## Chapter 6 Hospital-Based HTA in Three Spanish Hospitals

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#### 6.1 Introduction

The development of health technologies (HTs), especially tests and medical devices, is mainly targeted to hospitals. As main receptors of these technologies, hospitals need to choose the proper mechanisms and procedures that can help them to make sound decision in investments on HTs. The type of mechanisms and procedures chosen depend on the characteristics of the health-care system where the hospital is placed, their own organizational structure, as well as values and cultural determinants.

Health and health care in Spain is stated as a right by the Spanish Constitution, passed in 1978, health being considered both a private and public good. Spain has a National Health System, with universal coverage, free at the point of delivery. The 17 Spanish Autonomous Regions have complete power regarding public health, health-care planning, financing, and provision of health care. Health-care funding comes mainly from taxes, with the exception of small co-payments for ambulatory drugs and out-of-pocket payments for OTC and dentistry. The Spanish public health spending for hospitals and specialized care represents 56% of the total health-care

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budget [1]. Physicians working at public hospitals are paid by salaries; in some autonomous regions the salary is complemented by a variable payment which aims to encourage quality and productivity. Box 6.1 summarized key elements around hospital funding and mechanisms for introducing health technologies.

# Box 6.1. Key Characteristics of Spanish Health-Care System Around Hospitals and Health-Care Technologies

- Spain has a National Health System funded through taxes.
- Hospitals receive annual budgets based on historical budgets and contracted activity. The amount of budget received depends on the level of hospital (university hospitals, general hospitals, community hospitals).
- Decisions on drugs covered by the public health system lay on the government of the autonomous region. Hospitals have by law a drugs committee in charge of deciding, from public-covered drugs, which drugs will be included in the list of drugs provided by the hospital. Regarding medical devices and capital equipment, in general, each hospital is free to decide on their investment. Nevertheless, for some very expensive capital equipment that requires extra funding from a public payer (i.e., regional government), consultation with them is required.

Health technology assessment (HTA) has a long history and solid grounds in Spain [2, 3]. Nowadays, seven autonomous regions' HTA agencies (from Andalusia, Aragon, Basque Country, Catalonia, Galicia, Canary Island, Madrid) and representatives from the regional health-care administration of the remaining ten autonomous regions constitute the Spanish Network of HTA Agencies. Its main aim is to answer informational requirements from the Spanish Ministry of Health regarding the feasibility and opportunity of introducing new health technologies in the public health-care portfolio [4]. Nevertheless, the final decision on the introduction of types of medical devices and capital equipment rests at the local or hospital level (depending on the region).

The ways that Spanish hospitals take decisions on HTs are very heterogeneous across the country. In most hospitals, decisions on investing in new medical devices (MD) are made by the chief of a clinical department or by the chief medical officer (CMO) or by the chief executive officer (CEO) based on information provided by the clinician requesting the MD, complemented by some basic economic figures. In some hospitals, a committee for the evaluation of health technologies exists. These committees are composed of physicians from different clinical specialties in charge of deciding which new HTs can be introduced in the hospital; recommendations are mostly based in a narrative summary of scientific information provided, in some cases, by the epidemiology department in collaboration with the clinician asking for the HT. Final decisions are taken by deliberation and consensus. This system constitutes an intermediate step between the nonsystematic and somehow random

mechanism explained above for investment decisions and the most solid and structured base of getting robust information, which is provided by hospital-based HTA (HB-HTA). HB-HTA is a structured, comprehensive, and context-based process to provide hospital decision-makers with the needed information for investment [5]. It follows internationally recognized processes and methods for HTA with a more fit-for-purpose approach [5]. Since HB-HTA is context dependent, its organization and performance varies across hospitals.

