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HEALTH TECHNOLOGY ASSESSMENT IN AN ARGENTINEAN PROVINCE: ADAPTING EXISTING TOOLS

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Objectives: This study reports on the development of a critical process for health technologies incorporation concerning an Argentinean Provincial Ministry of Health (MOH) in collaboration with the University of Lanús from 2008 to 2010.
Methods: We describe the approach developed to adapt selected international experiences to provincial scenario. Bibliographic review, regulations examination, key informants interviews and iterative adjustments after various stages of consultation and consensus building with main local players, contribution from foreign experts, and piloting of process and instruments for ultimate fine-tuning are described. We examine final proposal in the light of new updated studies.
Results: Analysis of regulations revealed that rules governing the provincial system were historically linked to administrative resolutions in relation to procurement with poor consideration to clinical, epidemiological, organizational, and health policy aspects. Key informants from hospitals, MOH, and other governmental agencies agreed on the lack of a process capable of guaranteeing a decision about health technology incorporation based on a transparent use of the best available information, ready to deal with competitive pressures. This adaptation provided a structured and explicit process (introduction, implementation, and development) as well as essential and supporting tools.
Conclusions: MOH adopted the proposal for its progressive implementation while institutional evaluation capacity develops. Further studies are needed on the value placed on health technology assessment–based processes and recommendations by clinicians, managers, policy makers, and patients.

Keywords: Group acquisition, Purchasing hospitals, Biomedical technology, Health technology, Public hospitals

Decision making in health technology (HT) incorporation and usage is widely recognized as a complex process subject of multiple pressures from managers, applicant physicians, patients, vendors, industry, media, lawyers, publication bias, etc., posing a problem for health authorities (1–13).

Health authorities of the Argentinean Province named Tierra del Fuego, Antártida e Islas del Atlántico Sur (from here the Province) faced mentioned complexity. The Province is an island approximately three thousands kilometers south from the country's capital city of Buenos Aires. Its mostly urban 130,000 inhabitants are cared for by two middle complexity government's hospitals and thirteen outpatient health centers in charge of primary healthcare activities. This structure comes under the rule of a Ministry of Health (MOH), also responsible for appointing personnel and purchasing high cost items. Hospitals have their own budgets allowing them to buy consumables and lower cost capital items.

Health technology assessment (HTA) had an incipient development both at MOH and hospital levels. No formal HTA unit existed. Critical mass of staff with the competences to exploit best available data and information and to perform required studies was not in place.

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The need to improve HTs management using concepts and tools based on HTA has moved the MOH to start a collaboration project with the University of Lanús. Consequently, HTA has been, as Hansen (14) pointed out, the bridge between policy and decision-making domain and the research one. Technical cooperation from the University ended up providing the MOH with an agreed proposal to improve HT management for health system strengthening.

The purpose of this article is to describe the experience and to present process and instruments developed for the critical incorporation of HT to be implemented in the Province.

METHODOLOGY

The framework developed for the critical incorporation of HTs was based on a situation analysis and a literature review complemented through external consultation, a pilot implementation and users and stakeholders workshops, as follows. A working team was formed with two investigators from the University and three technical officers from the MOH.

Literature Review

A narrative nonsystematic review was completed searching documents published in Spanish, English, and Portuguese on electronic databases (Medline, Lilacs), Google Academic, Web sites of HTA technical sources (Observatories, PAHO, WHO, INHATA, EUNetHTA, Euroscan, etc) from 1999 to 2008. Year 1999 was determined as a baseline because more formalized

experiences for improving HT management at hospital, regional, or national levels started to be published by the end of the 1990s. Review deadline was established in 2008 because the research project finalization was scheduled for May 2010. Time was required to complete the following project steps until the presentation to the MOH authorities. However, search was later updated to 2011 to take advantage of new information and to provide further recommendations for institutional evaluation capacity building.

The following descriptors were used: Group Acquisition, Purchasing Hospitals, Biomedical Technology, Public Hospitals, Hospital Services, Health Technology Assessment.

HTs included were: medical equipment, devices, drugs, medical and surgical procedures. Rehabilitation procedures, organization systems, health promotion, and disease prevention interventions contemplated in some definitions of HT were not considered because their assessment using HTA methodology had not the same degree of development (11). Commonly used inputs were also excluded.

