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A comparative analysis of coverage decisions for outpatient pharmaceuticals: Evidence from Denmark, Norway and Sweden

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ABSTRACT

This study analyses the reasons for differences and similarities in coverage recommendations for outpatient pharmaceuticals in Denmark, Norway and Sweden, following HTA appraisals. A comparative analysis of all outpatient drug appraisals carried out between January 2009 and December 2012, including an analysis of divergent coverage recommendations made by all three countries was performed. Agreement levels between HTA agencies were measured using kappa scores. Consultations with stakeholders in the three countries were carried out to complement the discussion on HTA processes and reimbursement outcomes. Nineteen outpatient drug-indication pairs appraised in each of the three countries were identified, of which 6 pairs (32%) had divergent coverage recommendations. An uneven distribution of coverage recommendations was observed, with the highest overlap in appraisals between Norway and Sweden (free-marginal kappa 0.89). Similarities were found in priority setting principles, mode of appraisal and reasoning for coverage recommendations. The study shows that health economic evaluation is less prominent or explicit in outpatient drug appraisals in Denmark than in Norway and Sweden, that all three countries could benefit from improved communication between appraisers and manufacturers, and that final coverage recommendations rely on factors other than safety, comparative efficacy or cost-effectiveness.

1. Introduction

New and costly technologies coupled with an ageing population have led to rising health care costs in many countries. With finite resources, decisions must be made as to which services and products health care systems should offer and to whom. Health technology assessment (HTA) is increasingly used to inform decision-making, and considers both clinical and economic evidence, as well as ethical and social issues related to the introduction and use of new health technologies [1,2].

The present study adds to previous studies reviewing HTA processes and reimbursement decisions in individual countries and across countries [3–6] and to studies comparing drug reimbursement systems in Scandinavia [7,8]. HTA methodologies have been implemented in many ways across OECD countries. Studies of HTA processes and outcomes have revealed differences in the way costs and benefits are accounted for in the assessments [9], differences in the scope and timeliness of appraisals [10] and the contextual factors impacting the role of HTA in

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Table 1
Principles and structures for the conduct of HTA in pharmaceutical reimbursement in Denmark, Norway and Sweden, 2012.

System's characteristics	Denmark	Norway	Sweden
Pricing mechanism	Free pricing	Reference pricing	Value-Based Pricing (VBP) for reimbursed drugs, free-pricing otherwise
Financial responsibility of outpatient drugs	Centralised budget	Centralised budget	21 Counties
Financial responsibility of inpatient drugs	5 Regions	4 Health authority regions	21 Counties
National outpatient reimbursement agency	Danish Health and Medicines Authority (DHMA)	Norwegian Medicines Agency (NoMA)	The Dental and Pharmaceutical Benefits Agency (TLV)
Accountable to	Ministry of Health	Ministry of Health	Ministry of Health
Stakeholder participation in reimbursement committee	Clinicians, regional representative, patient representative	Clinicians, clinical pharmacologists, health economist, patient representative	Clinical pharmacologist, health economist, patient representative, regional representatives
Reimbursement criteria	The drug must: (1) be safe and efficacious, (2) have a well-defined indication, (3) have a price which is reasonable given the therapeutic value.	(1) The disease must be severe and long-term (greater than three months), (2) the treatment must be cost-effective, (3) the treatment must be well documented	(1) The human value principle, (2) the need and solidarity principle, (3) the cost-effectiveness principle
Pharmacoeconomic analysis	Voluntary	Mandatory	Mandatory
Type of reimbursement	General, restricted, individual	General, restricted, individual	General, restricted
National HTA agency	–Danish Centre for Health Technology Assessment (DACEHTA)	Norwegian Knowledge Centre for the Health Services (NOCK)	Swedish council for health technology assessment (SBU); Dental and Pharmaceutical Benefits Agency (TLV)
Local HTA agency	Some hospitals	Some hospitals	4 Regional units

Source: The authors from various sources [15–17].

priority setting [11]. Furthermore, the HTA methodology has been adapted to local settings and hospital level [12], and to drugs for rare diseases [13].

The country context in this study is motivated by the study countries' several shared features. On the grounds of their having a common history, as well as cultural, linguistic, economic, and social structure similarities, Denmark, Norway and Sweden are often perceived as being very similar. The characteristics that define the three countries' health care systems are low levels of cost sharing and high levels of tax-based financing for health services, with principles of universalism and equity standing strong [14]. The three countries typically exhibit a high degree of decentralisation and regional decision-making in the management and delivery of health services [14]. The key characteristics of drug reimbursement in the three countries are given in Table 1.

Similar reimbursement functions are organised at the national level for outpatient drugs in the three countries through the Danish Health and Medicines Authority (DHMA) in Denmark, the Norwegian Medicines Agency (NoMA) in Norway, and the Dental and Pharmaceutical Benefits Agency "Tandvårds- och läkemedelsförmånsverket" (TLV) in Sweden [15–17]. Reimbursement is granted as general, restricted to subgroups of patients, or, in the case of Denmark and Norway, at an individual case by case basis in which the physician may apply for reimbursement for her patient for a drug that does not have reimbursement status, or for which the patient does not meet the reimbursement criteria. In Denmark and Sweden the financial responsibility of outpatient drugs lies with the counties, while prescription drugs are paid for by a national insurance scheme in Norway.

Some differences can be found in the agencies' mandates. In addition to outpatient drugs, TLV and NoMA also appraise certain drugs of self-administrative forms initiated in hospitals and continued outside the hospital, while pharmaceutical treatments initiated in hospitals lay outside the Danish Health and Medicines Authority's (DHMA) mandate. Furthermore, TLV in Sweden and NoMA in Norway have undertaken non-binding appraisals for a number of inpatient drugs on behalf of the counties and health regions since 2010 and 2012, respectively.