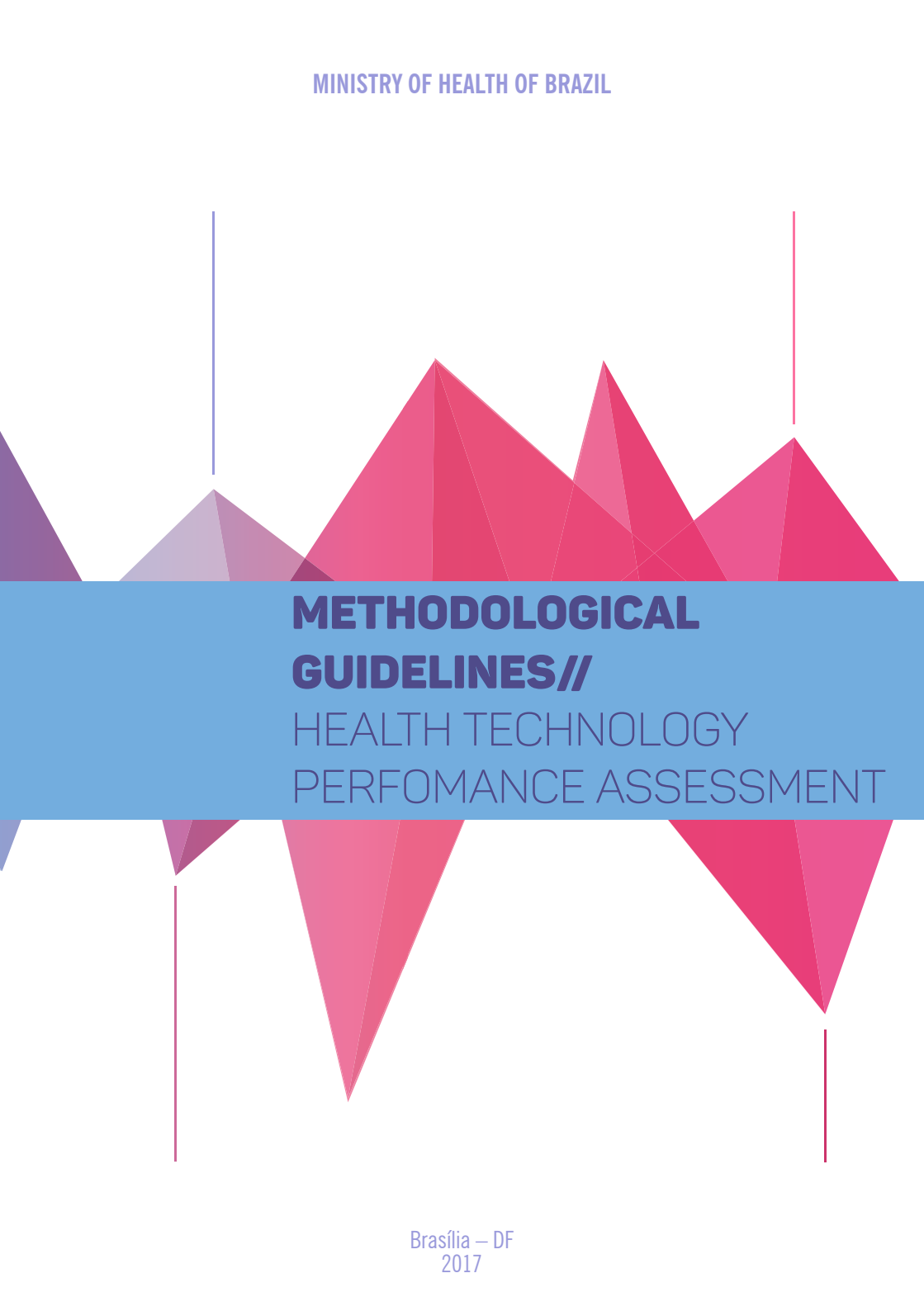


MINISTRY OF HEALTH OF BRAZIL



**METHODOLOGICAL
GUIDELINES//**

HEALTH TECHNOLOGY
PERFORMANCE ASSESSMENT

Brasília – DF
2017

MINISTRY OF HEALTH OF BRAZIL
Secretary of Science, Technology and Strategic Inputs
Department of Management and Incorporation of Health Technology

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PREFACE

In recent years, significant advances have been seen in the health care sector with the discovery of new technologies. These advances have been followed by an increase in the cost of treatments, which placed health care expenses among the highest spending values of public systems and families worldwide. Despite the undeniable scientific advances, many health care technologies released on the international market do not show the expected benefits and in some situations even introduce iatrogenic effects.

To address the need to measure, evaluate and select products, devices and procedures worth being adopted by health systems, scientific methods were developed to assist the process of incorporation of health technologies. A set of standardized analyzes of efficacy, safety, effectiveness, efficiency and costs have contributed in a significant way to the incorporation process for health technology. More often than not, several post-incorporation studies published in the literature show disturbing results demonstrating that many of these technologies, when used in real life settings, in fact do not have the benefits reported by manufacturers. For this reason, many challenges still permeate the underexplored process of performance assessment for incorporated technologies and the consequent need for a process of disinvestment and reinvestment in health care.

The performance assessment of health care technologies refers to the continuous evaluation of incorporated technologies aiming to analyze the results achieved in the context of the health system and the comparison with the agreed outcomes between the parties in the process of the incorporation. If the results in real life are below the expected, disinvestment and reinvestment processes should be started so that the available resources are best used.

The process of disinvestment and reinvestment in health care technologies can be understood as the interruption or reduction of investment in incorporated technologies that, despite additional costs, produce little or no health gain. Consequently, it aims to maximize health gain and benefits for patients with the available financial resources.

Therefore, if these evidences are confirmed, that given technology should no longer be financed by the health care system. The resources normally used for its provision may be allocated to other technologies that have real benefits for the population, or even for certain subgroups that could have greater benefits in terms of public health.

To develop this guideline a review of international literature was performed, with searches for published studies on the subject and research in websites of internationally recognized assessment agencies for health technologies. Collaborators were interviewed about the subject and, at the end of the interview, were asked to indicate other participants to be consulted – a process described in the literature as “snowball”. After this step, a draft was prepared and spread among the collaborators for contributions. Then, the revised version of this document was submitted to an international panel of experts from the academia, government and industry. In that panel, cases of health technology

performance assessments were discussed both in the field of primary care (diabetes) and in the field of less prevalent and complex diseases (multiple sclerosis). Following the case studies, the guideline was debated and revised, being presented here in its final version.

The performance assessment is in line with Article 196 of the Brazilian Federal Constitution, which states that the State must guarantee, through public policies, the highest health benefit to citizens. In this sense, the performance assessment aims to provide citizens with access to technologies that have actually proven their real-life safety and effectiveness despite the initial scientific evidence produced by the manufacturer.

This document presents guidelines and priorities to support managers, manufacturers and researchers in the preparation of the performance assessment of incorporated technologies, and the development of recommendations to the process of disinvestment and reinvestment. These guidelines aim to contribute to a better understanding on the process of selection and allocation of health resources for the general society.

1 INTRODUCTION

According to the World Health Organization (WHO), health technology “refers to the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives”. In a simplified way, health technologies are those that promote health, prevent and treat diseases and rehabilitate people (WORLD HEALTH ORGANIZATION, © 2016).

The process of incorporation of new health technologies – developed and consolidated in different countries – has been used in Brazil to rationalize the increasing expenditure on health care and to select technologies that offer the greatest benefits to society. These processes help in choosing the most suitable products. As in any lucrative market, within the context of the health sector, products that have no real benefits are often launched and generally imply an increase in the cost of treatments.

