cases where these cognitive pre-conditions are met, agencies will be more likely to generate a positive intention towards engaging in IA which is a strong predictor for actual IA in the future.

This study presents details about the attitudes and perceptions among senior agency staff at INAHTA member agencies regarding:

- The sources of social support received by the agency to conduct IA;
- The internal and external barriers that the agency faces to conduct IA;
- The degree of confidence that their agency can overcome these barriers;
- The advantages and disadvantages perceived to conducting IA; and
- The intention within the agency to assess impact and what is the likelihood that their agency will conduct IA in the future.

In February 2017, all INAHTA members (n=47 at the time of the study) were invited by email to participate in a qualitative study assessing their current IA practices and perceived social cognitions towards conducting IA, regardless of if they were measuring impact at the time the interview took place or not. In total, 26 agencies accepted to participate. Interviews took place between March and May 2017 and were conducted by one

researcher via Webex® or telephone. Interview results were transcribed and analyzed independently by two researchers by means of qualitative data analysis and reaching consensus on the thematic results.

Study results revealed that participants perceive various sources of social support towards conducting IA, mostly from agency directors, agency staff, the Ministry of Health or other funders, but also from healthcare professionals and INAHTA.

As regards perceived internal and external barriers to IA, many different obstacles were named such as lack of qualified staff and standardized tools or methods for IA, lack of financial and organisational resources, but also lack of staff motivation and integration of IA as a prioritized mission of the agency. Other barriers were a lack of consensus around the concept of IA, poor communication among players within the system, a limited IA culture, and lack of access to relevant data and inappropriate timing of IA.

Interview participants expressed an overall reasonable degree of confidence to overcome these barriers. Confidence was generally found to be higher in overcoming barriers internal to the agency than those external to it. This may be explained by the fact that the agency has greater authority to make internal changes than to resolve external issues that involve other groups.

The construct of *attitudes* within the ASE-Model refers to an individuals' overall evaluation of the behavior in question and it is conceptualized as the combined impressions of the perceived advantages and disadvantages. The more advantages that are perceived, the more favorable a person's attitude will be to perform the behavior in question, i.e. in our study this was the conduct of IA.[4] The perceived advantages of conducting IA were that it may help to identify gaps or weaknesses in HTA methods and processes to allow for improvements and to better tailor the HTA to the requestors needs. Other advantages that came forward through the interviews were financial justification for agency work and contributions to the health system, but also to strengthen the credibility of the agency. Disadvantages to conducting IA related to a lack of agency (financial) resources and potential threats to agency reputation should negative or undesirable outcomes be revealed in the IA. Tension with decision makers and/or requestors in conducting IA and the general difficulty of assessing the impact of complex HTA reports were also mentioned.

Finally, the intentions to conduct IA were assessed, representing the agency's motivation in the sense of their explicit plan or decision to exert effort to perform IA. The majority of study participants said there was a strong intention in their agency to conduct IA in the upcoming two to three years; however, despite this intention, only slightly more than half perceived it to be likely their agency would actually conduct IA within this timeline.

This study provides a descriptive interpretation to aid the understanding the conduct of IA by providing insights into the social cognitive determinants that are relevant to INAHTA member agencies. No predictive or more analytic assessment was intended with this study. Nevertheless, insight into these determinants can help agencies to identify opportunities and obstacles to conducting IA in their particular context and circumstances. The general implications of the study results are to reinforce the awareness of the usefulness of IA within the HTA process, to support initiatives to develop standardised methods and tools for IA, and create guidance on how IA can be imbedded within organisational structures and procedures.

This paper is the second of two reports produced in an investigation into IA practices among INAHTA member agencies. The current report describes agencies' perspectives on the factors that facilitate or inhibit the conduct of IA activities, and the first report describes the practices of IA among INAHTA members.[5]

Introduction

The goal of health technology assessment (HTA) is to support health care decision making on the introduction, use of, and disinvestment from, health technologies. To support this goal, assessments produced by HTA agencies need to be disseminated in ways that promote the uptake and impact of the HTA results while taking into account the context of the health system.[1,6] Although HTA is gaining an increasing importance to inform policy and clinical decision making, reflected in the growing number of HTA reports published and HTA agencies being established worldwide, there is limited literature available on the extent to which HTA findings impact upon decision making.[7,8] Moreover, few methods and strategies have been developed for assessing HTA impact that could assist HTA agencies in understanding and measuring the uptake and influence of their work.[8,9]

According to Koopmanschap et al[2] and others[1] the field of HTA research is still early in its understanding of how policymakers use the information provided in multidisciplinary evidence-based assessments of technologies in healthcare. Insights into the conditions under which healthcare decision makers use HTA information may promote transparency of the decision-making process and enable HTA producers to better align the evidence they provide to the needs of decision makers, thereby improving the utility of their work.[2] Moreover, assessing HTA impact can provide insights into the quality of the HTA process, to assure that the HTA's objectives have been met, to bring to light any difficulties with the decision making area that is informed, and to strengthen the usefulness of HTA more broadly. At a minimum, HTA producers should be informed if their work has been received, understood, and accepted and if there are any difficulties or further work required to improve the assessment processes.[1]

Various studies[2,10,11,12,13] have revealed that aspects of HTA impact may also be important for the decision-making process. For example, the health gain expected through the introduction of a new technology, the related budget impact, and cost-effectiveness may be important factors not only for indicating the impact of the HTA but also as key considerations in the decision-making process. Some individual studies offer insights on the impact of HTA on resources. A study focusing on 10 HTAs in the UK concluded a potential benefit of approximately £3 billion per year if the recommendations from HTA reports were followed.[14] Similar studies[15,16] have demonstrated the potential of HTA to help reduce costs and improve healthcare. Nevertheless, significant disparities have been observed in how HTA information has been used in decision-making, likely due to the quality and type of evidence presented[17,18,19] but also due to the different needs and standards of decision makers in a constantly shifting political and social landscape.

While the above-named studies have identified several advantages to conducting an assessment of impact for HTA, a limited number of studies have been published on the underlying mechanism of implementing HTA IA strategies.[20,21] In order to foster IA among HTA agencies, it is helpful to understand how agencies perceive this activity and which factors may facilitate (or impede) its implementation. Therefore, the current study aimed to examine mechanisms of HTA IA in order to create a deeper understanding of the factors that support or inhibit an HTA agency from prioritizing and implementing an IA program. For this understanding, a theoretical model integrating the social cognitions relevant to the context of the adoption of new health behaviors will be adapted to shed light on the conditions under which an HTA agency is likely to adopt (or not) an IA program.

The social cognitions lens and ASE-Model

Investigations into the adoption of programs in health care are not new. Previous studies[21,23,24,25] have investigated the adoption of new working strategies in the healthcare setting, and they found that the adoption of these innovations may be facilitated by several factors, reaching from macro-level organizational factors to meso and micro-level motivational factors.

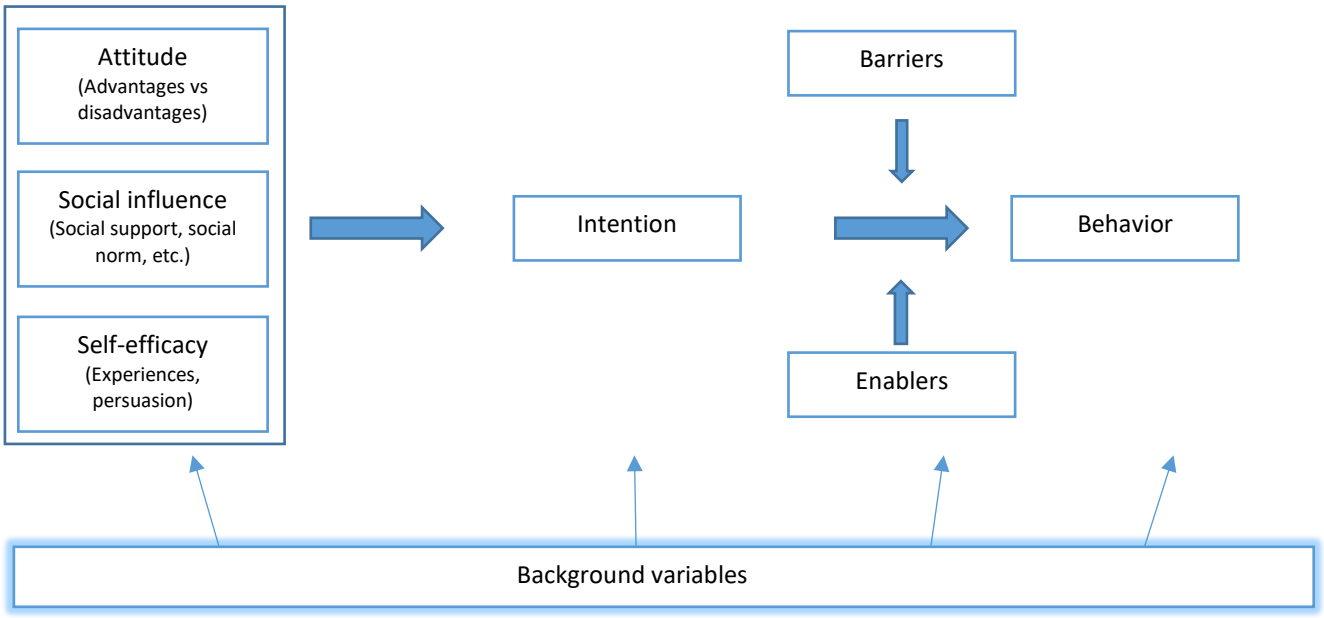
If the establishment and use of an HTA IA strategy by an agency is considered as *the adoption of an innovation*[22] by the agency, a new lens of investigation becomes available to examine the elements that facilitate or inhibit the adoption and use of such strategies. This lens has been used previously within the field of health psychology and broader health contexts and is referred to as the social cognitions lens.

The application of the social cognitions lens allows for a nuanced examination of the determinants that may facilitate or inhibit the implementation of an innovation by the adopting user[24,26,27] which in this case is the HTA agency. Studies focusing on social cognitive attributes of adopting users found that positive intentions and motivational factors determine a great part of the uptake of interventions by actors within the healthcare system.[20,23,28,29] Additionally, organizational factors (e.g., decision systems and staff capacity), sociopolitical contexts (e.g., rules and financial compensation), or characteristics of an innovation such as its complexity, can be primary determinants to the uptake of innovations in the healthcare sector.[20,23,28] Inhibiting factors could be related to limited capacities (e.g., time, financial aids and administrative support), lack of sufficient personnel, inadequate knowledge and strategies, or negative perceptions toward the impact of the work[30]. From these studies it is shown that motivational factors as well as organizational and sociopolitical factors within and around an organization are key to understanding the resulting adoption (or not) of the innovation.

Within the social-cognitions field, the Attitude – Social Influence – Self-Efficacy (ASE) Model[31] was selected as the underlying theoretical model to guide the investigative focus of this study. Although the ASE-Model has initially been used towards the understanding of health behavior and addressing behavioral change, the suitability of this model to adoption research in health policy and decision-making settings has also been described.[20,29,31] The ASE-Model (Figure 1) defines the proximal social determinants in the change or adoption of a health behavior, i.e., those determinants close to the adopting user (in this study the HTA agency) such as the motivational factors relevant for the explanation, prediction and adoption of a behavior. In sum, the ASE Model states that behavior can be predicted by intention, which in turn is influenced by motivational factors, including attitudes, social influences and self-efficacy.[31] The application of the ASE-model to examine the intention of HTA agencies to adopt practices of measuring HTA impact is innovative as it measures attitudes, external (social) influence or support and agency self-efficacy to assess the impact of their reports. The model as applied to the current study includes consideration of the barriers and enablers to the adoption process, which are known to be important factors of the intention to adopt [32,33].

