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Demonstrating the influence of HTA: INAHTA member stories of HTA impact

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Abstract

A central function of health technology assessment (HTA) agencies is the production of HTA reports to support evidence-informed policy and decision making. HTA agencies are interested in understanding the mechanisms of HTA impact, which can be understood as the influence or impact of HTA report findings on decision making at various levels of the health system. The members of the International Network of Agencies for HTA (INAHTA) meet at their annual Congress where impact story sharing is one important activity. This paper summarizes four stories of HTA impact that were finalists for the *David Hailey Award for Best Impact Story*.

The methods to measure impact include: document review; claims analysis and review of reimbursement status; citation analysis; qualitative evaluation of stakeholders' views; and review of media response. HTA agency staff also observed changes in government activities and priorities based on the HTA. Impact assessment can provide information to improve the HTA process, for example, the value of patient and clinician engagement in the HTA process to better define the assessment question and literature reviews in a more holistic and balanced way.

HTA reports produced by publicly funded HTA agencies are valued by health systems around the globe as they support decision making regarding the appropriate use, pricing, reimbursement, and disinvestment of health technologies. HTAs can also have a positive impact on information sharing between different levels of government and across stakeholder groups. These stories show how HTA can have a significant impact, irrespective of the health system and health technology being assessed.

Introduction

A central function of health technology assessment (HTA) agencies is the production of HTA reports to support evidence-informed policy and decision making. Publicly funded agencies have a particular interest in understanding the mechanisms of HTA impact, which can be understood as the influence or impact of HTA report findings on decision making at various levels of the health system (1). Further "downstream" impacts on clinical practice and patient outcomes or even impacts beyond the health system, such as effects within the legal or social domains, can also be monitored although causality can be difficult to establish (1;2).

The International Network of Agencies for Health Technology Assessment (INAHTA) is a network of fifty-two publicly funded HTA agencies in thirty-three countries around the globe (3). INAHTA members meet during their annual Congress for collaboration and knowledge exchange, and to advance the strategic goals of the network (4). A popular activity at the Congress is HTA impact story sharing, where member agency representatives exchange experiences (stories) of HTA impact. The result is increased knowledge among INAHTA members about different elements that enable HTA impact such as improving report quality and tailoring reports for decision makers; building strategic relationships to ensure impact; and strategies to respond to appeals or challenges that are raised by stakeholders.

This article contains summaries of four stories of HTA impact that were finalists for the 2018 *David Hailey Award for Best Impact Story* (5). Stories come from four INAHTA member agencies: Adelaide Health Technology Assessment (AHTA), in Australia; the Institut national d'excellence en santé et en services sociaux (INESSS) in Québec, Canada; the Health Policy Advisory Committee on Technology (HealthPACT) in Australia and New Zealand; and the Health Assessment Division of the Ministry of Public Health (HAD) in Uruguay.

Story 1: HTA and Vertebroplasty in Australia: A Story of Investment and Disinvestment Impact

Vertebroplasty is a minimally invasive procedure that involves the percutaneous injection, under radiographic guidance, of bone cement into the intertrabecular marrow space of fractured vertebrae. The aim is to stabilize the fractured vertebrae and relieve sometimes crippling back pain.

This story describes the impact of HTA on the Medical Services Advisory Committee's (MSAC) public funding decisions concerning vertebroplasty and on the uptake of vertebroplasty in Australia. MSAC advises the Australian Minister for Health on whether a new medical service should be publicly funded based on an assessment of its comparative safety, effectiveness, cost-effectiveness, and total cost, using the best available evidence. Following MSAC's consideration of a proposal, the Department of Health is required to consider the financial impact to government, consult with relevant stakeholders, seek Cabinet agreement, and draft and implement legislative change(s) to amend or add an item to the Medicare Benefits Schedule (6).

In 2005, 2011, 2018, and 2019, the procedure was considered by MSAC in Australia to determine whether a Medicare subsidy for the procedure was warranted. This decision making was made on the basis of HTAs commissioned by the Australian Government—the first two of which were made publicly available (7;8). A Public Summary Document described the factors that influenced MSAC's consideration of vertebroplasty in 2011, 2018, and 2019 (9).