The scientific advances have introduced in the current scenario an increase in the expenditure on health, while facing a limitation of available financial resources. For this reason, economy tools emphasize the need to establish an evaluation strategy to understand whether these employed resources are actually resulting in better health benefits for society. Each decision to use a resource implies sacrifice that, once used for a particular purpose, will no longer be available. These results in a fundamental concept of the economy: opportunity cost – understood as the cost of benefits not obtained by discarding one technology over another (LAPORTE, 2001). As a result, when choosing between the mutually exclusive alternatives, something is always lost. The main point that the concept of opportunity cost brings is that it is not rational to choose to lose more than gain, strongly suggesting considering the process of disinvestment and reinvestment as an optimization strategy for the use of health resources.

Disinvestment can be understood as the partial or complete delisting of a technology that has a low safety profile or unfavorable cost-effectiveness ratio from the list of technologies provided to the population. It aims to enable the reallocation of resources to other technologies with greater benefit (ELSHAUG et al., 2007; ELSHAUG et al., 2009). Furthermore, the use of the isolated term “disinvestment” can be interpreted as a reduction of the resources and consequently of the health care benefits for the population. Therefore, whenever possible, the direction and mode of economic resources allocation should be demonstrated. It is important to remember that the process of disinvestment/reinvestment is the result of real-life performance assessment of health technologies, measured after incorporation. In this context, it is expected that many of the evaluated technologies present compatible results with its maintenance in the list of products and procedures.

The use of term with less negative impact is important, since several challenges related to the reassessment of incorporated technologies and the process of disinvestment and reinvestment are found, including:

- **The need for greater theoretical basis** when compared to the process of incorporation of technologies. In case of interruption or modification in the provision of services, managers, health

care professionals and patients should be adequately informed about the scientific evidence used, the reasons for the discontinuation, the results and the benefits for society. The quality, accuracy and validity of the technical-scientific studies used to make decisions must be robust. It is not expected that the process of disinvestment and reinvestment be initiated or encouraged by the manufacturers themselves, so the production of such studies is more likely to be funded by the health system. An alternative is the inclusion of clauses concerning the costs of the performance assessment in the agreement of incorporation.

- **Social and political difficulty of removing a technology from clinical practice:** This difficulty occurs especially when there is no replacement by another technology that is considered “superior”. One way to minimize this challenge is to clearly establish the difference between simple resource savings and the intention to efficiently improve the health of the population (HENSHALL; SCHULLER; MARDHANI-BAYNE, 2012) and / or minimize the health risks resulting from their use.
- **Disinvestment can lead to the use of other less appropriate technologies:** It is important to consider whether the removal of a sub-optimal technology will cause improper or wrongful replacement by an even more inadequate one. For example, after ceasing the prescription of insomnia medicine, an increase in the prescription of potentially more dangerous sedative medicines, such as antipsychotics and antidepressants, may be observed. Unintentional consequences of disinvestment and reinvestment processes should be taken into account.
- **Waste of resources already invested:** For health systems that purchase, stock and provide health technologies, such as pharmaceuticals and medical devices, it is not enough just to identify and stop buying obsolete technologies. Managers should consider the need of consumption of existing stocks in the health system, as well as reverse logistics issues that may present themselves as complex, requiring joint efforts of managers at different levels and of technology producers.

THE SOCIAL ACTORS INVOLVED

For the process of disinvestment and reinvestment to occur, it takes the active involvement of diverse social actors at all stages of the process. Performance evaluations and decisions should be transparent and the implementation should include the transfer of knowledge to the actors (HENSHALL; SCHULLER; MARDHANI-BAYNE, 2012). Users/consumers of health systems should be encouraged to recognize their role as financiers of technologies, not only those that directly impact them, but also of all others. It is important that society understands the strategies adopted for the sustainability of the health system.

CLINICAL EFFECTIVENESS – REAL WORLD EVIDENCE

The continuous assessment of clinical effectiveness of available technologies is necessary. The field of epidemiology provides methods that contribute to clarify the clinical effectiveness, the so-called

real world utilization studies. These actions require planning and often will require the adoption of new regulatory and organizational frameworks to enable and facilitate the preparation of these studies. Such studies include the monitoring of clinical effectiveness with patients and prescribers to measure the results of the technology to be compared to the results of the clinical trials which formed the basis for the initial decision of incorporation.

2 FLOW DIAGRAM OF HEALTH TECHNOLOGY PERFORMANCE ASSESSMENT

The regulatory framework of the process of incorporation of new technologies should include a mechanism to allow/determine the health technology performance assessment (HTpA). The results of these studies will guide the decisions for maintaining or not the technology as established at the time of the incorporation. The process of disinvestment and reinvestment from HTpA should be established and agreed during the incorporation, as shown in Figure 1.

If the results of HTpA show need for the process of disinvestment and reinvestment, then a decision must be made regarding the choice of the most suitable modality of disinvestment. If any subgroup of patients still benefits from the technology in study, and if there is an acceptable cost-effectiveness ratio for the care of these patients, the adoption of strategies to implement restrictions to the technology use is recommended, as well as a consideration of price renegotiation with suppliers.

If, during HTpA, a new technology is found that can replace the one incorporated on the treatment of all patients or a subgroup of them, it is recommended to adopt the alternative modality of disinvestment. If, during HTpA, it is found that the decrease in the amount of technology provided for each individual patient improves outcomes or does not alter the beneficial effect, or improves the safety profile, the adoption of the retraction modality of disinvestment is recommended.

None of the modalities shown are mutually exclusive – for example, a technology can be replaced by another for one subgroup of patients, and have its access restricted to another subgroup. If any other modality of disinvestment is applicable, a decision of full delisting can be taken. Whichever the form, all disinvestment and reinvestment decisions must be followed by clinical guidelines update in order to guarantee the quality use of the health technologies and the best care.

The recommendation for maintaining (or not) the technology must be accompanied by a substantiated report that will be submitted to the health system manager responsible for the decisions of incorporation, who will make the decision to keep the technology in the current format, or to disinvest. The decision-making process should be preceded by an extensive discussion and involvement of the society. The adoption of mechanisms of public consultations at all stages is recommended. The final decision should be made public and, if the option is to disinvest, it should be indicated, whenever possible, the direction of resource reinvestment. Also, the specific aspects of the technology identified by HTpA should be informed.

Figure 2 shows a flow diagram of technologies that were incorporated before the adoption of a regulatory framework for HTpA, and for technologies not prioritized for HTpA incorporation as seen in Figure 1. In this case, the technologies to be evaluated may be selected by the health system managers, using prospection and active search, or be indicated by social actors, and especially by the academia.

The request for incorporated health technologies performance assessment made by different social actors should address previously established epidemiological and economic parameters for prioritization. After conformity analysis, valid HTpA demands will go through a prioritization analysis and, if prioritized, to the HTpA program.

