

Post-introduction Observation of Health Technologies. Methodological guideline. Abridged version.

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Glossary

Health technology: the equipment, devices and drugs and the medical and surgical procedures used in prevention, diagnosis, treatment and rehabilitation of disease, as well as the organisational and support systems used in the delivery of health care.

Health technology assessment: is a multidisciplinary process that summarises information about medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased and robust manner. Its aim is to inform the formulation of safe, effective health policies that are patient focused and that seek the best value.

New health technology: is a technology in phase of adoption, which has been available for clinical use for only a short time and is generally in the launch period or early post-marketing stage.

Emerging health technology: any technology not yet adopted by the health care system; pharmaceuticals will usually be in phase II/III of clinical trials or in the pre-launch period, devices will be prior to marketing, or within 6 months of marketing, or marketed but with a diffusion of under 10% or localized to a few centres.

Health product/medical device: any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software for its proper application intended by the manufacturer to be used in human beings for the purpose of: a) diagnosis, prevention, monitoring, treatment or alleviation of disease, b) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap, c) investigation, replacement or modification of the anatomy or of a physiological process, and d) control of conception; and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its functions by such means.

Surveillance system: process of systematic collection, analysis and interpretation of health data essential to public health to be used in the planning, implementation and assessment of programmes, including, as a basic element, the dissemination and application of such information.

Monitoring system: set of tools for generating and collecting data on health technologies for their assessment from the stage of introduction into the health care system until the stage of broader diffusion.

monitorised use: proposed mechanism for systematically generating and collecting data on new technologies for which there is insufficient information on safety, efficacy and efficiency to inform decision making on general funding by the public health care system.

Post-introduction observation of new technologies system: organised system of collection, analysis, interpretation and dissemination of data on new technologies once they have been financed/approved and are used in standard clinical practice. The main goals are to provide essential information on diffusion, accessibility, adequacy of use and identify important deviations in effectiveness, safety or investments.

Adverse effects: any injury, damage and/or complication deriving from the use of a given technology, as well as diagnostic errors (FP, FN) that have led to an alteration in the health status of patients, end-users or the environment.

Severe adverse effect: any injury, damage and/or complication deriving from the use of a given technology, as well as the diagnostic errors that have led to death or major deterioration in the health status of patients, end-users or the environment.

Abstract

INTRODUCTION: The development of a systematic, prioritised process for collecting, analysing, interpreting and disseminating data on new technologies, once these have been introduced into standard clinical practice aims to inform on the implementation, accessibility, acceptability and adequacy of use of new technologies as well as provide valuable and comprehensive information on the costs and investments stemming from their application. Similarly, it enables the detection and assessment of adverse effects or problems of effectiveness which arise when the new technologies are applied under real life use conditions and which are not identified in preliminary studies. The need for a methodological guideline is justified by the fact that currently there is no explicit methodology to guide the observation of health technologies once they have been adopted by the health care system.

OBJECTIVES: The principal goal of this guideline is to establish a structured methodological framework for the observation of new technologies after their introduction into clinical practice. The specific goals are: 1) to develop a prioritisation tool; 2) to identify the most appropriate data-collection instruments for post-introduction observation with their advantages and limitations; and, 3) to establish outcome indicators for assessing the different aspects of post-introduction observation.

METHODS: The sources of information for this guideline are based on: 1) systematic reviews; and 2) the consensus of experts. The group of experts is made up of professionals coming from the various Spanish Health Technology Assessment (HTA) agencies/units. The final selection and weighting of prioritisation criteria was carried out by a group of panellists representative of medical managers/administrators, clinicians and health service end-users coming from the different Autonomous Regions.

RESULTS: The guideline consists of 3 results sections. The first section provides the list of finally selected prioritisation criteria (n=14) and describes the tool developed for prioritising health technologies susceptible to post-introduction observation (PriTec.observation tool). The second section describes and assesses 4 instruments that could be used for data-collection, along with an outline of the advantages, drawbacks and considerations to be borne in mind when using them for post-introduction observation purposes. The last section of the guideline lays down the basic requirements for implementing a post-introduction observation system, and presents

14 specific outcome indicators for assessing the various aspects of post-introduction observation of new technologies.

CONCLUSIONS: 1) post-introduction observation of new technologies is a strategy which complements the procedures implemented to regulate the incorporation and introduction of new technologies; 2) this methodological guideline is the first document published on this topic and it might serve as a reference for any institution/body, national or international, which may be planning to and/or are carrying post-introduction observation activities; 3) the methodological guideline provides specific procedures and strategies for planning, implementing and evaluating the utilisation of new technologies; and 4) the methodology of post-introduction observation put forward is a preliminary proposal which will gradually be redefined with the implementation of these systems in different local, national and international settings.

RECOMMENDATIONS: 1) Application and adaptation of post-introduction observation methodology to different contexts.

Abbreviations & Acronyms

AETS: Agencia de Evaluación de Tecnologías Sanitarias del Instituto Carlos III.

AETMIS: Agence d’Evaluation des technologies et des modes d’Intervention en Santé.

AETSA: Agencia de Evaluación de Tecnologías Sanitarias de Andalucía.

CADTH: Canadian Agency for Drugs and Technologies in Health

ARs: Autonomous Regions.

CDRH: Centre for Devices and Radiological Health.

EC: European Community.

CEDIT: Comite d’Evaluation et de Diffusion des Innovations Technologiques, France.

ICD: International Classification of Diseases.

MBDS: Minimum Basic Data Set.

USA: United States of America.

FDA: Food and Drug Administration.

FP: False positives.

FN: False negatives.

HAS: La Hauté Autorité Santé.

INAHTA: International Network of Agencies for Health Technology Assessment.

RD: Royal Decree.

NPV: Negative predictive value.

PPV: Positive predictive value.

1. INTRODUCTION

1.1. Post-introduction observation of new technologies in the context of health technology assessment.

This section outlines the scope of action and goals of post-introduction observation and defines the HTA scenario for post-introduction observation of new technologies. This section tries to answer the following questions: Why should this be done? What purpose does it serve? What results are going to be obtained?

The great technological advances of the last 50 years have posed an important challenge to most health care systems around the world. Ensuring innovative quality care, which adjusts to the demands and expectations of end-users, managing budgets allocated to health, and safeguarding the basic principles of equity and accessibility is a very complicated task. Health technology assessment (HTA) is a multidisciplinary field of research which was created in the 1970s for the purpose of providing objective information to medical decision-makers and politicians, to support decision making about the introduction of new technologies (1). HTA was fundamentally developed to review aspects of safety, efficacy, cost and cost-effectiveness of new health technologies, and to assess the clinical, social, financial, organisational and ethical implications, both direct and indirect, stemming from their adoption, along with their desired and undesired effects.

Since its origins, HTA has been steadily evolving and extending its activities so as to adapt to the exponential growth in technological innovations and the important changes in the priorities of a society that is increasingly aware of its state of health and ever more demanding when it comes to therapeutic options. At the outset, HTA basically consisted of a comprehensive evaluation of the scientific evidence in order to provide support for decision-making with respect to the introduction of new technologies, with health technology being defined as, “the equipment, devices and drugs and the medical and surgical procedures used in prevention, diagnosis, treatment and rehabilitation of disease, as well as the organisational and support systems used in the delivery of health care” (2). In the 1990s, the need arose for new and emerging health technologies to be detected and assessed prior to their marketing and/or diffusion, in order to provide managers and administrators with useful and timely information on

technologies eligible for incorporation into clinical practice, and to facilitate the planning of activities, budgets and resources. Currently, a number of countries, including Spain, have implemented early warning systems for the identification and assessment of new and emerging health technologies (3-5).

In the last decade, in view of the great pressures to incorporate insufficiently assessed technological innovations, a number of initiatives have been established to monitor new and emerging health technologies before they are adopted by the health care system. Such monitoring is seen as a measure that allows for the conditional introduction of new technologies subject to collection of additional data. They are fundamentally designed to provide information on technologies which have potential to produce major improvements in health or quality of life, but there are doubts as to their safety and/or effectiveness (6). The need to monitor new technologies is included as a recommendation in many HTA reports carried out by Spanish HTA agencies (avalia-t, AETS, Osteba, etc) and by other agencies like CEDIT (*Comite d’Evaluation et de Diffusion des Innovations Technologiques*).or ANZHSN (Australian and New Zealand Horizon Scanning Network. At the level of the Spanish National Health System (NHS), conditional monitoring of new technologies is known as “monitorised use” (*uso tutelado*) and is considered within the legislation as a mechanism to generate and collect data in order to establish the degree of safety, efficacy, effectiveness or efficiency of a given technique, technology or procedure to inform decision making regarding its approval as a covered health benefit (RD 1030/2006) (6). In the Autonomous Region of Galicia (7) and País Vasco (8) the specific legislation establishes that, based on the available scientific evidence, some technologies might be proposed for conditional monitoring and be subject to specific centres, indications, protocols and assessment criteria.

Despite the fact that HTA has become a tool of great value for making decisions about the approval/funding of new technologies, many uncertainties are frequently associated with the introduction of new technologies that can only be assessed after their definitive approval and adoption in clinical practice (9). Preliminary scientific information is insufficient to assess the real impact that the new technology is going to have on the population or to assure that anticipated expectations are accomplished.

When a technology is approved, there is a possibility that diffusion and adoption does not take place as expected, owing to financial adversities, to the existence of organisational, structural or technical constraints or to the rejection by clinicians or patients. Similarly, it is likely that diffusion at

1st-level hospitals may not be the same as at 2nd- or 3rd-level hospitals, and this could give rise to important differences of accessibility to technological innovations for the different health areas or regions. These facts, linked to the different degrees of willingness of health professionals and/or institutions to use innovative technologies, can result in important variations in their use (10, 11). In some cases, institutions' competence and their desire to try new technologies can lead to over-use of such technologies, with the ensuing increase in costs and resources but without any proven benefit for the patient or with even greater adverse effects. In other cases, resistance to the use of new technologies could greatly influence the quality of the services offered.

The medical practice is based on the acquisition of knowledge and skills that should ensure professional aptitude and quality. Nevertheless, when new technologies are involved, there are frequently many doubts as to proper technology use, the selection of patients and as to the applicability of research results to daily clinical practice (9). It is foreseeable that when clinical indications are based on subjective criteria (e.g., seriously ill patients, not eligible for other treatments, etc.), there may be great heterogeneity in the selection of patients eligible for using the new technology is concerned. Deciding which patients are to be diagnosed/treated with the new technology may greatly depend on the occupational and social context (organisational structure, available resources, degree of specialisation, learning curve, values, internal policies, citizen pressures, etc.), and one consequence of this is the appearance of important variations in medical practice (12). Variations in medical practice are especially relevant when technologies use can clearly impact on patients' mortality, morbidity and/or quality of life. Radiofrequency ablation, indicated for hepatic metastasis of colorectal cancer, is a good example of a technology prone to displaying wide variability, with important repercussions on population health (13).