In addition to reviewing the Public Summary Document outlining the basis of MSAC decision making at each time point, an analysis of claims for reimbursement of the vertebroplasty procedure on the Medicare Benefits Schedule over the period of decision making was undertaken. Finally, a citation analysis was performed to determine the broader impact of the publicly available vertebroplasty HTA reports.

The evidence on vertebroplasty obtained for the 2005 HTA report was a nonrandomized controlled study and many case series. The report concluded that vertebroplasty was promising at reducing patient's pain but there was insufficient evidence to determine its safety relative to medical management (7). Subsequently, the procedure was funded on the Medicare Benefits Schedule on an interim basis. MSAC stated that the funding decision should be reviewed within 5 years (7).

An Australian randomized sham-controlled trial assessing vertebroplasty's efficacy was underway during MSAC's initial consideration of the procedure (10). Results of this trial and another American randomized sham-controlled trial (11) were available at the time of the second consideration of the procedure in 2011. A large amount of new evidence was available for the 2011 HTA report, including these methodologically rigorous trials. Taken together, the evidence suggested that there was a large placebo effect associated with the vertebroplasty procedure. However, there were some key uncertainties related to the impact of patient selection on treatment efficacy. The acute vertebral fracture group (fractures ≤6 weeks), for whom it was suggested there might be the greatest benefit (but for whom data were available only from open-label trials), was under-represented in the evidence base. The HTA report suggested that a sham-controlled trial was needed to determine the effect of vertebroplasty in the acute fracture group and concluded that for the older medically managed fracture group (>6 weeks), there was no benefit from vertebroplasty over placebo and a possibility of harm (8). Many Australian clinicians who had been providing vertebroplasty services were unhappy with this conclusion.

When MSAC considered the 2011 HTA report they did not support continued public funding of vertebroplasty. The judgment was based on the findings of the two randomized sham-controlled trials where vertebroplasty had not been proven to be more effective than conservative treatment (9).

Table 1 shows the initial increase in reimbursement claims for privately delivered vertebroplasty services following MSAC's 2005 investment decision, as well as the concomitant decrease subsequent to the 2011 reversal of that decision. An item for vertebroplasty was included on the Medicare Benefits Schedule in 2005 and removed in 2011 on MSAC's recommendation, after the committee had respectively considered each of these HTA reports.

The 2011 HTA report was publicly available and cited in a number of journal articles, international HTA reports and databases. Importantly, the report was cited as a motivating factor for the conduct of another Australian randomized sham-controlled trial of vertebroplasty undertaken in an acute fracture population subgroup, as described by Clark et al. (12), "the review *[HTA report]* concluded that the two masked trials were of superior methodological quality and provided evidence of lack of efficacy for vertebroplasty. However, the small representation of patients with uncontrolled pain and acute fractures of less than 6 weeks' duration in the masked trials caused uncertainty for the role of vertebroplasty in this subgroup. The review *[HTA report]* recommended a high quality placebo-controlled trial to specifically assess this patient group. This is such a trial" (p. 1409).

This trial controversially showed a statistically significant, although possibly not clinically important (9), effect of vertebroplasty on patient pain. Whereas another sham-controlled trial published in 2018, also on the acute fracture population, demonstrated no additional treatment effect from vertebroplasty (9;13). These heterogeneous findings proved challenging for MSAC's third consideration of vertebroplasty in November 2018 where it again rejected subsidy of the procedure on the basis "that there may be a small clinical benefit, but MSAC was uncertain of its clinical significance, and that the cost-effectiveness is highly uncertain with substantial risk of use beyond the proposed patient population" (9).

The application was reconsidered again at the March 2019 and March 2020 MSAC meetings (9). So, the story continues.