Applying the ASE-Model[3] is expected to help bring to light new insights into those factors that influence the intention and actual use of IA strategies. It is anticipated that this information will be of interest to HTA agencies that wish to consider starting or expanding a program to assess the impact of their HTA reports. By understanding the underlying social cognitions towards IA, an aid is given to HTA agencies to evaluate which areas may need to be addressed in their case in order to be successful in their efforts to implement an IA strategy.

Figure 1. Illustration of the ASE-Model[34]



Note: The current study does not describe background variables since these we were mainly interested in the role of social cognitive factors within the adoption of IA strategies by HTA agencies.

Study methods

The study was cross-sectional in its design and used individual telephone or Webex® interviews with an average duration of approximately 30 min. Interviews were conducted between March and May 2017, using a questionnaire instrument consisting of open-ended questions. Participants were asked about their perceptions about the sources of support for IA, internal and external barriers to IA, confidence that the agency would be able to overcome these barriers to doing IA, the perceptions of the advantages and disadvantages (i.e. attitudes) of doing IA, and the intention and likelihood that the agency will assess impact in the near future.

All INAHTA member agencies at the time of the study (n=47) were approached by an introductory e-mail sent by the INAHTA secretariat. The first communication provided information about the INAHTA impact assessment project and explained that any information provided in the interview would be held in confidence and reported in aggregate. Once INAHTA members agreed to participate, the researcher arranged both the date for the interview and the mode of interview (Webex® or telephone). Shortly before the interview, participants received the questionnaire by e-mail.

Upon agreement of the participants, interviews were audio-recorded. Once all the interviews were done, they were transcribed by two researchers (NB and TS) with overall guidance for the project provided by an expert advisory group (DH, SM, KM, AA, MO, SSW). Microsoft Word® was used for data-entry. Double qualitative analysis was conducted of the interview transcripts to minimise entry errors using the constant comparative method within an interpretive description framework[35]. In this approach, themes are identified within the framework of the practice of HTA agencies in conducting IA with the end goal to

improve professional understanding and to improve IA practice. This is a different model than other qualitative methods looking at, for example, culture (ethnography), human behaviour and rituals (anthropology) or social symbolism and interactions (sociology).[36]

Results

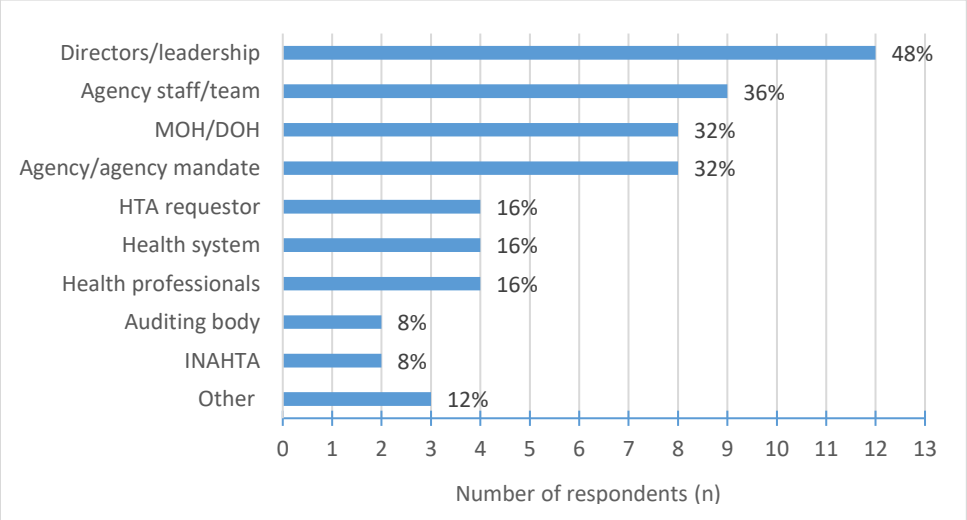
In total, 26 of 47 INAHTA member agencies accepted to participate in an interview (55% response rate). Interviews were conducted in April-May 2017. Appendix A presents a list of the agencies that had representatives participate in an interview and examples of the job titles to indicate their level of seniority. The names and agencies of the respondents have been separated from their responses and the study results are reported on an aggregate basis. Participants were asked to respond to each question, regardless of if their agency currently assesses HTA impact or not, since the objective was to obtain a description of the factors and barriers that they perceive in either case.

The results provide information about the key motivational variables based on the ASE-Model[30] for conducting IA, including social support, agency attitudes and agency self-efficacy, along with perceived internal and external barriers towards doing HTA IA. Moreover, the intention and likelihood that the agency will assess impact in the near future are presented.

Sources of support for assessing HTA impact

As the first motivational determinant, social support for conducting HTA IA was assessed by asking interviewees "If your agency assesses impact, where does the support for assessing the HTA impact come from?". Agencies were not limited to mention one single source of support but could report all the sources they would perceive as supportive for conducting HTA IA.

Figure 2. Sources of support for conducting impact assessment according to interview participants (n=26)



Interview participants perceived various sources of social support for conducting IA (see Figure 2 and Table 1). Foremost, agency directors and leadership provide the most support for conducting IA followed

by the support from agency staff. Agencies often perceive support for IA from the Ministry of Health or other funders who seek to determine the return on investment for the allocation of public funds to the agency. IA can provide evidence of the value for money of HTA activities. In other cases, the Ministry or funders may be less supportive of IA as it requires that resources be diverted from the production of HTA reports. The structure and processes of the health system can be a support to IA where health system databases and registries can be accessed by agency staff to collect data for IA or where the health system has institutional, structural or procedural guarantees that the HTA is considered in decision making. Health professionals can be supportive of IA where they are aware of HTA and have confidence in the scientific standards adhered to in HTA. INAHTA was also perceived as being a source of support for IA by conducting investigations such as this one to advance the field of IA and support member agencies in the adoption and use of IA frameworks.

Table 1. Sources of support for assessing HTA impact according to interview participants (n=26)

Theme	Summary of theme	Quote(s)	Frequency*
Agency directors and leadership	Agency leadership, directors, senior management and/or Board of Directors are supportive to the agency staff to conduct HTA IA.	*Q1: Within our organization the higher management of people […] the directors are supportive of evaluating the impact* *Q2: It is supported by our senior leadership.*	Some (48%; n=12)
Agency staff/team	Support for conducting HTA IA comes from the staff or team at their agency.	*Q1: The support comes from our own staff.* *Q2: Internally as well, within the team, we closely want to monitor and see we are adding value and that the work we are doing is actually having input and changing practice on the ground.*	Some (36%; n=9)
Agency and/or the agency mandate	Support for conducting IA comes from the HTA agency, i.e., as part of the regular agency quality assurance process or to assure sufficient value for money of the HTA program.	*Q1: The support comes from the agency.* *Q2: We do it because we want to do it because we want to know what happens about our assessments and we support it financially with our own resources from the [agency].*	Some (32%; n=8)
MOH/DOH	• The Ministry/Department of Health (MOH/DOH) is supportive of the assessment of HTA impact. • The agency may receive full or partial funding from the MOH/DOH and IA is one way to demonstrate that the allocation of public funds to the agency represents value for money.	*Q1: The government ministry who provides the money. I think everybody is supportive of it because they know if we cannot show results the Ministry would stop providing the money.* *Q2: We are in luck there, there has been institutional support from the [MOH] generally.* *Q3: The MOH has particularly demanded our organization to start assessing the impact of the HTA products, so you could say they are supportive, but this is quite a demand rather than a support.*	Some (32%; n=8)
HTA requestor	• The requestor of the HTA is supportive of IA, i.e., by being forthcoming with information when the agency follows-up to gather their perspectives about the impact. • Not all requestors provide the same quantity or quality of feedback. • Sometimes the desire to know is there but there may be limited	*Q1: So far, when we send them the forms, they all have provided feedback, so they are also very supportive to answer the impact form.* *Q2: I can say that mostly we get very positive feedback, sometimes it is not necessarily helpful, people say 'yeah thanks your report was great', but sometimes there are times that the report wasn't that helpful and here is why.*	Few (16%; n=4)

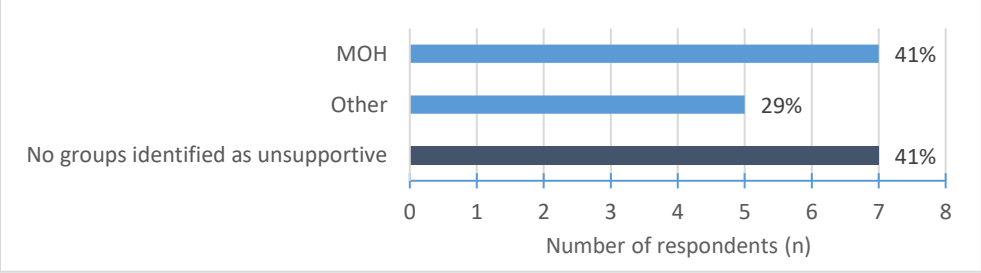
Theme	Summary of theme	Quote(s)	Frequency*
	funding by the requestor to pay for impact evaluation.		
Health system	• The structure of the health system can provide certain forms of support for conducting IA in two different ways: 1) through availability of registries or requirements for care providers to collect data on specific indicators, which provides a readily-available source of data for HTA IA; and 2) institutionalization of HTA, i.e., procedures that embed HTA in a formal system to support decision making.	*Q1: [Our country has] extremely good data because we have very many registries with national data so when [when we conduct studies we can] pick out data from the national registries…* *Q2: From the system. The system itself supports it. Because the HTA is directly embedded in the HTA system that supports the IA (or achievement of impact).*	Few (16%; n=4)
Health professionals	• Health professionals are supportive of HTA IA.	*Q1: Health professionals are also supportive.* *Q2: Groups that would most likely be supportive are stakeholders, health professionals.*	Few (16%; n=4)
Auditing body	• An auditing body within the broader health system assesses the HTA program for evidence of impact. • The agency is thus supported or motivated to have evidence of impact recorded and readily available.	*Q1: [There is a] public body [in our country which is] the most willing body in favour of IA. When they come and see what we do, they ask us a lot of questions about IA.*	Few (8%; n=2)
INAHTA	• The work of INAHTA in the area of IA has helped to support agencies in conducting HTA IA.	*Q1: In a certain measure INAHTA plays a role. Because the last two years we had to put in [HTA projects in the] form [of] two impact stories.*	Few (8%; n=2)

Note: *Categorization of themes in few (5-25%), some (26-50%), many (51-75%) and most (76-100%)

Groups who would not be supportive of assessing HTA impact

To understand sources of discouragement/disincentive to assess impact, participants were asked to identify any groups they perceived not to be supportive of IA (see Figure 3 and Table 2).

Figure 3. Groups that would not be supportive of IA (n=17)



The Ministry of Health was a potential source of disincentive since they may not prioritize IA either because they do not wish to spend resources on this activity or they see limited value in the results of IA.