On applying the technology under normal conditions of use, there is also the possibility that problems of ineffectiveness or side-effects unforeseen in pre-marketing studies might appear (14). Pre-marketing studies are conducted by groups of experts on small groups of patients and in modified conditions. It may happen that severe side-effects are not detected because these only appear in a small number of patients, yet the possibility also exists that problems of ineffectiveness and/or safety may arise due to clinicians' limited experience (learning curve). In techniques that require a high degree of specialisation, such as the case of hemiliver transplants from living donors, very important differences have been observed in morbidity and mortality depending on the volume of procedures performed (13). Side-effects or problems of effectiveness may also arise as a result of the new technology being

used on highly sensitive groups (children, the elderly, patients with other comorbidities), or among the health personnel responsible for its application. Likewise, inappropriate use or the combination of new technologies with other procedures or devices could also give rise to interactions and side-effects unforeseen in the literature. Such was the case of the combination of cholecystectomy with laparoscopy; techniques that separately displayed a high degree of safety but when combined gave rise to a great increase in the rate of biliary lesions. Investigating and quantifying adverse effects and/or problems of effectiveness is relevant for taking appropriate measures as soon as possible and ensure the health of the population (13).

The different post-introduction follow-up systems regulated worldwide are basically surveillance systems developed to report on the serious adverse effects of medical devices and suffer from an important degree of underreporting (15, 16). Problems associated with the overuse of new technologies in dubious/non authorized indications, lack of effectiveness, incompatibility with other treatments or complications that may appear only when the technologies are used in specific groups are frequently not identified by the available follow-up systems. Neither are structural, organizational or economic problems that can lead to an underuse of the technology.

The investigation of problems after the approval of technologies has basically relied upon the implementation of voluntary registries set up by different associations or independent research studies carried out by the health services. These studies, even though of great value, present the limitation that they are frequently not developed following a structured methodology and are undertaken in many cases only when clinicians become aware that there might be problems with the technologies. Commonly these investigations cover only areas of high clinical interest (cardiovascular diseases, cancer, etc) and are basically aimed at assessing specific aspects of effectiveness, safety or variability of use and do not offer information on other aspects that may be relevant to guarantee the quality of the health care (17-19).

The development of a systematic, prioritised process for collecting, analysing, interpreting and disseminating information on the utilization of new technologies, once these have been introduced into daily clinical practice is necessary for ensuring the quality of the health-care. It would allow for the identification and assessment of problems concerning implementation, accessibility, acceptability and adequacy of use, and would provide reliable and comprehensive information on the real costs and use of resources that are derived from its application. Since it integrates different sets of data

generated at local levels, it allows for the detection and assessment of relatively rare adverse effects or problems of effectiveness that are only observable with large sample sizes or in specific populations. Having large population groups for specific indications would also make it possible to identify specific subgroups with a high risk of suffering from adverse effects that would otherwise go undetected in preliminary studies. Equally, it would enable assessment of other aspects which might influence effectiveness and safety (structural, organisational, training-related, etc.). The main goals of a post-introduction system for observation of new technologies are outlined in table 1.

Table 1. Main objectives of a post-introduction observation system of new technologies.

OBJECTIVES	
General objectives	Specific objectives
1. To assess the diffusion of the new technology	1.1. Identify problems regarding the adoption of new health technologies (financial, organisational, structural or social). 1.2. Identify problems in acceptability.
2. To assess accessibility within the Health System	2.1. Establish the existence of accessibility problems.
3. To assess adequacy of use	3.1. Establish the adequacy of clinical indications. 3.2. Establish the adequacy of patient-selection criteria.
4. To verify effectiveness	4.1. Identify problems of effectiveness that may appear when the technology is applied in daily clinical practice. 4.2. Identify groups especially benefited or prejudiced by the use of this technology.
5. To verify safety	5.1. To check for the occurrence of deviations in severe adverse effects in the short/medium term. 5.2. To check for the occurrence of deviations in mild/moderate adverse effects in the short/medium term 5.3. Identify especially sensitive groups (e.g., children, the elderly, patients with co-morbidities, etc.).
6. To verify economic impact	6.1. Identify important cost overruns.

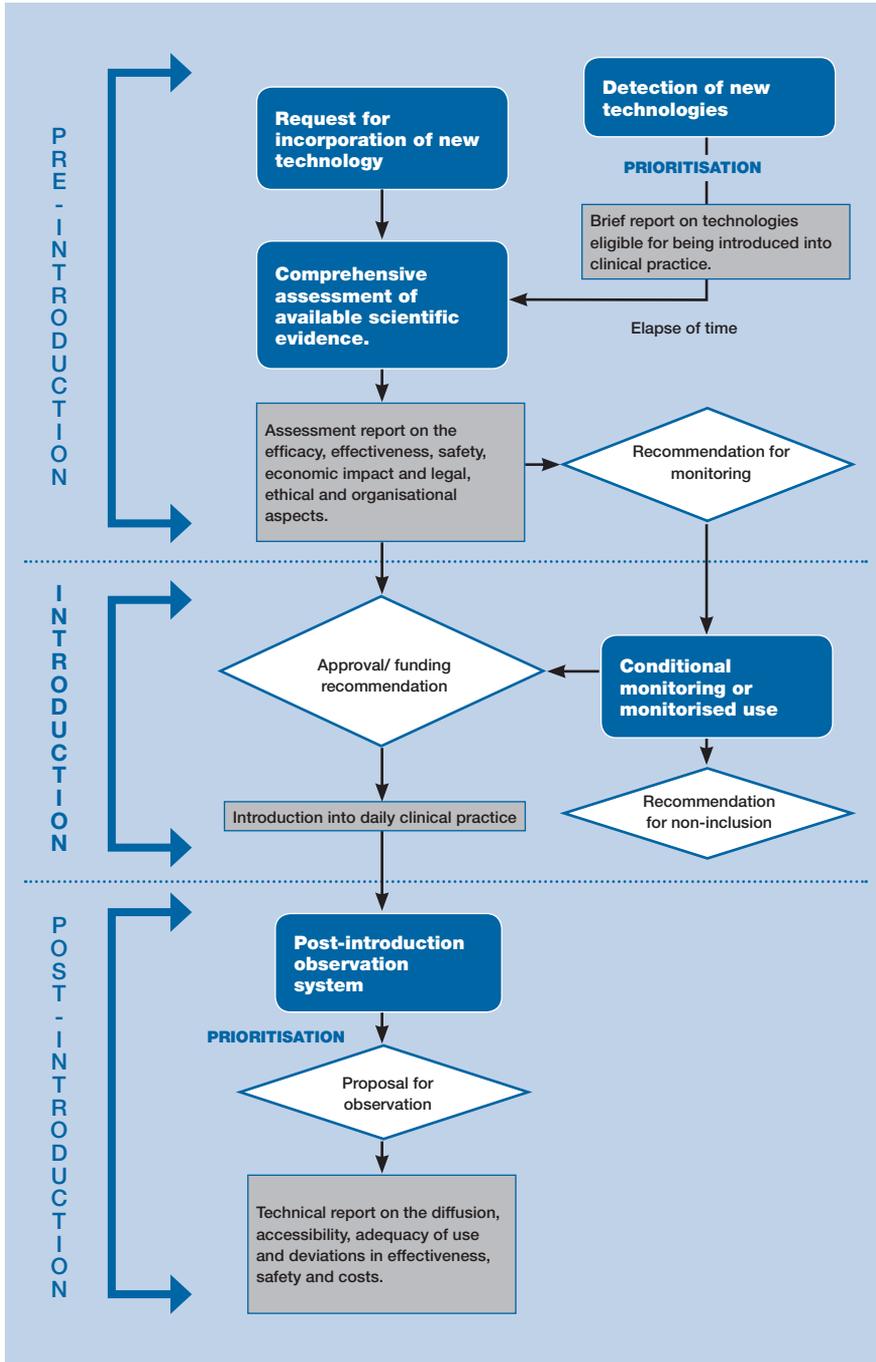
At present, there is no systematic, prioritised process in Spain, or in any other country in the region, for compiling information on new technologies once these have been approved and widely diffused throughout the health system.

Like other governmental associations/organisations, including the Australian Government Productivity Commission and the European Observatory on Health Systems and Policies (1, 20, 21), we feel that post-introduction assessment of new technologies is essential to inform decision-makers about the real implications deriving from the introduction of new technologies, to furnish relevant information on problems of implementation, accessibility, acceptability, adequacy of use and economic impact, and to identify specific problems of effectiveness and/or safety.

In line with the relevance of continuing HTA in the post-introduction stage, we propose that HTA must integrate 3 stages (pre-introduction, introduction and post-introduction) and comprise the following steps:

- Early identification and assessment of new and emerging health technologies.
- Comprehensive assessment of scientific evidence to provide support for decision-making about the approval of new technologies.
- Conditional monitoring of new, insufficiently assessed technologies in order to establish the degree of safety, efficacy, effectiveness or efficiency of a given technique, technology or procedure and inform decision making regarding its approval as a covered health benefit.
- Observation of new health technologies once they have been approved/financed by the health care system and are used in daily clinical practice.

Figure 1. Stages in health technology assessment



1.2. International situation and legislation regarding post-introduction observation of new technologies

This section describes the international situation and legislation regarding post-introduction observation of new technologies. The following questions are addressed: Are there other international initiatives to assess new technologies once they have been introduced into daily clinical practice? Are they regulated? What are their objectives? How are they organized?.

The systematic review carried out did not identify literature on standardised systems for post-introduction observation of new technologies, as conceived in this document, although it did identify various initiatives that could be included in post-introduction observation of new technologies, since they fulfil some of the proposed objectives. Within Europe it is important to document the Directive 2007/47/EC of the European Parliament and of the Council (22), which will become effective in March 2010, and requires for manufacturers to confirm conformity with the requirements concerning the characteristics and performances under normal conditions of use of the medical devices¹ and the evaluation of the side-effects and acceptability of the benefit/risk ratio. As a general rule clinical evaluations must be performed. The evaluation of this data, where appropriate taking into account of any relevant harmonised standards, must follow a defined and methodologically sound procedure based on:

1. A critical evaluation of the relevant scientific literature currently available relating to safety, performance, design characteristics and intended purpose of the device.
2. A critical evaluation of the results of all the clinical investigations made.
3. A critical evaluation of the combined data provided in the previous sections.

