Health economic decision-making: a comparison between UK and Spain

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Objective: This review examines the impact of economic evaluation in informing national or local policies within both jurisdictions. We focus on the factors that have made the economic evaluation evolves differently in both settings.

Areas of agreement: Economic evaluation facilitates decision-making regarding the efficiency of interventions. The existence of national or local bodies regulating the process has contributed to increasing its use in decision-making and the development of its methods.

Areas of controversy: Cost-effectiveness approach is based on the assumption of health maximization subject to a budget constraint. Decision-makers are not only interested in health maximization alone. This may result in policy-makers failing to consider economic evaluations into their allocation decisions.

Areas to develop research: Methods that incorporate wider decision-makers goals (mainly local) and research to study the real impact of economic evaluation in terms of improved efficiency and equity are particularly required.

Keywords: economic evaluation/decision-making/health technology assessment

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Introduction

Economic evaluation has been developed to help decision-makers achieve efficiency in health care. If resources were not limited and health systems could provide any health technology to any patient demanding it, then there would not be a need for economic evaluation. Unfortunately, scarcity cannot be avoided, with the implication being some health technology will be rejected.¹ Starting from this premise, economic evaluation of health care provide decision-makers with a useful tool that permits the comparison of competing technologies in terms of the benefits they provide and the resource use required to...
reach these benefits. This process is also described as the fourth hurdle, as cost-effectiveness is added to the efficacy, safety and quality criteria. The foremost methods of analysis are cost-effectiveness analysis (CEA) and cost-utility analysis (CUA). Both approaches are based on the assumption that health gains have to be maximized given the available budget constraints. The main difference relates to the way in which health gains are expressed. Whilst in CEA health gains are expressed in terms of intermediary outcomes, such as cost per cancer avoided or cured, in CUA these benefits are expressed in terms of quality-adjusted life-years (QALYs). QALYs are a generic measure of health benefits that combine health-related quality of life (morbidity) and mortality (survival) in a single measure. The results of the analysis are summarized in terms of incremental cost-effectiveness ratios (ICERs): cost per QALYs in the case of CUA. In order to decide if a technology is worth its cost, decision-makers must compare the ICER of the new technology against a maximum willingness to pay threshold. This maximum threshold represents the health forgone elsewhere because of the implementation of the new treatment. Only those technologies that are below a ‘certain’ threshold have a positive net benefit for the health system and hence considered as cost-effective. Health benefits provided by cost-effective interventions should be greater than the opportunity costs of services that will have to be displaced in order to adopt them.

The first jurisdictions that recognized the advantages of recommending choices based on cost-effectiveness approach were Australia and Canada. It is now 20 years since then and as expected in any research field there have been major developments in the area. Methodologies applied have become progressively sophisticated at the expense of transparency and in some ways this could denote a barrier to a major use of economic evaluation in decision-making. In Europe, the creation of the National Institute for Clinical Excellence (NICE) has certainly contributed to a change in the perceptions about economic evaluation and its potential to facilitate the technology assessment of technologies.

This article examines the impact that economic evaluation has had in informing national or local policies within the health-care systems of UK and Spain. This is a comparative study of two health systems that share some basic characteristics. Both are publicly funded and health care is mainly provided through a public health service. Similarly both have a complex network of health technology assessment (HTA) bodies. However, due to cultural and organizational factors, the role of economic evaluation and the way that it has been incorporated into policy-making have been drastically different. Thus, the objectives of this study are to provide (i) an overview of how the economic
evaluation of health technologies has been introduced; (ii) an outline of
the impact of economic evaluation in informing national or local
health are policies; (iii) an analysis of key factors that might have deter-
dine a different ‘speed’ of adoption and (iv) a reflection about future
challenges to be faced by both jurisdictions.