HEALTH TECHNOLOGY PERFORMANCE ASSESSMENT

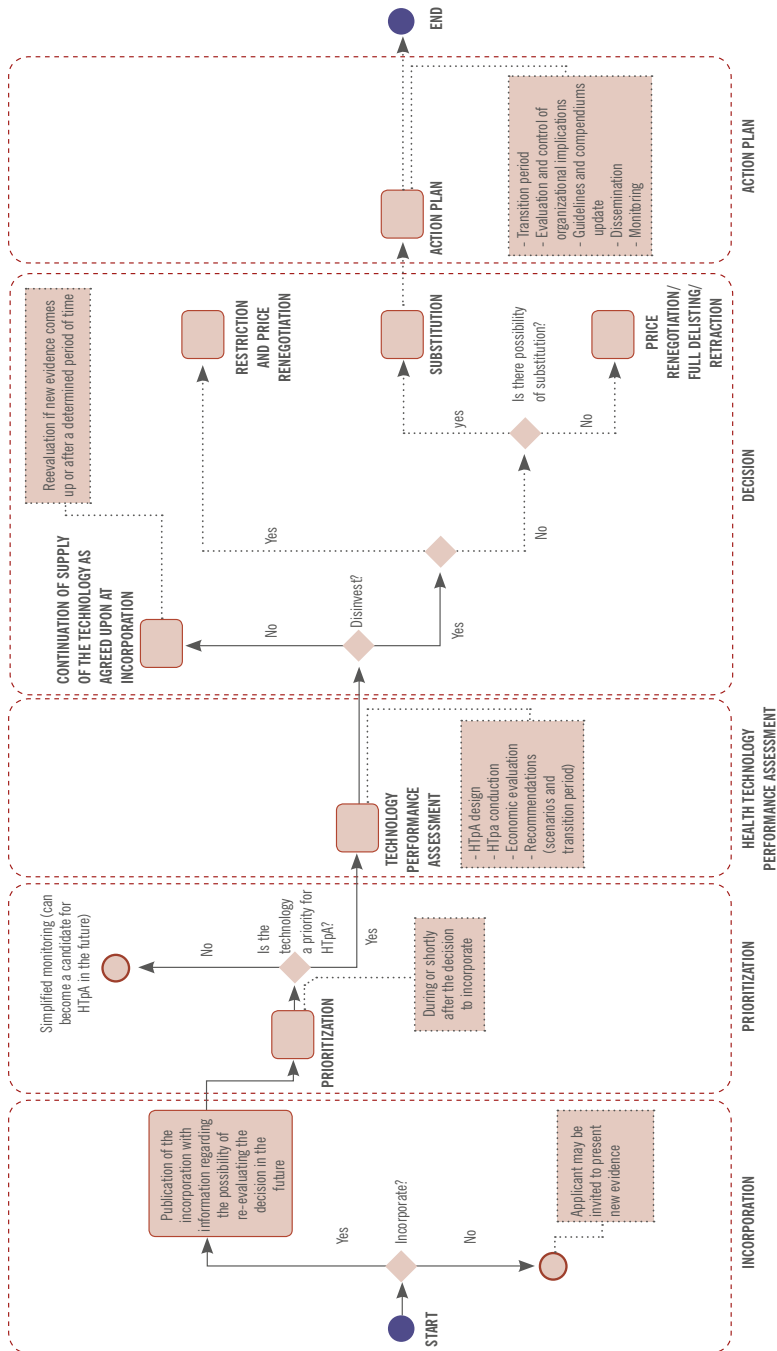


Figure 1 Stages of Health Technology performance Assessment - Regulation at entrance

Source: Self elaboration.

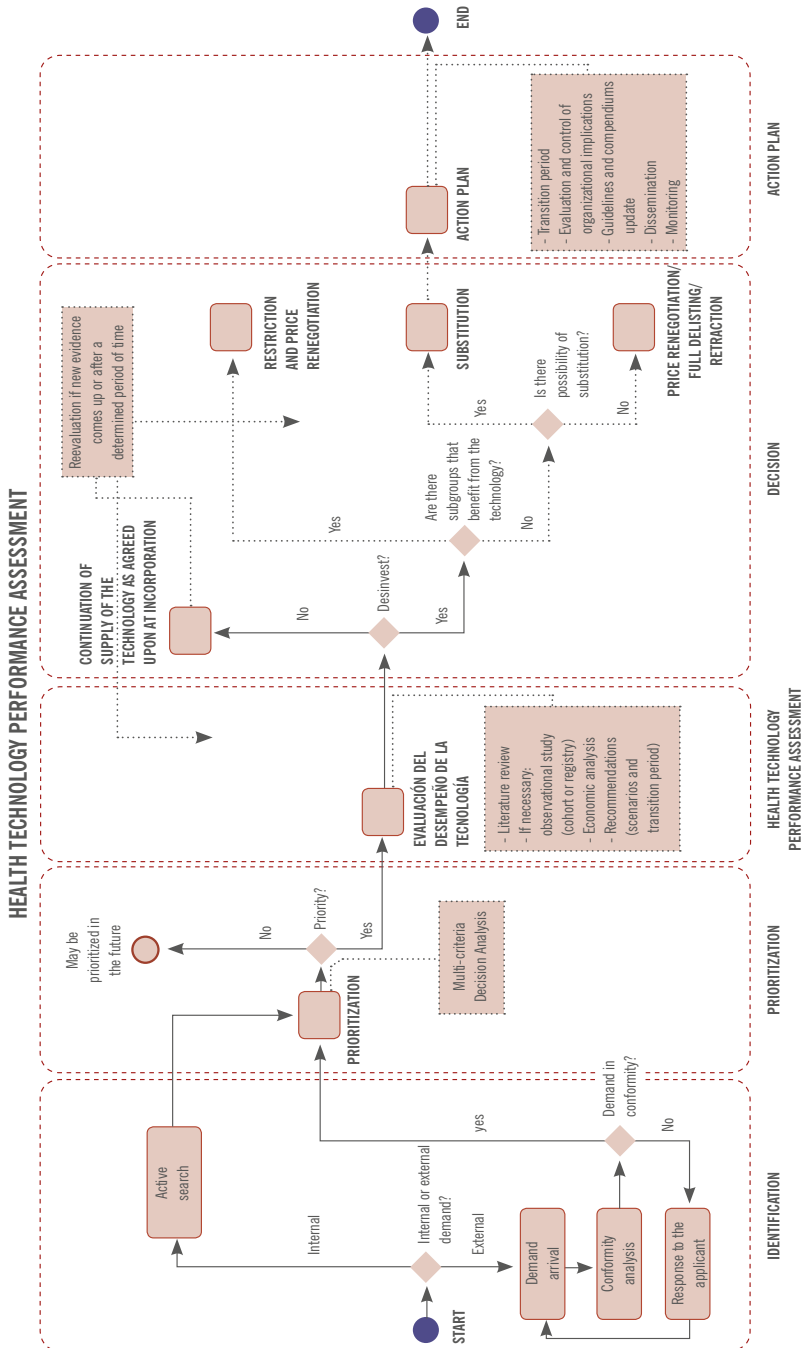


Figura 2 Pasos de la Evaluación de desempeño de Tecnologías Sanitarias - Las tecnologías incorporadas
 Source: Self elaboration.

3 MONITORING THE CLINICAL EFFECTIVENESS OF INCORPORATED TECHNOLOGIES

It is recommended to establish a program for monitoring the clinical effectiveness and the quality of use of medicine, procedures and equipment through periodical health technologies performance assessment. The planned actions begin with a prospective and active search for potential technologies for evaluation and consequent process of disinvestment and reinvestment.

Different technologies may require different methods and deadlines for clinical effectiveness assessment. Different situations such as a new antibiotic incorporated for an acute infection or a biological agent for a chronic disease will require different epidemiological methods and times of study. The use of administrative databases is recommended and can help evaluate the performance of incorporated technologies. An example of this type of study is the evaluation of survival and cost-effectiveness of cyclosporine versus tacrolimus for renal transplantation maintenance in Brazil, where real-life data show that tacrolimus has no therapeutic advantage over cyclosporine despite clinical trials presented at licensing (GUERRA JÚNIOR et al., 2010; 2015).

The outcomes of the clinical trials used for incorporation should be the main focus for real life results. Several types of studies are available and can be used in these situations to measure the clinical effectiveness with relative simplicity. It is important that the method adopted always consider data that are produced directly through the use of technology by patients and prescribers in the health system settings. The coordination and execution of real-life studies should be carried out by staff without conflicts of interest.

Patients, medical societies, academic research centers and health professional schools can be considered partners. The last two can be invited to participate in both the prospect of potential technologies and in their re-evaluation. It is fundamentally important that the participants in this process do not have conflicts of interest, such as consults/contracts with pharmaceutical companies or other private interests that may affect the technical/moral judgment of the evidence. If necessary, manufacturers can be heard during the evaluation process, as well as provide or clarify scientific evidence supported or produced by them.

