INAHTA

INAHTA Position Statement
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Disruptive Technologies

INAHTA POSITION

The concept of disruptive technologies is highly relevant for health technology assessment (HTA) agencies and decision-making bodies, because truly disruptive technologies radically alter models of care and therefore require a thorough evaluation, including economic and organisational impact assessments.

From the perspective of health technology assessment, the status "disruptive" does not constitute a value on its own, but the attributes of a technology (e.g., cheaper, faster, simpler) may make it disruptive relative to existing standards of care.

If certain predictors (see below) lead to the conclusion that a technology has the potential to become disruptive, a comprehensive assessment, including organisational and economic impact should be undertaken. In addition, the evolution of the technology across its life-cycle should be monitored, including the analysis of post-market and real-world evidence (RWE) data.

HTA should consider the principles of how technologies become disruptive in order to inform decision-makers about possible ways to stimulate uptake of a highly efficacious innovation that is clinically non-inferior (or marginally inferior) to existing (effective) technologies, but offer other advantages, e.g., less invasive or faster relative to the current standard, including facilitating pathways for market entry and reimbursement (e.g., coverage with evidence development).

SUPPORTING STATEMENTS

WHAT IT IS

According to the definition put forward by Christensen, "disruptive" describes a cheaper, simpler, more mobile technology, which may even produce results of higher quality, and which can be delivered by people with different skill sets in less specialized institutions/settings. Disruption takes place when a disruptive technology displaces an established one, causing substantial changes within the market. The Christensen group provided the only known definition on this topic so far.

The concept of disruptive innovation has been derived from observations and analysis of developments in areas outside of health care and has only recently been applied to health care. Essentially, a new business model is introduced that is enabled by a new technology and sometimes replaces competitors' products. Market uptake is the primary "outcome" measure of disruption. Although this measure, among others, is not precisely defined, it can be assumed that a substantial shift in market share if not an outright replacement impacts a company's profit margin and policies. Depending on the technology, disruption can take place in different settings and timeframes, e.g., within hospitals or in community care. There are not many examples of truly disruptive technologies in health care.

For each health technology and related medical problem, different aspects could be relevant to assess potential disruptiveness. Christensen proposed a classification of medical problems into three categories: acute conditions, chronic diseases, and nonstandard complex medical problems. For the diagnosis and therapy of acute conditions (e.g., rapid antigen testing for streptococcal pharyngitis), disruptiveness could be associated with the involvement of differently skilled and equipped providers. For chronic disease, disruptiveness could be associated with a different management model (e.g., care management through nurses and remote monitoring in patients with heart failure). For nonstandard complex medical problems, disruptiveness is less likely. However, if the Covid-19 pandemic, for example, is seen as a nonstandard complex

medical problem, potential disruptiveness has emerged both for an accelerated development and delivery management model of vaccines based on mRNA and of health care provision patterns due to the pervasive role played by telemedicine. Both are candidates to become models for enabling disruption in health care in the future.

WHAT IT ISN'T

The popular use of the term "disruptive" is often disconnected from the definition of disruptive technology. Quite often, technical innovations or new drugs that provide additional value as compared to the current standard are described as disruptive, when they could be more accurately described as sustaining innovations. "Sustaining" innovations merely improve existing technologies without changing existing business models. In that sense, most innovations within medicine can be regarded as sustaining innovations. These innovations add new options and occasionally replace the current standard at least in part, or open up new opportunities for new patient groups. Simple replacement of an existing standard in healthcare by a new one is not sufficient to constitute a disruptive technology.

WHAT IS RELEVANT FROM AN HTA PERSPECTIVE

Identification of disruptive technologies is often complicated by the fact that disruptiveness can often only be judged in retrospect, after markets have changed. The number of truly disruptive technologies is limited, as can be shown by a systematic literature search. Percutaneous coronary interventions, transcatheter aortic valve implantation, oral direct acting antiviral medicines for hepatitis C, retail clinics, or acute stroke care are examples for which some evidence suggests they have disrupted markets.

Some predictors can be derived from the literature and available case studies, e.g., the potentially disruptive technology:

- is less invasive, ensures faster recovery or earlier discharge,
- is more mobile, offers point-of-care provision, is more convenient,
- is more accessible for patients at lower cost,
- introduces a highly standardized diagnosis or treatment scenario,
- facilitates the management of chronic conditions with a more autonomous role for patients,
- changes the clinical pathway or organization of care,
- offers lower cost per service or product,
- can be operated by less equipped facilities,
- involves other health professionals / providers with different, often less specialized, skills.

There is often limited data on efficacy and safety on healthcare innovations when they enter the market. Real world data (RWD) could therefore play an important role in addressing these uncertainties. Indeed, during the **life-cycle** of a technology, the status of a technology may change several times as treatment pathways are iteratively developed and adapted according to accumulating evidence. The assessment of a technology per se does not always allow the prediction of its disruptive potential. To become disruptive, a business model that enables or facilitates market uptake must be developed. Regulatory processes and standards of quality could impact the market uptake of a potential disruptive innovation.

Technology assessors should flag an innovation as being potentially disruptive if it is considered to be an innovation that delivers considerable added value in health care by for example, opening a completely new clinical pathway. All HTA dimensions should be considered when planning an assessment in these situations. **Economic and organizational impacts** are likely to be of particular importance. Consequently, more comprehensive as opposed to rapid HTA approaches are likely to be required to assess truly disruptive technologies, because it would include various dimensions of evidence such as clinical, economic and patient preference and values. The evolution of the impact of technology along its life-cycle should be monitored. Timing of an assessment and the role of HTA in different phases of the life-cycle are important considerations. The role of post-market data collection and RWE is particularly important for determining whether a health technology has been disruptive or not, and whether the net value of any disruption is positive.

Since the Christensen concept describes a different **business model** as a crucial part of a disruptive innovation, health economic analyses should consider potential resource impact, pricing and reimbursement scenarios in cases of a potentially disruptive innovation that would bring significant advantages for health systems and patients. Such scenarios may also

include innovations that are clinically non-inferior (or only marginally inferior) to existing (effective) technologies but offer other advantages, e.g., less invasive, faster, easier to implement or to access.

When a technology appears to become disruptive from the perspective of technology assessment, i.e., it is more valuable than the existing technologies considering effects and costs, a business model or other regulatory mechanisms should enable its rapid diffusion. HTA should **inform decision-makers** about possible ways to stimulate adoption (and possibly delisting inferior technologies). One option is coverage with evidence development or another facilitated pathway for market entry (e.g., special reimbursement for a given period or incentives to offer the technology). In this case, the costs of those adoption interventions should be explicitly included in the economic analysis of the technology.

WHY INAHTA HAS ISSUED THIS POSITION STATEMENT

The term "disruptive technology" has become a buzzword in recent years, yet few examples from healthcare can be identified that are truly disruptive and satisfy the Christensen definition. INAHTA agency members expressed interest in the application of the disruptive technology concept within healthcare settings, indicators that a health technology might be or become disruptive, and what changes, if any, are required to existing HTA methods to assess disruptive technologies.

Review cycle for statement:

- This statement is to be reviewed by the INAHTA Board (or a task group established by the Board for this purpose) at the 1-year point since the release date.
- After the year 1 review, the statement is to be reviewed every three years by the Board (or task group designated by the Board).
- The objective of the review is to assess the value of the statement relative to the INAHTA strategic plan and any issues that have been raised by members in the use of the statement.

INAHTA position statements are agreed to by a minimum threshold of 70% of INAHTA members.

For more information about the INAHTA Position Statement Process, contact the INAHTA Secretariat at INAHTA@ihe.ca.