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Which Factors Enhance Positive Drug Reimbursement Recommendation in Scotland? A Retrospective Analysis 2006–2013

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ABSTRACT

Objectives: To identify the factors that influence the Scottish Medicines Consortium (SMC) in deciding whether to accept pharmaceutical technologies for use within the Scottish health care system. **Methods:** A database of SMC submissions between 2006 and 2013 was created, containing a range of clinical, economic, and other factors extracted from published health technology assessment reports. A binomial outcome variable was used, defined as the decision to "accept for use" or "not recommend" a technology. Univariate and multivariate analyses were conducted to assess the impact by means of odds ratios (ORs) of the submitted evidence on the recommendation decision. **Results:** Out of 463 applications, 265 were accepted for use (57%) and 198 (43%) were not recommended for use within National Health Service Scotland. Univariate analyses showed that 13 variables significantly affected the SMC decision. Of these 13 variables, 7 variables were shown to have a meaningful impact in the multivariate analysis. Four of these concerned the outcome of cost-effectiveness analyses; the fact that a submission was supported by a cost-minimization analysis was the strongest positive variable (OR = 10.30) and a submission showing a product not being cost-effective (i.e., incremental cost-effectiveness ratio above £30,000/quality-adjusted life-year gained) was the strongest negative predictor (OR = 0.47). The other variables concerned whether the submission was related to a product indicated for a nervous system disease (OR = 0.41), whether it was indicated for nonchronic use (OR = 1.66), and whether the submission was performed by a big company (OR = 2.83). **Conclusions:** This study demonstrated that the outcome of cost-effectiveness analyses is an important factor affecting the SMC's reimbursement recommendation decision.

Keywords: decision making, health technology assessment, reimbursement, Scotland.

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Introduction

Given limited health care resources and rising expenditures on pharmaceuticals, policymakers are increasingly confronted with the challenging task to improve patient outcomes and reimburse new pharmaceutical interventions [1]. In several countries, including England and Wales, Scotland, The Netherlands, Belgium, Canada, Australia, and Sweden, health technology assessment bodies have been set up to advise on whether health care interventions should be recommended for public reimbursement [2–4]. Most health technology assessment bodies consider evidence not only on clinical effectiveness and safety but also on various other factors such as cost-effectiveness and budgetary impact. With more and more national health authorities requesting health economic evaluation for their reimbursement decisions, the significance of economic factors in the advisory or decision-making process has increased.

The importance of individual components of evidence, for example, clinical outcomes, disease characteristics, and health economic outcomes, which are submitted to local health authorities as part of a reimbursement dossier, however, is generally not described. There is an exception for the National Institute for Health and Care Excellence (NICE) in England and Wales, which uses the incremental cost-effectiveness ratio (ICER) threshold of £20,000 to £30,000 per quality-adjusted life-years (QALYs) gained. Yet, NICE appraisals suggest that various factors are taken into account and a drug can be positively assessed even if the ICER exceeds that threshold. More precisely, as the ICER of an intervention increases in the range of £20,000 to £30,000 per QALY gained, the NICE Committee's judgment about the acceptability of the technology as an effective use of National Health Service (NHS) resources will specifically take account of other factors, such as the degree of certainty around the ICER, innovative nature of the technology, inadequately captured quality-of-life

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benefits, and potential "life-extensive" nature of the treatment under assessment [5]. Nevertheless, most countries have not set a formal cost-effectiveness threshold for reimbursement; therefore, it is not clear how the economic results relate to other factors in the decision or advisory process.

A number of quantitative studies have been previously conducted to investigate what factors are influential and how much impact these factors have on reimbursement decisions in specific countries, including England and Wales [6–10], The Netherlands [11], and Australia [12,13]. To our knowledge, no study has been conducted for the Scottish Medicines Consortium (SMC).