It is recommended that the development and implementation of strategies promote the active involvement of diverse social actors in all stages of the HTpA and the process of disinvestment and reinvestment. Information and scientific evidence from HTpA should be publicized and all pertinent issues clarified. Users/consumers should be encouraged to take a role in the process of disinvestment and reinvestment and their participation should be highly considered. All the planned actions should foresee the assessment of effectiveness of technologies used in the health system. The adoption of a regulatory framework and organizational planning should allow and facilitate the process of disinvestment and reinvestment in technologies. These actions contribute to a better quality of use of medicines, procedures and equipment, enabling excellence in assistance to users and, at the same time, optimizing the use of health care resources.

4 THE INCORPORATED TECHNOLOGIES AND THE HEALTH TECHNOLOGIES STILL NOT INCORPORATED

By establishing the possibility of performance assessment with wide publicity at the time of incorporation, the manager allows a re-evaluation of the decision, as it already occurs in other consumer relationships, when the product is routinely evaluated to check its conformity to the information provided by the manufacturer and expectations generated by the buyer. This creates space for the process of disinvestment and reinvestment in resolution technologies. In the process of incorporation of a new technology, it is important to clarify that the HTpA study may be conducted. The results of this study may lead to a revision of the incorporation decisions, including the restriction of use by clinical guidelines, as well as of prices paid to the suppliers.

The list of technologies incorporated before the adoption of the performance assessment mechanism should be reviewed in order to select those that should be the object of prioritization for HTpA. Economic parameters such as cost of treatment and budgetary impact, as well as epidemiological indicators, such as prevalence, incidence and safety should be considered in the prioritization stage. Those technologies not prioritized for HTpA at incorporation may become priorities in the future, following the same process

4.1 Identification of potential technologies for Health Technology Performance Assessment (HTpA)

The indication for HTpA may arise from the health system management, from society or academia. Ideally, all incorporated technologies should be subject of HTpA. However, the direction of efforts for technologies with indications of poor performance could be more efficient and financially interesting. The HTpA for incorporated technologies should be considered when the technology provided by the health system is completely or partially inadequate in meeting one or more of the essential requirements for its use, as specified in detail below:

Safety

- There is unacceptable potential safety risk for users, society or the environment related to the use of technology;
- There is evidence demonstrating that the technology generates unacceptable risk-benefit concerns;
- There is evidence that new technologies get the same results, but record significantly higher levels of safety.

Effectiveness

- Absence or low evidence of efficacy and effectiveness of the technology;
- There is evidence showing inefficiency and ineffectiveness of the technology in one or more indications;
- There is evidence showing that new/other technologies, with the same results, have better cost-effectiveness ratio;

- There is evidence showing that new technologies, with the same price, record higher levels of efficacy/effectiveness.

Cost

- There is evidence demonstrating that the monetary value of the technology is not translated in the proposed benefit;
- There is evidence showing that there are other technologies that provide the same results with lower prices/ costs;
- There is no reduction of the technology price over time, being, thus, non-competitive with other cheaper technologies that guarantee the same results.

Cost- effectiveness

- There is evidence proving that a competitive technology presents a better cost-effectiveness ratio than the one that is available.

Disuse

- There is evidence showing that the technology is no longer being used by the users of the health system.

Inappropriate use

- There is evidence showing that the technology is being improperly used. For example, in excess, or when it is used by groups for which the technology is not intended to.

Logistics

- There is evidence showing that a competitive technology, with the same results, needs a simplified logistics plan, with proven lower costs, more suitable to the conditions of use.

Availability

- The unavailability of technology in the market, due to, for example, deviation of quality during the production, non-renewal of registration of marketing or the interruption of production.
- The unavailability of essential material or accessory for the proper functioning of the technology.

Acceptability

- There is evidence showing that the technology produces important discomfort/pain, undesirable side effect that causes the interruption of treatment;
- There is evidence showing that the technology produces negative repercussions because it is considered “invasive”;
- There is evidence showing that the technology leads to poor quality of life;
- There is evidence showing that the technology records relevant levels of nonadherence.

Adequacy

- There is evidence showing that the technology is considered by health professionals as not relevant for clinical practice.

Contraindications

- There is evidence showing that after the incorporation, the technology has a relevant contraindication that endangers or limits the use by patients in clinical practice.

The identification of a technology that is a candidate for HTpA may happen during the process of incorporation of another technology. In the cost-effectiveness analysis, if the new technology is dominant to the already incorporated one, this may be indicated to the prioritization stage.

The lack of an alternative therapeutic can become a barrier in the process of disinvestment and reinvestment, with exceptions in cases of relevant security problems or a significant negative balance between benefits and risks.

4.1.1 The horizon scanning for emerging technologies

The horizon scanning for emerging technologies contributes to optimize the performance assessment of incorporated technologies. This is because it would avoid focusing efforts and time in the assessment of a technology that could be naturally replaced by another soon to be launched in a short to medium period of time. The identification of candidate technologies, still in phase of clinical trial, can facilitate the decision to prioritize for HTpA or not. That is, would it be worth assessing for disinvestment, in the case of a technology that would soon be replaced by another one considered to be better? The decision, in this case, could be postponed, in order to assess if the new technologies in development will in fact replace the one on the list in the near future.

4.1.2 Prospection/active search

In a scenario of limited resources alongside a growing need for investment in new technologies, special attention should be given to technologies responsible for higher spending. Research tools, such as methods to analyze and gather data on drug use, the studies of indicators, and a technology use review, among others, are suggested by the World Health Organization and can be used to identify candidate technologies for the performance assessment and for the process of disinvestment and reinvestment. It is important to evaluate the unnecessary use of health technologies, because when misused, they end up wasting resources that could be used to benefit the patients themselves (WORLD HEALTH ORGANIZATION, 2003).

Active searching or prospecting of technologies for HTpA should be part of the evaluation process of technologies incorporated by health systems. The adoption of a Permanent Program of Performance Assessment of Technologies should facilitate the periodic review of technologies provided at all levels of care.

The use of clinical protocols and their periodic updates are relevant tools to rationalize the use of technologies and related costs. In practical terms, the evaluation for the incorporation of a new technology could lead to the identification of candidates for HTpA. The active search for reports of contraindications and restrictions of use and for safety alerts from regulatory agencies, international

organizations and health care technology assessment institutes also helps with the identification of technologies for HTpA.

The adoption of a strategy of search and revision of all devices is recommended, with procedures and medicines used by a medical specialty, in particular those indicated by the clinical guidelines and / or therapeutic protocols of each disease. The re-evaluation of all items, identified in the flow diagram of treatments, aims at updating guidelines and protocols and at improving clinical outcomes for patients. These strategies contribute to avoid the unmanaged replacement of a technology, randomly selected and disinvested, by another technology which may not be the optimal choice in clinical practice. The medical societies and patient groups can be collaborators to the identification of potential technologies for the evaluation of clinical effectiveness.

Non-drug technologies, often included in available procedures, can be more difficult to identify during the review of the list of incorporated technologies. This problem can be overcome by systematic review of the literature at fixed intervals. Elshaug et al. (2012) used specific terms combined in with searches in electronic databases to identify non-drug technologies candidates for disinvestment (Chart 1). To the suggested terms others must be added, that produce more specific results, such as the MeSH terms of the health care field in focus (e.g., cardiology, oncology, etc.).

Chart 1 Bibliographic search strategies for monitoring non-drug technologies candidates for the process of HTpA

Item	Terms
Safety	(unsaf*) OR (danger*) OR (adverse event) OR (poor outcome) OR (low quality) OR (harm*) OR (containdicat*)
OR	
Effectiveness	(ineffect*) OR (supersede*) OR (irrelevant*) OR (outdated) OR (new evidence) OR (overuse*) OR (unproven) OR (inappropriate*) OR (equivoc*) OR (uncertain*) OR (obsolete) OR (inferiority) OR (superiority)
OR	
Political solutions	(disinvest*) OR (coverage with evidence development) OR (CED) OR (access with evidence development) OR (AED) OR (access with evidence generation) OR (reallocat*) OR (resource release) OR (reinvest*)
OR	
Pharmaceutical exclusion	(drug therapy [mh]) OR (drug industry [mh]) OR (pharmaceutical services [mh]) OR (pharmaceutical preparations [mh]) OR (pharmacogenetics [mh]) OR (pharmacoepidemiology [mh]) OR (technology, pharmaceutical [mh])
* : Truncation character; [mh]: Medical subject heading	

Source: Self elaboration.

