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The Definition of Innovation in Health Technology Assessment (HTA): A Review of the Literature

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Background and research aim

The growing focus on the value of new drugs for patients and society, fueled by the establishment of health technology assessments (HTAs), has also led to a more differentiated notion of innovation in the context of pharmaceutical products. Increasingly, health care systems call for “true innovation”, where the central criterion to identify a new drug as truly innovative is supposed to be the drug’s benefit or usefulness. The goal of this paper is to provide an overview of the current debate about the definition and assessment of innovation and how it influences the decision-making of HTA bodies and other relevant institutions to inform reimbursement and pricing decisions.

Methods

To compile the relevant literature for our overview, we conducted a semi-systematic literature review that includes both peer-reviewed and grey literature. We followed a three-step approach. First, we searched for peer-reviewed literature using PubMed and the Social Science Citation Index through the Web of Science portal. Second, reference lists from the studies selected were screened for further relevant literature. Finally, we searched for official HTA guidelines, reports, and other grey literature on the websites of HTA bodies of 11 countries and other national and international health policy agencies.

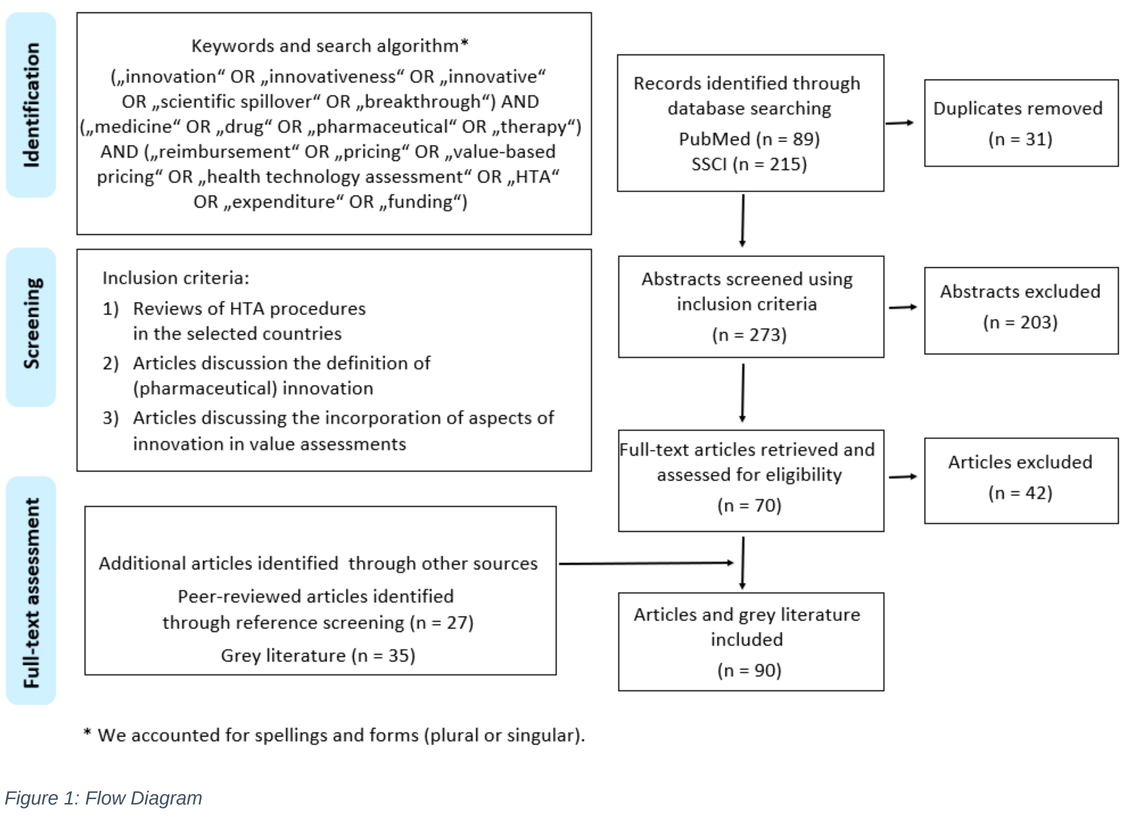


Figure 1: Flow Diagram

Results

France (HAS): The nature of treatment is mentioned explicitly as criterion for the assessment of medical benefit differentiating between symptomatic relief, preventive treatment, and curative therapy.[1] Additionally, as part of the guidelines for the evaluation of added medical benefits, the “novelty of the action mechanism” is defined as one of the characteristics a new drug must have to be considered as an innovation,[1] although it is not stated if and how this influences the assessment.