Although HTA is very well known by hospital doctors and managers, due to the long tradition of HTA agencies in Spain, HB-HTA is still in its early phases, but is increasingly gaining the interest of hospital decision-makers [6]. No formal mandate in the autonomous regions exists for implementing HB-HTA. This chapter aims to explain the HB-HTA experiences of three very different Spanish hospitals. The Hospital Clinic of Barcelona (HCB) is a high-tech university hospital in Catalonia; it has 4,500 employees (600 physicians) and 666 beds. The hospital has a unique organizational structure. It is organized in nine clinical institutes, each comprising several clinical departments (e.g., traumatology, rheumatology, rehabilitation, maxillofacial surgery), and two institutes that provide support to these nine institutes (i.e., diagnostic imaging institute and biomedical diagnostic institute). Clinical institutes function as small hospitals inside the HCB, each having a clinical director and a financial director. The other hospital is the Virgen del Rocio and Virgen de la Macarena hospitals (VR&VM), which are two university hospitals in Andalusia that recently have merged in a common management. Together they have 12,860 employees and 2237 beds, and are the largest hospitals in Spain. The hospitals are organized in clinical departments that report to the general management of the hospital. Finally, the Hospital Sant Joan de Dèu (HStJD) is a general hospital inside a health-care network (Parc Sanitari Sant Joan de Dèu); it has 292 beds and 800 employees. The hospital provides basic, and some specialized health care, and is organized through clinical departments reporting to general management.

## 6.2 Organizational Characteristics of HB-HTA

Since differences in context exist among hospitals, HB-HTA is differently organized. At the HCB, an HTA unit was created 8 years ago under the Innovation Directorate. This stand-alone HB-HTA unit [5] carries out HTA reports for the 11 clinical institutes of the hospital. Therefore, it is a support structure, working across institutes, which reports directly to CMO and the CEO of the hospital. The team of the unit includes a medical doctor (the head), a health economist, and a public health scientist. The unit works in close collaboration with the clinician asking for the HT and the financial director of his/her clinical institute, making the proper recommendation. Final decisions on the introduction of the HT are taken by the clinical director of the institute based on the recommendation made in the HB-HTA report; no participation in decisions regarding HT from clinicians working in other clinical institutes exists. On the contrary, the VR&VM hospitals' HB-HTA is based on a

joint commission for HTA (coming from the old commission at the VR hospital from 2002). Members of the commission include clinicians from different backgrounds (internist, pediatrician, rehabilitation, thoracic surgeon, intensivist, pharmaceutical, biochemical specialists) and public health and an epidemiologist specialist. The commission is led by a medical doctor expert in HTA. The commission is in charge of approving or rejecting the proposed HTs that want to enter the hospitals, irrespective of the clinical specialty; in other words, the recommendation is made by the commission, and the final decision is made by the CEO of the hospital. In the same way, the HStJD has an HTA Committee that recommends on any type of HT proposed to be introduced in the hospital. Nevertheless, here members of the HTA Committee include the head of quality, a psychiatrist expert in health economics, the head of research, a nurse manager, a librarian, and a surgeon (the chair of the committee); although each member of the committee represents a specific area of expertise needed for HTA, their main job is clinical practice. The HTA Committee is coached by the head of the HTA Unit at HCB, who attends all the meetings. This committee makes recommendations and raises it to the hospital steering committee for final decision.

Common features from the three hospitals include provenance of the request for assessment, funding of the unit/program, and enforcement of the recommendation on final decision. Requests for new HTs come mainly from individual clinicians, who usually participate in the meetings (either during the assessment or in deliberations); nevertheless, sometimes the request directly comes from the CEO, the CMO, or the financial director. The hospital budget is the main funding source for the HB-HTA unit/program. This funding is mainly for the salary of the head of the unit/program; funds for other members of the team, who are not contracted as clinicians by the hospital, come from competitive grants. Finally, all the recommendations made by the HB-HTA unit/program are advisory and nonmandatory; nevertheless, rarely a recommendation is not adopted by final decision-makers.

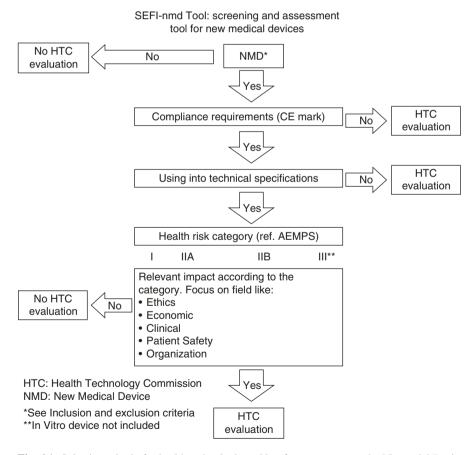
Recently, according to the Andalusia Health Services regulations [7], the HTA unit at the VR&VM hospitals has been granted to lead an HTA Provincial Committee (i.e., for the Seville province) which includes representatives of all the hospitals of the province plus professionals of the local administration. This new committee aims to support the local administration on decisions for investment in new HTs. The positive recommendations will be raised to the manager of the local purchasing logistic platform for its acquisition.