**Economic evaluation of health technologies**

**Spain**

In Spain the National Health Service (SNHS) is a decentralized system,
with universal coverage and finance from general taxation. Health care
is provided free of charge except for pharmaceuticals. Since the decen-
tralization of the SNHS there are 17 regions that have complete respon-
sibility for their own health-care delivery and its finance. The Regional
Health Systems are coordinated through the SNHS Inter-territorial
Council (IC). The typical structure of a health system consists of a re-
regional ministry and a regional health service performing as provider.
The most frequent model consists of two separate organizations, one
for primary and one for specialist care; although single area structures
integrating both organizations are becoming popular. Basic health-care
zones organized around a single primary care team are the gateway
into the system.4

HTA was introduced in the late 1980s and is required at both nation-
al and local levels. The decentralization has led to the coexistence of a
national HTA agency (The Instituto de Salud Carlos III-ISCIII) with
another seven regional agencies. The ISCIII, in collaboration with the
regional agencies, is responsible for the assessment of the new tech-
nologies to be incorporated into the national catalogue (or when ex-
cluding those already provided). The technologies assessed include
drugs, devices, procedures, programmes and settings in health care.
The existence of drug assessment units promoted at a central level by
the Ministry of Health have prevented a major comprehensive assess-
ement of pharmaceuticals by HTA agencies.5 Apart from HTA assess-
ment reports the agencies also produce clinical practice guidelines,
programmes to detect both emerging and obsoletes technologies and
decision-making tools addressed to patients, health professionals and
policy-makers.

The central or regional governments demand HTA information to
the agencies on technologies that are considered a priority and relevant
for the NHS. The ISCIII coordinate the regional agencies and they
conduct the required HTA assessment. The assessment of new tech-
nologies is mainly focused on the study of safety, efficacy, effectiveness
and accessibility rather than on principles of efficiency and opportunity cost. The evaluation report is finally submitted to the IC which decides about the inclusion or exclusion of technologies in the national catalogue. The decision of the IC is then implemented by the central and regional governments, which have the capacity to make regional additions to the national catalogue.

There is a long tradition of economic evaluation in Spain. The required skills to conduct quality studies exist and there have been important methodological developments in this field. The cost-effectiveness approach is the most frequently used type of economic analysis. Over the years the quantity and quality of evaluations have been increased. To date the Ministry of Health has sponsored two proposals for methodological standardization of economic analysis. The first published in 1995 and the second in 2011. In 2002 a first reference to the cost-effectiveness threshold was published and following this estimates for the monetary value of the QALY for different regional settings were also calculated.

However, the use of economic evaluation is not mandatory in Spain. Unlike in the UK there is no singular body that explicitly conducts CEA to assist the decision-making process. Hence, CEA is only applied on a voluntary basis by HTA agencies, regional directorates of pharmacy, academic teams and manufacturers. The situation is remarkable as the health legislation has repeatedly anticipated the use of economic evaluation as a tool to achieve health-care efficiency, in practice its role is far from being clear yet. The Spanish Medicines Law of 1990 considered the possibility of the implementation of economic evaluation to guide health administration decisions. Additionally, the Strategic Pharmaceutical Policy Plan of 2004 proposed the use of pharmacoeconomic analysis in order to achieve a more rational use of medicines. Similarly the Decree 1030/2006 does state efficiency as a criterion to be considered in allocation decisions. Unfortunately none of these initiatives were ever put into practice. The Spanish Health Economics Association (AES) brings together academic health economists, health managers and practising physicians. AES and other health professionals have repeatedly expressed concerns about the urgent need to incorporate the use of cost-effectiveness as explicit criteria guiding the HTA programme.

The HTA for pharmaceuticals is coordinated at a national level and follows a different process than other health-care technologies. In fact there are different organizations involved in the assessment of pharmaceuticals. Regional Directions of Pharmacy review economic evaluation dossiers submitted by manufacturers and do conduct elementary economic evaluation when required. In contrast to the thorough approach of NICE, the assessment of pharmaceuticals by HTA agencies is rather
limited. However, they have contributed with other procedures that simplify assessment. This is the case of the Andalusian HTA agency (AETSA) and its pharma-therapeutic guideline (GINF) to facilitate the incorporation of new drugs into hospitals. In parallel to the HTA activity, there are regional committees for the assessment of pharmaceuticals that mainly focus on the primary care setting. These committees consider the cost of the drugs when making their recommendations. The case of the GENESIS working group illustrates how pharmacy units based in hospitals and coordinated at a regional level are increasingly incorporating information on cost-effectiveness when developing their pharmaco-therapeutic guidelines. This division of functions, with different levels of coordination and integrated by health professionals with very different technical skills do distort in some way how the economic evaluation process is perceived in this setting.

