

What Makes a Medicine Innovative? A Literature Review of Evaluation Frameworks

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Introduction and aim

Pharmaceutical innovations are highly significant to society, governments, companies and the overall economies of countries. Identifying and evaluating innovative medicines is central to both healthcare decision-making and resource allocation. However, innovation is an ambiguous concept in the pharmaceutical sector. The aim of this study is to identify the evaluation frameworks that can be used to examine the innovativeness of medicines and to identify the domains of emphasis in these evaluations.

Methods

A review based on a systematic literature search was conducted. The MEDLINE, Embase, Healthcare Administration Database and PsycInfo databases were searched for articles published. Articles classifying or evaluating the innovativeness of medicines were included in the literature review. The articles were used to formulate different dimensions of innovativeness.

Results

A total of 45 articles were selected from the literature search. There were a total of 24 different evaluation frameworks, which could be categorised into evaluation frameworks ($n=16$) and country-specific frameworks ($n=8$). The components of the innovation evaluation framework were categorised into three main categories: therapeutic, therapeutic need and pharmacological. Under the main categories, the themes were further subdivided into more specific subcategories: therapeutic benefit, added value, quality of clinical evidence, unmet need, safety, new mechanism of action and administration. There is no established definition or generally accepted framework for assessing the innovative nature of medicines. There were differences between the frameworks, and the same subdomains were emphasized differently. However, certain key aspects of the evaluation of innovation were repeated. Therapeutic benefit and unmet need were identified as important and widely used evaluation criteria.

Conclusions

A transparent and systematic framework for assessing innovation is essential to support decision-making. Such a framework enables consistent and justified identification of genuinely innovative medicines, facilitating their effective and appropriate adoption. A harmonized approach would benefit all stakeholders and align incentives with societal needs.

Table 1. Dimensions of innovation

Dimension	Subdimension	Definition of subdimension
Therapeutic	Therapeutic benefit	Improves meaningful health outcomes
	Added value	The incremental benefit of a new treatment compared to existing treatments
	Quality of clinical evidence	Robustness of the scientific evidence
Therapeutic need	Unmet need	No available treatment or satisfactory treatment
Pharmacological	Safety	Less side effect, better benefit/risk consideration
	New mechanism of action	A novel way a substance produces an effect in the body, for example new targets or new pathways
	Administration/formulation	Simpler regimens that improve convenience and adherence

Figure 1. Flowchart



Key findings



There is no established definition or generally accepted framework for assessing the innovative nature of medicines.



There were a total of 24 different evaluation frameworks.



The most important subdimensions of innovation are therapeutic benefit and unmet need.

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