A number of other groups were mentioned including: technology developers that may prefer a more political decision-making process; agency leadership; or agency staff who may not be convinced IA is an important part of the HTA work. A significant number of participants stated they could not think of any groups who would not be supportive of IA.

Table 2. Groups who would not be supportive of assessing HTA impact (n=17 total participants)

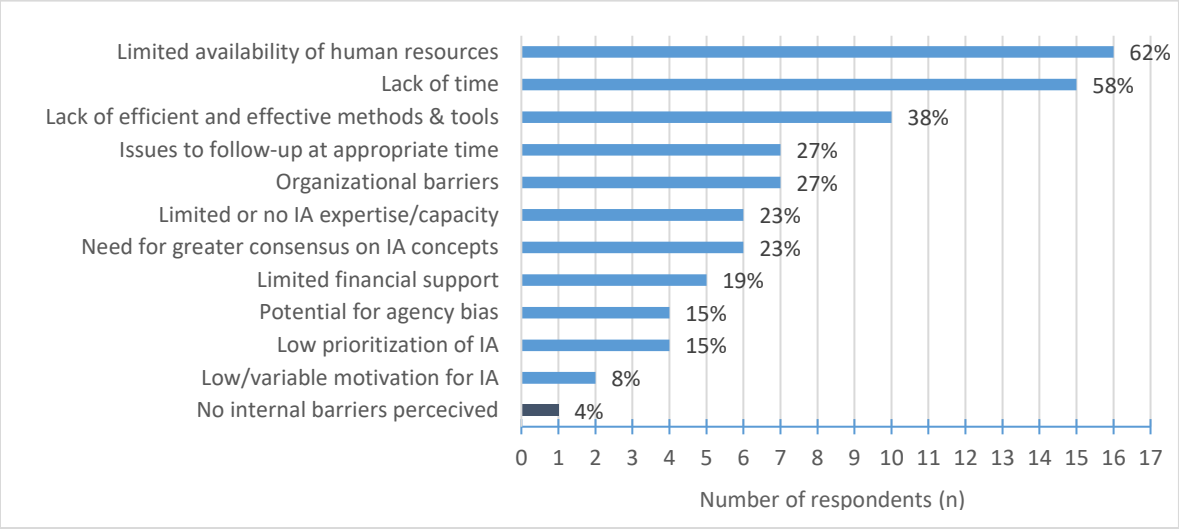
Theme	Summary of theme	Quote(s)	Frequency*
MOH/DOH	• Limited or no support from the MOH for conducting IA. • The MOH does not place priority on knowing the impact, and there is therefore no demand for this from the MOH. • MOH prefers the agency to focus on producing HTAs, not IA. • Where MOH is requestor, sometimes not supportive due to time required to provide feedback about the impact.	*Q1: We receive large part of budget from national health insurance, but when I said that there is no global strategy about IA, this means that neither the MOH nor the [health insurance body] comes and ask us what we do about IA.* *Q2: If we perform IA and decrease the other activities, maybe they won't be supportive.* *Q3: I would not expect resistance from the MOH, but if you have data the question might arise why they are doing decisions like this or that, and they don't have enough time […] to make such a complicated explanation.*	Some (41%; n=7)
No groups seen as not supportive	• Participant could not think of any groups who would not be supportive. • For some stakeholders, it is uncertain if they would be supportive or not of IA.	*Q1: I cannot think of any [who would not be supportive].* *Q2: None that are not supportive, it is a very supportive environment, but that does not mean that it is easy.* *Q3: I cannot think that anyone has not been supportive, but neither is it interesting that we have not had direct calls from government. We have never been asked explicitly by government to do it – the desire to do it has been more coming from us.*	Some (41%; n=7)

Note: *Categorization of themes in few (5-25%), some (26-50%), many (51-75%) and most (76-100%)

Internal barriers to assessing HTA impact

To understand some of the barriers perceived by interview participants to conducting IA, they were asked, "Whether your agency assesses impact currently or not, which kind of internal barriers to assessing HTA impact do you perceive facing your agency?".

Figure 4. Internal barriers perceived facing the agency (n=26)



Several themes emerge in the perceived internal barriers to conducting IA reported by interview participants (see Figure 4 and Table 3). The lack of human resources was identified as the top internal barrier closely followed by a lack of time to conduct IA. Also identified was the lack of efficient and effective methods and tools for conducting IA which can lead to imprecise or inconsistent results. Challenges to find the best time to follow-up with the requestor to gather data for IA was another barrier identified by some participants and also organizational barriers such as a lack of clear role assignments in the agency for conducting IA or a weak mission for IA.

Staff with limited or no IA expertise was another internal barrier identified as was the need for greater consensus on IA concepts. Conducting IA involved financial costs and a few participants reported that limited budget or financial support can be an internal barrier to IA. Furthermore, the agency conducting an assessment of their own reports could introduce bias either in the selection of reports that show favorable results or selecting outcomes that are likely to yield positive results. A few participants noted that a low prioritization of IA and low or variable levels of motivation among staff to conduct IA can also present internal barriers.

Table 3. Internal barriers perceived facing the agency (n=26)

Theme	Summary of theme	Quote(s)	Frequency*
Limited availability of human resources	• A lack of human resources is an important barrier for IA because it is additional work to track the impact, particularly when looking at different levels of the healthcare system over a long period of time. Outsourcing the IA may not be feasible due to difficulty in finding qualified experts capable of conducting IA while avoiding conflicts of interest.	*Q1: It will come down to resources issues as it is a big job to be tracking impact and implementation.* *Q2: It was a lot of work and that is also potentially, why it did not happen again, because we know it is a huge work.* *Q3: There is the need for very expert resources to work on this. It is not easy to find people who are able.*	Many (62%; n=16)
Lack of time	• Limited time available for conducting IA.	*Q1: The main thing would be to try to fit in the HTA IA amongst all the deadlines we have to currently do the actual HTA.*	Many (58%; n=15)

Theme	Summary of theme	Quote(s)	Frequency*
	• Many HTA agencies face challenges with limited staff and a high workload for producing HTAs, which is their primary business.	*Q2: I think time is still an issue; finding time to fit it in routinely and finding data [analysis staff] to support it.*	
Lack of efficient and effective methods & tools	• Limited availability of validated, effective methods and tools for conducting IA which can lead to imprecise or inconsistent results. • The efficiency and consistency of collecting impact information may need to be proved.	*Q1: To properly assess impact at more levels than the decision-making level, a more formalized HTA IA strategy and work plan is required and has to be put into place.* *Q2: The biggest internal barrier is we do not have a validated framework. We have been concerned and not sure if our process is valid or right. Currently our IA process depends on document search and the judgment of our researchers.* *Q3: Well we did kind of create [our IA strategy] from scratch … I didn't get a sense from a lot of different other organizations that they had a comprehensive impact strategy in place. […] we really kind of built our own ... there is nothing that we could use that was published or that someone else had, or reliability-tested in advance.*	Some (38%; n=10)
Issues to follow-up at appropriate time	• HTA agencies face a time lag required to successfully assess the impact of the HTA. A single IA at one single moment may not be sufficient and several assessments may be required in order to reveal the impact at follow-up. • By the time follow-up to assess impact is undertaken, the staff or systems may have changed or have moved on to other project priorities. • There may be a resistance to respond for assessing impact on a regular basis for each HTA during the follow-up. • Staff changes during the follow-up of the HTA may hinder a proper IA since the person who requested the report may not be there anymore and then the new person may not be aware.	*Q1: I think that is the real impact of our report that would be a long time and this would require us to follow-up a few times, that once is not enough. So in order to do that we need to follow-up for a few years, then this would be one of the internal barriers: the time.* *Q2: [A] Main major barrier in my point of view … is that the effects of the report are not seen as soon as the project is assembled, it actually takes some time before you can say whether [the] effects it had and by the time you could probably say something about the effects.* *Q3: We finance a lot of projects and although at some point we said we will go back to the investigators after 3 years and even after 6 years well sometimes things have totally changed so we cannot keep up with it.* *Q4: I assume it would be the case for any HTA in any country, is the case that you cannot measure the effects until after a certain time. […] The timing I don't know if you want to say that as a barrier – the fact that the effect comes so much later that is a real problem because once you do the assessment by that time that project has already been done and you are working on something else.*	Some (27%; n=7)
Organizational barriers	• Organizational aspects can hinder IA, i.e., a lack of clear division and arrangement of tasks in the agency to assess impact.	*Q1: Also the task divisions that can be difficult as well [...] When the evaluation program started it was more or less our team took the lead, and now we try to give the responsibility a bit more to the colleagues with the expertise*	Some (27%; n=7)

Theme	Summary of theme	Quote(s)	Frequency*
	• A lack of independence or a weak mission for IA of the HTA agency can limit the ability to conduct IA. This can be especially relevant to agencies located within the MOH. • Resistance to change in processes within the agency can be a barrier to introducing IA.	*on the subject and who created the HTA product, but this is still difficult.* *Q2: If we would have a stronger mission about IA, it would be more developed.* *Q1: Maybe it is a lack of full independence because we are submitted to the internal organizational pattern.*	
Limited or no IA expertise/capacity	• Limited availability of staff who are experienced in IA methods. • It can take time to build up capacity to do robust IA.	*Q1: I think perhaps one of the larger internal barriers is the capacity to undertake this work. We use a range of methodologies to undertake research IA. It is also the time to build up knowledge and expertise.*	Some (23%; n=6)
Need for greater consensus on IA concepts	A need for: • Consensus around the concept of what IA is in order to develop methods and tools to assess it properly. • A clear definition of IA because there are different understandings across HTA staff but also across different stakeholder groups (government, public, patients, etc.). • The question about the different levels of HTA impact, and the difficulty of assessing it at the macroeconomic level.	*Q1: You have to define impact first. If you are going to say the metrics around an HTA will be considered impactful if it does a, b or c. […] Without those, it is hard whether how many are impactful and how many aren't.* *Q2: An important point – it is curious as well that agencies seem to define their own impact- I don't think it's then measured against what their customers would define as impact or what would your government perceive as impact.* *Q3: Where perhaps it has been more challenging is impact is a term that means different things to different people, different questions have differing evidence needs, standards of evidence are varied in terms of what is required, and format of the evidence is going to depend on the group that you are meeting the needs of.*	Few (23%; n=6)
Limited financial support	• IA requires financial support, which can be a barrier where programs face budget constraints.	*Q1: […] We are aware of the importance of establishing a system of HTA IA that includes more diverse outcomes. We need to research this, but this kind of research project has not been prioritized in the budget constraint that our agency faces.*	Few (19%; n=5)
Bias	Potential risk of bias in the IA, i.e.: • Where the agency assesses their own reports there is potential selection bias, either seeking positive outcomes or selecting reports for IA that are likely to yield positive results. • In cases where IA is not conducted systematically.	*Q1: This IA always has a certain bias if we do it internally because of course we want to have impact and look for very specific things while external experts potentially wouldn't have the bias.* *Q2: The IA is not systematic and it is on a voluntary basis so it is very biased.*	Few (15%; n=4)
Low prioritization of IA	• A low prioritization of IA within the agency.	*Q1: Also IA prioritization* [as a barrier for doing HTA IA].	Few (15%; n=4)