#### **6.3** Characteristics of the Assessment Process

The person/team that performs the assessment differs between hospitals. The HB-HTA at the HCB is in charge of the entire assessment process. Doctors informally contact the unit for an assessment, and prioritization of assessments is made on a first-in first-assessed basis. Nevertheless, parallel assessments are usually carried out due to demand. Professionals at the HB-HTA unit perform the assessment

(i.e., search and review of the literature, economic analysis, organizational impact, etc.) in close collaboration with both the clinician requesting the HT and the financial director of the clinical institute. Regular meetings are scheduled along the assessment (on average, three meetings per assessment; in the first meeting the scope of the assessment is done), and the final recommendation is taken by consensus based on the results of the HB-HTA report. The same process is followed by the HStJD, with the difference that the assessment is made by the members of the HTA Committee (sharing work on expertise basis) also in close collaboration with the requesting physician. In the case of the VR&VM hospitals, in addition to the HTA tool, an electronic software is used for requesting assessments for specific HTs [8]. The information is complemented by economic and organizational information. Specific selection criteria are used to identify appropriate HTs to be assessed (Fig. 6.1) [9].

Several tools and procedures are used for the assessments. An adaptation of the mini-HTA tool, developed in 2005 [10], is used by HCB and the HSJD. The



**Fig. 6.1** Selection criteria for health technologies asking for assessment at the Virgen del Rocio and Virgen de la Macarena hospitals [9]

mini-HTA provides hospital decision-makers with comprehensive information including a description of the new HT, scientific evidence, impact on patient, economic impact, and organizational impact [10]. The tool used by the VR&VM hospitals was developed in 1999 by the Andalusia HTA Agency, and recently updated, to help hospitals in their decisions regarding HTs [11].

Methods used to produce the assessment follow conventional HTA methods [12, 13]. All reports made by these hospitals include a review of the scientific literature. Nevertheless, when an HTA report from an national/regional HTA agency already exists for the HT being evaluated, the review of the literature is adopted, with an update of scientific literature, when needed. If no HTA report is available, the review is made from scratch. As regards the economic evaluation, VR&VM hospitals and HStJD mainly carry out cost analysis. The HCB perform all types of analysis including cost-effectiveness (using natural units of effectiveness, e.g., patients corrected diagnosed), cost utility (using quality adjusted life years), cost minimization, and cost analysis. The selection of the economic analysis to perform is influenced mainly by the available evidence on the new HT and its comparator, as well as by the request of the clinician (who is the one who select the effectiveness measures at the beginning of the assessment scoping). All hospitals perform a budget impact analysis, and this is very relevant information requested by hospital decision-makers [5]. Organizational determinants are always included in the HB-HTA reports; this is a key element to inform the final decision since, for example, an HT may appear to be cost-effective, but could impact highly in the organization of care, and, therefore, its introduction could be difficult to implement (e.g., adapting new clinical pathways, changing professional responsibilities, etc.).

Though assessments of HTs are usually done using published data, the world-wide movement to move the inputs from HTA specialists early in the stage of development of the HTs [14], is placing the hospital as a field camp to produce the needed information for HTA. The HCB has set up strategic alliances with several HT developers in the quest to obtain robust and fit-for-purpose HTA information. HTA inputs and methods are included in the clinical trials and in the analysis of their information (e.g., cost-effectiveness analysis). The relevant characteristic of this approach is that the studies are considering real clinical and cost data from a hospital, improving the external validity of results to similar hospitals.