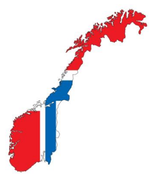
England (NICE): The “innovative nature of a health technology” is called upon as an additional decision criterion when substantial health-related benefits may not have been captured in the quality adjusted life year (QALY) measure and the incremental cost-effectiveness ratio (ICER) is above the £20,000 per QALY threshold.[2] There are three conditions that were considered by the HTA committees when calling upon the “innovative nature”: novelty (e.g. innovative mechanism of action), substantial benefit (e.g. step-change in treating patients), and demonstrable and uncounted benefits (i.e. demonstrable, but not yet considered in the assessment).[3]

Netherlands (ZIN): According to a review by Angelis and colleagues, the nature of treatment is implied in the Dutch setting,[4] however, this could not be documented based on our review of more recent guidelines from the Zorginstituut Nederland.[5] In the same guidelines ease of use or mode of treatment delivery is only considered as a value component independent of clinical outcome for diagnostics and medical devices.[5]

Results

Canada (CADTH & PMPRB): While guidelines from CADTH do not explicitly consider a treatment’s nature or ease of use and comfort, the PMPRB explicitly states that the nature of treatment is not considered unless it results in increased efficiency or a reduction in important adverse reactions.[6] Regarding ease of use and comfort, the Canadian PMPRB considers route of administration and patient convenience as secondary factors (among others) that, on their own, be rewarded with a rating up to moderate therapeutic improvement.[6] However, the CADTH in its guidelines for economic evaluation states that patients’ time for travel and receiving treatment can only be included in an additional non-reference case analysis as a cost element.[7]

Japan (Chuikyo & C2H): In the Japanese setting, a distinction is made linking nature of treatment to a therapeutic value. That is, the Japanese Central Social Health Insurance Council (Chuikyo) considers a new action mechanism only (as one of four possible elements) in order to grant a so-called innovativeness price premium if it is clinically useful.[8]



Norway (NOMA): While the reviewed HTA guidelines from Norway do not explicitly consider a treatment’s nature, the difference in the duration of treatment administration or travel time for patients and caregivers must be estimated and presented as costs.[9]

Belgium (CMR): Applicability and user-friendliness are indicated as elements of therapeutic value that should be reflected on or provided in a separate analysis if they are relevant and not already captured in the assessment of additional health benefit in the same guidelines.[10]

Germany (IQWIG): German HTA guidelines do not explicitly consider a treatment’s nature or ease of use and comfort. Yet, ease of use and comfort might be considered implicitly through treatment satisfaction (patient-reported outcomes considered as optional additional aspect) if morbidity or side effects are impacted.[11]

Australia (PBAC): A treatment’s nature might be considered informally in the Australian HTA process, but no information to this effect could be found in our review. Australia does allow for non-health outcomes such as convenience of drug administration to be presented in a supplementary analysis, including a monetary estimate, if there are no other substantive added health benefits.[12]

Sweden (TLV) & Italy (AIFA): Our review of the HTA guidelines from the Italian Agenzia Italiana del Farmaco (AIFA) and from the Swedish Dental and Pharmaceutical Benefits Agency (abbreviated TLV) did not explicitly or implicitly identify a treatment’s nature or ease of use and comfort as a considered dimension.

Conclusion

While there is a vivid debate about which aspects of pharmaceutical innovation should be considered as relevant value elements, implementation in HTA frameworks is still diverse and in large parts unsystematic. Whether wider aspects of innovation should be rewarded, will eventually be a societal and political decision. However, with many value frameworks of HTA systems still being in more or less early stages of development, the pros and cons of rewarding wider benefits through pricing and reimbursement decisions should be carefully weighed and considered from a long-term perspective.

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