

عنوان مقاله:

An Overview of Stakeholders, Methods, Topics, and Challenges in Participatory Approaches Used in the Development of Medical Devices: A Scoping Review

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خلاصه مقاله:

**Background** There is a wide variety of participatory approaches to involve stakeholders in the development of medical devices, but there is no comprehensive overview of these approaches. We therefore studied what participatory approaches are used in the development of medical devices as well as the most important characteristics and challenges of these approaches. **Methods** We conducted a scoping review and searched PubMed, Embase and Web of Science for articles published between July ۲۰۱۴ and July ۲۰۱۹. Papers were included if they presented original research featuring any form of stakeholder participation in the development of medical devices. We used The Spectrum of Public Participation to categorise the approach of each paper. Subsequently, we described the characteristics of each approach: the stakeholders involved, data collection methods, and topics addressed. We also identified challenges of the approaches as reported by researchers. **Results** ۲۷۷ papers were included, which could be categorised into three levels of participation: collaboration, involvement, and consultation. Patients and healthcare professionals are frequently engaged in all approaches. The most often used methods are workshops in the collaboration approach papers, and interviews in the involvement and consultation approach papers. Topics addressed in all approaches are: the problem, device requirements, design choices, testing, and procedural aspects of involvement. Reported challenges entail issues related to sampling, analysis, social dynamics, feasibility, and the limited number of topics that can be addressed. **Conclusion** Participatory approaches reported in literature can be categorised in three overarching approaches that have comparable methodological characteristics. This suggests that if researchers want to apply a participatory approach it is not necessary to adopt a pre-determined approach, such as 'participatory action research' (PAR). Instead, they can independently determine the degree of participation, stakeholders, methods, topics, and strategies to account for challenges, making sure the participatory approach fits their research question and context.

کلمات کلیدی:

Stakeholder Engagement, Participatory Research, Medical Device Development, User-Centred Design, Public Participation

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