All hospitals mainly assess medical devices (medium and small size), diagnostic tests, and capital equipment. Drugs are assessed exceptionally, since all hospitals have a drug committee, stated by law [15], in charge of assessing and deciding on the new drugs to be prescribed in the hospital. Table 6.1 shows examples of HTs assessed by the three hospitals. The level of innovativeness of HTs to be assessed depends on the type of hospital. For example, HStJD being a general hospital usually assesses HTs that are already available in other hospitals of the region but which are new for them (e.g., laser for prostate cancer), while HCB and VR&VM hospitals being high-tech hospitals usually assess more innovative and sophisticated HTs (e.g., robots). The HTs assessed belongs to the different clinical specialties in the hospital. Percentage of HTs assessed from one or other clinical specialties differs among hospitals. For example, 45 % of the HTs assessed by VR&VM hospitals

**Table 6.1** Examples of health technologies assessed by the Spanish hospitals: Hospital Clinic of Barcelona, Hospital Sant Joan de Dèu, and hospitals Virgen del Rocio and Virgen de la Macarena

Health technology	Clinical area
Capital equipment	
Frameless stereotaxy	Neurosurgery
Intraoperative radiation therapy with linear accelerator (breast cancer)	Oncology
Da Vinci robot (prostate cancer)	Urology
Robot APOTECAchemo (production oncologic preparations)	Pharmacy
MRI screening for breast cancer	Oncology
Medium-sized medical devices	
Deep brain stimulation (Parkinson, other dystonia)	Neurology
Semiautomatic metaphase locating and on-screen karyotyping system	Biochemistry
Circumferential epithelial RF ablation for Barrett's esophagus	Gastroenterology
Autologous platelet gel (for total knee arthroplasty)	Orthopedic surgery
Orthosonic system for cemented arthroplasty revision	Orthopedic surgery
Extracorporeal shock wave therapy for nonunion long bones	Orthopedic surgery
Left ventricular assistive device	Cardiology
Implantable medical device for hypertension	Cardiology
Electrochemotherapy (melanoma)	Dermatology
Laser (prostate cancer)	Urology
Video head impulse test (VIHT) (vertigo)	ENT
Small medical devices	
Multigene assay test (for breast cancer)	Oncology
Reusable electrosurgical device for bipolar vessel sealing	General surgery
Diagnostic tests	·
Diagnostic test for nonalcoholic fat liver disease (steatosis)	Hepatology
Diagnostic test for prostate cancer	Urology
Point of care test for flu diagnosis	Infectious diseases
Point of care test for catheter-related infection	Infectious diseases
Diagnostic test for liver fibrosis	Hepatology

belong to genetic tests (16%), pathological anatomy (15%), and general surgery (14%) [8], while the 46% of the HTs assessed by the HCB belong to the clinical areas of oncology (18%), orthopedic surgery (14%), and neurology (14%) [16]. These differences surely respond to the different contextual determinants; for example, genetic tests were considered by the VR&VM hospitals as key HTs to be assessed, and, therefore, a strict and systematic follow-up and assessment was implemented in these hospitals.

The recommendation from HB-HTA reports in Spanish hospitals provides a range of potential options to support final decision; these options are based on the results provided by the analysis as well as, in some cases, considering the mandate of the hospital. For example, in the deliberations for final recommendations at the HCB, the variable "innovativeness" is very relevant; being a high-tech university hospital, one of its main mandates is to innovate in health care. Therefore, HTs that are new

for the hospital but could already be present in other hospitals of the geographical area could not have a strong recommendation. The range of recommendations provided to hospital decision-makers also differs by hospitals; some examples are as follows: accepted, accepted under specific circumstances (clinical indication and implementation), accepted with negotiation of prices, accepted but need to be followed up (for 1 year or more), accepted under research protocol (purchasing of HT could be done by hospital or through research funds or lending by company), no acceptance, and future assessment needed (reasons: lack of basic requisites, scarce evidence on effectiveness, the HT that could be effective but is not cost-effective).

Finally, at the top hospital decision-making, choices among HTs from different clinical specialties often should be made after assessment. When several HTs are competing for a piece of the hospital annual budget, the top hospital decision-makers should choose on sound grounds coming from the assessments performed. To facilitate these types of decisions, the HCB has elaborated the so-called Matrix4Value, based on the results from the mini-HTA of each HT assessed [17]. This matrix plots the result from the assessments of HTs in a graphic where the *Y*-axis represents the risk for the hospital to introduce the HT (considering the following variables of the mini-HTA tools: staff need, impact in physical space, impact on the organization of health care, incremental cost, net cost, and investment effort for the institute/hospital), and the *X*-axis represents the benefits the introduction of this HT could have for the hospital (including the following variables: safety, clinical benefits, patient impact, cost-effectiveness, quality of evidence, and level of innovation). Figure 6.2 shows an image of the matrix.