Story 2: Translating Patient Insights into Action to Fill the Evidence Gap Concerning the Appropriateness of Replacing an Implantable Cardioverter-Defibrillator in Québec, Canada

Malignant arrhythmias can occur unexpectedly and may result in sudden cardiac death in patients with severe heart failure. An implantable cardioverter-defibrillator (ICD) is a device placed in the heart to prevent a sudden death by producing an electrical therapy or shock when it detects a malignant arrhythmia. It is indicated in patients who have already experienced a malignant arrhythmia and survived (i.e., secondary prevention) or who are at risk of such arrhythmia (primary prevention). This device currently requires a replacement of its generator every 5–7 years to prevent complete depletion of the battery.

Clinical ICD indications at the time of initial implantation are clearly set out in international guidelines. However, there is a clinical evidence gap concerning decisions at the time of generator replacement. For example, there is uncertainty as to whether

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Table 1. Medicare Benefits Schedule reimbursement claims for provision of vertebroplasty 2005–15 (Medicare Australia data 2018)

	Australian State/Territory								
	NSW Services	VIC Services	QLD Services	SA Services	WA Services	TAS Services	ACT Services	NT Services	Total Services
2005	9	0	10	6	6	0	0	0	31[a]
2006	300	34	119	39	165	1	1	0	659
2007	432	41	118	32	140	3	7	1	774
2008	341	53	106	25	116	3	10	0	654
2009	399	36	164	29	124	8	9	1	770
2010	395	22	145	26	113	4	4	0	709
2011	279	24	112	19	173	3	4	0	614[a]
2012	52	1	2	2	5	0	0	0	62
2013	7	0	1	0	1	0	0	0	9
2015	1	0	0	0	0	0	0	0	1
Total	2,215	211	777	178	843	22	35	2	4,283

NSW, New South Wales; VIC, Victoria; QLD, Queensland; SA, South Australia; WA, Western Australia; TAS, Tasmania; ACT, Australian Capital Territory; NT, Northern Territory.
[a]Year of MSAC public funding decision—2005 decision to fund on interim basis, 2011 decision to discontinue funding.

continued use of an ICD is still pertinent for the patient whose clinical profile has improved, or for a patient who has never had an arrhythmia in the many years after ICD implantation. How should the evolving life goals of the patient be considered at the time of generator replacement? For some patients, there may come a time when a sudden death might be acceptable or even desirable in comparison to other end-of-life trajectories (14).

The INESSS mandate from the Ministry of Health was to examine this ethical and human evidence gap and to assess the appropriateness and clinical relevance of replacement of ICD generators, particularly for primary prevention patients. Since it was clear that patient engagement was of paramount importance for this mandate, it was decided that in addition to our standard process of collaborating with a committee of clinical experts, we would collaborate with a committee of patients with ICDs. One goal of working with a patient committee was to mobilize their experiential knowledge of living with heart failure and arrhythmia, of quality of life with an ICD and of the decision-making process. A second goal was to produce recommendations that were relevant, acceptable, and applicable to them. To achieve these goals, we collaborated with our patient committee to establish the evaluation questions and to discuss and contextualize the scientific literature prior to development of the recommendations.

The impact of patient engagement was immediately evident when establishing the research questions. While our traditional methods led to research questions concerning clinical criteria and results, with the patients, these questions transformed to become: What is the patient experience of living with an ICD and of the decision process at the time of ICD replacement? Our research questions concerning organization of care transformed into questions concerning best practices to achieve informed choice at the time of implantation, replacement or deactivation of an ICD and to improve the care pathway for Québec ICD patients (14;15).

The impact of patient engagement was also evident during the literature review. When preliminary results were discussed, the patients were able to confirm some of our proposed conclusions but also identified gaps concerning topics that were important to them. For example, in response to their comments we conducted an additional literature search on the experiences of family members.

Proposed recommendations were sent out by email to both the patient committee and clinical expert committee for voting and comments. The feedback from both groups was then shared anonymously with both committees during a second round of deliberation and revision. However, to finalize recommendations relating specifically to shared decision making, we held an in-person meeting involving both committees and our evaluation team, during which a nurse-researcher presented her experiences and ongoing research in the area (16). The resulting discussions between the clinicians and patients led to important changes in the recommendations. Of the eleven recommendations in the final document, seven related either to patient quality of life, to decision making or to optimal conditions for including the patient throughout the process of replacing an ICD generator. The recommendations focused on multidisciplinary, integrated follow-up of patients and best practice for incorporating patient wishes and life objectives.