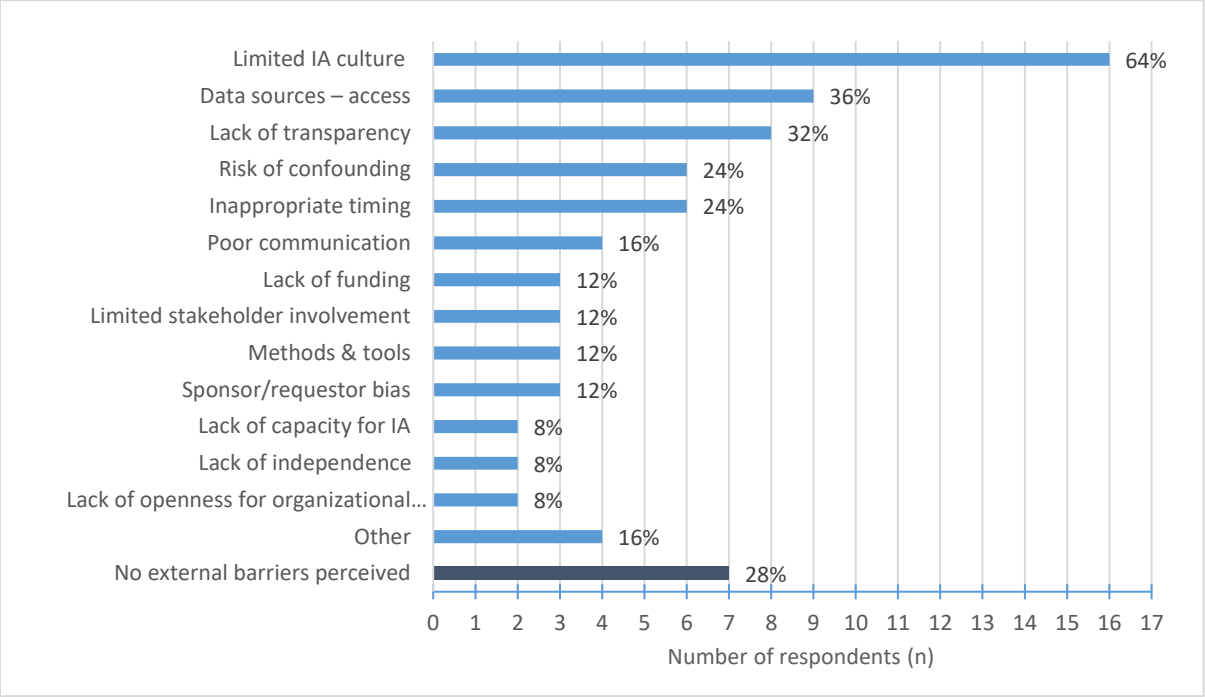
Theme	Summary of theme	Quote(s)	Frequency*
Low/variable motivation for IA	• A lack and/or different levels of motivation for IA among staff at the agency.	*Q1: Not all colleagues are equally motivated to perform the IA. They think they produced a very good product now it is up to the healthcare providers, and let's move onto the next subject.*	Few (8%; n=2)

Note: *Categorzsation of themes in few (5-24%), some (25-49%), many (50-74%) and most (75-100%)

External barriers to assessing HTA impact

To understand some of the barriers to conducting IA, participants were asked, "Whether your agency assesses impact currently or not, which kind of external barriers to assessing HTA impact do you perceive facing your agency?".

Figure 5. External barriers perceived facing the agency (n=25)



Several themes emerge in the perceived external barriers to conducting IA reported by interview participants (see Figure 5 and Table 4). The most common challenge identified by many participants was the limited culture of IA, meaning a limited awareness, understanding, acceptance and interest in IA among the requestors or within the health system more broadly. A lack of transparency in decision and policy making was reported by some participants and a reluctance for healthcare providers to open up about their practice and uptake (or not) of the recommendations can make gathering data for IA challenging. There can also be challenges to establishing a causal relationship between the HTA and the impacts, and some participants noted this and the number of confounding factors. Another external barrier is the difficulty to find the best time to conduct the IA which was reported by some participants

since the requestor may delay the release of their report and follow-up may be required at multiple points over several years.

A number of external barriers related to the availability, reliability and access to data sources were identified by some participants. For example, sometimes there is simply a lack of data sources, difficulties to obtain permissions to access the data, or questions about the reliability, validity or completeness of the data. Another external barrier was poor communication between the agency and the requestor, often with the requestor being non-responsive to agency requests for follow-up. Limited funding was perceived as another external barrier since HTA assignments do not often allocate a portion of the money to conducting IA afterwards. Limited stakeholder involvement was identified by a few participants as an external barrier particularly limited involvement of patients due to a lack of organized patient groups.

According to interview participants, methods and tools for conducting IA are not often very well developed and a few also noted that the requestor may have a bias and reluctance to provide IA information particularly if the HTA recommendations do not align with their views. A couple of participants reported barriers related to the lack of independence of the agency due to interference of lobby groups and the lack of openness for the government administration to adopt IA practices. Additionally, the following external barriers were mentioned by one participant each: a lack of explicit sharing of tasks between public bodies; a lack of credibility of the agency for doing IA partly due to the fact that IA is perceived as a somewhat young discipline; clinical autonomy or defensiveness of clinicians to the perceived over-reach of HTA into their clinical decision making; and anticipated limited support from the MOH.

It must be noted that some participants (28%) stated they did not perceive any external barriers to conducting IA.

Table 4. External barriers perceived facing the agency (n=25)

Theme	Summary of theme	**Quote(s)**	Frequency*
Limited IA culture	• Limited culture of understanding, acceptance, and prioritization of IA related to the requestors or within the health system more generally. • Limited awareness of what IA is and how requestors can provide the information needed. • Low or lack of interest or priority for IA by the requestor, which can take time away from producing additional HTA reports. • Limited comfort, trust, or perception of utility of HTA IA by requestors or health system leadership more generally.	*Q1: [It is a] more general problem of culture because we are not very strong in assessment of public policies in general not only in the health sector.* *Q2: Most people that ask for evidence or ask for an HTA, they are not thinking right at the start that they are going to need to provide impact. And a lot of them may not even know what that is…* *Q3: Measuring impact is not a priority. We are a body to help them, and not there to ask tough questions why they are not in line with our recommendations.*	Many (64%; n=16)

Theme	Summary of theme	Quote(s)	Frequency*
Data sources – access, availability and reliability	Agencies can encounter challenges with data access, e.g.: • Lack of (appropriate) data; • Difficulties in obtaining permissions to access data; • Questions about the reliability, validity or completeness of data sets; • Delays to access data from other departments who are busy with other duties; • Decentralized data collection systems make access complicated and time consuming, particularly when data is not shared across the system; • Limited and/or selective access to data can lead to a biased IA.	*Q1: Sometimes we also have issues with data protection issues … so for example if we are not allowed to analyze or to set up certain data collection structures […] this will later on not allow proper analyses of the impact.* *Q2: …There is no centralized system or database, it is all quite decentralized […] and it takes a long time for us to retrieve the information […].* *Q3: [...] [A]dministrative data especially in outpatient care lack validity and if they are available at all and if available they are invalid and probably out of date or incomplete[...].*	Some (36%; n=9)
Lack of transparency	• A lack of transparency in the decision or policy making process can impede IA since how the decision maker uses the recommendations is not accessible or the reasoning why they followed recommendations (or not) is not clear. • There may be reluctance for healthcare providers to open up about their practice and uptake (or not) of the recommendations.	*Q1: But then we have to probe a little deeper and ask if they can share what they might have done with that. And sometimes we get the answer "well it's confidential", or it's pending because this would go into Ministry, or into the government, so it becomes a little bit top secret for a while, right.* *Q2: They are often cagey about the policy synthesis that was done or who made the decision and what it was based on […] So there is this lack of transparency that is often a problem for us too, if we wanted to pursue a really good, rigorous evaluation of impact.* *Q3: Sometimes it can be there are reasons they do not want to open up about their practice or the way they practice because healthcare providers are not fully implementing the changes needed.*	Some (32%; n=8)
Causal relationship – risk of confounding	• It can be difficult to establish a causal relationship between the HTA recommendations and a change in policy or practice due to confounding factors. • Health systems can be non-linear making tracking impact from a change back to the HTA recommendations challenging.	*Q1: One other thing which is complicated and this is the actual thing of measuring impact is that so if you release a report you look at two years from now what has changed and you see oh wow you know the prescription of this drug has really decreased but how then could you say that this is because of the [agency] report because they have been a number of other factors that happen the same time and the causal relationship is very difficult to prove.* *Q2: Well, the impact of an HTA depends on a lot of other things; it is a complex system. What we are trying to do in our theory of change is say "if all the other stages prior to that are happening, then there is a likelihood that we will have an influence*	Some (24%; n=6)

Theme	Summary of theme	Quote(s)	Frequency*
		on patient outcomes". But in terms of quantifying that – it will always be really impossible.	
Inappropriate timing	• Inappropriate timing of the HTA IA is an external barrier, for instance, uncertainty about the best time for follow-up, or the challenges of aligning the follow-up with the policy process and the release of the report or decision.	*Q1: […] when do you ask people? Because we send straight away the review form after the advice, and quite often people have come back and said it's too early to tell. So, how long is it reasonable to follow-up with people?* *Q2: Sometimes they don't like to release the report straight away, so it is hard to do an IA on something where they say they don't want this report published for the next year or two because they are still thinking about it or there are things they are still waiting for before they can make the decision.* *Q3: I guess it comes down to timing, because right away if we are asking shortly after the client has the report, sometimes it will be a "black box", but what we will do, we will find out when it is sharable, like maybe it's an announcement coming out from the government, or it's a change in policy. And once that is official, then we go back to them and then we were able to share it too because now it is in the public. And this is really where sometimes months and years come into play… so we have some very long-tail projects here that have been going on for years [...] I guess time is a factor and I guess the lesson for us is patience.*	Some (24%; n=6)
Poor communication	• Poor communication when the agency asks the HTA requestors for information to assess the impact of the HTA. • The requestor does not often initiate the discussion, the burden of communication rests with the HTA agency.	*Q1: In case the decision makers do not follow the recommendations there is no feedback, there is no active communication in our direction. We have to look for the information and then […] they give the interviews and they give us the data but they are too lazy or inactive to provide automatic relay of information.*	Some (16%; n=4)
Lack of funding	• Lack of funding support to conduct IA.	*Q1: Even to think about getting that kind of research funded I think would be difficult given our current fiscal restraint and budget concerns. It's not that it is not important – it very much is – but I kind of doubt if we will ever get that far… so another barrier is the funding to do this kind of research that would be required for that.*	Few (12%; n=3)
Limited stakeholder involvement	• Limited involvement of stakeholders in the IA process, e.g., poor communication with patients.	*Q1: Limited stakeholder involvement since we do not have patient groups, for example.*	Few (12%; n=3)
Methods & tools	• The methods and tools of doing IA are often not very well developed.	*Q1: One challenge is that the science of doing IA is not very well developed. It is still difficult and there is a lack of tools or impact models.* *Q2: Lack of a global strategy about the measure of impact on the national level and the consequences.*	Few (12%; n=3)