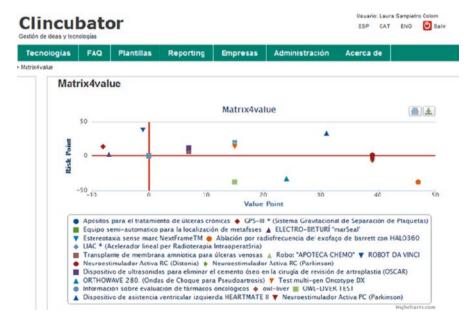


Fig. 6.2 Matrix4Value: mini-HTA-based algorithm which discriminates across HTs assessed [17]

### 6.4 Impact of HB-HTA

The aim of HB-HTA is to contribute to the improvement of the quality of hospital health care. This contribution will be attained by making HT recommendations that mainly improve patient outcomes, while keeping the economic sustainability of the hospital. However, it is very difficult to evaluate the cause-effect relationship between HB-HTA and clinical outcomes since the achievement of final desired clinical outcomes usually requires a long follow-up, and, therefore, this cause-effect relationship could be confounded or masked by multiple noncontrolled variables [5]. Nevertheless, there are a series of short-term and midterm impact variables that can be measured, which can be surrogates of the positive impact of HB-HTA inside the hospital.

HTA at hospitals is not always understood and used as expected [18]. HB-HTA can contribute to better understanding professionals at hospitals, the real ground of HTA. As an example, after the first assessment, professionals at the HStJD HTA Committee changed their initial economy-focused perception to a more clinical and economical balanced view of HTA. Members were asked to rank the importance of dimensions of HTA in a Likert scale (1 being not relevant and 10 very relevant) before and after the first assessment [19]. Figure 6.3 shows the results.

Satisfaction of hospital professionals that have collaborated in the assessment is also another short-/midterm impact indicator. The HCB made a satisfaction survey

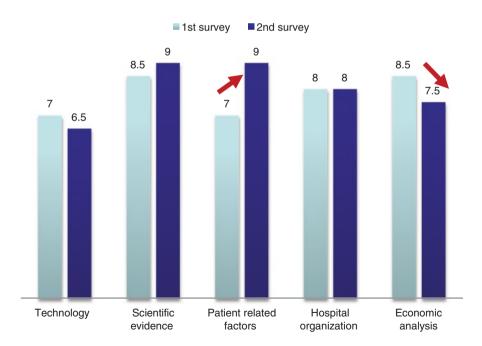


Fig. 6.3 Perceptions of relative importance of HTA dimensions before and after the first HB-HTA report of the Hospital Sant Joan de Deu' HTA Committee members [19]

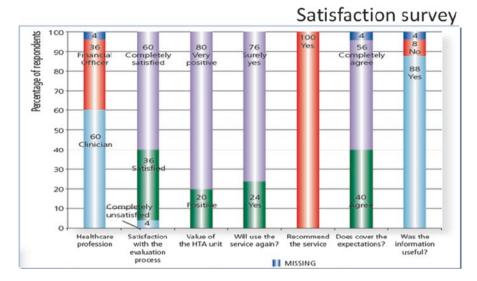


Fig. 6.4 Results from the satisfaction survey among hospital professionals who have collaborated in HB-HTA reports at the Hospital Clinic of Barcelona [20]

(anonymous) among 24 professionals that collaborated in one or more assessments. The results from the survey showed a high level of satisfaction with the HB-HTA process (Fig. 6.4) [20]. These results show that performing an inclusive, transparent, systematic, and robust HB-HTA process is a passport for accepting any type of result from HB-HTA.

Finally, the economic effect of recommendations provided by HB-HTA is also a long-term impact variable to assess. Projections can be made through modeling. After the assessment of 23 HTs by the HB-HTA unit at the HCB, 12 of them were accepted, and it was estimated that their net present value will yield to  $\epsilon$ 4,100,000 savings for the hospital over the next 10 years. Conversely, 11 HTs were not recommended; if these latter HTs had been introduced in the hospital, they would have generated a loss for the hospital of  $\epsilon$ 13,600,000 over the next 10 years [5].