Document selection was guided by the following criteria: they described policies, methods, processes, procedures for HT incorporation preferentially to the public health sector; provided instruments, standard forms, or formal results of incorporation using some kind of HTA; identified and described actors, interests, enablers, and barriers for critical decision making about HT.

Documents recovered were assessed independently by two members of the research team who extracted relevant information addressing key aspects of formal incorporation process such as field of application (HTA unit, hospital, health center), type of HT to incorporate, criteria, steps, guidance documents, identified obstacles and enablers, actors involved, and recommendations for decision making. Standardized forms were used for data collection.

Questionnaires, application or request forms, check lists, guides, instructions were analyzed to determine core domains, topics, and issues, and also similarities and differences.

Throughout the study, information was summarized qualitatively.

Situation Analysis

A situation analysis was performed to provide a general overview of HTs incorporation at the Province until the moment of the study, focusing at the potentially influential conditions that could facilitate or prevent the implementation of changes.

It was based on two main sources: (a) Regulations analysis. Provincial official documentation governing HT acquisition, introduction and management since 1970 till 2009 was studied to describe the regulatory framework and process established. The research was conducted on the database of province regulations seeking for its content, HTs involved, authority in charge for its fulfillment, application monitoring. (b) Key informant interviews were held with different actors identified as holding some knowledge, responsibility and/or expertise regarding HT request, purchasing, incorporation, usage, and/or monitoring.

Key informants came from the political field (present and former ministers and secretariats); managers at Government, MOH, and hospital level responsible for the purchasing process; and professionals involved as solicitors or potential solicitors and users of HT. Nineteen key informants were interviewed by team members using a semi-structured questionnaire covering their opinion about: policies and regulations on HT incorporation, explicit procedures, incorporation criteria, prioritization and decision-making process, procedures regarding different kind of HTs and the monitoring of their adoption, unit with main technical responsibility at each level; actors, stakeholders, and interests; barriers and enablers of critical incorporation.

Interview guide was piloted and adjusted. Interviews implementation followed literature recommendations. Conversations were captured in paper and eventually recorded. Results were organized following main issues contemplated in questions. Analysis must be viewed as a synthesis and interpretation by the research team.

Adaptation Process

Adaptation process took elements from other similar initiatives (2;4;6;15–18). It had not only the objective to fine tune to context but to valorize HTA as an instrument to aid in decision making, stakeholders engagement, and HTA institutionalization.

It included:

Proposal Preparation. Process, procedures, and tools were developed based on literature review and situation analysis. An iterative group judgment technique, in which core aspects of the proposal such as domains, topics, and issues were independently analyzed by each team member was used to review and define a first draft of the framework. Identified questionnaires/forms/check list were used as a basis to elaborate a tailored application form. Advice of external experts from two Spanish HTA agencies was obtained on: process and essential tools (application form, conflict of interest declaration, initial assessment, and structured final evaluation report). Their recommendations were considered to refine the proposal to be piloted.

Pilot Implementation of the Proposal. It was aimed to assess the incorporation of two HTs selected by the MOH: mobile mammography for the health clinics and a complete echocardiography equipment. Each of the involved actors played their role as applicants, hospital director, health technologies evaluation unit. Team members acted as the evaluation committee in a simulated scenario using the elaborated tools.

Consensus Building and Proposal Adjustment. Three workshops were conducted: one with the participation of MOH authorities and other government officials and other two with health personnel

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Table 1. Main Aspects Revealed by the Literature Review