4.1.3 External demands

The demands for HTpA can be requested by any social actor – citizens, health care professionals, associations, industries, among others. To start the process, the applicant must present documentation containing the following information about the candidate technology:

- Name of technology using the international common denomination;
- Therapeutic Indication for which the process of disinvestment and reinvestment is proposed;
- Reason(s) that justified the HTpA in accordance with the essential requirements presented in the section “Identification of Potential Technologies for Health Technology Performance Assessment (HTpA)” and supporting evidence (a report or article)
- Information needed for prioritization;
- Proposed modality of disinvestment (renegotiation to reduce price; full delisting; restriction; retraction; or substitution);
- For the substitution modality, specific information about the substitute technology may be required.
- Suggestion for reallocation of resources in the case of disinvestment and reinvestment process.

Several countries have used initiatives such as Choosing Wisely® (NPS, Australia) to allow consumers and physicians involved in clinical research to identify and nominate low-value technologies in health care. These can become candidates for the performance evaluation of health technologies. As they are “bottom-up” initiatives, they have the potential to avoid the stigma of “loss of rights” that can follow the process of disinvestment and reinvestment. The electronic forms and partnerships with professional organizations and patient groups are fundamental to the success of this type of activity.

4.1.4 Conformity analysis

The demands for the process of HTpA from social actors must be submitted to a conformity analysis to verify that all required documents are present. At this stage, a merit assessment can be undertaken, and the demand can be judged as valid or invalid, according to the following criteria:

- The technology is already in process of HTpA;
- The technology is not provided by the health system;
- The documentation does not address the requirements for the process of evaluation.

4.2 Prioritization

The prioritization during or right after the incorporation may consider the following suggested aspects: budgetary impact; unitary price; time since licensing (safety profile assessment); uncertainty of therapeutic value; therapeutic innovation (new therapeutic class, a treatment considered groundbreaking). Technologies not prioritized at incorporation can be identified internally or by external demand in the future and forwarded to prioritization.

When different technologies are identified by active search and external demand, and there is no possibility to analyze them concurrently, it may be necessary to consider their priority to HTpA. In such cases it is recommended to use “Multicriteria Decision Analysis” using Value Measurement Models (using the weighted sum). In this method, the criteria and respective weights are established. The weights must reflect the importance of each criterion for decision making (DEPARTMENT FOR COMMUNITIES AND LOCAL GOVERNMENT, 2009; THOKALA; DUENAS, 2012).

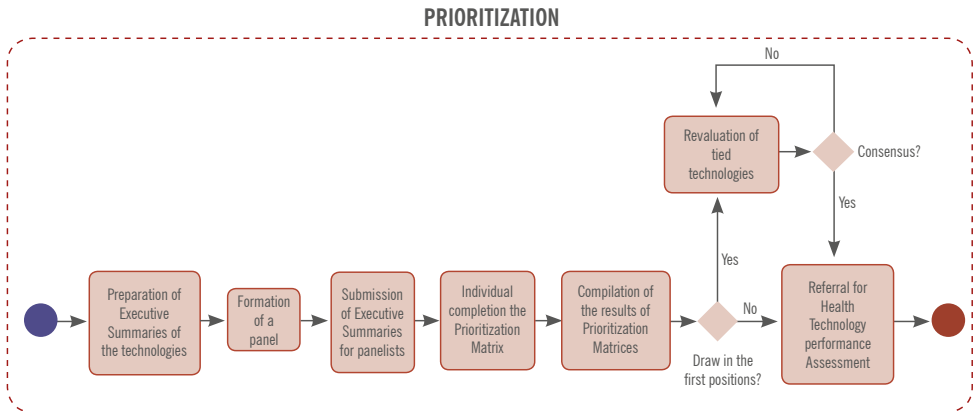
For the evaluation of the continuity of technologies in the list, some minimum criteria adapted from those proposed by Elshaug et al. (2009) for HTpA, and from the criteria used by the Canadian Agency for Drugs and Technologies in Health (CADTH) for prioritizing technologies for incorporation (HUSEREAU; BOUCHER; NOORANI, 2010) must be met. Different criteria may be set according to the type of technology, e.g. medicine, devices, surgical techniques, etc., or groups of diseases.

- Safety issue** { Among the identified technologies, the ones related to health risks should be prioritized;
- Cost of service** { High cost per procedure, high cost due to the volume, or an aggregate measure of both;
- Probable impacts** {

 - Related to health care: eg., gross estimate of quality-adjusted year of life;
 - Related to costs: eg., gross estimated of savings per patient; release of additional resources, etc;
 - Overall assessment of the maintenance of equity in care, if the finances of health care technology are modified (eg., access for subgroups of patients);
- Cost-effective alternative** { Priority should be given to technologies for which there are cheaper alternatives with equivalent or better results;
- Burden of disease** { Conditions associated with low disability or morbidity or low mortality rates (excluding orphan diseases) can influence the prioritization of different health conditions with high disability / morbidity or mortality. Low burden conditions may reduce the potential for dispute; high burden diseases can represent a greater scope for reinvestment / reallocation of resources;
- Sufficient evidence available for decision** { Rigorous assessment requires robust evidence. Typically the evidence is not 100% conclusive, but they must be suitable to be useful in decision making;
- Possibility to generate evidence for decision-making** { Time and budget possibility of conducting a study to support decision making when there is little evidence available;
- Futility** { An intervention that probably does not result in “significant survival” or benefit can be prioritized;
- Possible political impact** { Interventions in areas where there is political engagement should be carefully evaluated, because this can be considered of more or less priority depending on the political moment;
- Rate of release of new technologies** { Technologies used for diseases that are the focus of scientific and industrial interest should be prioritized. New technologies are often released in the market (greater possibility of replacement technology).

The steps to be followed in the process of prioritization of demands are shown in Figure 3 and explained in detail below:

Figura 3 Periodization process of technologies for Health Technology performance Assessment (HTpA)



Source: Self elaboration.

Step 1: Preparation of an executive summary, previously structured, for each of the demands, so that it is feasible to compare the main features. This summary should emphasize absolute numbers that allow comparing the features at the same level of importance and use the same scale of measure. Strategic indicators must be included, e.g.: burden of disease; level of complexity of care, financial values and the population covered, among others.

Step 2: Formation of an expert panel for the evaluation of the demands. It is advisable to collect declarations of conflict of interest from all members.

Step 3: Send the panelists the executive summaries of technologies under consideration and the prioritization matrix.

Step 4: Analysis of the findings with the individual filling under the prioritization matrix. Each participant assigns a score from 1 to 5 for the technologies under consideration. At this stage, technologies are compared to each other with respect to each criterion, and there may be a tie. When there are subcriteria these can be translated into numbers, i.e. 5 is equivalent to “very serious” (safety issue), 1 to “none” (safety issue) (Chart 2).

Chart 2 Example of prioritization for health technology performance assessment (HTpA) in health systems

Technologies	Criteria							
	Safety Issue	Costs	Probable Impacts	Alternatives	Burden of disease	Sufficient evidence	Possibility of generating evidence	Futility
Technology A	1-5	1-5	1-5	1-5	1-5	1-5	1-5	1-5
Technology B	1-5	1-5	1-5	1-5	1-5	1-5	1-5	1-5

Technology Z	1-5	1-5	1-5	1-5	1-5	1-5	1-5	1-5

Source: Self elaboration.