#### 6.5 Conclusion

Although Spain has for long time had several experiences in using HTA at hospital level, in most hospitals these experiences have not always followed what is internationally understood and accepted by HB-HTA [5]. The introduction of HB-HTA units or programs in hospitals represents trade-offs on resource spending. Although, usually, the amount of resources to set up is minimal (frequently equals to the salary of the leader/head of the unit/program), it has a cost opportunity for the hospital, i.e., physicians or nurses will not be hired by investing this resources in an HTA

expert. The scarce resources nowadays in hospitals, as well as the fact that hospitals are being seen mainly as a place for health-care provision, make this trade-off one of the barriers to introduce more HB-HTA units/programs in Spanish hospitals. Other barriers and facilitators have been identified in 2007 through a DAFO study with 21 national and international experts in HTA (n=13 working in HTA agencies; n=8 working in HB-HTA units/programs) [21]. Main weaknesses identified in the mentioned study include the lack of well-trained human resources, lack of knowledge of the relevance and usefulness of HB-HTA for hospitals among clinicians and hospital managers, and lack of transparency in the management, planning, and decision-making process in hospitals. Strengths includes high qualification of hospital professionals regarding research and teaching and its direct access in HB-HTA, tradition in some hospitals of committees for HT evaluation which will make HB-HTA more easily understood, and the performance of HTA in a real clinical setting (using real data) among others, have been mentioned.

The accumulated experience from these three hospitals allows the identification of several success factors that ease the set up and running of HB-HTA units/programs as well as the acceptance of the results from the assessments [20, 22]. These facilitators include the transparency of the assessment process (i.e., discussion of results and uncertainties during the assessment process), the inclusion of the professionals that will use the HT (i.e., involve all actors in hospital that will have a direct relation with the HT), rigor in the assessment (i.e., using the best methods and techniques for each assessment), an assessment process and results that reach an equilibrium between the scientific rigor and the health-care pragmatism, credibility of the professionals leading and working in the HB-HTA unit/program, high-quality HB-HTA reports, HB-HTA activity aligned with the mission and strategic plan of the hospital, and the existence of an explicit support of the top hospital management to HB-HTA.

HB-HTA units described in this chapter are evolving, adapting themselves to constant hospital and environmental health-care changes. Several hospitals in Spain are interested in starting HB-HTA units/programs, but, in general, there is no formal support from national/regional HTA agencies to help on this. Nevertheless, hospitals with HB-HTA units/programs and those interested on implementing them come along in claiming for the need to interconnect hospitals with similar or different experiences in HB-HTA through formal networks [5]. In Spain, a first attempt was done a some years ago in Catalonia trying to build a network of hospitals for HTA (XHATS—Xarxa Hospitalaria d'Avaluació de Tecnologia Sanitaria). A strategic plan of the network was defined and a website created, but it was not implemented due to changing priorities [23]. Recently, the HTA Committee for the province of Seville has been created, and several assessments have already been performed; this experience is worth following and learning from its results. Nevertheless, the creation of HB-HTA network, being local, regional, national, or international, is already a wish. No formal network exists, but internationally there are some seeds toward this direction in Europe (AdHopHTA EU) [5] and in Canada (Pan Canadian network HB-HTA) [24]. HB-HTA networks will help in improving the way HTA is performed and organized in hospitals, through the creation of communities of practices, to exchange information on specific HTs to be assessed, allowing having quicker answers for hospital decision-makers.

Another trend for HB-HTA observed in one of the Spanish hospitals is the "living labs like" role of the hospital in HTA evidence generation. Traditional HTA has relied on published evidence, but frequently the needed HTA information is not found, often because evidence production have been addressed to answer informational requirements not sufficient for HTA [25]. Industry and HTA professionals are moving the scientific dialog on HTA informational requirements earlier in the developing curve of HTs [26]. Hospitals are the place to help producers of HTs to gather and analyze the required data in the real world.

In conclusion, taking into account that in Spain 60% of the public health-care expenditure is addressed to specialized health care and considering the experience gathered by HCB, the HStJD, and the VR&VM hospitals, the promotion of HB-HTA units/programs in Spanish hospitals could have a significant positive impact both in the quantity and the quality of the health-care expenditure.

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