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Review

The bare necessities? A realist review of necessity argumentations used in health care coverage decisions

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ABSTRACT

Context: Policy makers and insurance companies decide on coverage of care by both calculating (cost-) effectiveness and assessing the necessity of coverage.
Aim: To investigate argumentations pertaining to necessity used in coverage decisions made by policy makers and insurance companies, as well as those argumentations used by patients, authors, the public and the media.
Methods: This study is designed as a realist review, adhering to the RAMESES quality standards. Embase, Medline and Web of Science were searched and 98 articles were included that detailed necessity-based argumentations.
Results: We identified twenty necessity-based argumentation types. Seven are only used to argue in favour of coverage, five solely for arguing against coverage, and eight are used to argue both ways. A positive decision appears to be facilitated when patients or the public set the decision on the agenda. Moreover, half the argumentation types are only used by patients, authors, the public and the media, whereas the other half is also used by policy makers and insurance companies. The latter group is more accepted and used in more different countries.
Conclusion: The majority of necessity-based argumentation types is used for either favouring or opposing coverage, and not for both. Patients, authors, the public and the media use a broader repertoire of argumentation types than policy makers and insurance companies.

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1. Introduction

Public outrage often ensues when decision makers exclude forms of care, such as orphan drugs or expensive cancer medicines, based on an incremental cost-effectiveness ratio (ICER) that is below par. This outrage not infrequently precedes a reversal of the decision [1,2]. At the same time, however, not all forms of care with a sufficiently low ICER are covered. Viagra, for example, is highly effective and not that expensive, but almost never provided by the state; decision makers deem it unnecessary to do so [3,4]. Hence, (cost-) effectiveness is not the decisive factor in all funding decisions. In these situations, another factor trumps it: the perceived *necessity* of coverage. To aid operationalisation, this paper will survey the content, use and context of the necessity criterion, an umbrella term for need- and solidarity-related argumentations used – not just decisively, and not just in coverage decisions made by policy makers and insurance companies.

In this paper, we will review argumentations underpinning the necessity, or lack thereof, of coverage of a certain treatment or therapy, as explicated in academic literature. To cast our net wide, we have chosen to include not only 'actual' decisions, that is, coverage decisions made by policy makers and insurance companies, but also what we term 'hypothetical' coverage decisions. The latter type generally comes in the form of surveys (of, e.g., decision makers or the public) or ethical or economic analyses exploring possible reasons for (denial of) coverage. By examining both actual and hypothetical decisions we hope to provide insight into all potential considerations that may be invoked when deciding whether the coverage of a therapy or treatment is thought to be necessary. This is relevant as surveys and public opinion are considered of note (and of use) within coverage decision making practice [5,6], as are scholarly reflections, as exemplified by the international take-up of the accountability for reasonableness framework [7,8].

1.1. Objectives and focus of review

We followed the realist review method as described in the RAMESES publication standard [9]. This method is used to review

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sundry literatures on a specific policy intervention, in order to describe why and how these interventions do what they do in their context. Using this method, researchers aim to uncover what works, for whom, and in what circumstances by conceptualising meta-level theories that detail patterns of how mechanisms-in-contexts lead to certain outcomes [10–12]. In such an iterative research process, we refined how argumentations bearing upon necessity of coverage (mechanism) are used in justifying both actual and hypothetical coverage decisions (outcome), as found in academic literature. These decisions are made in context: by different decision makers from different countries, and, in case of actual decisions, placed on the decision agenda by different actors. Thus, the argumentations may be seen as interventions that have a proposed or actual outworking, also depending on contexts they are situated in. This review will address the following questions:

1. Which, if any, argumentations (mechanisms) are currently used in hypothetical and actual coverage decisions to justify whether coverage of a treatment is, or is not, necessary?
2. How do these argumentations justify the hypothetical and actual coverage decisions (outcomes) for different treatments, in different countries, put on the agenda by different agents (contexts)?

2. Methods

2.1. Rationale for using realist synthesis

Little attention has been given to "the problem of operationalizing for decision makers essentially qualitative and normative criteria such as whether the technology serves an 'ethical' or 'medically necessary' purpose" [13]. Furthermore, "social and ethical parameters of value (...) are anticipated to become as critical for reimbursement decisions (...) as economic and clinical criteria" [14]. In light of the lack of operationalisation and its (potentially) crucial role in coverage decisions, we conducted a literature review of the argumentation types that fall under the necessity criterion.