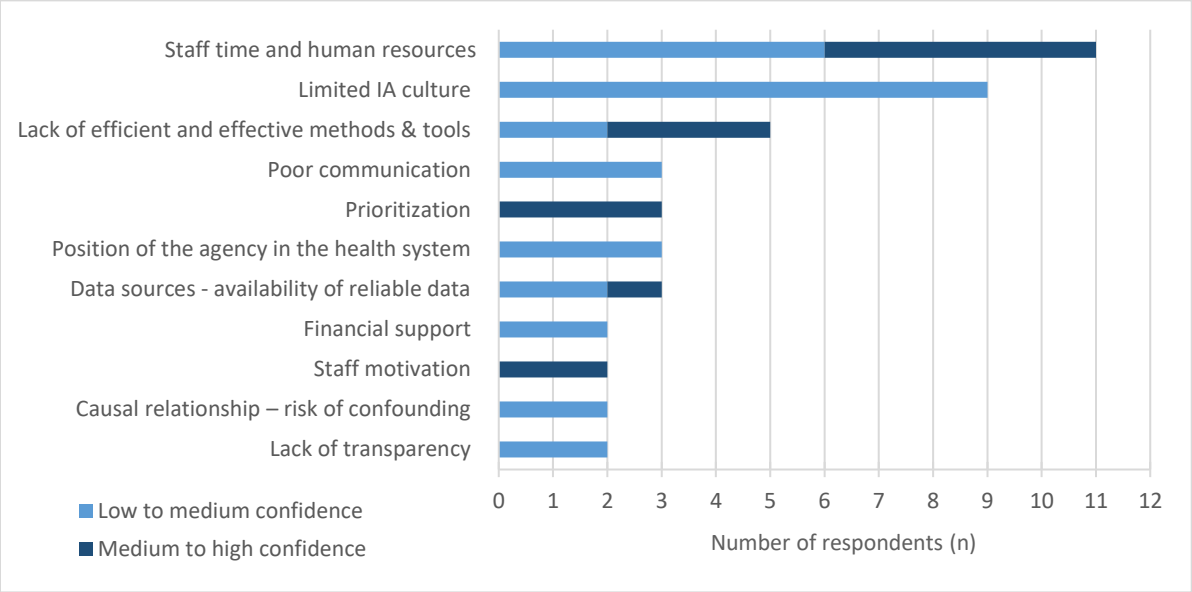
Theme	Summary of theme	Quote(s)	Frequency*
Sponsor/requestor bias	• Potential requestor bias where the HTA results do not align with their preferences then they may be reluctant to provide IA feedback.	*Q1: […] there is an inherent bias there since they are potentially a budget holder and also a decision maker about the subsidy decisions.* *Q2: If it doesn't go the way the requestor would like, then the advice is not as positive as they would have liked, then it is even more difficult to get people actually engaged to give you their feedback. They may not do it at all, or they may do it in a way that is perhaps not entirely constructive.*	Few (12%; n=3)
Lack of capacity for IA	• A lack of capacity for IA, which is related to a lack of local expertise.	*Q1: There is a lack of local expertise, and we are trying to overcome that by developing local talent […] and by being pragmatic.* *Q2: We have a number of HTA specialists in the country, but many are experts to conduct HTA themselves, there are only a few people involved in KT and policy research in the country.*	Few (8%; n=2)
Lack of agency independence	• A lack of independence would be a concern.	*Q1: [Perception that] advocacy or lobby groups that interfere with our work*	Few (8%; n=2)
Lack of openness for organizational change	• Lack of openness to adopt IA practices.	*Q1: Openness for organizational change within governmental administrations maybe this approach of evaluating work processes is less common for this kind of administrations.*	Few (8%; n=2)
No external barriers reported	• Some agencies do not perceive external barriers to assessing the impact of their HTAs.	*Q1: I don't see there would be any external barriers. I cannot think of any. (Our agency is located outside government [and] it is important for us to evaluate our programs because we are publicly funded so we ought to be able to show that the programs we offer are good value for money.)* *Q2: Overall, there are no external barriers and there is no deficit of transparency for doing HTA IA. The Ministry of Health and the health insurances find it principally important; there is no risk from the decision makers for doing IA.* *Q3: In our experience, we do not really experience any external barriers to assessing HTA impact. We are quite lucky since the system is quite impact savvy, which has been supported by the research assessment framework we have.*	Some (28%; n=7)

Note: *Categorization of themes in few (5-24%), some (25-49%), many (50-74%) and most (75-100%)

Confidence to overcome barriers to assessing HTA impact

To determine the degree of self-efficacy of the agency to overcome perceived challenges, participants were asked, "Whether your agency assesses impact currently or not, how confident are you that your agency would be able to overcome these internal and external barriers? Are there some barriers that you are more confident your agency would be able to overcome than others?".

Figure 6. Confidence to overcome barriers (n=24)



Self-efficacy is operationalized by the agency's confidence in being able to carry out IA in the face of extenuating circumstances. Despite the above-named barriers to conducting IA, participants expressed a reasonable degree of confidence that their agency could overcome these challenges (see Figure 6 and Table 5) Confidence was generally found to be higher in overcoming barriers internal to the agency than those external to it. This may be explained by the fact that the agency has greater authority to make internal changes than to resolve external issues that involve other groups. Participants at agencies with in-house expertise and sufficient funding for IA were more confident to overcome challenges of limited staff and time, but also other challenges such as having access to effective methods and tools, increased prioritization for IA, improved staff motivation and availability of data sources. On the other hand, challenges related to poor communication and a limited IA culture that places low value and relevance on IA were generally perceived as being more difficult for agencies to overcome. Success in overcoming these barriers requires time and persistent messaging to build awareness of the benefits of IA to the agency and the health system more broadly.

Table 5. Confidence to overcome barriers

Theme	Summary of theme	Quote(s)	Frequency*
Staff time and human resources.	• Lower confidence to overcome barrier of staff time and human resources since obtaining additional funding or retaining qualified experts is difficult.	*Q1: There are some things that are difficult to change – the number of people working and the time for this, maybe if we show them this report then maybe; but it is a government agency so it is difficult.* *Q2: We need resources and the experts in HTA […]. In our agency, we have a challenge to find the experts or the coworkers and to have them stay here for a long time.*	Some low to medium (25%; n=6)
	• Higher confidence to overcome barrier of staff time and human resources expressed by agencies with available funding and expertise.	*Q1: However, in case the agency aims to do more IA, the human resources would be made available.* *Q2: Well I mean resources would be easy because you can hire a person who is responsible for this.*	Few medium to high (21%; n=5)
Limited IA culture	• Lower confidence level to overcome the barrier of limited IA culture where, e.g., the focus is on the use of the HTA (not IA), limited confidence of the interest of the MOH and other health policy makers in IA, low value placed on IA or it is seen as an internal issue for the HTA agency only and not relevant to the broader health system. • Any success in overcoming this barrier requires time and persistent messaging about the benefits of IA.	*Q1: […] It is more an internal instrument to stress our production, or to do better, or to have a process for evaluating the IA.* *Q2: I don't know that they would know what to do with an IA now anyway. A lack of knowledge and a lack of thinking about those outcomes and how they could better use it. Their focus is more about how to use HTA better. … We […] get most of our support from the government who does not have this as a priority […].* *Q3: Evaluations are barely done […], it is just not part of the job.*	Some low to medium confidence level (38%; n=9)
Lack of efficient and effective methods & tools	• Lower confidence to overcome barrier of lack of methods and tools since this takes time to develop and build consensus among stakeholders for acceptance.	*Q1: How confident - that's a difficult one. I think we should first of all think of a strategy, this is something we do not really have. […] What I think is we should do that, if we decide that we should measure in a more systematic way, the influence of what we are doing, we should first of all think of a strategy, in order to see the barriers and try to take them down.* *Q2: […] The idea of the tools and the area of interoperability is moving forward and will eventually be overcome in some capacity.*	Few low to medium confidence level (8%; n=2)

Theme	Summary of theme	Quote(s)	Frequency*
	• Higher confidence to overcome the barrier of lack of methods and tools where people feel greater optimism that this is possible, and/or where this is supported by IA staff already working in the area.	*Q1: We are pretty confident that the internal barriers can be overcome in a short-term period. We realized it is important to monitor the policy impact, we are going to organize a policy compilation on task monitoring policy impact.* *Q2: Well the easiest barrier to overcome is of course if there are diverse views on the evaluation [methods] because we can always try to find consensus.*	Few medium to high confidence level (13%; n=3)
Poor communication	• Lower confidence to overcome the barrier of poor communication where the working processes are entrenched, although a few participants were more optimistic.	*Q1: I am pessimistic also because I don't foresee any change in the communication and way of working between [our agency] and its requestors, it is difficult to put it into place if there is no formalized mission within the [law].*	Few low to medium confidence level (13%; n=3)
Prioritization	• Higher confidence to increase the prioritization of conducting IA by the agency.	*Q1: […] that is just a question of prioritizing whether or not - so theoretically at least that could be overcome.* *Q2: The problem also being in the government agency is that governments change. So the priority to HTA can change too. This year this has been the rule – all of them have wanted it. Some wanted more, others wanted it less, but all are saying this is the best way to inform decisions, it has to have HTA behind it; it is needed. But you never know what will happen in the future […].*	Few: medium to high confidence level (13%; n=3)
Position of the agency in the health system	• Lower confidence levels overcome barriers to conducting IA due to the position of the agency within the MOH or uncertainty to be supported in an ongoing IA program	*Q1: Provided it becomes a separate agency in time, most of the barriers [...] will be overcome. If we remain within the MOH or as a government organization long term, we may just have to accept that some of the decision-making processes in place will have to remain unchanged, and that could potentially limit the scope of our work to a degree.* *Q2: The problem is the position of [our agency] within the political system […].*	Few low to medium confidence level (13%; n=3)
Data sources - availability of reliable data for IA	• Lower confidence to overcome barriers of data availability where the health system is not digitalized (access to data)	*Q1: Much more difficult is it to overcome the barriers in terms of data availability data quality and so on, so we are not very confident that this will change in the near future […]. Maybe in the future if the healthcare system becomes more digitalized this may open new possibilities for IA.*	Few low to medium confidence level (8%; n=2)
	• Higher confidence where the evidence of impact is clear such as when reports used in national guidelines.	*Q1: I also think that theoretically some stuff could be easy to do like the ones when we know that our reports are used for national guidelines I mean they even base it and they refer to our reports that is quite obvious.*	One medium to high confidence level (4%; n=1)