Baseline	Control mechanisms in place to introduce health technologies were not sufficiently reliable to ensure the incorporation and use of those which get better results on health status.
Pattern of progress	Formal and explicit introduction of HTA in hospitals has progressed at a slow pace and without a uniform pattern.
Main factors affecting rational decision making	Conflicting interests among players.
	Power struggles between departments and services.
	Vendors promoting the acquisition of their technologies with different strategies.
	Patients demands and expectations about the quality of health care received bound to their increased participation in the decisions that affect their health.
	Increased malpractice lawsuits.
	Mass media promotion of health technologies.
	Resistance of professional organizations whom consider HTA as a strategy for cost control and as an interference with the incorporation of innovation.
	Decision-makers prone to prefer experts' opinion and information disseminated at conferences due to the time involved in the evaluation process.
	Professionals poor willingness to accept decisions contrary to their request.
Central elements in international experiences	Apply to the public sector hospitals and health centers at central, regional and local levels.
	Apply to all new health technologies / innovations.
	Follow formal, explicit and structured processes.
	Include elaborated guides / forms / check lists / questionnaires / instructions.
	Use explicit criteria / considerations for inclusion or rejection.
	Share main domains for application and evaluation.
	Applications are evaluated at different levels and findings and recommendations are reported in diverse formats but with some degree of standardization.
	Require Committees to evaluate and elaborate final recommendations.
	Committees may vary in number of members, members profiles, may be ad – hoc, temporary or permanent, and may be at different levels (hospitals, regions, national).
	Include sounded recommendations for incorporation (with or without modifications) or against incorporation.
	Recommendations are, in general, not compulsory for health authorities.
Main findings	The existence of an explicit process based on HTA principles facilitates the interaction between health professionals, managers and decision makers and others involved in the acquisition, incorporation and use of health technology.
	Guides, forms, glossaries and other resources promote the use of a common language between stakeholders useful to understand the whole HT incorporation process (from request to implementation).
Synergies	The coexistence of initiatives to strengthen data demand and information use, to reinforce health information systems, to build evaluation capacity and to improve accountability in decision making fosters cooperation and sharing expertise in the HTA field.

Source: Authors´ own elaboration.

from both provincial hospitals and health centers. Workshops' purpose was to discuss and adjust the proposal and to arrive to agreements on its implementation.

RESULTS

Literature Review

Fifty documents from Australia, Brazil, Canada, Colombia, Denmark, France, Israel, Italy, New Zealand, Norway, United States, Spain, United Kingdom, as well as from the European Observatory on Health Systems and Policies, WHO, HTAi, and EUNetHTA were considered relevant by assessors and incorporated to analysis. They uncover main aspects involved in the process to increase rationality in HTs incorporation which are summarized in Table 1.

Situation Analysis Results

Eighteen official documents or group of documents, including the provincial constitution, several bills and decrees regarding some general or specific aspects of HTs incorporation were recorded and analyzed.

In the Province, HT incorporation and management regulations were historically related to their procurement following legal and administrative protocols. Consequently, they have been neglecting demographic, epidemiological, and organizational aspects; criteria of security, efficacy, efficiency, effectiveness, applicability; ethics and technology coherence

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Table 2 Steps of the Proposed Process, Actors and Roles, Instruments, and Support Tools

Step	Involved actors and role	Key instruments	Support tools
HT preliminary request	Health professional fills the form	Application form (abbreviated version) Conflict of interest declaration	• Internet resources directory • Glossary • Evaluators code of conduct • HTA unit main responsibility and essential functions
Request appraisal	Hospital director (or equivalent authority) makes a preliminary evaluation about HT incorporation acceptability, appropriateness and feasibility	Director standardized report Conflict of interest declaration	
Review the request eligibility	HTA unit decides whether or not the application fulfill the criteria to undergo the complete evaluation process	Application form (abbreviated version) Director standardized report Conflict of interest declaration	
HT complete request	Health professional fills the form long version	Application form (long version)	
Evaluation	Committee appointed by the HT unit elaborates a report which supports the evaluation decision	Application form (long version) Director standardized report Conflict of interest declaration Committee standardized report	
Advice to the Minister	HTA unit	Application form (long version) Director standardized report Committee standardized report	
Decision on incorporation	Minister accepts or rejects proposal of incorporation	Committee standardized report	
Communication of results	HTA unit inform the applicant about the evaluation decision	MOH internal communication	
Resolution of appeals	MOH legal department	Legal regulations	
Reports dissemination	HTA unit disseminate Committee reports	MOH Web site	
Implementation	Hospital/center unit	Director and Committee standardized report	
Monitoring of incorporation	HTA unit	Monitoring plan	

Source: Authors´ own elaboration.

with policies; network services and hospital/center offers; and the health technology life cycle.