Some highlights of impact were that the patients enjoyed the scientific process of learning from the literature and from our field evaluation of ICD replacement in Québec as well as the co-construction of recommendations with the clinicians. They appreciated being recognized for their experiential knowledge. The professionals were reminded of the patients' challenges in accessing information about their medical condition and their ICD, as well as their difficulty in retaining information. They became aware of the lack of documentation in the medical charts to inform a review of evolving healthcare goals with their patients. Some memorable quotes of this experience include those from a(n):

(1) Ethicist: "Integrating the perspective of patients in the development of a health technology evaluation report is one way to allow ethics to live in this report, by giving a voice to those most directly affected by the device being evaluated."
(2) Epidemiologist: "As an epidemiologist, I deal with numbers. The patient committee brought home that each number represents a human being."

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(3) Research professional: "Working with a patient committee has made me feel that my work as a scientific researcher is more concrete and has more meaning."
(4) Physician: "The implication of patients as experts in this project has allowed INESSS to redefine the relevance of these treatments with the key persons concerned with them. The patients have permitted the integration of their unique experience of navigating the different steps in decision-making."
(5) Patient: "We are here as expert-patients, and it was really helpful to hear and talk with others, because they lived a similar experience."

In order to for this work to have a more lasting impact, INESSS worked with patients and clinicians and the Ministry to develop and diffuse tools to aid the decision-making process. In conclusion, engagement of patients added a new and energizing dynamic to our evaluation and recommendation processes. Moreover, and very importantly, this is a story of an experience that transformed the way our evaluation team thinks about the work that they do.

Story 3: Horizon-Scanning Drives Development of a National Health Genomics Policy Framework in Australia

In 2013, massively parallel sequencing, or next-generation sequencing (NGS), for clinical purposes was starting to diffuse through the Australian healthcare system in an *ad hoc* and uncoordinated manner. Australia's universal healthcare system (Medicare) did not fund genomic sequencing, be they gene panels, whole exomes, or whole genomes. This resulted in a growing inequity of access, facilitated by Australia's federated healthcare system, where the six States and two Territories—not the Federal Government—are the primary funders of the clinical genetic and genomic workforce and laboratory testing.

NGS has been used in research since the 1990s. In 2013/14, this technological advance was driving down sequencing costs, providing an opportunity for NGS uptake into clinical practice that could, hopefully, lead to faster and more accurate diagnoses. Clinicians and researchers anticipated a "tipping point" would be reached where it may be more cost effective to sequence a gene panel, a whole exome, or even a whole genome rather than target specific gene mutations, as was considered best practice in 2013/14.

NGS was becoming established in pathology laboratories and being used clinically, with limited consideration of workforce implications, patient safety and consent, practice standards and guidelines, or cost–benefit analysis. NGS uptake was driven by individual clinicians and researchers but with no collaboration or consultation with policy makers, funders, and the broader community, effectively demonstrating that the technology was outpacing policy, planning, and consideration of reimbursement pathways. At the same time, media reports and community expectations were fueling patient demand for access to genomic sequencing. Furthermore, some jurisdictions were allocating funding for targeted genomic sequencing (typically exomes), but not all jurisdictions had the capability or capacity to do this, further driving inequity of access for patients nationally.

State and Territory health department officers formally requested HealthPACT, Australia's national horizon-scanning agency, to undertake a horizon-scanning review of NGS to inform what, if any, actions policy makers and funders should take regarding this disruptive technology.

HealthPACT examined the published and emerging literature in regard to the safety and effectiveness of NGS technology using a modified horizon-scanning methodology. This allowed identification of local issues expected to arise with the introduction of NGS into Australian and New Zealand clinical practice. The identified issues were to be considered by each of the Federal and eight State and Territory Governments regarding their respective level of support and the appropriate implementation, diffusion, and reimbursement of NGS into national and local healthcare systems. Because Australia is a federation, the horizon-scanning report and its recommendations needed to consider the impact of NGS technology, since the national and state health departments have different responsibilities for, and fund different parts of, the health system in Australia.