After completing the matrix, the final score is given by:

$$\text{Final Score} = W_1 \times S_1 + W_2 \times S_2 + W_3 \times S_3 + W_A \times S_4 + \dots + W_i \times S_i$$

In which:

- *W* is the criterion weight
- *S* is the score attributed to the technology concerning each criterion

Step 5: Submit the finished matrix to the person responsible for the panel, which will list the technologies in descending order of score, i.e., from the priority one for non-priority one. In case of disagreement, or in the case of tie, a meeting can be called to establish consensus.

A cut-off margin, determined previously to the prioritization, can be adopted to establish which technologies will or will not be evaluated in the HTpA. Those technologies that do not reach the cut-off point may be reassessed in a future prioritization panel.

By adopting the prioritization by medical specialty, therapeutic guidelines and clinical protocols, it could be easier for health care professionals involved to point out the different items for prioritization using the method of “Decision Support Multiple Criteria”, in the form of Value Measurement Models.

5 HEALTH TECHNOLOGY PERFORMANCE ASSESSMENT

The HTpA and the process of disinvestment and reinvestment in health is indicated when a particular technology no longer presents a good cost-effectiveness ratio, or low levels of safety, adhesion, acceptance and adequacy. The purpose of the HTpA is to provide clear and complete information to the health system manager and the decision making process.

The report of HTpA should be succinct and the recommendation must be clear and objective. These aspects are very relevant, since scientific information should be understandable and capable of guiding and supporting manager decisions. Clinical outcomes measured in the health system are the results of clinical effectiveness to be compared with values shown in clinical trials by manufacturers.

5.1 The results of HTpA

HTpA may suggest that the technology remain in the list, or that there is disinvestment. When the results of HTpA show clinical effectiveness lower than the expected according to the values provided by manufacturers in the incorporation agreement, measures, not mutually exclusive, can be taken: full delisting; restriction (limitation of access); retraction (reduction in the amount of the technology provided to each patient); and substitution for all patients or for a sub-group. Each of these modalities of disinvestment has distinct advantages and implications for clinical practice and management (Chart 3). In addition to restriction or retraction, the adoption of mechanisms to reduce the price of acquisition of the technology is recommended, to a level compatible with the clinical effectiveness measured in the health system. Contractual or legal mechanisms may be needed to facilitate the renegotiation process.

Chart 3 Meanings, advantages and disadvantages of the disinvestment modalities

MODALITIES	MEANING	ADVANTAGES	DISADVANTAGES
FULL DELISTING	The removal by the health system of a particular technology	<ul style="list-style-type: none"> • It offers greater and faster rationalization of the use of health care resources • It can help prevent ambiguity about the availability of services and products to groups or subgroups of users 	<ul style="list-style-type: none"> • Most times it is unpopular • Political difficulties to implement (principle of continuity of public service) • Potential increase in demand of alternatives (unmanaged substitution), including judicial ones • It can take a long time to implement

continues

conclusion

MODALITIES	MEANING	ADVANTAGES	DISADVANTAGES
RESTRICTION	The provision of technology by the health system will be restricted to groups or subgroups of users, strictly with the criteria for its use	<ul style="list-style-type: none"> • It offers rationalization of the use of health care resources • It can be reversed or enlarged as required • It can promote safer services 	<ul style="list-style-type: none"> • Politically unpopular • It may seem discriminatory • Potential increase in demand for alternatives (unmanaged substitution) • Difficult to monitor and maintain
RETRACTION	The supply of the technology by the health system will be reduced in number, e.g. 1 instead of 2 mammograms in a year	<ul style="list-style-type: none"> • It offers fast rationalization of the use of health care resources • Potentially more acceptable than full delisting 	<ul style="list-style-type: none"> • Potential increase in demand for alternatives (unmanaged substitution) • It can be difficult to monitor and maintain • Lower financial benefits than full delisting
SUBSTITUTION	The currently offered technology will be replaced by another that has the same performance and it must be more cost-effective	<ul style="list-style-type: none"> • It ensures that an equivalent treatment/ service is available • Potentially more acceptable than full delisting, restriction and retraction • It can help prevent unmanaged substitution 	<ul style="list-style-type: none"> • Guarantee of clinical efficacy of the substitute technology • It may be unpopular • Lower financial benefits than full delisting

Source: Adapted from Daniels et al. (2013).

5.1.1 Health technologies price renegotiation

When the HTpA indicates for not maintaining a given technology and the manager chooses for restriction or retraction of the technology, it is essential to undertake a comparative analysis of costs or of technology usage, so as to negotiate with suppliers prices compatible with the market and with the new consumption scenario. This has been described in the literature as a pricing method based on therapeutic value, “value-based pricing”.

For the price renegotiation, the manager has important tools to evaluate the technology, using data on the quality of use, persistence and compliance, safety, and cost-effectiveness. Other information can be used, such as data on the process of centralized or decentralized acquisition, local and regional market acquisition values, and when available, international price parameters.

The introduction of a new item, in substitution to another previously listed, should also be preceded by price negotiations, with the possibility of immediate or gradual cost reductions. It is recommended to adopt strategies that provide a shared risk with the manufacturer/supplier in the incorporation and acquisition processes, establishing the possibility of HTpA in the contract.

It is noteworthy that the price renegotiation can be used as an alternative in order to maintain a technology on the list. If the price decrease converts a technology considered 'not cost-effective' to 'cost-effective', the maintenance of that technology may be preferable to the process of disinvestment and reinvestment. Likewise, the wide dissemination of the results of clinical effectiveness among prescribers and patients is recommended to promote better quality in the use of technologies subjected to HTpA.

5.2 Stages of the Health Technology performance Assessment

The process of HTpA resembles the one for Health Technology Assessment (HTA) used for the process of incorporation of a product, medicine, procedure or equipment. The main difference lies in the fact that for HTpA, additional data on economic resources spent and clinical results are measured, mainly, after the use of technology by the patients served since the initial decision of incorporation. Indicators of access and organizational and logistical aspects related to the technology are also important for performance assessment. HTpA steps are shown below:

- **To review the therapeutic and economic objectives** that led to the introduction of the technology, to define what should be reassessed;
- **To investigate the clinical setting** in which the technology was introduced, i.e., the current line of treatment and therapeutic guideline;
- **To investigate the demand**, i.e., the annual consumption of technology in terms of units and number of patients using the technology (prevalence and incidence) in the health system, classified by the International Classification of Diseases (ICD);
- **To review the logistics process** of planning, acquisition, distribution, storage and dispensing/use of the technology to check critical points that could result in higher costs and/or reduced clinical effectiveness, i.e., the need for cold chain or other technological limitations of the formulation, complexity of the acquisition and distribution process due to transportation and associated costs, among other aspects;
- **To estimate the adherence** of patients and professionals to the technology (when relevant);
- **To estimate access** to the technology (when relevant);
- **To tabulate parameters of efficacy** of the studies used in the incorporation (clinical trials and systematic reviews);
- **To set the methods and conduct epidemiological and economic studies** to assess safety, effectiveness and costs, measuring clinical outcomes from patients and the financial resources spent by the health system. Ideally, the technology must be compared to the gold-standard already provided by the health system. The intermediate outcomes or substitutes – “surrogate endpoints” – should be avoided. Clinical and administrative registries can be used, if properly qualified;

- **To compare results of effectiveness** with evidence of efficacy considered for incorporation;
- **To conduct the assessment of cost-effectiveness** using data of effectiveness and resources spent by the health system. If necessary, data from systematic reviews with meta-analysis can be used to compose the modeling process if they are unavailable in the health system.