1 Any instrument, apparatus, appliance, software, material or other article, whether alone or in combination, together with many accessories, including the software... (Directive 2007/47/EC)

In February 2008, an e-mail survey was sent to all members of the International Network of Agencies for Health Technology Assessment (INAHTA) distribution list, to identify all post-introduction observation activities under way in the respective countries of origin. The INAHTA is made up of 46 agencies belonging to 26 countries around the world, (<http://www.inahta.org/Members>). Response was obtained from 15 agencies in 9 countries (35%) including Spain. According to the information furnished by these agencies, four countries are currently undertaking post-introduction observation activities (Australia, Spain, Italy and France) though not in a structured manner. In the case of France, the technologies to be assessed and the post-introduction observation activities depend, in great measure, on specific recommendations of the CEDIT. In the Autonomous Region of Galicia, the decision to conduct a follow-up of technologies after their general approval is not based on specific criteria but on the recommendations issued by an Advisory Committee, which takes into account, among other aspects, the recommendations of the Galician Health Technology Assessment Agency (RD 1030/2006) (23). Taking into account the low response rate and the fact that the survey covers only HTA organisms many post-introduction observation activities might not have been identified.

1.3. Legal framework for the introduction of technologies in Spain

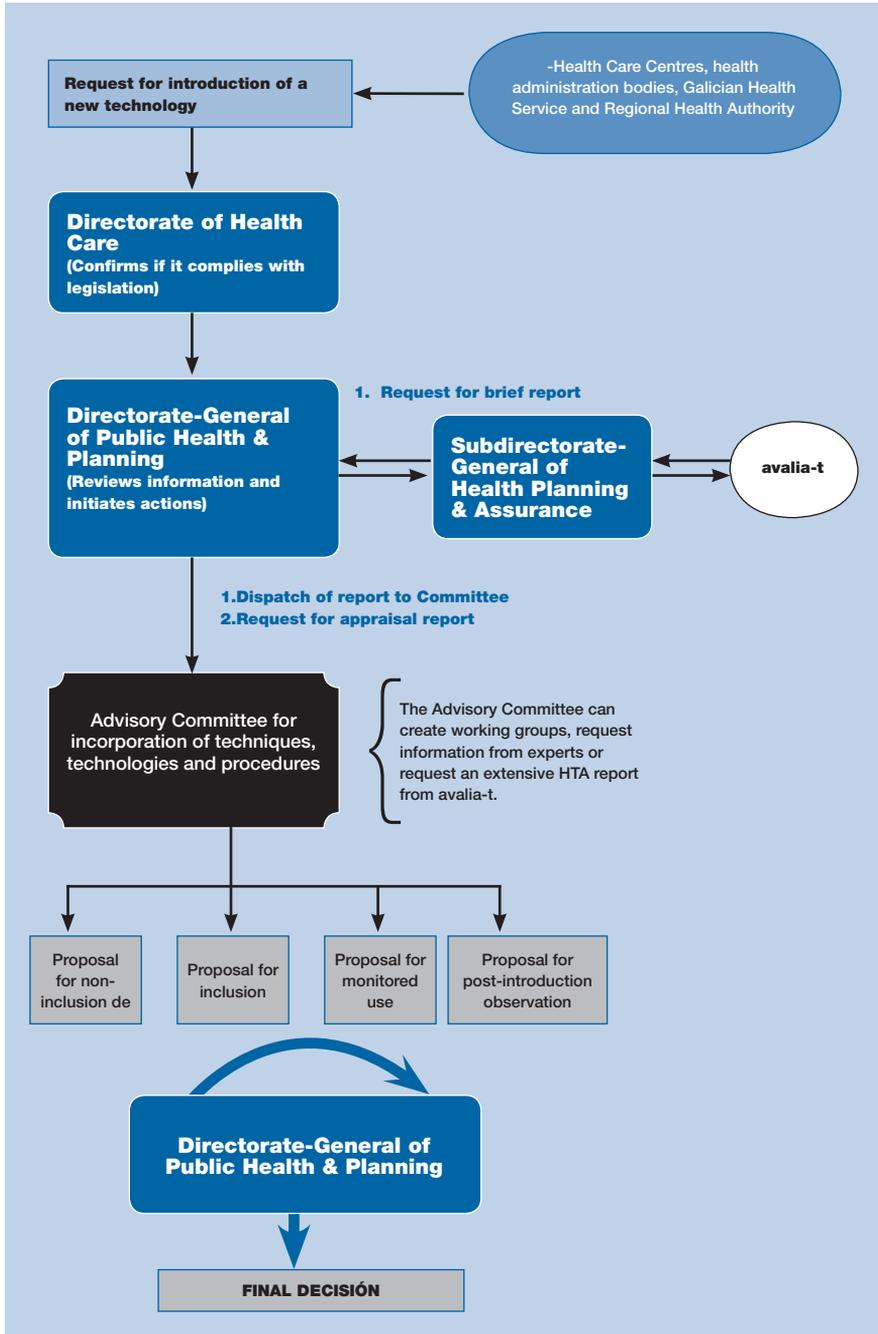
This section outlines the statutory provision governing the introduction of new technologies in Spain and the specific regulations governing the Autonomous Region of Galicia.

At a national level, health-technology assessment and monitoring are envisaged by law as indispensable procedures for decision-making with regard to the incorporation of new techniques, technologies or procedures into the National Health System's common service portfolio, but this does not apply to post-introduction observation. The latest Ministry of Health & Consumer Affairs Order 3422/2007 of 21 December puts forward that (24), when the scientific evidence available is deemed insufficient for decision making regarding the generalised financing of new techniques, technologies or procedures in the NHS, a proposal for an assessment study must be formulated via monitored use or some equivalent mechanism.

Within Spain, the Autonomous Region of Galicia has drawn up a specific statutory regulation to establish the procedure for incorporating techniques,

technologies, procedures or other means of delivering health-care which are included in the NHS portfolio, into the Galician Health Service (Official Galician Gazette - *Diario Oficial de Galicia/DOGA*; order of 7 July 2003) (7). Article 5.2 provides that some technologies may be deemed eligible for special follow-up (monitored use), and prior to their definitive incorporation be conditioned to specific centres, indications, performance and assessment criteria. Although it is not envisaged under current legislation, certain health technologies are subject to a process of post-introduction observation, aimed at conducting a follow-up of their use after they have been introduced into the service portfolio. Unlike special follow-up, the use of this technology is not restricted to special centres because the intention is to evaluate their use under real conditions. Figure 3 depicts the procedure for incorporation of new technologies in Galicia:

Figure 2. Incorporation of new technologies in the Galician Public Health Services.



2. JUSTIFICATION FOR A METHODOLOGICAL GUIDELINE FOR POST-INTRODUCTION OBSERVATION OF NEW TECHNOLOGIES.

This section explains the reasons for drawing-up the methodological guideline for post-introduction observation of new technologies.

In view of the fact that systematic, prioritised observation of new health technologies following their introduction into the health system, as set forth in this document, is a relatively new initiative, not only in Spain but also in neighbouring countries, there is no standardised methodology for establishing an observation of health technologies after their introduction into the health system.

The need for having a methodological guideline is justified by the fact that post-introduction observation is a complex procedure, not only in regards to implementation and operation, but also to the assessment of results. It entails multiple facets, ranging from what technologies should be considered for post-introduction evaluation, to the collection of data and result analysis.

The systematic observation of all health technologies after their approval is unviable in financial and organizational terms. It is necessary to identify and classify in order of importance the health technologies that may require a post-introduction observation. A structured protocol should be available for prioritisation or there is a risk that this process will be biased due to different pressures and conflict of interests.

This guideline is also needed to identify valid and reliable data-collection instruments, as well as to establish outcome indicators to measure relevant aspects of the diffusion and use of new technologies once they are adopted and used in general clinical practice.

The existence of this guideline would enable health care to be delivered with greater quality, by enhancing patient safety and identifying possible inequities in the health system.

3. SCOPE & GOALS OF THE METHODOLOGICAL GUIDELINE

This section outlines the sphere at which the guideline is targeted and the goals sought to be attained; and responds to the following questions, namely: For which sphere? To what end? For which end-users?

This methodological guideline is conceived as being a support document for any body or entity, national or international, which is planning to carry out activities involving post-introduction observation of new technologies.

The guideline's principal aim is to establish a structured methodological framework for observation of new technologies after their introduction into general clinical practice. The specific objectives of this guideline are:

1. to establish a methodological tool for identifying and prioritising new health technologies eligible for post-introduction observation;
2. to identify possible data-collection instruments and assess their usefulness and feasibility in post-introduction observation of new technologies; and,
3. to establish the principal outcome indicators for assessing different aspects considered in post-introduction observation.

Each of these specific objectives will be dealt with independently, so that the guideline can serve as a general support document for implementation of a post-introduction observation system, or to provide guidance on any of the specific sections of the guideline.

Guideline end-users will be HTA agencies, hospital health assessment commissions, coordinators of scientific societies registries, manufacturers, public health schools, health managers, administrators and/or any health professionals involved in the planning and/or conduct of different post-introduction observation activities.

4. METHODOLOGY

This section describes the methodology for the elaboration of the 3 sections of the guideline.

In order to draw up this guideline, the following work units were set up:

- *Technical group*: made up of 3 methodology experts from avalia-t. This working group was responsible for defining the scope of the project, proposing the methodological bases for the development of the guideline and establishing a work system. Its functions were to analyse the evidence, assess the results, draft the results and draw up recommendations, all processes done in close collaboration with the working group.
- *Working group*: made up of 11 HTA experts from different Spanish HTA agencies/units, namely: Galician Health Technology Assessment Agency (avalia-t) (n=3); Health Technology Assessment Agency, Carlos III Institute of Health (AETS) (n=2); Basque Government Health Technology Assessment Department (Osteba) (n=2); Madrid Regional Health Technology Assessment Unit (UETS) (n=1); Andalusian Health Technology Assessment Agency (AETSA) (n=1); Barcelona Clinical Hospital Innovation & New Technology Assessment Unit (SESCS) (n=1); Health Assessment and Planning Department of the Canary Island Health Service (n=1). The working group acted as consultant, project reviewer and made different contributions to the various sections of the guideline.

In order to accomplish the specific objects of the present guideline, 3 independent result sections were developed, namely: 1) Prioritisation of new technologies for post-introduction observation; 2) Tools for data-collection; and, 3) Outcome indicators. Each section was drawn up using a specific methodology that is described in the following sections.