HealthPACT's horizon scan identified issues of pressing concern that included:

(1) meeting future workforce requirements (especially bioinformatics and genetic counseling);
(2) improving education, training, and literacy of the clinical workforce and the general public;
(3) infrastructure (investment in appropriate technology, data storage, and data processing); and
(4) ethical, legal, and social implications of introducing NGS into mainstream medicine.

Rather than the eight Federal, State and Territory Governments grappling alone with these issues, HealthPACT recommended establishing a time-limited national working group to consider the broader introduction of NGS into routine clinical practice.

HealthPACT considered that a national coordinated approach to policy development across jurisdictional boundaries was urgently needed to ensure appropriate adoption of NGS into clinical practice, with consideration given to:

(1) commissioning an economic study to evaluate and quantify the costs, benefits and risks of investing in genomic medicine;
(2) education and training, including workforce planning and genomic literacy;
(3) infrastructure (hardware, software, and data acquisition and storage);
(4) practice standards and guidelines; and
(5) translational research to develop bioinformatics pipelines and facilitate data sharing.

The recommendations of HealthPACT's horizon-scanning report were considered significant enough to warrant HealthPACT escalating the report to the national committee of Federal, State and Territory Government chief executives for actioning. This national committee endorsed the HealthPACT advice and requested development of a national framework to address those issues raised by HealthPACT, as well as providing a mechanism for collaboration by clinicians, researchers, and community.

Following a national consultation process led by representatives of each of the Federal, State and Territory Governments, the *National Health Genomics Policy Framework* (the Framework) identified five strategic priorities to support the integration of genomics into healthcare for Australians:

(1) Person-centered approach: to deliver high-quality care for people through a person-centered approach to genomics.
(2) Workforce: to build a skilled workforce that is literate in genomics.

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(3) Financing: to ensure sustainable and strategic investment in cost-effective genomics.
(4) Services: to maximize quality, safety and clinical utility of genomics in healthcare.
(5) Data: to ensure responsible collection, storage, use, and management of genomic data.

This Framework (17;18) agrees a high-level national approach to policy, regulatory, and investment decision making for genomics is essential. It is a cross-jurisdictional plan that provides for better coordination of genomic activities across Australia to harness the benefits of genomics in an efficient, effective, ethical, and equitable way, for the benefit of all Australians, including containment of costs in Australia's health system. All health ministers across Australia, from the Commonwealth, six State and two Territory Governments, each endorsed the Framework in late 2017. An Implementation Plan was subsequently developed and approved by all health ministers in late 2018 (19).

This Framework has so far resulted in improved consultation and information sharing between jurisdictions and their separately funded genomic sequencing initiatives and Medicare funding (ensuring universal access) for targeted clinical genomic sequencing, predicated on health technology assessment of safety, clinical, and cost-effectiveness.

The impact of the HealthPACT report was observed in the (i) development of a national clinical consent process and form that facilitates access to genomic sequencing for clinical and research/clinical trials; (ii) development of a national data/information management platform (no mean feat in a federation); and (iii) new Commonwealth Government commitment of AUD 500 million (USD 366 million) over 10 years to support ongoing research into genomics, including a project investigating the role of genomic sequencing in pre-conception carrier screening of more than 1,000 rare disease mutations to inform family planning decisions.

Story 4: Incorporation of New Drugs to the National Drugs Formulary in Uruguay: the Case of Lenalidomide

The main objective of health technology assessment in Uruguay is to inform the Minister of Health to decide coverage of or disinvestment from health technologies by the National Health System (NHS). The Uruguayan Agency of HTA is in charge of assessing any drug, medical device and procedure that is incorporated to the National Formulary and covered by NHS for the whole population of the country.

In 2012, an HTA report was developed assessing the efficacy and safety of Lenalidomide for the treatment of multiple myeloma in second line. The report concluded that Lenalidomide was effective and safe for the treatment of myeloma and we undertook a cost-utility analysis.