It is recommended to prepare a report containing the following items in the end of the process:

- **Executive summary**
- **Introduction to the Problem**
 - a. **Specification of the technology and clinical benefits** to be evaluated;
 - b. **Explanation of the rationale for the evaluation** of the technology;
 - c. **Description of the treatment pathways** of which the technology is part;
- **Description of the annual demand of technologies** by the users of the health system, prevalence and incidence;
- **Description of the methods** used to measure the clinical effectiveness;
 - a. **Evidences found** in the literature and measured in the health system;
- **Results of the performance** assessment of the technology
 - a. **Clinical effectiveness versus efficacy estimates** from clinical trials;
 - b. **Access and quality of use**;
 - c. **Economic resources spent versus initial estimate**;
 - d. **Logistics aspects** – from purchase to dispensing/use of the technology;
 - e. **Cost-effectiveness analysis**
- **Recommendations**
 - a. **Recommendations** from the modalities of disinvestment and reinvestment in settings for better decisions;
 - b. **Indication of the transition period**

The importance of evaluating the economic resources spent is noteworthy (costs), even in cases when the technology is considered to be ineffective or presents a relevant safety issue. It is important to measure how much will be disinvested to cover costs that could improve outcomes and quality of life related to the care of the patients. It is important that the HTpA report be submitted to public consultation after its conclusion, and all critical points should be properly answered.

5.2.1 Recommendation regarding the continuity of the technology in the list

If the result of the HTpA indicates full delisting or restriction, it is necessary to identify the existing alternatives in the health system that can be used by the patients. Even in cases of safety issues or an unfavorable cost-effectiveness ratio, the disinvestment and reinvestment process may not be the best choice, because there might be no other technology available or, if there is, it might have an unfeasible cost of purchase for the health system.

Whenever possible, it is important that the recommendation briefly presents simulations of possible scenarios – from maintaining the technology in its current format to disinvestment in each indicated modality; with their clinical and social consequences, necessary contractual and logistical arrangements, and estimated sum of resources to be made available for reinvestment in each scenario.

In some critical situations, an experiment with the removal/substitution of the technology in a hospital or health service may be appropriate. The results of that study may be able to confirm the evidence of ineffectiveness described in the HTpA and then guide the final decision – by the managers. The study should be conducted in partnership with scientific institutions that know how to offer the best care to patients, and, at the same time, provide an academic environment for a fast and accurate evaluation of the results coming from the delisting of the technology.

The formation of panels by health professionals, patient organizations, manufactures and managers is useful to understand better the use of the technology and its results. This contributes to legitimate the process of disinvestment and reinvestment. The participants should be chosen by their peers, considering their scientific and clinical background, in addition to their degree of interest in the results of the assessment.

5.2.2 Transition period

The report sent to the health system manager containing the analysis results and the recommendation for disinvestment and reinvestment should provide a transition period, considering the time required to implement the decision, as well as the organizational and logistics aspects and the required dissemination strategies about the whole process of implementation of the modality of disinvestment to be adopted.

The transition period may take on three time horizons since the decision by the health system manager, and should be agreed with the actors responsible for implementing the decision, according to the following description:

- **Short term:** three months to one year;
- **Medium term:** more than twelve months up to two years;
- **Long-term:** more than two years.

It is expected that, by the end of period, the process of change in clinical practice is complete, that is, the technology is no longer used and, if so, the substitute technology has been fully adopted by the health services.

For medicine and health products and in situations in which the health system is responsible for logistical operations, such as the direct purchase and storage of technologies, the duration of the transitional period should consider the time required for the consumption of stock and the

completion of purchase contracts. If it is applicable, it should also consider the time and logistics for the purchase, storage and distribution of the substitute product to be made available to the population (Chart 4). In some situations involving high demand products, such as in primary health care, manufacturers must be consulted on the ability to meet the entire demand of the technology that will be indicated for substitution.

Chart 4 Strategy for completion of medicine and health product stocks according to the disinvestment modality

TECHNOLOGY USE	MODALITY OF DISINVESTMENT		
	Full delisting	Restriction	Substitution
CONTINUOUS	<p>Patients in use of the technology will continue to receive until the consumption of stocks or until change of prescription.</p> <p>New demands will not be served.</p>	<p>There is a justification requirement for the prescription.</p> <p>New demands will be attended in accordance with the restrictions established.</p>	<p>The patients in use of the technology will continue to receive until the consumption of stocks or until change of prescription.</p> <p>New demands will be served with the new incorporated technology.</p>
SPORADIC	<p>New demands will be served until the consumption of inventories.</p>	<p>There is a justification requirement for the prescription.</p>	<p>Patients will receive the technology in stock (the disinvested one or the new one).</p>

Source: Self elaboration.

In the retraction modality, as the technology will continue to be offered, but in smaller quantities, the duration of the transition period should take into account the dissemination of the decision.

When the decision is based on safety-related issues, it is recommended that duration of the transition period be kept to a minimum, considering the time required for dissemination of the decision, the necessary reverse logistics activities, and the therapeutic substitution by another technology.

6 IMPLEMENTATION OF DECISION

When the decision is to alter the list of technologies, adopting one or more of the disinvestment modalities, attention should be given to a number of issues to be carefully evaluated and that will require management intervention. The four “E’s” – Engineering, Education, Economy and Enforcement – schematize the operation fronts for the implementation of decisions (Chart 5).

Chart 5 Examples of strategies for implementation of decision to alter the provision of a technology

THE FOUR E’S	EXAMPLES OF STRATEGIES
ENGINEERING (ORGANIZATIONAL AND MANAGERIAL INTERVENTIONS)	Update guidelines and manuals; establishing prescription targets; hiring and training staff to work in the professional and patient education; establishing limits for the sales forces from industries in purchase contracts
EDUCATION	Distribution of printed materials for different target groups; improvement courses; academic detailing; training of professionals to use the substitute technology
ECONOMY	Positive financial incentives for prescribers (pay-for-performance)
ENFORCEMENT	Reinforce the assessment of compliance with protocols including criteria by independent institutions/professionals

Source: Adapted from Wettermark et al. (2009).

6.1 Organizational implications

With regard to human resources, it may be necessary to redistribute, hire and train staff in the health care network, and to conduct academic detailing activities (visits to the prescribers) for dissemination of knowledge and management of the substitute technology, when appropriate.

Actions of reverse logistics to collect the remaining products/medicines/devices may be necessary when serious effectiveness and safety issues are identified (ACURCIO et al., 2013). Advertising materials and websites often continue informing patients and health care professionals that a given technology is provided by the health system, even after the disinvestment. Therefore, it is important to catalog all published materials that indicate the use of the divested technology and remove them from circulation, promoting proper disposal.

It is suggested to prepare bulletins using lay language for patients and technical language for health professionals, with sufficient information/complexity to deal with problems related to the interruption in the supply of any given technology to the population. For example, it would be advisable to provide

information about what to do, or what to inform a citizen that should present themselves to a health care provider with a document informing the provision of the technology or with a prescription for the disinvested technology.

6.2 Guidelines and compendiums update

Guidelines and lists of medicines and covered procedures should be updated whenever disinvestment occurs. Guidelines can be adapted even when disinvestment does not occur, since HTpA will reveal important information regarding the patients cared for by the health system.

For situations in which the supply of a technology demands protocol compliance, inclusion and exclusion criteria should be (re)defined to include the implications of the **restriction** and **retraction** disinvestment modalities. For health systems in which the primary care provider is the first contact of the patient, guidelines should also cover recommendations for referral to specialist care. It is advisable to include “what not to do” in the guidelines, as adopted by the National Institute for Health and Care Excellence (NICE), to reduce the number of unnecessary or doubtful value interventions in the individual level and to improve the quality use of health technologies.

The development of simplified versions of the guidelines, with key messages for different public such as health professionals, managers and patients, contributes to a qualified use of technologies and can be physically or electronically distributed in addition to the complete guidelines.

Digital media and social networks are also important forms of communication. It is suggested to develop explanatory videos about the diagnosis and treatment of the disease for the dissemination of the changes resulting from the disinvestment modalities. These videos can be made available on the internet and physically distributed in partnership with professional councils and patient associations, as well as universities and education entities.