4.1. Development of the prioritisation tool.

To identify possible prioritisation criteria a bibliographic search was undertaken in the main bibliographic data bases (Medline, Embase, Cochrane y CRD HTA database). The search was completed with a manual review of the web pages of various national and international HTA organisms and health care systems in order to obtain additional information on experiences

and opinions in this field. Since no documentation was found on post-introduction observation, the list of prioritisation criteria was developed by consensus methods.

A. Selection of prioritisation criteria and domains

The initial list of domains and prioritisation criteria was drawn up by the technical group in consensus with the working group. The preliminary list included a total of 15 criteria grouped in 4 domains: a) population/end-users; b) technology; c) safety/adverse effects; and, d) costs, organisation and other implications.

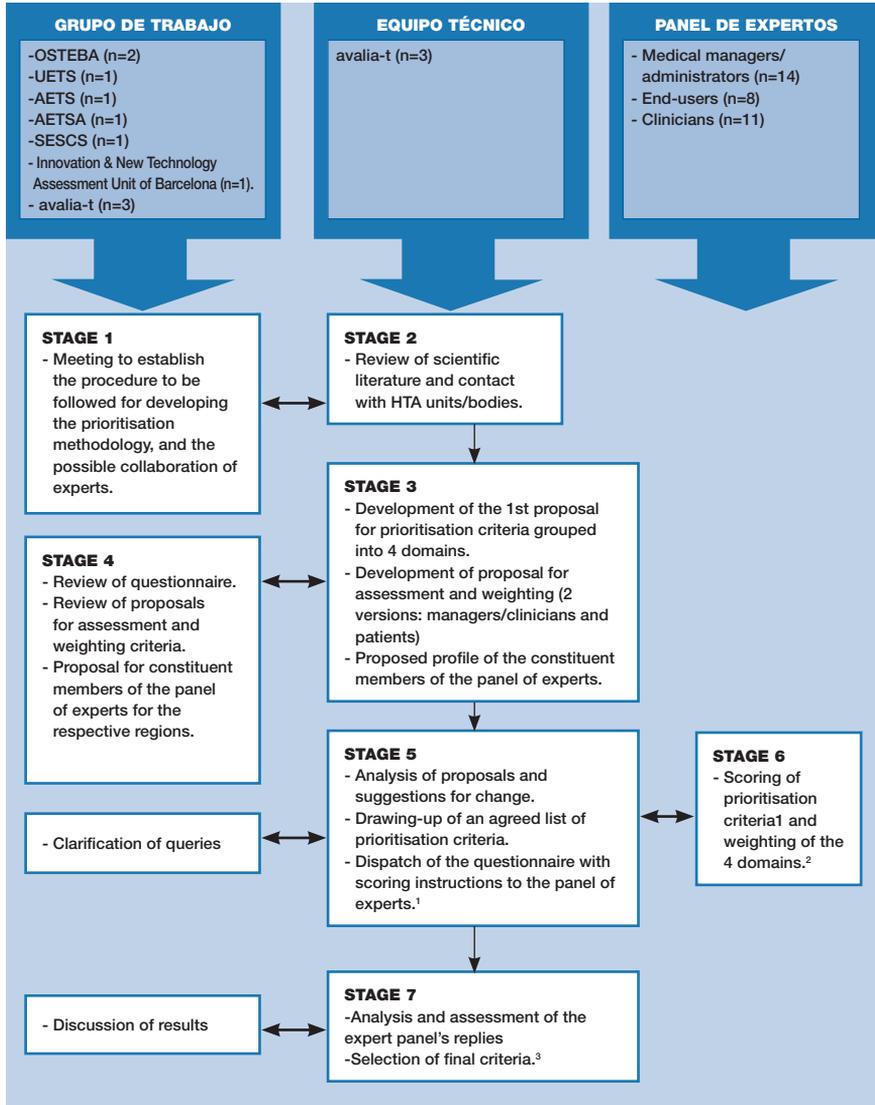
B. Domain scores and weightings

The scoring of the prioritisation criteria and weighting of the domains was carried out by an expert group integrated by a group of subjects representative of the different sectors involved in the adoption and use of new technologies. These include: *policy makers* (hospital directors and directors of health authority central services, such as health care, health assurance, public health, etc.), *clinicians* (primary and specialised care) and *system end-users* (patient associations, consumer and end-user organisations, consultancy groups, community participation groups and other types of users) from the different ARs that collaborated on the project. These panellists were proposed by the working group and technical group and came from their respective Autonomous Regions.

Of the 37 proposed panellists, 36 accepted to participate. These received the prioritisation criteria with their corresponding explanation and instructions for complementation. To facilitate comprehension of the questionnaire, two versions were elaborated: one for decision-makers/clinicians and one for end-users of the system. The prioritisation criteria had to be scored by the panel of experts on a scale of 1 to 9 points according to the attributed importance (see figure 3). The panel of experts allocated domains a partial weight over 100%, in view of their perception of the relative relevance of the domains for prioritising post-introduction observation. The number of panellists that completed the questionnaire was 32 (92%): Of these, 14 were decision makers (42,4%), 11 clinicians (33,3%) y 8 end users(24,3%).

The final included criteria were selected based on the median, with only those criteria having a value of 7 or higher being included. The final weight allocated to each of the 4 domains corresponded to the median of the weighting values allocated by the panel of experts to the prioritisation criteria. Figure 3 summarizes the prioritisation process.

Figure 3. Methodology for identifying, assessing and weighting prioritisation criteria



¹ **scoring of prioritisation criteria:** 7-9: clearly important element; 4-6: element in respect which there are doubts about its importance; 1-3: element of little importance.

² **scoring of domains 0%-100%:** allocation of partial weight on a total of 100% according to relative importance for post-introduction observation. The sum of total scores of the 4 dimensions assumes a value of 100%.

³ **selection of prioritisation criteria:** criteria with a median value of over 6. Criteria with lower values were discarded.

4.2. Assessment of data-collection instruments

A systematic review of the medical literature and a manual review of the web pages of national and international HTA agencies/bodies were conducted in order to locate reference documents and retrieve reports of different experiences in the monitoring/follow-up of new technologies. On the basis of these findings, 4 possible data-collection instruments were proposed: clinical registries, questionnaires/surveys, medical records (paper and electronic format) and available electronic databases such as Minimum Basic Set of Data (MBDS).

To evaluate the advantages and limitations, and establish the possibility of using each of these for post-introduction observation, a specific systematic search was conducted for each instrument in Medline, Cochrane and CRD HTA. Only relevant studies published from 2005 onwards were considered for assessment purposes. The search strategy and the selection criteria are documented in the full version of the guideline published in the web page of *avalia-t* (<http://avalia-t.sergas.es/>).

4.3. Implementation of a post-introduction observation system and development of outcome indicators

The strategy for implementing a post-introduction observation system was based on the recommendations put forward by a technical group from the Galician Health Technology Assessment Agency in consensus with a working group made up of 11 national HTA experts. At a first work session, the technical group established the fundamental requirements for implementing a post-introduction observation system, and using a consensus-based approach, selected the principal areas to be covered by the outcome indicators, along with the different aspects that could be deemed relevant within each area. For the purpose, account was taken, on the one hand, of the results of the systematic review, and on the other, of past experience of post-introduction observation gained in Galicia. As a result of this first meeting, the members of the technical group independently drew up a series of outcome indicators. These indicators were presented at a second work session of the technical group, and those that were deemed relevant for the study objectives were then selected on a consensus basis. Selection of the outcome indicators was based on the following criteria: 1) basic aspect for evaluating deviations in the use/results of new technologies, which could lead to important repercussions for the health of the population or the health

system; and, 2) feasibility of the measure. Following this meeting, the first list of outcome indicators was drawn up, with definitions of the various terms and the pertinent explanations.

These proposed indicators were sent by e-mail to the working group for its review, comments, suggested amendments or proposals for additional indicators. In line with these comments, the methodology was updated and the definitive indicators agreed.

5. RESULTS

5.1. Prioritisation of new health technologies for post-introduction observation

This section provides the list of the prioritisation criteria selected and describes the tool developed.

5.1.1. Results of selection and weighting

Of the 15 prioritisation criteria initially proposed, 15 were classified by the panel of experts as clearly important (score >6). The median value was 7 in 11 of these criteria, 8 in 2 of these criteria and 9 in 1 of them. One of the initial criteria obtained a median value of 6 and was not selected.

Table 2 shows the list of finally selected criteria, grouped by domain.

Table 2. List of prioritisation criteria grouped by domain	
Criterion	Explanation
Domain 1. Population/end-users	
Frequency of use	When it is known or envisaged that the technology may be applied to a large number of patients.
Disease burden	The condition or indication for which the technology is being used entails elevated mortality, morbidity, disability or affects the patient's quality of life to a major extent.
Impact on end-user/population	The technology may bring about important improvements in the state of health/wellbeing of the subjects or population to which it is applied (e.g., population screening).
Vulnerable populations	The technology has been designed to be fundamentally used on a highly sensitive group (e.g., pregnant women, chronically ill patients).
Domain 2. Technology	
Innovative technology	Where the design, materials or their operation are totally new or very different to other already existing technologies and/or there are no previous technological alternatives for this clinical indication.
Invasive technology	Any technology that requires surgical intervention or aggressive medical procedure for its use. This also includes implantable devices or systems designed to be introduced, wholly or in part, into the human body, with the intention that these are to remain there post-procedure.
Different expectations of use	The health technology may be open to having different applications in clinical practice and being used in clinical indications other than those approved.

Criterion	Explanation
Domain 3. Safety/adverse effects	
Safety	There is evidence in the literature of adverse effects and/or it is envisaged that these may occur, due to the existence of adverse effects with similar technologies or procedures.
Undetected potential adverse effects	The available evidence is deemed insufficient for supplying information on infrequent adverse effects. Studies include a small number of patients overall or for given subgroups, and/or the study follow-up period is short for the purpose of adequately assessing the appearance of medium-/long-term adverse effects.
Risks	There is the possibility that health staff may suffer harm as a consequence of its use (e.g., radiation) or it poses an environmental hazard (e.g., dangerous waste).
Domain 4. Organisation/costs and other implications	
Need for training	Technologies which require an intense period of training and the results of which may, in great measure, depend on knowledge acquired and personal abilities (learning curve).
Financial impact	Necessary investment in infrastructure, equipment and/or cost of fungible goods, maintenance or human resources.
Organisational or structural impact	Technologies that demand multidisciplinary, creation of new units, co-ordination among different units, or creation of specific units.
Other implications	It is envisaged that the technology may have an important impact on the ethical, social, cultural and/or legal sphere.

Table 3 shows the median weighting values assigned to the respective domains by the panel of experts as a whole.