Multiple myeloma first-line treatment with Bortezomib was covered by the National Fund of Resources (NFR is in charge of financing high technology for the NHS), but no second-line treatment was covered. The final conclusion of the HTA was that even though the drug was safe and effective, the price was too high and QUALYs were far above from the threshold of willingness-to-pay.

This decision had an important impact in the media and the Minister of Health was interpellated by Parliament because of the refusal to include Lenalidomide and three other high-cost drugs that were in the same situation: Cetuximab for metastatic colorectal cancer, Sorafenib for hepatocellular carcinoma, and Bevacizumab for lung cancer. In the case of Lenalidomide, the only negative output was economic evaluation and the drug was strongly being demanded by the population and academia.

Judicialization is understood as an influence of the "Judiciary over political decisions, taking on roles that should be exercise by the Executive and the Legislative" (20). Judicialization of the right to health has increased rapidly mainly in Latin America where national constitutions of several countries give citizens guaranteed rights, including health writ-for-protection litigation (21).

Since 2014, Lenalidomide has become one of the drugs with a higher number of writ-for-protection litigation cases and the strategy the agency uses to face this problem, such as the diffusion of HTA reports or training of lawyers in HTA, failed in this case: the number of writs-of-protection increased during 2015–17. This increase is part of the growing judicialization of health, described elsewhere (22).

In this context, the government conducted negotiations with the pharmaceutical industry to reduce the drug price. The reduction of price required taking into account the recommendation of the HTA report, and it was determined that the final price of the drug should be 30 percent of the initial price provided in the request for incorporation to the National Drug Formulary. Negotiation of the price was very difficult because the government never accepted a different reduction of price from that recommended in the report.

During 2017, several drugs with the same active ingredient from other pharmaceutical companies were registered at a much lower price. Lenalidomide was finally incorporated to the National Drug Formulary in second line in March 2018 as the drug complied with the requirements.

As the drug is provided since then by the NFR, its provision is guaranteed to the entire population of the country covered by the NHS.

We are continually redefining what we consider to be the impact of HTA and, until this case, the main issues we took into account about impact were:

(1) the coincidence between the recommendations of our reports and the decisions taken by policy makers;
(2) the contribution to face judicialization of health, which is a growing problem in our country;
(3) the acceptance of the conclusions of our reports by health professionals in general, including academia and professional medical associations; and
(4) the satisfaction of the group of patients that required this drug.

A new dimension that we had not considered until this case is the reduction of price as a result of a recommendation of an HTA report and the fact to take this output as an impact indicator. Economic evaluation demands highly trained professionals and a lot of time in general and, particularly in Uruguay, we have scare resources in this field. However, it has to be considered a very powerful tool at the time of negotiation of prices.

Discussion

The four impact stories provide insights into the different activities of HTA agencies and their interface with health system decision makers and other stakeholders. The stories present a range of

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methods used to measure impact including document review; claims analysis and review of reimbursement status; citation analysis; qualitative evaluation of stakeholders' views; and review of media response. HTA agency staff observed changes in government activities and priorities based on the HTA, for example, the use of the HTA findings to support the formation of national collaborations to address the identified issues and, in other cases, their use in pricing negotiations with the industry. The stories also showed that HTA impact assessment can provide information to improve the HTA process itself, that is, the value of patient and clinician engagement in the HTA process to define the assessment question and the focus of literature reviews in a more holistic and balanced way.

Conclusion

Each of the four stories described in this article recounts situations where findings of HTA reports impacted powerfully upon health system decision making and on the actions of governments. HTA reports produced by publicly funded HTA agencies are essential components of many health systems around the globe, supporting appropriate use, pricing, reimbursement, and disinvestment of health technologies for the benefit of patient outcomes and health system sustainability. HTAs can also have a positive impact on improving consultation and information sharing between different levels of government and across stakeholder groups. The INAHTA impact-story-sharing activity is a unique and meaningful way for public HTA agencies to build trust with one another, and to share inspiration and motivation in the challenging—and rewarding—work of HTA.

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