Actors agreed on the lack of an explicit process that guaranteed accountability and transparency in making decisions about HTs. No request formats or procedures were in place, and applications were considered by users and stakeholders as inadequately argued, insufficiently supported with scientific evidence and weakly assessed. Consequently, decisors were left in a fragile position to deal with competing interests, not always for the best of patients and services.

Main actors, their interests, and other factors influencing the decision-making process showed coincidences with other studies (1;4;8;19).

Products

A structured and explicit process was designed to assure that: conflict of interest was dealt, credibility of evaluation was cared with internal and external quality controls, and recommendations were understandable and well-argued to sustain implementation decisions. This process considered the following steps (Table 2).

Instruments were developed to accompany the process, that is, to ease application forms filling, evidence searching, information organization, alternatives comparison, evaluation judgment elaboration and recommendations formulation and harmonization. They were classified as essential and supporting instruments.

Essential instruments were as follows:

- Abbreviated and long application forms. These forms must be completed by applicants. The abbreviated one includes eight domains and twenty-five items. Domains in this version are: applicant identification, technology identification and use, technology appropriateness to health services organization, clinical indications, comparison with other existing technologies, personnel requirements, organizational aspects and costs of acquisition and installation. Its purpose is to guide the process to avoid wasting efforts in completing the long version when the requested technology is not eligible for the complete assessment process. Long form covers twelve domains and sixty-seven items. Added domains are adverse effects, risks, contraindications; incorporation monitoring; ethical considerations; patient information. Its main aim is to organize information to facilitate assessment by hospital authorities, Committee evaluation and elaboration of recommendations.
- Conflict of interest declaration. It has to be completed by every participant in the process. It is used to make explicit and prevent potential personal or institutional interests.

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- Initial assessment report by hospitals authorities. It has been designed to facilitate analysis of information and elaboration of recommendations at hospital level regarding coherence with the hospital services portfolio and hospital ability to make a secure and correct use of the technology.
- Peer review structured report. This report has to be prepared by a Committee of evaluators. It organizes information to facilitate the evaluation considering: appropriateness to health policy, balance between advantages and disadvantages in adopting technology, and center's capacity to assume the requested technology.
- Glossary of HTA basic terms. It includes fifty-four definitions of terms used in the process for their common understanding.

Support tools were as follows:

- Directory of Internet resources. It was developed to provide useful information available in Internet and to guide searches. Its content has been organized under the following titles: HT agencies, data bases, free of charge journals, health economics, clinical effectiveness studies, HTA, among others.
- Evaluators code of ethics. Evaluators have to adhere to a code of eleven points. Code purpose is to contribute to preserve evaluation methodological soundness, technical consistency, quality, neutrality, confidentiality, and fair treatment of proposals.
- Essential functions and basic organization for the creation of a HTA Unit. Twenty-one essential functions mainly related to the coordination of the whole process and the support to those involved in it were identified and developed. Basic structure and key profiles of job holders were also described.

Results from the Workshops

Stakeholders acknowledged that the proposal would help to: make decisions more transparent and explicit based on arguments instead of administrative requisites and costs of acquisition; facilitate the combination of scientific evidence, strategic vision of health services, organizational issues, and value judgments for a specific technology in a particular context; reduce asymmetries between services applying same "rules of game" to all applicants, thus restricting pressures, lobbies, or facilitated access to influence hospital management; avoid assessment bias due to decisors' professional background and / or specialization; break the "silos culture" and promote dialogue among multiple stakeholders; consider other elements that facilitate and enrich the analysis of unbalanced development of services.

Process and instruments (essential and supporting ones) were endorsed by the MOH in December 2010. They can be found at http://ministeriosalud.tierradelfuego.gov.ar/index.php/departamento-de-medicamentos-y-tecnologia-sanitaria/

DISCUSSION

The experience of adaptation to local context took lessons from the literature to increase rationality in incorporation and use of HTs. Literature review showed that incorporation of HTs is a complex process under different pressures due to conflicting interests which compete in decision making. This situation appears to be facilitated in the absence of explicit, structured, and transparent process. For those reasons, since the 1990s, many countries started to promote critical incorporation of HTs to increase its rationality.

The proposal developed in this experience promotes the use of best available information and existing evidence as a strategy to diminish the influence of different pressures (including possible corruption), bias, and intuition.