Table 3. Median weighting values assigned by the group of experts.	
Domain	Median score (%)
Population/end-users	35%
Technology	20%
Safety	25%
Organisation/costs	20%

5.1.2. Description of the prioritisation tool: PriTecTools

The prioritisation tool (PriTecTools) consists of a web application which can be accessed via the web page of avalia-t (<http://avalia-t.sergas.es/>). This tool lists the prioritisation criteria grouped by domains and allows for up to 50 different technologies to be scored and compared. By scoring the prioritisation criteria

from 1 to 9, the tool automatically calculates the score for each domain and the total score for each technology, furnishing the absolute and weighted scores (absolute; base 100, i.e., transformation of weighted score on a scale of 0 to 100; % total score). Furthermore, it furnishes the results in a comparative manner for the different technologies selected. **PriTec.observation** enables reports to be generated and any data and results obtained *in situ* to be stored in the form of tables and figures, so that these may be used in subsequent work sessions. No data entered into the application are stored on the web, which guarantees the total confidentiality of any data introduced. The tool is available in both Spanish and English. A full explanation on the tool's operation and score calculation can be found on the web application.

5.2. Data-collection instruments

This section presents the results of the assessment of the different instruments that could be used for data-collection. The aim is to provide some key points for selecting the most ideal data-collection instrument from the existing alternatives and contexts.

On the basis of the findings of the systematic review of the literature 4 possible data-collection instruments were proposed:

- clinical registries,
- questionnaires/surveys,
- medical records (paper and electronic format),
- available electronic databases such as Minimum Basic Set of Data (MBDS).

Table 4 presents a summary of the main conclusions of the systematic reviews specifically carried out to assess each one of these instruments, depicting the main advantages, limitations and considerations that must be taken into account when planning to use them for the post-introduction observation of new technologies.

In the complete version of the methodological guideline published on-line (<http://avalia-t.sergas.es>), the different instruments are briefly described and the main results of the studies included in the systematic review are shown, along with the evidence tables and search strategy.

Table 4. Principal results of the systematic review

Data-collection instrument	Advantages, limitations and important considerations
CASE REGISTRIES	<ol style="list-style-type: none">1) Although registries can be very useful tools for gathering comprehensive information on daily clinical practice, their usefulness in post-introduction follow-up is limited by the fact that their development is extremely complex and requires important resource use, both in terms of finance and in terms of staff and time.2) Follow-up losses and the lack of continuity in data registration are important limitations if such data are sought to be used for assessing adverse effects that appear in the medium-/long-term.
SURVEYS/ QUESTIONNAIRES	<ol style="list-style-type: none">1) Surveys or questionnaires can be tools of great value for post-introduction observation, in view of their relatively low cost and their potential for conducting a follow-up of patients where there is no structured review process on the part of clinicians.2) The main limitations of the surveys/questionnaires concern the possibility of low response rates, incomplete or biased information or lack of representativity.3) The planning of the survey is crucial for ensuring an adequate response rate. On planning how the survey must be conducted, the following considerations should be taken into account:<ul style="list-style-type: none">- Response rates are highest when face-to-face interviews are conducted but these entail a higher cost than telephone interviews or postal surveys.- Postal questionnaires are cheaper than other survey methods but response rates have been shown to be low in some cases. The evidence indicates however that, with adequate planning, the response rate could be similar to or even higher than that of telephone interviews, but that the proportion of unanswered questions is higher. Financial incentives are regarded as one of the best methods of improving the response rate. Previous contact and reminders are also viewed as highly effective methods of improving response rates. Other methods that increase the response rate include administration of short questionnaires, registered post, urgent post or dispatch in reply-paid envelopes.- Electronic questionnaires obtain response rates much lower than those obtained via other methods. The cost of questionnaires sent by e-mail is however far lower than that of postal or telephone questionnaires.- Patients and clinicians prefer postal to electronic questionnaires.4) There is insufficient evidence, in terms of both quality and quantity, for properly assessing the quality of the information obtained by any of these survey methods.

Data-collection instrument	Advantages, limitations and important considerations
MEDICAL RECORDS	<ol style="list-style-type: none"> 1) Extracting information from medical records does not imply an extra workload for health professionals but there is evidence that frequently data is missing and retrospectively accurate information is only available for objective data. 2) The available evidence is not sufficient to determine the quality of the routinely collected data. <ul style="list-style-type: none"> - The studies identified agree on the high quality of demographic data and easily diagnosed diseases but there is discrepancy as to the quality of data regarding other diseases. - There are no adequately designed studies to establish the validity of routinely recorded data for the assessment of clinical indications, side effects or affectivity problems. 3) There is evidence that the degree of reporting is higher when information is obtained directly from patients than when it is extracted from their medical records, but with the available data it is not possible to establish which of the two sources furnishes better-quality data. 4) There is evidence that electronic medical records could be used for post-introduction observation of new technologies if the following criteria are fulfilled: <ul style="list-style-type: none"> - electronic health records are the only source of data for recording patient information. - a system is implemented which enables close collaboration with clinicians to previously establish relevant outcome-reporting variables. - a software is available to enable the collection and transfer of additional data not usually recorded on clinical histories.
MBDS	<p>In the context of observation of new technologies, the use of the MBDS is limited because, when a new technology is implemented and for a period of time thereafter, new procedures are usually grouped under general categories which do not allow for identification of cases in which the new technology is used.</p>

5.3. Implementation and outcome indicators

This section describes the basic requirements to implement a post-introduction observation system and furnishes a series of outcome indicators for assessment of results. The aim is to guide and advise persons tasked with assessment on the different aspects to be borne in mind when it comes to implementing a post-introduction observation system, and provide them with a series of tools for analysing relevant aspects of post-introduction observation.

5.3.1. Basic requirements for implementing a post-introduction observation system

The implementation of a post-introduction observation system requires prior planning of the whole procedure, in close collaboration with a multidisciplinary team representative of all health professionals directly involved in the use of new technology. Before initiating a post-introduction observations a comprehensive assessment should be made of the information that must be collected, the data sources and resources available and the procedure for analysis of results.

Based on the results of the systematic review and the recommendations proposed by the working group, a post-introduction observation system for new technologies must comply with the following premises:

1. the outcome data to be collected should be part of the data that should be recorded in daily clinical practice because it is relevant for ensuring correct medical practice and patients' progress.
2. any increase in the number of diagnostic procedures and tests performed on the patient must be prevented.
3. the number of follow-up contacts should be in agreement with the routine check ups. It must be ensured that the number of follow-up visits is not increased save in specific cases in which there is no previous consensus among centres and a follow-up is agreed upon.
4. the variables to be collected must, as far as possible, be outcome variables that are either objective or capable of being rendered objective, with intermediate variables being avoided as far as possible.

Validated scales are to be used for assessment of results (pain, quality of life, etc.).

5. the follow-up, albeit not too long, must nonetheless be sufficient for obtaining an adequate number of patients in each target study-subgroup and allowing for detection of short-/medium-term adverse effects. As a reference, the minimum recommended follow-up time is 1 year. In cases where the technology might be indicated in a small number of patients or subgroup analysis must be performed, this period could be extended until a minimum number of interventions (patients) was reached (guideline: 25-30).
6. a common database must be used for data-management and there should be a support from a specialised reference unit for the purpose of standardising analysis of results (for example, HTA agency).

The requirements deemed fundamental for implementing a post-introduction observation system are displayed in table 5.

Table 5. Fundamental requirements for implementing a post-introduction observation system.

1. **Scope of the study:** It is necessary to delimit the health area, geographical area, province, region or country in which it is envisaged that the post-introduction observation procedure is to be implemented. It will also be necessary to define whether the post-introduction observation will solely consider centres that form part of the public health system or will also consider private centres. In addition, the scope of study must be specified, i.e., whether it is to include primary care, specialised care or all types of centres.
2. **Participant centres:** Contact must be made with the centres, departments and units that are involved in the use of the new technology, in order to request their collaboration and ask them to designate a contact person.
3. **Study protocol:** A study protocol must be drawn up in collaboration with a multidisciplinary group made up of health professionals involved in the planning, implementation, scheduling and use of the new technology, to agree on the characteristics of the post-introduction observation system. The proposed study protocol must be reviewed at each participant centre by the various specialists involved in the health care of these patients.

The study protocol must address the following points:

- a. *Definition of the goal and purpose of the study:* The study objectives and purpose must be defined *a priori*. The objectives will be what determine the target population, the data to be collected and the outcome variables (outcome indicators). Hence, the relevance of these being carefully considered in collaboration with the multidisciplinary group.
- b. *Target population:* It is essential to establish and clearly define the clinical indications and specific characteristics of the patients (age range, co-morbidities, severity, etc.) who are to form part of the target study population.

c. *Study subgroups*: It is essential to establish and define whether there are subgroups of patients that must be separately evaluated (clinical indications, age, symptoms, severity, co-morbidities, pregnancy, etc.). Similarly, in cases where there are similar though not identical procedures, procedures that call for a high degree of specialisation, or procedures that are used in combination with others, it is also necessary for the technique, manner and order of administration to be registered and for the study subgroups deemed of interest for analysis purposes (country, team, technique, etc.) to be established.

d. *Data-collection variables*: The variables to be included in the study must be stipulated, the specific criteria that define such variables must themselves be defined, and the method of coding the variables must be determined. In the case of each technology, it is important for adverse effects that are going to be classified as mild/moderate and those that are going to be classified as severe to be defined.

e. *Systematic data-collection*: The data sources and data-collection instruments (clinical history, specific questionnaires, etc.) must be chosen, and the procedure for collecting (person responsible, method of collection, measurement scales, etc.) and distributing the data (person responsible, channel and periodicity) established.

f. *Outcome indicators*: The outcome indicators that are deemed relevant for each technology must be chosen by consensus. Depending on the technology in question, it may be relevant for all aspects (diffusion, accessibility, effectiveness, safety, resource use and financial impact) or only some aspects of post-introduction observation to be considered. Within these, it may in turn be deemed relevant for one or more outcome indicators to be analysed.

g. *Patient follow-up*: Patient follow-up guidelines must be agreed upon and the duration of the study established. A follow-up time of 1 year is recommended but this may be increased if the intervention is indicated in few patients or if analysis by subgroup is required.

h. *Acceptable or desirable standards*: The standards deemed acceptable or desirable for each outcome indicator targeted for assessment (diffusion, adequacy of use, safety, effectiveness, costs, etc.) must be defined *a priori*. The multidisciplinary group will be responsible for establishing and agreeing upon the values deemed acceptable or desirable. For the principal variables, the values to be used to determine the success or failure of the technology must be carefully established, taking into account all the pertinent information, i.e., results reported in the scientific literature, data published in diverse data sources and personal experiences.

i. *Data-analysis*: The data-analysis procedure (unit responsible) must be established.

j. *Patient information*: It is recommended that the written information to be furnished to the patients at the various centres be decided upon and rendered uniform.

k. *Data confidentiality*: The procedure for maintaining the confidentiality of the data (masking of data, encryption, etc.) must be laid down.