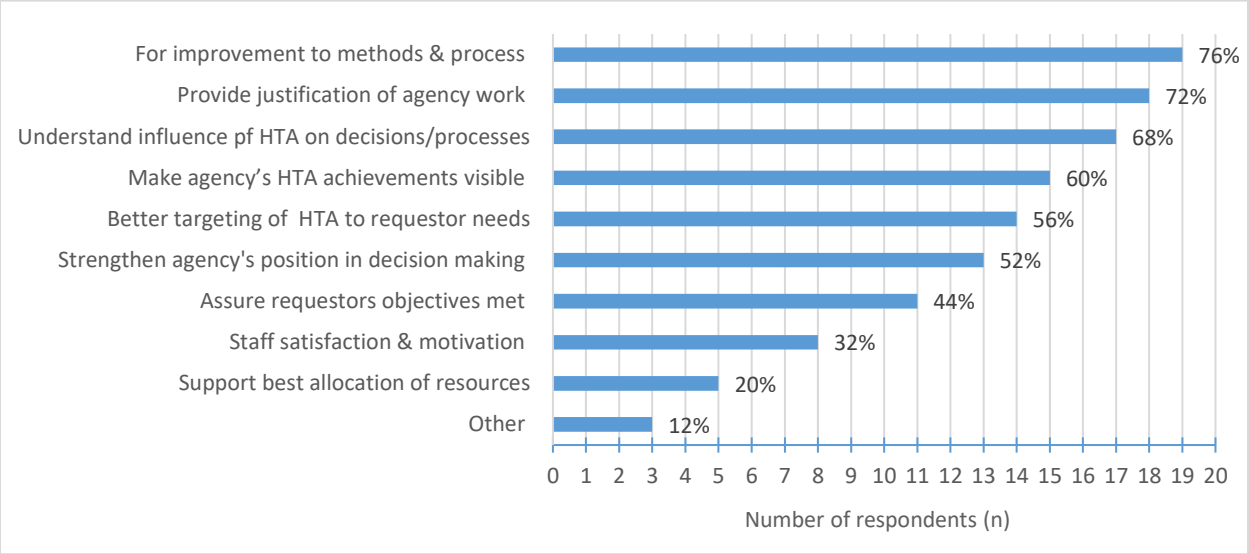
Theme	Summary of theme	Quote(s)	Frequency*
Financial support	• Lower confidence level to overcome the lack of financial support and funding for doing IA in the future due to budget pressures and financing decisions that are out of the agency's control.	*Q1: I think regarding the barriers about funding, that may not be overcome in the foreseeable future in terms of having more resources to do this more fully, just because of the way that budget pressures are within most Western countries.* *Q2: The internal barriers are linked to the external barriers in the sense that we do not have the financial support […], so it is largely out of our control [and] we don't have the resources to do it really well.*	Few low to medium confidence level (8%; n=2)
Staff motivation	• Higher confidence to increase staff motivation to perform more formalized and systematic IA	*Q1: I think the internal barriers can be overcome mostly in our case our team […] wants to perform more formalized IAs.* *Q2: But for example, the motivation of colleagues internally this is less and less of a problem, but you will always encounter colleagues who are not really willing to participate in the assessment or who do not think it is important. I think in all cases we can overcome these barriers.*	Few medium to high confidence level (8%; n=2)
Causal relationship – risk of confounding	• Lower confidence to overcome the risk of confounding due to other factors that may influence the actual impact of the HTA.	*Q1: The barrier about translating ultimately into patient outcomes, that is very tricky because you have got to have clearly constructed methods and collect that data, and that is very difficult to do. I am less confident we would be able to overcome that*	Few low to medium confidence level (8%; n=2)
Lack of transparency	• Lower confidence to overcome the lack of transparency perceived regarding the decision-making of the HTA requestor since this is not in their control and is a larger system issue.	*Q1: The decision making is not [so] transparent and the system still works - it is not bankrupt so not having clear what are the drivers of this lack of transparency. I am not sure when the need for greater transparency will actually come up, so I am not very confident because I don't see the system in crisis yet.*	Few low to medium confidence level (8%; n=2)
None reported/not applicable	• The question was not applicable to their situation.	*Q1: Since IA has no direct priority, the question is not much applicable to us.*	Few (13%; n=3)

Note: *Categorization of themes in few (5-24%), some (25-49%), many (50-74%) and most (75-100%)

Perceived advantages of assessing HTA impact

To understand the agency's attitude towards conducting IA, participants were asked, "Whether your agency assesses impact currently or not, what do you see as the advantages of assessing the impact of your HTAs?". In the ASE model applied in this study, attitudes are an individuals' overall evaluation of the behavior in question conceptualized as perceived advantages and disadvantages. The more advantages that are perceived, the more favorable a person's attitude will be to perform the behavior in question, i.e. in our study to conduct IA.[4]

Figure 7. Advantages of assessing HTA impact (n=25)



A number of advantages to conducting IA were reported by participants (see Figure 7 and Table 6). One of the main advantages perceived by interview participants to assessing impact is to identify gaps or weaknesses in HTA methods and processes so as to be able to make improvements. Even if an agency discovers that an HTA has had limited impact, this affords the opportunity for organizational learning. Ultimately, if the needs of the requestor are to be met, IA should inform agencies about where their products may be misaligned with the realities and expectations of those using the HTA product. As agencies come to understand the needs of their requestors, the HTA products can be better tailored to the particular question and context, rather than a 'one-size-fits-all' type of report. According to study participants, IA is also advantageous as a means to justify the financial resources that are allocated to the agency by making the agency's work visible and readily demonstrable to the Ministry of Health or other funders. Such evidence of impact shows the contribution of the HTA agency to the broader health system and to help guard against changes in political leadership or shifts in the political economy that may threaten the agency's place in the health system. Clear evidence of HTA impact can strengthen the credibility and trustworthiness of the agency and its HTA products and support staff satisfaction (and potentially retention) by showing the value of their work in the health system.

Table 6. Advantages of assessing HTA impact (n=25 total participants)

Theme	Summary of theme	Quote(s)	Frequency*
Provide feedback for improvement to the HTA methods or process	• A main advantage of conducting IA is to identify areas for improvement in the HTA methods or process used by their agency. • Even if it is learning about weak points in the agency processes, this is important to know. • Knowledge about weak points/areas for	*Q1: The additional thing for me is finding information that we can bring back into our processes and adapt them as necessary. We are always evolving the way we do things.* *Q2: We are always trying to find out from our point of view as researchers – is this useful, how can we make it better, are we answering the question that you wanted?* *Q3: I think an important aspect is the learning effect for our organization itself, the quality improvement within our organization to improve the impact of our HTAs.*	Most (76%; n=19)

Theme	Summary of theme	Quote(s)	Frequency*
	improvement can take time to become apparent.		
Provide justification of agency work	• IA is advantageous since it provides justification of the agency's work. • Demonstrates value for money and return on investment for the public investment in the agency. • Develops evidence of effectiveness that can support future requests for funding.	*Q1: Ultimately because that is why we exist and it is to prove that our existence is needed.* *Q2: Assessing impact is very important, especially for those who give you money, they may not want to support you in the future if they do not know what happens to your product or not and if people are using your product or not to make decisions.* *Q3: Making sure we are worth funding is important, not that we are just producing reports that are doorstops, that we are producing reports that are useful.*	Most (72%; n=18)
Understand what health care decisions/processes/ practices have been influenced by the HTA and in what ways	• IA generates understanding about what healthcare decisions, processes, and/or practices have been influenced by the HTA. • Where impact is limited, this is equally important to understand.	*Q1: In general, there are a number of advantages. First, there is no point doing an HTA if it is not going to influence policy because that is what we do.* *Q2: Our main purpose with the whole evaluation program is to understand what we are able to influence by producing our HTAs.* *Q3: There is everything to gain and nothing to lose by evaluating a program. If it is not having an impact and it ought to, something is wrong somewhere and you have to figure it out, and you cannot be afraid to figure it out.*	Many (68%; n=17)
Make the agency's HTA achievements visible and evident	• It makes the agency's HTA achievements visible and evident, it shows that the agency is doing important work that has an effect on one or more levels of the health system. • This evidence demonstrates the agency's value for money.	*Q1: In general, one can see what one does and what kind of impact it has on different levels of the healthcare system. […] With proper IA, it becomes visible what impact the work has on the practice level.* *Q2: I would say it is also important against the external worlds, to be able to show that we are there for something concrete.* *Q3: There is one argument that it makes the HTAs more visible, and yes I would say that is part of the good value for money if you can show that it is worthwhile investing in HTA that is part of the visibility strategy.*	Many (60%; n=15)
Support better targeting of the HTA to the needs of the requestor	• It helps support better targeting of the HTA to the needs of the requestor, and that this can lead to improvements in the structure, layout or presentation of the HTA report. • Supports better tailoring of the reports to decision maker needs.	*Q1: You need to gauge if it is having an impact to see how you can improve it to be sure it does have an impact. For example, is there some way that you are producing the HTA that is not palatable for the policy makers to read: is it too complex, is it too big, etc.* *Q2: It is in our mission to deliver the appropriate recommendations so it must be suited in the content but also in the format. We try always to adjust our different procedures, including the dissemination procedure.*	Many (56%; n=14)
Strengthen the agencies position as part of health system decision making	• It helps strengthen the position of the agency as part of health system decision making processes. • Strengthening translates to greater credibility, trustworthiness and	*Q1: Strengthening the agency position as part of the health system decision making structures, I think this is very important.* *Q2: A little bit to strengthen our position – we are very sensitive to funding, so it is part of us making ourselves*	Many (52%; n=13)

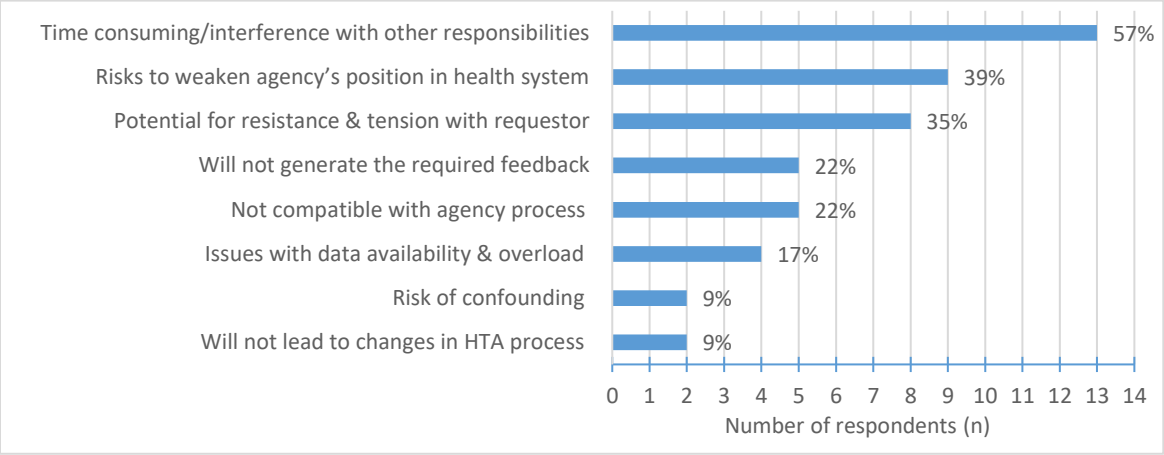
Theme	Summary of theme	Quote(s)	Frequency*
	respect for the agency work.	*a well-respected player in the decision process for the government so they keep funding us.* *Q3: But also I think it increases our trustworthiness to the external contacts and healthcare providers.*	
Assure that the requestors objectives have been met	• It provides a mechanism to assure that the requestor's objectives have been met; that their needs for the HTA have been satisfied.	*Q1: It is important to see the people who request work from us as customers and to understand if we are meeting their needs, not just in terms of the outcomes but also the timeliness of the decisions.* *Q2: [To] assure that the requestor objectives have been met.*	Some (44%; n=11)
Increase staff satisfaction & motivation	• It shows HTA agency staff the contribution their work makes to the health system. • Showing impact can increase staff satisfaction and inspire staff to deliver high quality reports. • Where HTA recommendations not followed, IA can help staff understand why.	*Q1: This is half the reason that I have people so keen to do HTA here since we see the direct impact of the HTAs we produce it is a good morale boost.* *Q2: I think the first [advantage] is to see that there is an impact for the organization but also for the researchers, I think it is very important for their motivation.* *Q3: It is good to have some explanation to explain why the evidence-based recommendations were really not followed or not fully followed. It is important also for the motivation, I think.*	Some (32%; n=8)
Support best allocation of resources	Supports best allocation of HTA resources to achieve two outcomes: • It helps ensure appropriate focus of HTA agency resources to address areas of the health system that most need HTA. • It helps achieve allocative efficiency and health system sustainability by improving HTA for evidence-informed decision making for cost-effective, high-value technologies.	*Q1: Because we could all spend weeks and months and years looking at technologies, but what we need to be really clear about is that we, with the limited resources we've got, we target HTA to where the health system needs it most.* *Q2: And in a more general sense I think it is important to follow up to see that indeed we do impact all of what I just mentioned to reach our goal which is having the best possible management of the healthcare budget to make sure that we use the resources for the best use for the right population.*	Some (20%; n=5)

Note: *Categorization of themes in few (5-25%), some (26-50%), many (51-75%) and most (76-100%)

Perceived disadvantages of assessing HTA impact

To further understand the agency's attitude towards conducting IA, participants were asked, "Whether your agency assesses impact currently or not, what do you see as the disadvantages of assessing the impact of your HTAs?".

