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The Challenge of Conditional Reimbursement: Stopping Reimbursement Can Be More Difficult Than Not Starting in the First Place!

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ABSTRACT

Background: Conditional reimbursement of new health technologies is increasingly considered as a useful policy instrument. It allows gathering more robust evidence regarding effectiveness and cost-effectiveness of new technologies without delaying market access. Nevertheless, the literature suggests that ending reimbursement and provision of a technology when it proves not to be effective or cost-effective in practice may be difficult. **Objectives:** To investigate how policymakers and the general public in the Netherlands value removing a previously reimbursed treatment from the basic benefits package relative to not including a new treatment. **Methods:** To investigate this issue, we used discrete-choice experiments. Mixed multinomial logit models were used to analyze the data. Compensating variation values and changes in probability of acceptance were calculated for withdrawal of reimbursement. **Results:** The results show that, ceteris paribus, both the general public (n = 1169) and policymakers (n = 90) prefer a treatment that is presently reimbursed over one that is presently not yet reimbursed. **Conclusions:** Apparently, ending reimbursement is more difficult than not starting reimbursement in the first place, both for policymakers and for the public. Loss aversion is one of the possible explanations for this result. Policymakers in health care need to be aware of this effect before engaging in conditional reimbursement schemes.

Keywords: allocation decisions, compensating variation, conditional reimbursement, coverage with evidence development, discrete-choice models, medical technologies.

Introduction

Economic evaluations of new health technologies have become an important source of evidence for policymakers to guide allocation decisions [1,2]. Nevertheless, the information on effectiveness and cost-effectiveness of new technologies is often imperfect at the time the reimbursement decision needs to be made. For instance, first evidence about cost-effectiveness is typically generated in controlled trials and primarily aimed at meeting the regulators' requirements about efficacy and safety of the new technology, but it is usually inconclusive about the effectiveness in real-life use and the cost-effectiveness compared with existing technologies. As a result, many allocation decisions have to be made under considerable uncertainty, which makes it difficult for health care policymakers to make a well-considered long-term reimbursement decision [3–5].

Conditional reimbursement has been proposed as a policy tool to deal with this uncertainty regarding health care allocation decisions, without delaying market access [2,4,5]. With conditional reimbursement, a new technology is included in the basic benefits package (in a health insurance system) or paid for by the government (in a National Health Services system) for a given period of time, under specified conditions. One of the common conditions is the collection of real-world data on costs and effectiveness of the technology. Hence, the policy instrument has also been labeled as coverage with evidence development, funding with evidence development, or access with evidence development. Using this policy instrument, policymakers can make new promising technologies available to patients at an early stage, and the long-term reimbursement decision can be postponed until more robust evidence of the performance of the technology in daily practice has become available [3,4].

Some countries, for example, United States, Canada, United Kingdom, Australia, France, Sweden, and Belgium, have already implemented some form of conditional reimbursement as a policy instrument for health care allocation decisions[5–8]. Nevertheless, only a few initiatives have been formally reviewed. Most countries are still having issues with the evaluation procedure as well as in determining suitable selection criteria and gathering sufficient evidence [9]. A study evaluating the first experiences with conditional

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reimbursement in Canada described that 38 interventions had been conditionally reimbursed since 2003, and that 13 of them had been evaluated by the time of the study. Of these 13 interventions, 6 were permanently reimbursed, 3 were permanently reimbursed after modifications, and for 4 interventions reimbursement was withdrawn [2]. In the Netherlands, conditional reimbursement was implemented in 2006 to ensure early access to new expensive inpatient drugs, with a budget impact of at least €2.5 million [10]. In 2013, this policy was extended to a selected group of outpatient drugs that met the criteria for temporary reimbursement. If a drug is conditionally reimbursed, hospitals receive an additional earmarked budget to cover the expenses. This is combined with the obligation to gather data on appropriate use and cost-effectiveness in real-world clinical practice. After 4 years an evaluation is carried out to inform the final reimbursement decision [6,9].

First experiences of countries using conditional reimbursement in practice showed that the reassessment process appears to be a complex and politically sensitive procedure. Gathering the additional evidence in practice appears to be challenging and policymakers seem to adopt a fairly passive role in withdrawing reimbursement, probably because of the social resistance surrounding these decisions [11]. Therefore, researchers and policymakers primarily aim to determine the conditions under which conditional reimbursement can be considered a feasible or optimal strategy and the type of evidence that needs to be gathered during the period of conditional coverage [12,13].