4. Organisation: Once the planning stage has been finalised, it will be necessary to proceed to the implementation stage. This stage can be divided into 3 parts:

- a. Development of data-collection instruments (specific questionnaires).
- b. Drafting of detailed instructions covering the data-collection and dispatch procedure. These must include the definition and coding of all variables.
- c. Development of a common database.

5. Data-quality control: Provided that it is feasible, consideration should be given to an external review of 5% of entries in order to assess the quality of the data registered. This activity could be undertaken by the unit responsible for data analysis.

6. Plan for dissemination of results and alert system for unforeseen problems: It is recommended that, prior to the start of the study, agreement is reached on how to proceed in the event of detection of problems and how the results of the study are to be disseminated.

5.3.2. Outcome indicators

This section of the guideline displays a list of key indicators for measuring the different aspects of post-introduction observation of new technologies. The purpose of these outcome indicators is to measure relevant aspects of the diffusion and use of new technologies once they are used in standard clinical practice, in order to furnish valid and reliable information on the quality of health services. In the provision of health services, “quality” measures to what extent the result obtained is the desired -optimal- according to the scientific knowledge and the context in which such services are offered. Limitations, in the sense of not achieving the desired effect, may stem from a flawed structure or incorrect process, due to over-, under- or misuse of medical technologies (25).

Table 6 shows the list of proposed indicators, grouped according to the respective aspects considered relevant for post-introduction observation of new technologies: diffusion, accessibility, adequacy of use, effectiveness, safety and economic impact. In the following tables, the specific characteristics of each indicator are described.

Table 6. List of outcome indicators	
Domain	Name of indicator
Diffusion	Adoption of the new technology
	Coverage of the technology
Accessibility	Accessibility
Adequacy of use	Adequacy of patient selection criteria
Effectiveness	Effectiveness
	Effectiveness by subgroup
Safety	Severe adverse effects
	Mild adverse effects
	Adverse effects by subgroup
Economic impact	Adequacy of costs

Indicator	Adoption of the new technology
	In what proportion of centres has the new technology been adopted?
Justification	The approval/funding of a new technology does not assure that it will be efficaciously adopted within the health system. Frequently, the implementation of a new technology requires, not only financial investment, but also structural and organisational changes, availability of trained staff, and time. Ascertaining the centres that have adopted the new technology can be essential in order to detect problems of implementation.
Formula	$\frac{\text{Total number of centres that have adopted the new technology within a given period of time}}{\text{Total number of centres at which adoption of the new technology is deemed desirable within a given period of time}} \times 100$
Explanation of terms	<p>Adoption of a new technology: implementation and use of the new technology in clinical practice in the centres considered within the target area.</p> <p>Centres at which the adoption of the new technology is deemed desirable: centres at which the adoption of the technology is deemed desirable/foreseeable must be defined a priori. Depending on the health system and/or type of technology, these could be all the centres within the target area, all centres with the relevant specialisation or solely reference centres or centres that have been authorised to use the new technology.</p>
Scope of study	The scope of study (geographical area, province, region, country) must be defined in order to delimit the centres that are to be targeted by the study and are to form the numerators and denominators of the formula.
Guideline standard	80%-100%.
Time frame	- A mean follow-up of 1-year after approval/funding of the new technology is taken as reference. This period may be extended to 2-3 years in the case of technologies that may require major financial, organisational or structural changes.
Data-sources	<ul style="list-style-type: none"> - Suppliers or manufactures of the new technology (technologies that require a specific apparatus, device or fungible goods for their use). - Health-centre service catalogue (if existing and updated). - Direct contact with each centre and/or department (innovative procedures or techniques based on the learning of skills). - Contact with administrative centres tasked with approval of centres and allocation of resources for public health care.

Indicator	Coverage of the technology
	How many patients of those eligible to use the new technology, actually use it?
Justification	Ascertaining the relationship between patients eligible to use the new technology and those that use it in clinical practice is important when it comes to detecting problems of coverage, detecting whether there may be an over-use of the new technology with respect to what was envisaged, or detecting possible resistance to its use (under-use)
Formula	$\frac{\text{Total number of patients that have used the new technology within a given period of time}}{\text{Total number of patients eligible to use the new technology within a given period of time}} \times 100$
Explanation of terms	<p>Patients that have used the new technology: consideration will only be given to subjects for whom results of applying the technology are available. Scheduled interventions that were not performed must be excluded.</p> <p>Patients eligible to use the new technology: patients in the target area who meet the selection criteria set a priori by the multidisciplinary group.</p>
Guideline standard	80%-100%. This must be set a priori.
Scope of study	The scope of the study (hospital, health area, geographical area, province, region, country) must be defined in order to delimit the units and services to be targeted by the study.
Time frame	A mean follow-up of 1-year after approval/funding of the new technology is taken as reference, though this may be extended in the case of technologies indicated in a small number of patients. This must be set a priori.
Data sources	<p>Patients that have used the new technology:</p> <ul style="list-style-type: none"> - clinical registries, medical records and/or MBDS registries <p>Patients eligible to use the new technology:</p> <ul style="list-style-type: none"> - Disease frequency registries (number of cases, prevalence..) - Studies published in the scientific literature - Registries on the number of procedures using alternative techniques to those that this would replace.

Indicator	Accessibility
	What is the degree of use of the new technology in the various geographical areas?
Justification	When a new technology is introduced, an appropriate patient-reference circuit must be established to ensure that the degree of use is independent of this technology's availability in the health area. Calculating and comparing the use of a new technology in different geographical areas is fundamental for identifying problems of geographical accessibility.
Formula	$\frac{\text{Number of patients residing in a predefined geographical area who have used the new technology within a given period of time}}{\text{Patients residing in a geographical area eligible for using the new technology within this period of time}} \times 100$
Explanation of terms	<p>Subjects that have used the new technology: consideration will be given only to subjects for whom results of applying the technology are available. Scheduled interventions that were not performed must be excluded.</p> <p>Subjects susceptible to using the new technology: patients in the target area who meet the selection criteria set a priori by the multidisciplinary group.</p>
Guideline standard	This must be set a priori
Scope of study	The scope of the study (health area, province, region, country) must be indicated, in order to delimit the health centres and areas to be targeted by the study.
Time frame	A mean follow-up of 1-year after approval/funding of the new technology is taken as reference, though this may be extended in the case of technologies indicated in a small number of patients. This must be set a priori.
Data sources	<p>Patients that have used the new technology:</p> <ul style="list-style-type: none"> - clinical registries, medical records and/or MBDS registries <p>Patients eligible to use the new technology:</p> <ul style="list-style-type: none"> - Disease frequency registries (number of cases, prevalence) - Studies published in the scientific literature - Registries on the number of procedures using previous alternative techniques for the same indication.

Indicator	Adequacy of patient selection criteria
	Are the patient-selection criteria used within the various centres, departments or units in line with what is deemed appropriate and/or desirable for this technology?
Justification	It is important to ascertain whether patients on whom the new technology is used meet the selection criteria. Inappropriate use could cause the loss of important resources without any proven benefit (financial, personal, time) or even impact negatively on the health of the population.
Calculation formula	$\frac{\text{Number of patients among whom the technology has been used, who meet the inclusion criteria}}{\text{Number of patients that have used the technology}} \times 100$
Description of terms	<p>Inclusion criteria: consideration will be given to the clinical indications and to the different characteristics of the patients (age, degree of pain, ineligibility for other treatments) which are used to define patients to be treated/ diagnosed with the new technology. The inclusion criteria will be established a priori, taking into account the authorised selection criteria for use of the technology within the health system (if these exist), scientific evidence and/ or opinion of experts.</p> <p>Subjects that have used the new technology: consideration will only be given to subjects for whom results of applying the technology are available. Scheduled interventions that were not performed must be excluded.</p>
Guideline standard	100%
Scope of study	The scope of the study (hospital, health area, geographical area, province, region, country) must be indicated, in order to delimit the departments and units that are going to be deemed the study target.
Time frame	A mean follow-up of 1-year after approval/funding of the new technology is taken as reference, though this may be extended in order to attain a minimum number of 25-30 interventions (patients). This must be defined a priori.
Data sources	- clinical registries, medical records and/or MBDS registries.

Indicator	Effectiveness
	Is the new technology's degree of success in line with expectations?
Justification	The expectations foreseen in preliminary studies may not be fulfilled when the technology is applied in daily clinical practice (different level of experience, patient profiles, etc.). Should this be so, it may well be necessary for the use of such technology to be reconsidered.
Formula	$\frac{\text{Number of subjects among whom a beneficial effect has been observed}}{\text{Total number of subjects that have used the new technology}} \times 100$
Description of terms	<p>Beneficial effect: effect deemed acceptable or desirable for this technology. According to the type of technology, the outcome variables to be used to define the new technology's success and the values deemed acceptable or desirable for this variable must be defined a priori.</p> <p>Total number of subjects that have used the new technology: deemed to be all subjects in the target population who have been treated or diagnosed with the new technology.</p>
Outcome variables	They must be set a priori. As far as possible, these variables must be objective or capable of being rendered objective.
Guideline standard	90%-100%. This must be set a priori.
Scope of study	The scope of the study (hospital, health area, geographical area, province, AR, country) must be indicated, in order to delimit the units and departments that are going to be considered.
Follow-up time	A mean follow-up of 1-year after approval/funding is taken as reference, though this may be extended in order to attain a minimum number of 25-30 interventions (patients).
Data sources	<ul style="list-style-type: none"> - Specific clinical registries - Medical records - Surveys/questionnaires