A realist review describes an intervention from different types of literatures, in our case actual coverage decisions (qualitative analyses of coverage decisions or policies) as well as hypothetical ones (economic analyses, ethical analyses, surveys, interviews, and opinion pieces). It searches these articles not just for information on the intervention (that is, the argumentation) but also for how the context (country, agenda setter) may have influenced the use of the intervention and its outcome (the decision including decision type: hypothetical or actual decision). This is subsequently summarised in context-mechanism-outcome patterns. From these patterns, meta-level theories are formulated that explain the working of these interventions-in-context. The primary reason for choosing the realist review method is practical; this method provided a focused lens to zoom in on particular aspects of actual and hypothetical coverage decisions, which in turn aided comparison of a broad variety of articles. Using this method for a non-classical intervention proved, moreover, an interesting methodological issue to grapple with. The second reason for utilising this method lies in its philosophical underpinnings. A realist philosophy holds that actors can and do effectuate change in context, but are themselves shaped by the contexts they are part of. In this sense, it is likely to be acceptable to (social) scientists and policy makers alike.

2.2. Scoping the literature and searching processes

As an exploratory foray into grey literature and policy documents yielded too few explicated argumentations, we focused on peer-reviewed literature. For our primary background search thereof [12], we used the conceptualisation of the necessity criterion in the Netherlands [15], as a request for operationalisation of this criterion from the Dutch Health Care Institute catalysed this study. We subsequently discovered similar and/or underlying conceptualisations and related terminology in other countries, like 'need' and 'solidarity', which helped inform our search strategy. The full search was conducted in Embase (see Table 1 for search terms), and translated to Medline and Web of Science [16], which is recognised to be an effective combination for reviews [17]. We used three general elements separated by the Boolean operator 'AND' as this kept the total number of articles workable (under 6000). These general elements are a) the type of provision, b) the process of decision making, and c) the content in terms of criteria. Utilising a), we aimed for a representative sample, therefore a wide variety of provision types was included (benefit package, health insurance, and/or health catalogue or service). For elements b) and c) specificity was the goal; we zoomed in on coverage decisions (also often termed 'rationing' or 'priority setting' decisions) and precisely on those decisions that employ the necessity criterion. In selecting the exact search terms, we aimed for results that included the articles retrieved and selected from the primary background search, for example [3,4,18]. For each of the three elements we included relevant thesaurus terms (Emtree terms for Embase and MeSH terms for Medline). We excluded conference papers, letters, notes and editorials, as well as articles written in any language other than English, but did not employ any date restrictions [19].

Table 1
Search terms used in Embase.

('insurance'/de OR 'health insurance'/de OR 'child health insurance'/de OR 'national health insurance'/de OR 'private health insurance'/de OR 'public health insurance'/de OR 'national health service'/de OR 'reimbursement'/de OR (insurance* OR reimburse* OR (national NEAR/3 (service OR coverage)) OR (cover* NEAR/6 deci*) OR ((partial* OR polic* OR universal OR unlimited OR limited OR temporar* OR permanent* OR recommend* OR plan OR plans) NEAR/3 coverage) OR (basic NEAR/3 package*) OR (health NEAR/3 catalogue*)):ab,ti)
AND
('decision making'/de OR 'ethical decision making'/de OR 'medical decision making'/de OR (decision* OR decide OR rationing OR priorit* OR (analys* NEAR/3 (inclusion OR exclusion)) OR (coverage NEAR/3 (negativ* OR positiv* OR determin* OR deny OR denial*))):ab,ti) AND ('resource allocation'/de OR (coverage OR inclusion* OR funding OR (resource* NEAR/3 allocat*) OR 'should be provided' OR 'what to provide'):ab,ti)
AND
('health care cost'/de OR 'cost of illness'/de OR 'economic evaluation'/exp OR ethics/de OR bioethics/de OR 'medical ethics'/de OR 'ethical decision making'/de OR 'health care policy'/de OR 'needs assessment'/de OR (necess* OR cost* OR (disease* NEAR/3 burden*) OR expenditure* OR solidarit* OR (therapeutic NEAR/3 (value* OR need*)) OR (budget* NEAR/3 impact*) OR ethic* OR 'health benefit*' OR (benefit NEAR/3 (risk OR analysis)) OR 'health technology assessment*' OR 'health care poli*' OR (need* NEAR/3 (assess* OR healthcare OR health-care))):ab,ti)
NOT
([Conference Abstract]/lim OR [Letter]/lim OR [Note]/lim OR [Editorial]/lim)
AND
[english]/lim

2.3. Selection and appraisal of documents

The first author (TKV) scanned titles, abstracts, and keywords in Endnote to include decisions that were made on the macro (government) or meso (local health authorities, sickness funds, and insurance companies) level [20]. BB, the last author, scanned a random subset of 537 studies. Together, an agreement rate of 96% was reached and further disagreement was resolved through discussion. This first round of inclusions amounted to a total of 666 studies. Next, TKV read all candidate papers in full and excluded 594 of the 666, ending up with 72 studies. Through snowballing, a

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