

Developing a conceptual framework to support coverage decisions for vaccines adoption in Lombardy (Italy)

It aims to develop a transparent and comprehensive standard framework for the inclusion and prioritization of new vaccines in the regional immunization program. The framework should act as a guide to consistently inform policy makers in the Region of Lombardy. The research consists of three phases:

PHASE 1

Objective: To review the literature on decision-making coverage around the adoption of vaccines and to propose a transparent and comprehensive framework based on evidence-based criteria using the DECIDE approach.

Method: We systematically searched literature (MEDLINE, Embase, The Cochrane Library) and funding agency websites from 1990 to 2013. We included systematic reviews (SRs) and primary studies describing decisional supportive tools for community vaccine adoption and qualitatively summarised the reports. The proposed dimensions were extracted and compared to recognize similar ones. The critical dimensions were integrated so as to generate a framework that guides decisions on vaccine adoption.

Results: 14 studies (5 SRs and 9 primary studies) were included, all published after the year 2000. The conceptual models featured broad differences in the terminology used, even though the construct of the dimensions appeared to be largely overlapping. The most frequent dimensions were “burden of disease,” “vaccine characteristics,” and “economic considerations.”

We identified 10 dimensions proposed in the studies included, all of which resembled those of the DECIDE framework. We then linked the 10 dimensions to those of DECIDE. At the same time, the studies were used to define proposal criteria useful to describe the dimensions. In table 1, we present a description of the dimensions of the framework, the related questions and the number of criteria proposed.

Table 1

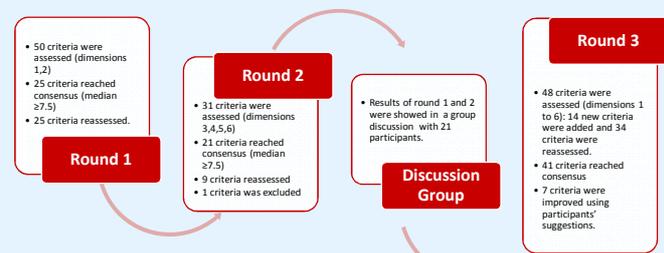
DIMENSIONS	DESCRIPITON	QUESTION	CRITERIA PROPOSED
Burden of disease	Description of epidemiologic and clinical features of the disease/condition of interest in terms of seriousness of consequences.	Is the vaccination a priority?	27 criteria
Vaccine characteristics and impact of immunisation programme	Description of the effect and adverse events of the vaccine using the GRADE method. Overall quality of the available evidence of effects across all of the outcomes that are critical to making a decision.	What is the net benefit of the vaccination? How confident are we about the net benefit of the vaccination?	23 criteria
Values and preferences	Consideration of values and preferences of patients/care givers about the balance between desirable and undesirable effects of the vaccine.	What is the appreciation and value of the vaccination in the population?	4 criteria
Resource use	All the information about costs and use of resources.	What are the costs of the vaccination and are they limited compared to the benefits?	9 criteria
Equity	Impact on health inequities.	Would some part of the population taking advantage from the vaccination compared to other groups?	7 criteria
Feasibility	Information on applicability, professionals' acceptability, possible barriers, impact on professional style and type of practice, and the organisational impact.	Which vaccination barriers or facilitators act at the system level?	11 criteria

PHASE 2

Objective : To share and validate the framework proposed using a Delphi method.

Method: A total of 59 participants from multidisciplinary areas, including policy-makers, managers, methodologists, general practitioners, paediatricians, infectious disease specialists, drug policy experts, economists, epidemiologists and members of patient associations were invited by e-mail to participate in the Delphi study. A questionnaire was constructed based on DECIDE's dimensions and criteria identified by the authors in phase 1 of the current project. This resulted in 81 structured questions asking about the relevance of each criteria. Participants were requested to rate these factors on a 9-point Likert scale ranging from 0 (not at all important) to 9 (extremely important). We then conducted a three-round Delphi consensus process through Internet and a discussion group.

Results: A total of 46 participants accepted the invitation. The final framework consisted of 6 dimensions and 80 criteria. The results of Delphi rounds are presented in the figure below.



PHASE 3

Objective: To study the feasibility of the developed framework in regards to a vaccine.

Method: This phase will be divided into two parts. 1) Developing a framework: From the criteria considered to be relevant in phase 2, we will complete the information corresponding to each dimension (“Burden of disease”, “Vaccine characteristics and impact of immunisation programme”, “Values and preferences”, “Resource use”, “Equity” and “Feasibility”), focusing on a target vaccine. 2) Delphi method (round 4): We will send the framework to the participants of the Delphi in order to achieve a consensus for the final framework.

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