Within the National Health Service for Scotland (NHS Scotland), 14 geographically based local NHS boards and a number of National Special Health Boards are responsible for the provision of health care [14]. The SMC, a consortium of NHS Scotland, was established to benefit patients by providing NHS boards and their Area Drug and Therapeutics Committees with a single source of advice about the value of each new medicine and the patients for whom it would be most beneficial [14,15]. In particular, the SMC advises NHS Scotland whether a newly licensed drug should be reimbursed on the basis of the value for money it represents to NHS Scotland. The SMC provides a central reimbursement recommendation as soon as possible after the launch of the product, which is based on the clinical and economic evidence provided by the manufacturer [15,16]. The advisory process involves the assessment of both clinical and economic evidence as submitted by the manufacturer by lead clinicians, pharmacists, and health economists together with representatives of health boards, the pharmaceutical industry, and patient associations [15,16]. The SMC can positively assess and accept a drug for either routine or restricted use, or, alternatively, it can suggest rejection of public funding of the medicine [16]. On completion of the SMC assessment process, its advice for NHS Scotland is published and the final formulary inclusion decision is made by the local health boards using this advice. It is important to note that NHS boards will consider all SMC-accepted advice as a matter of course but can still decide not to include such medicines on their own local formulary, that is, where the medicine does not represent sufficient added benefit to other medicines already on the formulary for the same indication [15]. Detailed information is available on the organization's Web site (www.scottishmedicinesconsortium.com) [15].

Arguably, Scotland is often one of the first European countries where manufacturers file a submission dossier requesting public reimbursement for their product. Manufacturers submit their evidence to the SMC before they submit it to the relevant health technology assessment body of England and Wales, NICE [14,17]. It seems that SMC's assessment of evidence approach is closer to that used elsewhere in Europe and its activities are to a large extent complementary to the ones of NICE [14,18]. The SMC advisory process is transparent in the sense that all decisions and argumentations are published on SMC's Web site since 2002 [15]. Hence, feedback of the SMC on a submission might have implications on decisions of other health authorities and affect the product's pricing in Europe on grounds of the reference pricing system [19].

The purpose of the present study was to investigate the weight that different pieces of evidence, submitted to the SMC for reimbursement assessment, have on the final recommendation decision by the SMC.

Methods

A comprehensive database was created including information from all drug appraisals performed by the SMC between January 2006 and July 2013. They year 2006 was chosen as the starting point for the SMC data collection for this analysis because this year was considered to be the one in which SMC's role was strengthened and evolved into the one that it currently has [20]. The SMC publishes the reimbursement recommendation itself together with wide-ranging details on the submission in a standardized format that is accessible to the general public [15]. Information from "full submissions" (i.e., submissions for the first time) as well as resubmissions was included in the database. Appraisals that were labeled as "abbreviated submission" or "IRP guidance (Independent Review Panel)" were not considered for this research because they provided limited information on the submitted evidence.

From each appraisal, numerous variables were extracted. These included the opinion of the SMC (a product being accepted for routine or for restricted use was treated as one category) and several factors that were grouped into five main classes: clinical evidence, therapeutic indication–related information, disease characteristics, health economic evidence, and other relevant information. Altogether, the data set included 20 variables that were thought to potentially influence the recommendation of the SMC. Table 1 presents these variables together with their definitions and possible sets of values.

The extent to which the submitted evidence influences the final recommendation of the SMC was assessed by odds ratios (ORs) estimated from binomial logistic regression analyses. The STATA software was used [22]. Analyses took place in two phases; in the first phase, univariate logistic regression models were set up to examine the relationship between each individual independent variable (explanatory variables) and the decision of the SMC (dependent variable), defined as "to accept" or "not to recommend" a product for use within NHS Scotland. In the second phase, a multivariate logistic regression analysis was undertaken to assess how the presence of multiple factors influences the recommendation of the SMC. The explanatory variables that indicated a statistically significant relationship with the dependent variable in univariate analyses (i.e., $P \leq 0.05$) were included in the multivariate model. If for a multinomial explanatory variable at least one category was significantly associated with the outcome, then the whole multinomial variable was considered for the multivariate analysis. Missing information led to the exclusion of an observation from regression analyses.

Variable selection in the multivariate logistic regression model was performed using a backward elimination procedure [23]. Specifically, the backward elimination procedure started with all considered variables (i.e., variables with a P value of <0.05 in the univariate analysis), tested the deletion of each variable for model improvement (exit criterion was a P value of >0.05), and repeated this process until no further improvement was possible. The backward elimination algorithm was chosen for this study because it is a commonly used and well-accepted method for variable selection and because it is less adversely affected by correlations among explanatory variables than are other methods (e.g., forward selection and stepwise regression methods) [23]. The predictive power of the multivariate model was assessed by the area under the receiver operating characteristic curve.

For the base-case analysis, resubmissions were treated as original submissions. One could argue, however, that the result of a resubmission was not independent from that of the original submission because at the resubmission the manufacturer could address the critique expressed by the SMC during the first assessment and could eventually increase the chance of a positive recommendation. If this is true, depending on the strength of this correlation and the number of resubmissions, standard errors of the analyses may not be correct even though parameter estimates would be still unbiased. To acknowledge

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