The Spanish Cabinet has recently approved the Royal Decree Law 9/2011 on improving the quality and cohesion of the national health system. One of the measures contemplated to control the budget is the creation of a central Committee that will determine drugs and their prices based on cost-effectiveness criteria. Although limited to pharmaceuticals this initiative increases the potential for the use of economic evaluation and hence has been positively received. However, similar proposals existed in the past and were barely implemented.

**United Kingdom**

The UK’s health-care system is primarily public, with a range of different trusts and authorities delivering and impacting on health-care provision. Approximately three-quarters of the UK National Health Service (UKNHS) budget goes to the primary care trusts (PCTs), who are responsible for delivering health care and health improvements within a local area. PCTs are grouped into regional Strategic Health Authorities (SHAs); these groups help develop local NHS strategy and provide a link between PCTs and the national Department of Health. PCTs have their own budgets and set their own priorities, within the overriding priorities and budgets set by the relevant SHAs and ultimately the national Department of Health.

In the UK there are three national HTA organizations that conduct cost-effectiveness evaluation. These bodies seek to improve the overall standards of care, reduce variation in clinical practice and to ensure the best use of resources so that patients receive the greatest benefit. The NICE operates in England, Wales and Northern Ireland and assesses only the health interventions and pharmaceuticals decided by the Secretary of State for Health. NICE guidance includes clinical
guidelines, technology appraisal, public health and interventional procedures. With the exception of the last one, economic evaluation is essential to the rest of the Institute’s programmes, but particularly for the Technology Appraisal Programme. The Scottish Medicines Consortium (SMC) only evaluates new drugs and operates in Scotland. Finally, All Wales Medicines Strategy Group operates in Wales and provides advice to the Minister for Health and Social Services on strategic management and prescribing of high cost medicines.

The three bodies make decisions in terms of relative cost-effectiveness and all use the same set of thresholds when determining if accepting or rejecting a technology. However, the assessment processes and the methods established differ among them. Most importantly, the SMC advice is issued to the Scottish Health Boards but is not mandatory whilst NICE technology appraisal’s guidance is subject to a mandatory requirement regarding funding.

In this article we focus on the activity of NICE for three reasons. First because in terms of economic evaluation NICE is the only organization that has developed its own cost-effectiveness framework. Secondly because the scope of the programme includes not only drugs but all health-care technologies. Third because its appraisal process is not restricted to manufacturer’s submissions. The Technology Appraisal guidance combines two forms of analysis: third-party and manufacturer-based cost-effectiveness assessment. Both types have different impact on the decision-making process but using both, selecting which is appropriate depending on the characteristics of the technology evaluated offers in our opinion clear advantages for any health system.

NICE Technology Appraisal Programme produces guidance on the use of new and existing technologies, although the majority of appraisals are pharmaceuticals. The Institute has two appraisal processes. The Multiple Technology Appraisal (MTA) and the Single Technology Appraisal (STA). Traditionally NICE guidance was based on MTA. This type of analysis consists of a third-party commissioned assessment to review published evidence and develop a cost-effectiveness model adapted to the Institute’s scope. Similarly to the SMC and in order to allow faster guidance since 2005 NICE also conducts STAs. Although the process is similar, the critical review of the academic group is limited to the cost-effectiveness model submitted by the manufacturer. The introduction of the STA process has reduced the time it takes to produce NICE guidance; however, the allowance of consultation means that it is still lengthier than the SMC process.

