POST-INTRODUCTION OBSERVATION OF NEW TECHNOLOGIES: THE NEGLECTED GAP IN HTA

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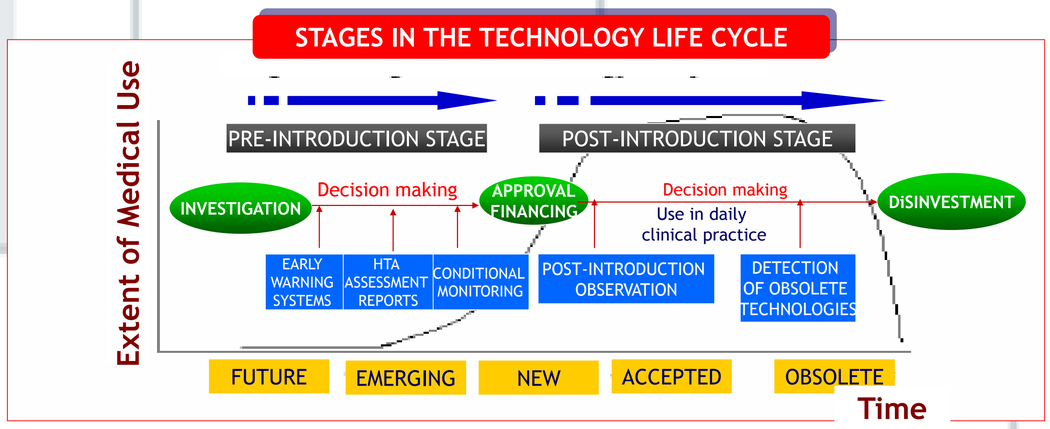
INTRODUCTION

❖ Post-introduction observation of new technologies is a strategy which can complement the procedures implemented to regulate the introduction of new technologies

❖ The development of a systematic, prioritised process for collecting, analysing, interpreting and disseminating information on the utilization of new technologies in the early stages of introduction is essential to:

- *Identify and assess problems concerning implementation, accessibility, acceptability and adequacy of use*
- *Identify problems of effectiveness and safety that may appear when the technology is used in daily clinical practice*
- *Establish if costs and consumption of resources are in line with what was expected from preliminary investigations*



OBJECTIVE

❖ To provide specific guidance for implementation of prioritised post-introduction observation frameworks and discuss the advantages and limitations of this proposal

METHODS

WORKING UNITS

- ❑ TECHNICAL GROUP (3 avalia-t staff)
- ❑ WORKING GROUP (11 National HTA experts)
- ❑ PANEL OF EXPERTS (Policy makers, clinicians and users)

METHODOLOGICAL SECTIONS

- ❑ DEVELOPMENT OF PRIORITISATION TOOL
- ❑ ASSESSMENT OF DATA COLLECTION INSTRUMENTS
- ❑ IMPLEMENTATION AND OUTCOME INDICATORS

SOURCES OF INFORMATION

- ❑ SYSTEMATIC REVIEW OF LITERATURE
- ❑ CONTRIBUTION OF LOCAL AND NATIONAL HTA EXPERTS
- ❑ CONTRIBUTION OF POLICY MAKERS, CLINICIANS AND USERS

FINDINGS

- The tool lists 15 prioritisation criteria grouped in 4 domains and allows for scoring and comparing up to 50 technologies
- The prioritisation tool can be obtainde for free at WWW. PRITECTOOLS.COM

DATA COLLECTION INSTRUMENTS

CLINICAL REGISTRIES

- Allow for obtaining high quality information on daily clinical practice

LIMITATIONS

- require important resource use (dedication time and staff)
- follow up losses and lack of continuity is frequent in middle/long term data collection

SURVEYS/QUESTIONNAIRES

- Present a relatively low cost and potential for assessment of patients with no structured clinical follow up

LIMITATIONS

- the response rate can be low and information can be incomplete or biased or lack representativity
- the quality of the information obtained is relatively unknown

ELECTRONIC RECORDS

- Extracting information does not imply an extra workload on health professionals

LIMITATIONS

- Data is frequently missing and retrospectively accurate information is only available for objective data.
- The available evidence is not sufficient to determine the quality of routinely collected data

RECOMMENDATIONS FOR DATA COLLECTION

✓ In the Spanish 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.

✓ In the near future, electronic medical records could be the tool of choice for post-introduction observation.

MAIN RESULTS FROM REVIEW

✓ There is no ideal instrument for data collection

✓ The choice of a data collection instrument depends on:

- *Information to be obtained*
- *Type of technology to be observed*
- *Organizations approach*
- *Structural and financial means*

IMPLEMENTATION AND OUTCOME INDICATORS

❖ This section provides the basic requirements to implement a post-introduction observation system and furnishes a list of relevant outcome indicators

DOMAINS	INDICATORS
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 Adequacy of resources

STRUCTURE OF INDICATORS

Explanation	Brief description of indicator
Justification	Fact that justifies the use of the indicator to assess that the technology achieves the desired effect when it is introduced into the public health basket
Formula	Equation expressing the relationship to be measured
Description of terms	Detailed explanation of the numerator, denominator, inclusion criteria or other aspects that may be relevant
Scope of study	Definition of the units and services targeted by the study (hospital, health area, geographical area, region, country)
Acceptable standard	Standard deemed desirable or acceptable (*must be established a priori*)
Time frame	The follow up time that the technology must be followed up after approval/funding of the technology. The reference is 1 year but this might be extended in the case of technologies indicated in a few number of patients or technologies with anticipated medium/long term adverse events (*must be established a priori*).
Data-sources	Description of the sources used to obtain the information that enables the calculation of the indicator

RECOMMENDATIONS FOR IMPLEMENTATION

✓ The current methodology is a consensuated proposal of relevant aspects that must be borne in mind when setting a post-introduction observation assessment.

✓ Adaptation to different contexts might be required before application.

MAIN RESULTS DERIVED FROM REVIEW AND WORKING GROUP

✓ Outcome data collected should be part of data recorded in daily clinical practice

✓ Any increase in number of diagnostic procedures and tests should be avoided

✓ Number of follow up contacts should be in agreement with routine check ups

✓ The variables should be either objective or capable of being rendered objective

✓ Follow up should not be too long but sufficient for obtaining an adequate number of patients or allow for short/medium term adverse events detection (**Reference; 1 year)**

✓ A common database must be used for data-management and support given by a specialised reference unit for standardadising of results

CONCLUSIONS

✓ Post-introduction observation allows for an early assessment of the effectiveness of new technologies in different clinical scenarios and provides relevant information to decision makers on the real impact in health care. The present guideline can serve as a reference for any international institution/body which is carrying out or planning observation activities.

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