6.3 Regulatory mechanisms, economic incentives and academic detailing

The adoption of regulatory mechanisms and financial incentives can improve adherence by health care professionals to protocols and therapeutic guidelines. The efficiency of the financial incentives has a strong dependence on strategies of dissemination and acceptance. Several strategies can be used to disseminate key messages to health professionals with an impact on their behavior in day-to-day practice. The key dissemination strategy adopted by the private sector is drug-detailing (visits to the prescribers), focused primarily on professionals who act as opinion markers among their peers. Inspired in that strategy, the health system can adopt the academic detailing to promote adherence to established guidelines, such as – “Pay for performance”, in which health professionals who adhere to guidelines by attaining to prescription targets and reaching clinical outcomes receive financial incentive, is another strategy that can be adopted. For the incentive to be effective, it is necessary to adopt reliable information systems and seasonal processes of clinical audits.

6.4 Dissemination - social actors and targeted groups

The dissemination strategies should be focused on the main social actors involved in the provision of the technology: managers, health professionals and users, their associations and other public actors. Companies with conflicting interests may be a barrier to the dissemination and adherence of the best clinical practices to and by health care professionals. Advertising strategies, economic incentives to health professionals and the use of drug-detailing can compromise the adoption of the best clinical practices. For this reason, it is important to adopt contractual mechanisms in the process of acquisition of the technology to prevent such actions that are contrary to the public interest. It is fundamental to ensure adherence to updated guidelines. One way to guarantee that is to reserve a part of the investments in new technologies and to update the guidelines to promote academic detailing. The dissemination should be focused on transparently explaining the decision, with a clear presentation of the rationale and the causes and consequences of changing the therapeutic guideline. This will ensure the full understanding by those who provide and use the technology, as well as to prevent the occurrence of unmanaged substitution and possible conflicts that may take the form of lawsuits requesting the disinvested technology, resulting in higher costs and damage to the health system image.

The managers of all sectors involved should be considered partners in the execution of the decision; therefore, they must have access to complete information on the exclusion/inclusion of technology. The dissemination can occur through official documents and meetings with the participation of representatives of health system users.

Health professional councils should also be considered partners in the implementation of disinvestment and reinvestment, as they can provide important tools for dissemination such as their magazines and journals, and the dissemination of information through e-mail or newsletter to their affiliates.

Patient associations are also recognized as key stakeholders in the implementation of the disinvestment and reinvestment, as their support is critical to the success of the intent, especially when they are well informed about the clinical benefits and when they are invited to participate in decisions about reinvesting resources.

6.4.1 Dissemination and adherence strategies

As discussed in previous sections, a key strategy for the dissemination of decisions on disinvestment and reinvestment is the visitation to the prescribers for **academic detailing for dissemination of the key messages**.

In this strategy, inspired by the actions of the pharmaceutical industry, prescribers are visited by health professionals who explain treatment guidelines and the modifications in the list of medicines and procedures provided by the health system. This is a result of health technology assessment (incorporation) and health technology performance assessment (disinvestment and reinvestment). This is a powerful strategy of communication that can be adapted to the needs of each type of

professional visited. For prescribers, it presents itself as convenient and efficient in terms of time spent and behavioral changes, but it should be conducted by a reliable and accredited institution. On this occasion, the prescriber will also be informed about the transition period, the filling of medical reports and other documents required to justify future prescriptions, when **restrictions or retraction** are adopted. In addition, advertising material is to be distributed to patients and will be delivered to the prescribers, so that each professional becomes a partner in the dissemination of information on modifications in the therapeutic guidelines.

An adaptation of this modality can be done with group academic detailing, in which a small group of prescribers (no more than five is recommended) attends a meeting for dissemination and explanation of modifications in the lists of covered medicines and procedures. The collective approach can be more interesting economically; however, the quality of the activity should be valued by maintaining its feature of “close contact” between detailer and prescriber, which differentiates academic detailing from short courses. In both the individual and the collective approaches, “key prescribers”, such as residency preceptors and department heads can be chosen.

Academic detailing can be adapted into visits to public stakeholders such as public attorneys and judges, focusing on clear explanations of the reasons for the therapeutic guideline modification. Also it is necessary to inform what the health system will continue, or will provide, the treatment of the disease that was affected by the disinvestment and how the access to these technologies will be.

The dissemination to users is especially important in the case of technologies used continuously, and it can occur through the distribution of a bulletin, in simplified language, with the explanation of the modifications on the therapeutic guideline. This bulletin can be distributed to users by their referred health professionals. It is important to transmit to the health system user complete and reliable information, in a clear way, about the reasons for the update, its consequences and, when applicable, the included technology as substitute for the one discontinued.

The bulletin must answer questions such as:

- *Will I stop receiving my medicine?*
- *Why?*
- *Until when will I receive my medicine?*
- *Is my health at risk because I have used this medication until today?*
- *Should I stop using this medicine today?*
- *Does my doctor/dentist know this?*

The users should be instructed to seek their provider for more information and treatment adjustments. Mass dissemination channels such as radio, television, newspapers and the internet can also be used when needed, especially if the treatment is widely used.

When possible, the dissemination to users should occur after the dissemination to health professionals, since these should be prepared to answer questions and requests from users regarding the update of

guidelines and lists of medicines and procedures. The provision of a **direct communication channel** is also strongly advised, via telephone or internet, for example, so that users can ask questions related to the updates with trained professionals. Such a channel should also be open to health care professionals.

6.5 Implementation

Monitoring of the utilization of the technology is required to validate or change the decisions taken based on HTpA. This also enables the evaluation of the implementation process of the updated guideline and enables success tracking of the dissemination strategies and regulatory mechanisms. It is very relevant to monitor the health outcomes from the revision of the decision to incorporate a health technology, since the success of disinvestment and reinvestment is indicated by reaching the same or improved health results and optimization of resources. Possible strategies for monitoring include establishing registries with clinical and demographic data from electronic data collection systems. Partner institutions can be selected to conduct the study, which must be approved by the Research Ethics Committee.

7 FINAL REMARKS

The process of investment and disinvestment in technologies should be focused on the best risk-benefit ratio for the population, aiming to provide more cost-effective treatments and services, and optimizing the use of resources.

The choice for a modality of disinvestment in health technologies generally are more complex than the decision to incorporate a new technology, and it may face complicating factors such as a lack of scientific evidence, publication bias, and political, ethical and social issues, as it can be understood, erroneously, as “loss of an acquired right”.

The strategy to be adopted for the implementation of the updated therapeutic guidelines may vary considerably from technology to technology, especially depending on how disseminated the use of the technology is and its acceptance by society. Thus, the update of guidelines should be fully transparent and participative, always based on the best scientific evidence available and supported by effective dissemination of information.

The full delisting of a technology should be the main focus of the analysis only when there are severe safety issues and ineffectiveness. Probably, few technologies are candidates for this modality of disinvestment. Even if the studies indicate evidence of unsatisfactory cost-effectiveness ratio, the perceptions of users and how they deal with the technology are points of great relevance for the legitimacy of the decision-making process by the health system managers. In these situations, the dissemination of updated guidelines and the reduction of acquisition prices could be the best strategies.

Another point of great importance concerns the identification of subgroups of users who benefit from the candidate technology for the process of disinvestment and reinvestment. It is vital that strict criteria are established to ensure that those users are not harmed by the decision to disinvest. Also, the commitment of managers to reinvest resources in other activities and services related to the affected illness or disease group can enhance the acceptability by both professionals and patients. Most health systems are major buyers of technologies, be it services, equipment or pharmaceutical products. Thus, it is important to establish a conduct that is free from conflicts of interest and based on scientific evidence during the whole process of HTpA, to avoid speculation in the market and to allow for a viable medical/pharmaceutical industry sector.

The disinvestment decision should provide the best use of resources and the improvement of health conditions in the community. However, it should not be used to exclude minorities from access to essential technologies, despite the low number of beneficiaries. Decisions must be in agreement with the principles established by the health systems and based on technical, legal and mainly ethical parameters.

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