Adaptation was useful to enforce the understanding of HTA importance and to foster evaluation capacity strengthening.

It combined a top down and a bottom up approaches. The provincial political level showed interest in promoting HTA and stakeholders, at both meso and micro level, were involved in the proposal definition. This also called "converging approach" (19), where the effort is mutual between political players and researchers, has been adopted as the better way to create proposal viability and sustainability. Consequently, it should be owned by main authorities and health workers groups.

In the first place, following Goodman (20), this proposal was aligned with the purpose to provide technical assistance and information to authorities and hospitals managers in relation to HTs incorporation and management. In accordance with the same author, it adopts a "*project oriented*" approach because assessment focuses on a local placement or use of a technology in a specific institution. Although the information used in a project-oriented assessment may include findings of particular technology and problem-oriented judgments, local data exploitation and analysis are essential to determine HT adoption and secure usage. For this reason, the strengthening of health information system is linked to HTA development. Initiatives like the one described in this study increase local data demand and promote its use. Consequently, they are crucial to improve effectiveness and sustainability of health systems. HTA is not an isolated process or a dispute resolution method of all sorts of problems but a mechanism to improve the quality of decision making. In that sense, it is worth remembering that HTA is just one of the sources considered when making decisions. Decision itself is beyond its scope, as has been highlighted in some studies (13).

In the second place, the proposal is applicable to "new technologies" but not with the meaning adopted by "horizon scanning" projects/programs/networks (21–25).

This proposal's operative definition is related to health technologies considered "new" in the organization (hospital or health center) and not those technologies that will be incorporated to the market and clinical practice in a near future. Although the need to harmonize terminologies with international initiatives is understood, local implementation has to be in accordance with the degree of development of evaluation capacity. Moreover, definition adopted in the proposal is shared with other experiences with same focus and orientation, such as those developed in Canada, Australia, Denmark, New Zealand, Spain, United Kingdom, etc.

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Step by step implementation needs to be considered to allow an organizational learning process and evaluation capacity building development. In the present experience, it involves at least:

- Definition of the scope of the responsible unit aligned with health policies, plans, and MOH vision;
- Training project implementation to develop required expertise and to establish close cooperation and networking relations with national and international HTA networks and agencies and academic institutions;
- Allocation of required resources (staff, computers, Internet resources, software, communication, access to data bases, etc.);
- Development and harmonization of processes and procedures to support evaluation practice;
- Strengthening of reporting and dissemination systems;
- Preparation of a communication plan as a strategy to reduce the sense of "barrier" that the proposal may create.

These key activities will require sustained coordination and collaboration between areas and a strategic planning toward the short- and long-term.

The present experience is the first of its type in Argentina. It should not be generalized to other settings because is very context specific. However, we believe that lessons learnt from a concrete adaptation experience in a province of a middle income Latin-American country may be useful to others who are working in different scenarios to strengthen decision-making process and data use and demand.

As parts of a federal nation, each Argentinean Province has its own mandate to formulate policies and design processes and procedures. Nevertheless, since the National Health Plan was launched in 2004, HTA is clearly in the national agenda. Therefore, the information synthesized and the methodology proposed in this study may be useful to other provinces that face HTA development. A second Argentinean province that started to progress in this field has recently used this experience as one of the basis to develop its own model.

CONCLUSIONS

The need to make these processes more reasonable has drove countries to develop policies, structured procedures and tools based on the rationale behind HTA. Experiences have shown that, despite the initial skepticism and medical concerns (because of information overload, administrative tasks, processes seen as means to limit innovation, cut expenses, and increase control over their professional autonomy), the implementation of such structured procedures have eased the progressive use of information in the decision-making process, resulting in a more responsible adoption of biomedical technologies.

Literature review has shown that HTs evaluation and management are an integral part of public health practice. Decisions should not be driven by technological imperative, market requirements or other pressures from manufacturers, professional associations, doctors, patient groups, individual patients, and politicians. HTs acquisition and use should be done according to patient's needs, organization of health services, and facilities networks and health policy with the support of evidence on safety, efficiency, effectiveness, and cost-effectiveness.

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CONFLICTS OF INTEREST

Both authors report their institution, the National University of Lanús, has provided the funds for project implementation.

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