	Subgroup effectiveness
	Is the new technology's percentage of success in line with what was expected for certain subgroups of patients?
Justification	Preliminary studies often fail to envisage assessment of effectiveness in specific subgroups (children, the elderly, subjects with serious co-morbidities) and this may differ significantly from overall effectiveness. Similarly, where similar though not identical procedures or procedures that require a learning curve are involved, effectiveness may also differ significantly as between the various subgroups (team, degree of specialisation, etc.).
Formula	$\frac{\text{Number of patients in a study subgroup among whom a beneficial effect has been observed}}{\text{Total number of subjects in the subgroup that have used the new technology}} \times 100$
Description of terms	<p>Study subgroup: subgroups susceptible to registering differences in terms of effectiveness. These must be established a priori.</p> <p>Beneficial effect: effect deemed acceptable or desirable for this technology. According to the type of technology, the outcome variables to be used to define the new technology's success and the values deemed acceptable or desirable for this variable must be defined a priori.</p> <p>Total number of subgroup subjects that have used the new technology: deemed to be all subjects in the target study subgroup who have been treated or diagnosed with the new technology.</p>
Outcome variables	They must be set a priori. As far as possible, these must be objective or capable of being rendered objective.
Guideline standard	90%-100%. This must be set a priori.
Scope of study	The scope of the study (hospital, health area, geographical area, province, region, country) must be indicated, in order to delimit the departments and units that are going to be considered.
Follow-up time	A mean follow-up of 1-year after approval/funding is taken as reference, though this may be extended in order to attain a minimum number of 25-30 interventions in each subgroup.
Data sources	<ul style="list-style-type: none"> - Specific clinical registries - Medical records - Surveys/questionnaires

	Severe adverse effects
	What proportion of patients present with severe adverse effects?
Justification	In daily clinical practice, it frequently happens that severe adverse effects not envisaged in preliminary studies appear, or that these appear in a greater proportion of subjects. Quantifying these variations is important for ensuring patient safety.
Formula	$\frac{\text{Number of patients among whom a severe adverse effect has been observed}}{\text{Total number of patients on whom the new technology has been used}} \times 100$
Description of terms	<p>Severe adverse effects: for practical purposes severe adverse effects are deemed to be any injury, damage or complication deriving from the use of the technology, including diagnostic errors (FP, FN) which can lead to death or major deterioration of patient's state of health. The type of adverse effects to be considered for study purposes must be established a priori.</p> <p>Total number of subjects that have used the new technology: deemed to be all subjects in the target population who have been treated or diagnosed with the new technology.</p>
Acceptable standards	This must be defined a priori
Scope of study	The scope of the study (hospital, health area, geographical area, province, AR, country) must be indicated, in order to delimit the departments and units that are going to be considered objective of the study.
Follow-up time	A mean follow-up of 1-year after approval/funding is taken as reference, though this may be extended in order to attain a minimum number of 25-30 interventions (patients). This must be defined a priori.
Data sources	<ul style="list-style-type: none"> - Specific clinical registries - Medical records - Surveys/questionnaires

	Mild to moderate adverse effects
	What proportion of patients present with moderate and/or mild adverse effects?
Justification	Analysis of adverse effects is the basis for identifying genuine opportunities for improvement. Adverse effects, albeit not severe, may affect patients' quality of life and, where frequent, can give rise to considerable resource use.
Formula	$\frac{\text{Number of subjects among whom moderate and/or mild adverse effects have been observed}}{\text{Total number of subjects on whom the new technology has been used}} \times 100$
Description of terms	<p>Moderate and/or mild adverse effects: for practical purposes these are deemed to be any non-severe injury, damage or complication deriving from the use of the technology, as well as any diagnostic error (FP, FN) that has led to an alteration in the patients' state of health. The type of adverse effects to be considered for study purposes must be established a priori.</p> <p>Total number of subjects that have used the new technology: deemed to be all subjects in the target population who have been treated or diagnosed with the new technology.</p>
Standards acceptable	These must be defined a priori
Scope of study	The scope of the study (hospital, health area, geographical area, province, region, country) must be indicated, in order to delimit the units and departments that are going to be considered objective of the study.
Follow-up time	A mean follow-up of 1-year after approval/financing is taken as reference, though this may be extended in order to attain a minimum number of 25-30 interventions (patients). This must be defined a priori.
Data-source	<ul style="list-style-type: none"> - Specific clinical registries - Medical records - Surveys/questionnaires

	Adverse effects in subgroups
	Are the adverse effects in line with what was expected in especially susceptible subgroups?
Justification	Especially sensitive subgroups (children, the elderly, pregnant women, subjects with serious co-morbidities), subgroups with different degrees of specialisation or different ways of performing the intervention (apparatus, protocols, teams, etc.), could register previously unexpected adverse effects.
Formula	$\frac{\text{Number of subjects in a subgroup among whom an adverse effect has been observed}}{\text{Total number of subjects in the subgroup that have used the new technology}} \times 100$
Description of terms	<p>Study subgroup: subgroups susceptible to present a higher proportion of adverse effects. These must be established a priori.</p> <p>Adverse effects: for practical purposes these are deemed to be any injury, damage or complication deriving from the use of the technology, as well as any diagnostic error (FP, FN) which has led to an alteration in the patient's state of health. The type of adverse effects to be considered for study purposes must be established a priori.</p> <p>Total number of subjects that have used the new technology: deemed to be all subjects in the target population who have been treated or diagnosed with the new technology.</p>
Standards acceptable	These must be defined a priori.
Scope of study	The scope of the study (hospital, health area, geographical area, province, AR, country) must be indicated, in order to delimit the units and departments considered for study purposes.
Follow-up time	A mean follow-up of 1-year after approval/financing is taken as reference, though this may be extended in order to attain a minimum number of 25-30 interventions in each subgroup.
Data sources	<ul style="list-style-type: none"> - Specific clinical registries - Medical records - Surveys/questionnaires

	Adequacy of costs
	Are the observed costs in line with what was expected?
Justification	For adequate planning, it is essential to ascertain whether the estimated costs are in line with the real costs of the technology.
Formula	$\frac{\text{Observed costs under specific chapters of major financial impact}}{\text{Estimated costs under specific chapters of major impact}} \times 100$
Description of terms	<p>Costs: includes costs needed for implementing the new technology but also costs derived from its utilisation in clinical practice. Includes costs of apparatus, support material, fungible costs, maintenance costs, waste management, health service transport, etc.). The costs to be considered for study purposes must be established a priori. Costs must be measured in monetary units.</p> <p>Chapter of major impact: according to the type of technology, the cost chapters responsible for major resource use must be established a priori.</p>
Standards acceptable	These must be defined a priori.
Scope of study	The health centres to be targeted by the study must be defined a priori.
Data sources	<ul style="list-style-type: none"> - Specific registries - Pharmaceutical companies, producers and distributors of the technology - Ad hoc calculation

For new technologies that could have important implications in the consumption of resources it might be important to establish specific resource use indicators. These could include, among others, staff hours, length of hospital stay, operation time, etc.

6. GENERAL CONSIDERATIONS AND LIMITATIONS OF THE PROPOSED POST-INTRODUCTION OBSERVATION

We feel that post-introduction observation of new technologies is a strategy which, in great measure, complements procedures implemented in Spain to regulate the incorporation and introduction of new technologies. Although it could be claimed that there is a certain degree of overlap with other activities undertaken during the post-marketing stage of new technologies, we understand that post-introduction observation is a clearly differentiated strategy, not only on account of its different approach, but also because it affords previously unavailable information that could be crucial for ensuring the equity and quality of health services.

To date, follow-up systems implemented after the introduction of new technologies at an international level have fundamentally been designed to assess potentially relevant technologies, for which there is no scientific evidence to determine their safety, efficacy or effectiveness, with the aim of deciding on their definitive funding/approval (monitorised use/monitoring) or evaluating whether the manufacturers' basic requirements as to safety and effectiveness are being complied with. Post-introduction observation of new technologies is a strategy designed for technologies where, despite an apparent absence of problems of effectiveness and/or safety, their characteristics (i.e., they are applied to large population groups, to conditions with high mortality/morbidity, to highly sensitive group, and/or are very innovative, costly, etc.) may nevertheless render it vital for their application and performance to be recorded under real conditions of use, in order to guarantee accessibility and adequacy of use, and detect possible problems of effectiveness and/or safety in the short/medium term. Possessing reliable and timely information is essential for being able to remedy aspects that may influence the quality of the services performed or, on the contrary, for fostering the use of technologies under given conditions (subgroups of patients, modalities of use, etc.).

Given that the present proposal for post-introduction observation is based on epidemiological principles solid numerators and denominators can be obtained. Moreover, the fact that it is conceived as an active data-collection system means that the great shortcoming of surveillance systems, i.e., low reporting rate and possible information bias, can be remedied.

Table 7 shows the main differences between the follow up systems established in Spain, which might be common to many other developed countries.

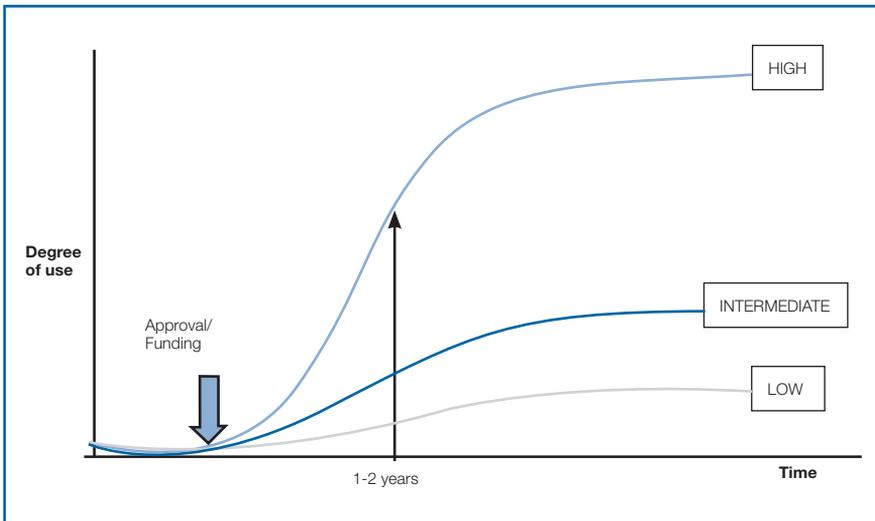
Table 7. Principal health-technology follow up systems established to date in Spain.				
	Yellow card	Monitored use	Medical device vigilance systems	Post-introduction observation
Target technology	Medications	Techniques, technologies and procedures (except medications)	Medical devices	Any health technology (except medications).
Effectiveness of technology	Known	Not totally known	Known	Known
Purpose	To ascertain low-frequency, severe adverse effects	To ascertain effectiveness and safety	To ascertain any dysfunction or deterioration in the characteristics or operation of the medical device which may have caused or causes the death or deterioration of the patient's health.	To ascertain diffusion, acceptability, adequacy of use and detect problems of effectiveness, adverse effects and costs, particularly those that arise in the short-/medium-term.
Participants	Physicians and pharmacists	Physicians	Manufacturers and end-users (in most cases)	Health professionals, patients and industry
Selection of participants	None	Ministry of Health & Consumer Affairs	None	Centres that may incorporate the technology.
Level of implementation	National	National	National	National

Post-introduction observation of new technologies is clearly differentiated from monitoring because it is formulated as a structured strategy to identify, collect and analyze relevant information that is collected routinely during clinical practice. The current proposal, in contrast to monitoring, requires a minimum investment of time from clinicians and provides them with direct information of the real problems concerning the application of technologies in real practice. However, as in other follow up systems, clinician's must be made aware of the value of the information obtained to guarantee their collaboration. All health professionals involved in the utilization of the technology must be implicated. Similarly, to set up these systems time and resources are needed and these can only be obtained with adequate financing.