The programme covers three different phases: scoping, assessment and appraisal. NICE determines the scope for each appraisal indicating both the patient population and the relevant comparators to be studied. The manufacturer then presents a submission adapted to the
NICE scope that reviews all the available effectiveness and cost-effectiveness evidence related to the technology. The assessment usually comprises a systematic review of the clinical evidence and an economic evaluation and it is conducted by an independent academic group appointed by NICE. The assessment report along with other stakeholders inputs are provided to the Technology Appraisal Committee. In addition to this basic evidence, the appraisal also requires consideration of issues related to equity and quality. After a consultation period of 1 month open to the stakeholders the Final Appraisal Determination (FAD) is produced. In cases where there are no appeals the FAD forms the basis of the NICE guidance to the NHS. Technologies Appraisals result in guidance regarding treatments for use in line with clinical practice or the marketing authorization, optimized use in specific circumstances, use only in the context of research or not recommended. PCTs normally adapt NICE guidance to contain costs and remain in budget. In the primary care setting, general practitioners (GP) are becoming increasingly autonomous. In case the patient’s physician considers it appropriate then the NHS must fund technologies recommended by NICE within 3 months of being issued. This implies that other technologies might have to be displaced in order to fund the new ones. No funding is routinely available to conduct recommended research.\textsuperscript{20}

NICE measure the cost-effectiveness of technologies in terms of the incremental cost per QALY (ICER). For the reference case, changes in health-related quality of life (HRQoL) must be reported from patients using a generic instrument (preferably the EQ-5D) and utilities based on public preferences from the UK population. A new drug is considered to be cost-effective when its clinical effectiveness (compared to available alternatives) justifies its additional cost. There is no fixed threshold to recommend the use of new technologies.\textsuperscript{21} However, NICE usually recommend funding when the threshold value of a QALY ranges from £20 000 to £30 000 per QALY gained or lower. Decisions about technologies which ICERS are < £20 000 per QALY gained are normally based on the cost-effectiveness estimate. For ICERS > £20 000 per QALY gained judgements will take into account the degree of uncertainty around the ICER (the less certain about the ICER presented the more cautious the Committee will be); whether there are strong reasons to indicate that the assessment of the change in HRQoL has been inadequately captured (severity of disease); and the innovative nature of the technology.

NICE is now accepting a higher QALY threshold for end-of-life (EoL) treatments. If NICE considers that EoL criteria are met then a higher threshold could be applied for these drugs.\textsuperscript{22}
Impact of economic evaluation

Research on the use of economic evaluations in policy decision-making shows an increase of its use among jurisdictions and mainly at a national level particularly in the UK. Despite a positive attitude towards it, there is a clear discrepancy between the potential of economic evaluation perceived by decision-makers and its limited use in practice, especially at local levels. In general cultural and methodological barriers and the difficulties in transferring budgets are viewed as the main obstacles to a major use. Published evidence also proposes a competing approach to currently dominant economic analysis as a way to link the value for money and budgetary impact, more in touch with decision-makers affordability needs. NICE recommendation are not exempt from controversy and in that sense it gives the impression that generally NICE have done well in going beyond polemic decisions. The Institute’s effort to identify subgroups of patients where technologies are cost-effective has meant that recommendations for restricted use are more commonly issued than those implying the reject of interventions. Although evidence on the implementation of NICE guidance is rather limited it appears that the influence on NHS decisions could have been irregular. In that sense NICE has been normally more persuasive in changing prescribing patterns than in influencing decisions on surgical procedures or use of medical devices.

In the UK health decisions are made at the national or macro level by the Government or institutions such as NICE; at the local level by PCTs; and at a micro level by GPs. Economic analysis is very much integrated into the decision-making process of the NICE appraisal programme and hence operates at a national level. In contrast to this it seems that its influence at a local level is rather limited, the inflexibility in health-care budgets being main obstacle. Local committees focus mainly on evidence of clinical benefit, and budget impact, CEA rarely informs local decision-making. At the same time disinvestment decisions are rarely discussed by local committees. It seems that there is a gap between the concept of long-term efficiency and decisions make at the lowest level. Research in the UK has shown that there is a need to make local decisions-makers sensitive to the economic evaluation approach and its relation with the need for prioritization.