Figure 8. Disadvantages of assessing HTA impact (n=23 total participants)



Several disadvantages to conducting IA were reported by interview participants (see Figure 8 and Table 7). Conducting IA can become a disadvantage when it takes significant or unreasonable amounts of time away from the 'core' business of preparing HTA reports. It can be particularly challenging where no additional funding is available or where it is placed on top of other responsibilities of staff. Paradoxically, having evidence of HTA impact could be used by the agency to justify requests for additional funding to overcome a limited availability of human resources. As outlined by few participants, threats to agency credibility are another disadvantage to conducting IA, since if impact is not achieved nor convincingly demonstrated, this could portray the agency as ineffective. On the other hand, strong IA results could portray the agency in a negative light as a rationing institute where HTA reports are used to support negative reimbursement or other disinvestment decisions.

A further potential disadvantage with IA is its iterative and investigative nature that may provoke tension with decision makers and/or requestors. In such cases the agency may be seen by the requestors as trying to monitor or evaluate their work. This may be particularly true where an agency has no formal IA strategy; having a formal IA process can reduce the perception by requestors that they are being personally evaluated. Another disadvantage reported by participants is the complexity of HTA reports and the challenges to measuring impact when there are many HTA recommendations or conclusions/results to assess within one report. Large volumes of data can make IA burdensome; however, conversely, agencies may also have to deal with situations of insufficient data availability. Furthermore, defining which outcomes will be measured and avoiding confounding data is not easily done.

Table 7. Disadvantages of assessing HTA impact (n=23 total participants)

Theme	Summary of theme	**Quote(s)**	Frequency*
Time consuming / interference with other tasks and responsibilities	• IA is time consuming and takes time away from focusing on other tasks, responsibilities and priorities. • Particularly challenging for smaller HTA units. • Despite being time consuming, conducting IA is seen as worthwhile.	*Q1: A disadvantage is the time consuming nature of IA and its interference with normal HTA activities that you would have the staff for this, and you would need to make it a priority when you have so many other priorities to reach.* *Q2: Certainly, it is time consuming and there is interference with other tasks and responsibilities [and this] is a challenge for us. We are a small unit and*	Many (57%; n=13)

Theme	Summary of theme	Quote(s)	Frequency*
		have such a high volume of work for the amount of people that we have. *Q3: [It is] time consuming, of course, but we do not see this as a disadvantage, we think it is worth the effort.*	
Risks to weaken the agency's position as part of health system decision making structures	• The results of the IA could weaken the agency's position or credibility as part of health system decision making processes. E.g., if little or no impact is achieved or if the complexity makes it impossible to clearly measure impact. • IA can make the agency appear as a rationing institute.	*Q1: It is a complex situation to asses our impact, it needs resources, it is not always obvious that for some of our recommendations there has been some that have had important impact.* *Q2: We sometimes see that actually when trying to assess that you don't see any impact of your product – that is possible of course. […]As a governmental organization, it could make us more vulnerable to criticism.* *Q3: Well the disadvantage to prove that very many of the reports do have an impact on cost-effectiveness of the decision-making you very easily get the image of being a rationing institute.*	Some (39%; n=9)
It risks leading to resistance and tenses the relationship with the HTA requestor	• IA could lead to resistance or tension with the HTA requestor. I.e., if the assessment reveals something that is unexpected, if the decision maker feels their work is being scrutinized, or if follow-up is done several times over a period of time.	*Q1: Risk leading to resistance and tensions with the relationship with the HTA requestor – this could be one especially if you get something you do not expect.* *Q2: One of the disadvantages is the Minister is stuck with some recommendations made by our agency and he is not following it as he said he would be. So there is some political discomfort over that.* *Q3: Sometimes this has been the case that the constant pestering with these difficult qualitative questions they get almost like survey fatigue – they get annoyed and overwhelmed. This would be a risk and it would be a bad thing.*	Some (35%; n=8)
It will not generate the required feedback	• Assessing impact precisely is difficult; the data collected may not be appropriate, satisfactory, complete or comprehensive enough to represent the impact achieved. • IA is not required so the feedback generated is a waste of effort. • Added value of IA is not clear.	*Q1: In many instances it is really difficult to really see what the impact is of our product.* *Q2: I sometimes wonder if it will not necessarily generate the feedback we want or for the government or whomever requests the IA requires.*	Few (22%; n=5)
It is not compatible with the agency work process	• Assessing impact is not compatible with the agency work processes, therefore it would bring limited value and be problematic to attempt. • Sophisticated evaluations are not priority part of agency work. • In countries with small population, impact magnitude	*Q1: It is not part of our mission. It is not in line with our process because we need to put our effort on the assessment.* *Q2: Well I think a disadvantage is that it is currently not compatible with our work process since it is not our mission to do sophisticated evaluations.* *Q3: The country has a small population and the number of patients and budget impacts are very small compared to other countries, so doing full*	Few (22%; n=5)

Theme	Summary of theme	Quote(s)	Frequency*
	is limited and therefore not conducted.	*evaluations that can take 9-12 months with all the modeling may not be necessary if you are looking at decision that might affect 20 patients. So we need to be pragmatic as well.*	
Issues with data availability & overload	• Appropriate data may be limited in availability or an overload of data is received.	*Q1: For me on the other end, seeing the impact data, it is like oh my goodness, this is far too much. So I have to really filter to be able to get the real issue, to what the real impact is.* *Q2: If an evaluation uncovers weaknesses in data availability or gaps in knowledge or whatever this might be counted as an advantage or disadvantage depending on your point of view.*	Few (17%; n=4)
It will not lead to any relevant changes in the HTA process	• IA results will not lead to any relevant changes in the HTA process. • It can be unclear how to use the results in a meaningful way.	*Q1: That is a problem too, you might get a great report and some results, but it is all about what you can do with it and what you plan to do with it that is the problem.*	Few (9%; n=2)
Difficulty of appropriate timing: risk of confounding	• Difficult to find the most appropriate time to measure impact and how to resolve confounding factors.	*Q1: The timing and also the problems of actually how to measure it so it is the confounding factor thing.*	Few (9%; n=2)

Note: *Categorization of themes in few (5-25%), some (26-50%), many (51-75%) and most (76-100%)

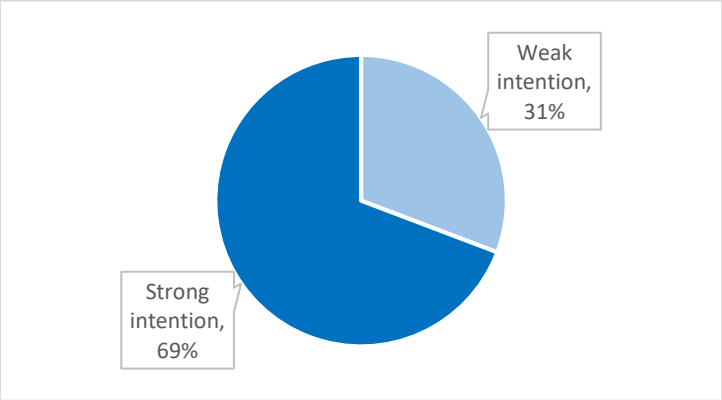
Intention to assess impact

As a proxy determinant of actual behavior, the performance of IA is determined by the agency's intention to engage in it. The majority of study participants conveyed an understanding of the advantages of conducting IA which was reflected in the intention perceived within their agency to conduct IA in the near future. The majority of the study participants said there was a strong intention in their agency to conduct IA in upcoming two to three years. However, despite this intention, only slightly more than half of the participants perceived it to be likely their agency would actually conduct IA within this timeline.

Strength of the intention

The intention to do HTA IA was assessed by asking to what extent interview participants agreed with a statement with Likert scale answer options ranging from 1 "strongly disagree" to 7 "strongly agree". Interview participants were first asked to indicate to what extent they agree with the following statement "My agency has the intention to assess HTA impact in the next two or three years.'' Responses are presented in Figure 9.

Figure 9. Perceived intention of agency to assess HTA impact in the next two years (n=26)

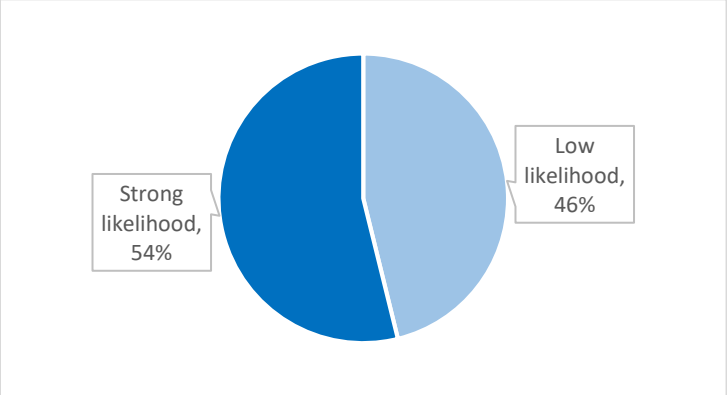


Eight participants reported a weak intention (arithmetic mean=2.38) for their agency to assess HTA impact in the next two or three years. On the other hand, the majority of the participants had a strong intention (arithmetic mean=6.61) that their agency will assess HTA impact in the next two or three years. Weak intention was categorized as responses between 1-5 on the Likert scale, while strong intention as between 6-10. One participant additionally mentioned that "The intentions are strong and good, but there may not be enough resources to follow those intentions through" while another participant said that "Our agency would assess if the budget is available. The intention is clear, it is just the barriers about this".

Likelihood of assessing impact

The likelihood of doing HTA IA was assessed by asking to what extent interview participants agreed with a statement with Likert scale answer options. Interview participants were first asked to indicate to what extent they agree with the following statement "How likely you think it is that your agency is going to assess HTA impact in the next two or three years?". Responses are presented in Figure 10.