For practical reasons, it is proposed that post-introduction observation should cover the initial stages of implementation and continue for a minimum period of 1 year after the new technology is approved. An adequate period of time must be allowed to elapse so as to detect adverse effects that appear in the medium term and identify any possible problems of implementation and/or acceptability. It is foreseeable that the use of new technologies by health professionals will evolve in line with the innovation diffusion model proposed by Beals et al (26). According to this model, new technologies will spread in the form of an S-shaped curve, with diffusion passing through 5 differentiated stages, namely: 1) from first knowledge of an innovation; to 2) forming an attitude toward the innovation; to 3) a decision to adopt or reject) to 4) implementation of the new idea; and to 5) confirmation of this decision. Based on this theory, we feel that 1 year could be sufficient for detecting possible variations with respect to what was originally foreseen. This period of time will likewise be enough for detecting adverse effects that may arise in the short-/medium-term, though this is preliminary information, and thus it might well be of interest in the majority of cases for this follow-up period to be extended so as to detect the long-term adverse effects as well. However, we see this as being somewhat unfeasible, in view of the great cost that it -together with the introduction of other alternative technologies- would entail, and it is therefore only recommended in specific cases where technologies are applied to a small number of patients or analysis by subgroup must be performed

Figure 4 depicts the way in which the use of technology would evolve where the degree of acceptance/implementation was: 1) high; 2) intermediate; and 3) low.

Figure 4. Evolution of the degree of use with respect to the degree of acceptance/implementation.



The current methodological guideline outlines the specific procedures and strategies for planning, implementing and assessing the use of new technologies. It is a consensus-based document that was drawn up by a working group made up of experts in health technology assessment, with the participation of managers/administrators, clinicians and patients, who are the main parties involved in the planning and use of new technologies. This renders it quality and favours its acceptance. The main aim of publishing the guideline in an abridged format, with the results shown in schematic tables, is to favour its use. There is evidence to show that presentation in this more practical format is a factor that greatly facilitates its use in health policies (27).

This is the first document to be published on the topic and it is thought that it could serve as a point of reference for any institution/body, national and international, which may be involved in planning and/or implementing post-introduction observation activities. Similarly, scientific societies could also make use of this document for the promotion of new technologies, where clearly beneficial results are obtained.

However, despite the fact that the methodology might be extrapolable to other countries with similar health systems, it must be stressed that certain adaptations might be required since it is fundamentally based on the opinion of experts and experience obtained in a specific context (Galicia). In

the following paragraphs the main considerations for each of the 3 sections of the guidelines are discussed.

6.1. Prioritisation tool

The prioritisation tool that has been developed is highly innovative, since it is the only one of its kind that currently exists for automatically identifying and prioritising health technologies for which implementation of post-introduction observation would be especially relevant. It is a simple and easily usable tool, which is envisaged as being extremely useful for any institution/organisation proposing to implement a post-introduction observation system.

We feel that this tool has external validity, in view of the fact that members of all Spanish technology assessment agencies took part in its development and that the prioritisation criteria were selected and weighted by a group representative of all groups involved in the use of new technologies (medical managers/administrators, clinicians and patients).

The non collaboration of international experts in the elaboration of the criteria and weighting of the domains could be seen as a limitation to the extrapolation of criteria to other contexts. It could be argued that the criteria and weightings are not applicable in health systems with different characteristics and priorities, such as could be the case of United States. In our opinion, the proposed prioritisation criteria are equally valid in other international contexts, though we do not rule out the fact that slight differences may exist with regard to the relevance of such criteria. Similarly, there is also the possibility that additional criteria, not considered by the present working group, may be proposed. Although the prioritisation tool is proposed as a bench mark for prioritisation of new technologies, it is nonetheless envisaged that it may undergo slight modifications with the passage of time.

6.2. Data collecting instruments

The conclusion that is drawn up from the results of the bibliographic review is that there is no one ideal instrument for implementing post-introduction observation. The choice of one instrument or another depends, in great part, on the information to be obtained, the technology sought to be observed, the individual institution's/organisation's/centre's structure/approach, as well as the structural, organisational and financial means available for undertaking such monitoring.

Before starting a post-introduction observation, the information sought to be collected, existing possibilities and available means must be comprehensively assessed, and the design of the data-collection system properly planned.

It is generally accepted that post-introduction observation should be based on active data-collection because existing evidence on passive systems, including surveillance systems, suggests that these furnish more information than do voluntary systems (28, 29). Passive systems suffer from an important degree of under-reporting world-wide and may be biased by incorrect information (15, 16). The reason for this lack of reporting has been well documented in the case of pharmaceutical research and could clearly be applicable to other health technologies (30). Among other things, reasons for under-reporting include complacency, fear of medical-legal implications, and uncertainty as to whether the medication or device has really been the cause of the adverse effect.

Different experiences highlight the fact that the experience and collaboration of clinicians, technical staff, patients and health decision-makers is an absolute requirement for achieving success in any safety-related initiative. An observation system will only be successful if it is implemented by taking into account the needs and experiences of clinicians and patients (28).

Bearing in mind prior experiences in monitored use (6) and the results of the bibliographic review, we put forward that, in our context, post-introduction observation could be undertaken by means of clinical registries, using questionnaires completed by clinicians for collecting data of an administrative and clinical nature at the time of short-term intervention/treatment and telephone surveys of patients for medium/long-term follow-up. Telephone surveys are also proposed as the tool of choice for obtaining information on the technique's diffusion.

We recommend that the questionnaire should be in paper rather than electronic format, since the conclusion drawn from the bibliographic review is that the latter seems to register very low response rates, a result largely confirmed in monitored use.

Based on the fact that there is evidence to show that the degree of reporting is higher when information is obtained directly from the patient, and taking into account the fact that monitored use experiences identified important problems of continuity, we suggest that medium-/long-term information be obtained directly from patients (6). Although the evidence indicates that face-to-face interviews yield higher response rates, the geographic dispersion of the population makes this option enviable due to the considerable time and high cost involved. Bearing in mind that the greater part of the population has telephone access and that the non-response rate is lower than that of postal surveys, we view this as the most suitable option. Nevertheless, it is necessary to recall here that the information drawn from surveys is context-specific. It largely depends on the prior information received by the patient, his/her motivation, and the interviewer's skills. Accordingly, this calls for collaboration from the clinician to increase the response rate, and for interviewers to have adequate training in conducting personal interviews.

In future, electronic medical records could be the tool of choice for post-introduction observation. At present, however, in view of the fact that in many countries, including ours, such histories are still in the implementation stage and that in others they are still in the initial stages of development, it is too soon to for this data-collection instrument to be considered.

6.3. Implementation and outcome indicators

We feel that it is extremely important to have a standardised methodology for post-introduction observation of new technologies. The assessment methodology set forth in this guideline is a preliminary proposal on the relevant aspects to be borne in mind when considering the implementation of post-introduction observation, the outcome indicators to be used, and the way in which the information is to be obtained. This proposal has been agreed upon by a national group of HTA experts and is, to a great extent, based on experience gained at a regional level (Galicia). We should however like to stress the fact that this is an initial proposal which will have to be further developed and modified, as and when more information on the operational performance of post-introduction observation systems is forthcoming. In its current form,

only the basic aspects of the outcome indicators are reflected, without data-analysis and -interpretation being explored in any great depth.

Despite being intended as a guideline, the proposed outcome indicators serve as a point of reference for identifying and evaluating important deviations in the impact of new technologies once these have spread throughout the health system, and for identifying problems of effectiveness or safety. Detecting important deviations from the current standards renders it possible for timely corrective measures to be applied, thereby serving to enhance the quality and efficiency of health services. The use of a common methodology to obtain results also enables comparisons to be made among different centres, areas and regions, and possible shortcomings or, on the contrary, areas of excellence to be identified.

In our opinion, the proposed assessment methodology is valid for any centre, body or institution, national or international, which may envisage initiating post-introduction observation activities. The outcome indicators established are based on essential data that are usually collected in daily clinical practice and would entail no extra work for health-care professionals. However, we recognise the fact that the feasibility of this proposal may, in great part, depend on the availability and quality of the information existing at the level of the various health systems. For instance, the possibility of using electronic medical records as a data source depends on a number of factors, such as: 1) the model of electronic clinical history implemented (overall, exclusively at a specialised level, primary care, etc.); 2) the degree of use of such e-histories in the health organisation and/or system (sole data-collection source, data also recorded in paper format, etc.); 3) the data recorded (completeness, quality, coding); and 4) the software available for data-collection and -transfer. With respect to case registries, their viability has been observed to be dictated, to a large extent, by the collaboration of clinicians. Involving clinicians in planning and data-collection is a difficult task that calls, on the one hand, for an awareness as to the need for assessing new technologies post-introduction, and on the other hand, for appropriate institutional, structural and technical support.

7. CONCLUSIONS

- 1) Post-introduction observation of new technologies is a strategy which can complement the procedures implemented to regulate the incorporation and introduction of new technologies.
- 2) The current methodological guideline is the first document published that sets forth a standardised methodology for post-introduction observation of new technologies. It is thought that it can serve as a reference for any institution/body, national or international, which may be planning to and/or are carrying post-introduction observation activities.
- 3) The methodological guideline provides specific procedures and strategies for planning, implementing and evaluating the utilisation of new technologies.
- 4) At present, post-introduction observation could be undertaken by means of clinical registries, using questionnaires completed by clinicians for collecting data of an administrative and clinical nature at the time of short-term intervention/treatment and telephone surveys of patients for medium/long-term follow-up. In the near future, electronic medical records could be the tool of choice for post-introduction observation.
- 5) The outcome indicators proposed are valid to identify and measure important deviations in the utilization of new technologies once they are diffused within the health care system and identify effectiveness and safety problems.
- 6) The methodology of post-introduction observation put forward is a preliminary proposal which will gradually be redefined with the implementation of these systems in different local, national and international settings.

8. RECOMMENDATIONS

We recommend that the methodology be adapted to the respective context prior to its application. It is further advisable that a pilot test be conducted in the various health systems to assess the functioning of these procedures in line with each individual setting (public, private, specialised care, primary care health systems, etc.).

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