In Spain decision-makers have no legal obligation to use economic evaluation to inform efficiency. Accordingly, economic evaluations are not performed on a systematic basis. Despite the lack of government support, cost-effectiveness has become an explicit criteria to set health priorities for some of the regions (e.g. Canaries Ministry of Health) and to guide recommendations on the use of new pharmaceuticals that
are likely to have a major cost or social impact in others (e.g. Andalusian Ministry of Health). However, little is known about the impact of these regional initiatives. The influence of CEA studies in decision-making at primary care levels is also rather limited. The most enthusiastic supporters of using economic studies are hospital pharmacists, whilst GPs and other health professionals expressed worries about the potential use of economic evaluation to assist their daily clinical decisions. In contrast to the limited impact of CEA, the use of budget impact analysis (BIA) has played a major role in the Spanish setting. BIA studies are perceived as an essential tool to complement CEA as they inform how to finance the implementation of the technology. This technique is commonly used as the only criteria to guide pricing and reimbursement decisions of pharmaceuticals. The same applies to positive lists elaborated in some regions and hospitals. HTA agencies and GPs use BIA to make recommendations on other health technologies.

As expected both health-care systems idiosyncrasies and cultural factors have clearly influenced the different level of impact that economic evaluation has had in the two jurisdictions. However, the lack of general knowledge and expertise about the cost-effectiveness approach and the paucity of administrative databases that facilitate context analysis are still serious limitations for the Spanish setting.

The ‘European Network on methodology and Application of Economic Evaluation Techniques’ (EUROMET) analysed the impact of health economic evaluation studies on decision-making in nine European countries: Austria, Finland, France, Germany, Great Britain, Norway, Portugal, Spain and the Netherlands. Although it was mainly focused on pharmaceuticals, the results of this study shows that the barriers detected in other settings are similar to those detected in this review and mainly related to administrative, methodological and practical applicability issues. The lack of expertise and availability of data, the little knowledge of economic evaluation and structural barriers were highlighted as main constraints. In the opinion of the European decision-makers interviewed increasing the flexibility of health-care budgets from one sector to another would encourage the transferability of economic study results.

Similarly to the Spanish case, policy-makers are also reluctant to use formal CEA in the USA. Although there have been several proposals that plead for the incorporation of cost-effectiveness approaches to aid resource allocation decisions, the reliability of economic studies and the fear that such use would be a precursor to rationing of care have strongly limited its development. At present relative effectiveness is highly promoted and the debate is focused on whether it is necessary
to establish an independent and central body charged with developing formal procedures to CEA.42

There is also an increasing interest in introducing the use of CEA in Latin America. However, allocation decisions are highly driven by government policies. The lack of financial funds, expertise and the poor interactions between health stakeholders has prevented a wider use of CEA in this setting.43

Key factors that have made that it evolves differently

This comparative analyses highlights two key factors that have possibly meant that economic evaluation in Spain has lagged behind compared with the UK. First the lack of a national regulatory body seeking to inform the decision-making process on the provision of health care. Secondly, the absence of a standardized and formal procedure describing the methodology and the principles to be applied to the HTA program.

The ISCIII is a national but not a central body. Although the Institute aims at coordinating the Spanish HTA network, it has shown little capacity to lead or coordinate regional agencies at both national and international levels. Moreover, its guidance is neither independent nor mandatory so their recommendations might or might not be taken into account. Hence, its role is not equivalent to the role played by NICE.

In the UK the guidelines come directly from NICE, i.e. from the decision-making body itself whilst in Spain the guidelines have been developed by academic and HTA researchers in order to specify the methodological standards required in the field. NICE guidelines are updated every 4 years in order to include recent research into their methods and hence reduce the uncertainty in decision-making. This allows incorporating the topics that have raised challenges to the institute. If it is considered that the methods are in accordance with the NICE principles of robustness, transparency and inclusiveness then they are incorporated into the guideline.44 The main revisions that took place in 2008 were related to key issues in utility measurement,45 costs,46 heterogeneity,47 evidence synthesis48 and cost-effectiveness thresholds.49 A recently published review gives light into the key topics on research methods that should be prioritized in order to reduce the gap between the research of methods and the needs of decision-makers.50

Randomized control trials are a very valuable source of evidence to inform about the cost-effectiveness of technologies. Decision-makers appreciate this type of analysis since it prevents the use of extrapolation and extensive assumptions. In the UK economic analysis is formally
integrated into the design of clinical trials. Furthermore, it is recommended that this type of analysis includes an explicit evidence synthesis and decision modelling exercise.51 This is not the case in Spain, where there is still a lack of administrative databases that facilitate context analysis and decision-making.