A traditional reimbursement decision is typically related to allowing or not allowing a new technology to enter the health (insurance) system. Given that the technology was not yet funded, this implies the status quo (not entering) or a gain (entering). Under conditional reimbursement, the second ("final") decision is either to continue funding (status quo) or to end (temporary) funding, which may be considered a loss. This difference is by no means trivial. Once a technology like a pharmaceutical is used in practice, ending reimbursement may be less feasible than deciding not to reimburse in the first place, in particular when the technology was proven to be effective in practice, but not cost-effective. This relates to the general tendency to value equally sized gains and losses differently, with losses looming larger than gains. This phenomenon of loss aversion is a well-known aspect of prospect theory [14,15].

In the context of allocation decisions, loss aversion may imply that policymakers may be willing to accept higher cost-per-quality-adjusted life-year (QALY) ratios for technologies already reimbursed (under conditional reimbursement) than they would accept for technologies not yet reimbursed (in the conventional decision-making context). So far, this asymmetry in removing something from the package versus allowing something in the package has remained largely unexplored. The aim of this study was to investigate how policymakers and the general public in the Netherlands value removing an existing treatment from the basic benefits package relative to not including a new treatment in the first place, in the context of health care allocation decisions. In other words, is stopping indeed more difficult than not starting? A discrete-choice experiment (DCE) was designed to investigate preferences for different technologies, with a set of relevant criteria for health care allocation decisions obtained from the literature and information on the present reimbursement status of the treatment as choice attributes. Data were collected from both health care policymakers and the general public.

Methods

Discrete-Choice Experiments

DCEs have proven to be useful in eliciting individuals' preferences in health care decision making [16,17]. DCEs are based on random utility theory, which assumes that a respondent, confronted with a choice between different scenarios, always chooses the alternative that gives the highest utility. The utility of alternative j in choice situations for respondent n is given by Equation 1:

$$U_{nsj} = V_{nsj} + \varepsilon_{nsj}. \quad (1)$$

U_{nsj} can be separated into two components: V_{nsj}, the observed component of utility, and ε_{nsj} ,the residual unobserved component. In this basic multinomial logit (MNL) model, the unobserved component, ε_{nsj} ,is assumed to be independently and identically extreme value type 1 distributed [16,18].

Identification and Presentation of Attributes and Levels

The focus of this study was to explore how policymakers and the general public value removing an existing treatment from the basic benefits package relative to not including a new treatment in the first place. Therefore, the main attribute of this study was the present reimbursement status of a treatment. To emphasize the fact that a certain treatment was not only reimbursed but also used by patients, the levels of the attribute were defined as "existing treatment, presently reimbursed and used in practice" and "new treatment, presently not reimbursed and not used in practice."

Besides this main attribute of the study, additional criteria potentially relevant in health care allocation decisions were identified from the literature. Recent related studies by Koopmanschap et al. [19] and van de Wetering et al. [16] were used as primary sources of information for potentially relevant choice attributes in the Dutch policy context. On the basis of the literature, the following additional attributes were selected: age of patients, quality of life before treatment, health gain from treatment, cost per QALY, budget impact, and probability that the cost per QALY would double. The attributes and their corresponding levels were identical for policymakers and for the general public. An overview of the attributes and the corresponding levels is presented in Table 1.

Because the general public is less familiar with the terminology and the common interpretation of absolute levels of cost-effectiveness and budget impact in the policy context, we gave them an indication on whether a certain level could be considered favorable (Table 1).

The attributes, levels, and presentation of choice sets were pilot-tested in a sample of 156 respondents of the general public. To be able to evaluate the attributes and the construction of the design, a number of questions concerning the complexity, plausibility, and comprehensibility of the choice options were added to the pilot study. The pilot study revealed that 39.7% of the respondents thought that it was difficult to opt for one of the groups in the choice sets. Nevertheless, from respondents' explanations to this question it appeared that this was mainly because people preferred not to choose between groups of patients at all. The results showed that 65.4% of the respondents took all attributes in consideration while making their decision. The attribute that was most often considered important was health gain as a result of treatment, followed by quality of life before treatment and age. Only 44% of the respondents considered the probability that the cost per QALY would double to be an important argument for their choice between groups of patients. Finally, people were asked whether they had sufficient information to make a well-considered decision; 17.9% of the respondents answered that they needed additional information—predominantly on the personal circumstances of the patients, the success rate of treatment, and the life expectancy after treatment. Given that more than 80% of the respondents indicated that the scenarios provided sufficient information and the large variety