Figure 10. Perceived likelihood that agency is going to assess HTA impact in next 2-3 years (n=26)



Some participants (n=12) reported a weak intention (arithmetic mean=2.38) for their agency to assess HTA impact in the next two or three years. One participant indicated that "[he/she doesn't] know and it is difficult to say. It does not depend on us". On the other hand, more than half of the participants (n=14) revealed a strong intention (arithmetic mean=6.61) of their agency to assess HTA impact in the next two

or three years. Weak intention was categorized as responses between 1-5 on the Likert scale, while strong intention as between 6-10. One participant reflected further on the question and mentioned:

> *I think this question needs to be pieced out: how likely will we [be] at evaluating the right things that show it? Maybe this work will help agencies identify what they should be evaluating. I know we will be successful at evaluating something, I don't know if that something will show we successfully evaluated it. This is the learning curve – and the bigger discussion is this – bringing forward that you can successfully evaluate something, but did you evaluate it successfully. We are learning to assess impact successful; it will be an iterative process of discovery to learn what will be a successful project.*

Study limitations

Certain limitations of this study should be noted. Its qualitative cross-sectional design and the fact that only INAHTA members participated in the study may limit the transferability of the findings to other HTA producers, particularly to privately funded HTA bodies. INAHTA is the largest international body for publicly-funded HTA agencies and a reasonable response was received from across its membership to be helpful to understand these issues in public agencies.

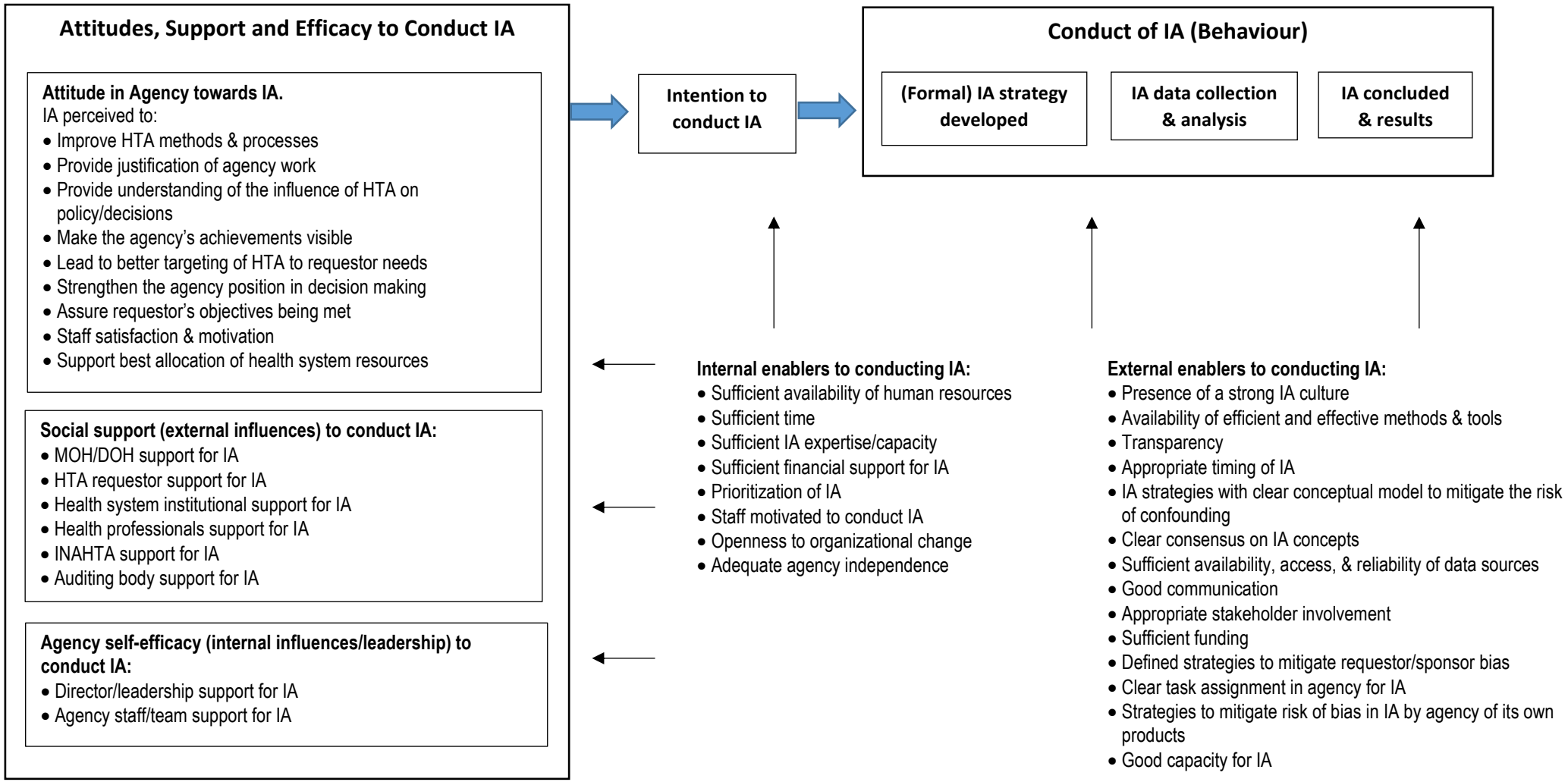
The answers provided in the interviews reveal the perceptions of the one or two senior officials or staff members who participated in the interview therefore the responses may not necessarily be representative of the official agency view. Socially desirable answers may have been provided by interview participants which may lead to an overestimation of the advantages and an underreporting the perceived barriers and disadvantages of IA. However, as a strategy to mitigate this interview participants were told that their responses would be confidential and reported on an aggregated basis. Another potential limitation was the variability in the interview method. Telephone and Webex® were used depending on the preference of the interviewee. Face-to-face interviews may have provided more certainty in study findings, and the involvement may have been more effective. Nevertheless, we believe this does not endanger the credibility of the results, which were audio-recorded, transcribed, analysed and hence reviewed by two researchers. The questionnaire instrument contained evidence-based examples drawn from the IA literature for the participants' reflection in providing their answers. There is a risk that these examples may have constrained the range of possible responses provided by participants, although the researchers observed that participants felt free to either support or refute the examples and they did not refer only to these in providing their answers. Due to interviewing error, 16 participants were not explicitly asked the question, "Are there any groups who not be supportive of impact assessment?" Results for this question are therefore to be interpreted with some caution as the full scope of responses was not obtained and gaps likely remain.

In the future, it would be helpful for the field of IA to understand what agencies have done with the information generated by IA, and to examine the evidence of impact assessment changing the practice of HTA. Returning to study the attitudes, perceptions and practices of IA in HTA agencies in the future will help to identify the trends and perceptions of IA as a tool used to improve HTA process and to achieve improved impact of HTA products.

Discussion and implications for practice

As HTA is a growing subject of investigation within healthcare systems, the importance of IA to accompany HTA cannot be ignored. The ASE-Model has traditionally been applied to examine and address individual health behaviors. The use of the adapted ASE-Model in this study provides a unique framework to understand some of the forces acting upon the intention and actual behaviour of HTA agencies to assess the impact of their HTA reports. Figure 11 presents a high-level picture of the facilitators that support an agency in conducting IA, which, when taken together, suggest a pathway for achieving the establishment of an HTA impact assessment program. This overview may be helpful for agency leadership where they are intending to put in place such a program.

Figure 11. Pathway to conducting IA according to the ASE-Model



The findings of this study are intended to support HTA agencies in determining their state of readiness to start or strengthen processes to assess the impact of their HTA reports. By considering the sources of support, attitudes and influences, along with the perceived barriers and enablers to assessing impact that were revealed in this investigation, agencies can determine what specific challenges they are facing and what areas need to be strengthened to create a clear intention to assess HTA impact and to enact the behaviour of conducting IA.

Each HTA agency is unique and functions within the processes, norms, and culture of the health system where it is located. For this reason, it should not be presumed that all agencies must necessarily assess HTA impact. For example, some health systems have in place legal or procedural requirements for the HTA reports to be considered by decision makers, and therefore the HTA agency has little incentive to formally assess impact. However, it is worth noting that in such cases, while this short-term impact is ensured there is no guarantee of achieving impacts beyond the decision-making process or to determining the need for changes to and improvements in the process and methods used. On the issue of 'downstream' impacts on clinical practice and patient outcomes, study participants had varying views, with some reporting that their agency is endeavouring to measure downstream impacts whereas others felt such impacts, while important, are not within the responsibility of the agency to assess.

Looking at the internal and external barriers to conducting IA, there were important barriers perceived in the lack of experienced staff and in the lack of time and budget, which often limits the agency's capacity to conduct IA. Many agencies face challenges with limited staff and a high workload for producing HTAs with little left over to conduct IA, which may also explain a reduced motivation among staff members. Moreover, agency staff do not typically have access to validated, effective methods and tools for doing this work and so agencies must be sure to sufficiently support agency staff to conduct IA by providing adequate training, tools and time for this work.

The study showed a clear need for consensus around the concept of IA in order to develop appropriate assessment methods and tools. Proper tools and methods can help IA to become more systematic, decreasing the likelihood of selection bias where assessors seek positive outcomes or choose to examine reports that are likely to yield positive results.

In the majority of cases, the most significant challenge facing agencies is a health system that has a limited IA culture, meaning there is limited understanding, acceptance, and prioritization of IA. Interview participants reported low awareness and/or prioritization of IA within their agency or across the health system leadership more generally. Fostering a relationship of trust between HTA producers and users is important to achieving the communication required for successful IA, for instance ensuring the appropriate timing of the IA to have the best chance to capture the needed data to show impact.

Assessing impact can be time-consuming and costly to do and the process can encounter numerous barriers and challenges to be effective. Nevertheless, the choice to not assess impact also carries some risk to the agency. For instance, should the agency be asked by the Ministry of Health or other funding body for evidence of the effectiveness and achievements of the HTA program, having readily available evidence of impact can be of strategic importance to defend the agency against funding cuts or other challenges. This can be particularly useful during times of political change where the demand and support for HTA may diminish or where an agency must otherwise demonstrate their value to other health system stakeholders.

It is suggested that, as a first step, HTA agencies wishing to start or grow an IA process conduct a situational analysis to determine which facilitators are present or could be encouraged in their

particular setting, and which inhibiting factors are present and could be diminished or eliminated. The current study showed that the majority of participants perceived a strong intention in their agency to conduct IA in the near future, regardless of if they had already implemented a formal IA strategy or not. Ultimately, agency leadership must determine if IA is an appropriate activity at a particular time given the local structure of the health system and the role and remit of the agency within it.

Conclusion

Applying a social-cognitive framework to the field of HTA IA brought light and new insights into those factors that influence the intention and actual application of IA strategies in HTA agencies. It is anticipated that the findings of this study will be of interest to HTA agencies that wish to consider starting or expanding IA activities within their agency.

Appendix A. Interview participants

Note: Senior staff from the following 26 INAHTA member agencies participated in this study. Examples of the position titles of interview participants include CEO, Department Head, (Executive) Director, Head of Unit, Team Lead, Principal Research Lead, Program Officer, etc. To preserve confidentiality respondents, the titles of the individuals who participated in an interview are not listed in the table.

Agency with representative(s) participating in the study
ACE, Singapore
AHTA, Australia
AOTMiT, Poland
ASSR, Italy
Avalia-T, Spain (Galician Agency for Health Knowledge Management)
CADTH, Canada
CDE, Taiwan
CEM, Luxembourg
CENETEC, Mexico
G-BA, Germany
HAD-MSP, Uruguay
HAS, France
HIS, Scotland (SHTG)
HQO, Canada
IHE, Canada
INESSS, Canada
KCE, Belgium
LBI-HTA, Austria
MaHTAS, Malaysia
MTU-SFOPH, Switzerland
NECA, South Korea
NIHR, United Kingdom
Osteba, Spain
SBU, Sweden
ZIN, The Netherlands
ZonMw, The Netherlands

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