The Table 1 offers a comparative of the key factors that have influenced the implementation of the fourth hurdle in both settings.

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<td><strong>UK</strong></td>
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<td><strong>Decision-making process on the provision of health care</strong></td>
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Discussion and future challenges

According to this comparative review it is clear that despite the different use of economic evaluation in both settings, barriers faced by decision-makers seems to be common to both jurisdictions. Although the importance of these barriers might vary across levels of decision-makers, the most difficult ones are common to all levels of decision and are mainly related to the reliability and relevance of studies.

NICE provide us with a clear example of the potential advantages of an independent central body that includes CEA as part of the evidence to make mandatory allocation decisions. However, evidence suggests that there is a need to descend to meso- and micro-levels and study the real impact of economic evaluation in terms of improved efficiency and equity. The NICE appraisal programme is set at a national level whilst disinvestment decisions are made at a local level. Economic evaluation implies cross-service budget flexibility that the NHS locally does not in practice enjoy. In this sense the introduction of programmes looking at disinvestment opportunities to assist local decision-makers is a key step in improving the allocation of NHS resources and removing geographical inequalities. It seems that NICE will have to face those challenges at the same time that it deals with the government proposals for UKNHS reform. Among other plans its intention to create GP consortiums with power to commission health services or the new pricing system for pharmaceuticals (value-based pricing) will likely impact the institute’s role and model.

In Spain political factors have constrained the formal use of economic evaluation to guide health allocation decisions. Although it seems that the things are going in the right direction, it is clear that the commitments made in the law cannot be delayed any further and must be urgently delivered. It is now the turn of the new government recently appointed to define how the essential requirements are going to be met. Hence, two challenges lay ahead to ensure this proposal is translated into efficiency in health-care provision. Mandatory reporting has shown to have a positive impact on the UK system so in order to guarantee a real impact at the health-care policy level it is first necessary that this law becomes mandatory and applicable not only to pharmaceuticals but also to all types of technologies. Secondly, it is essential to establish a central entity charged with developing a transparent, standardized and accountable procedure that meets the needs of the NHS decision-makers

1We recognise that the range of proposals set out by the Government to reform the UKNHS are likely to impact strongly in the health system. However how cost effectiveness analysis could be used to inform the VBP is not the objective of this paper and therefore it is not discussed in this review.
and that involves health professionals, patients, HTA agencies, academia and industry. As others have already stated it will be indispensable to identify an integral strategy to promote the efficiency culture within the health system by providing all levels of decision-makers with the appropriate training and incentives required. Likewise this might be an appropriate opportunity to evaluate the efficiency of the current existing HTA structure and to adapt the skills of HTA professionals to the technical requirements needed to appraise and conduct CEA.

**Conclusion**

Country-specific challenges ask for country-specific solutions. The NICE Technology Appraisal Programme with specific reference to cost-effectiveness represents a valuable experience to be considered by the SNHS. In the UKNHS, cost-effectiveness criteria operate primarily at the national level whilst at the local level decisions (particularly on disinvestment) are made based on broader criteria. In Spain there seemed to be more local input into decision-making and hence more potential for the use of cost-effectiveness criteria for both investment and disinvestment decisions.

Decision-specific problems ask for specific economic analysis designs. CEA cannot be the only instrument to guide allocation decisions but policy-makers require an economic approach that allows them to know the impact that the adoption of new technologies will have in health budgets in terms of their costs and net benefits in health. In this sense the influence of economic evaluation on decision-making would likely to be improved if greater effort were given to incorporate the cost-effectiveness approach within the budget framework of national health services.

The development of a capacity building strategy based on the experience and practices of NICE and the exchange of expertise between health economists from both settings would clearly advance the implementation of the cost-effectiveness approach in the Spanish jurisdiction.

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