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The socioeconomic impact of in-silico models for implantable medical devices: a conceptual framework

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The use of in-silico technologies for implantable medical devices has gained importance in the last decade. From a medical perspective, the term 'in-silico' mainly refers to computer simulations of clinical trials based on virtual cohorts. So far, there is a lack of a concept how the impact of in-silico models on socioeconomic factors can be evaluated. As part of the EU-funded project SIMCOR, one objective was to conceptualize the impact of in-silico on implantable medical devices. We applied an iterative process described in Jabareen (2009) to build a conceptual framework based on concepts from a comprehensive literature review and expert interviews from academia, companies, and regulatory bodies. Repeated steps of literature work, exploratory interviews and discussion sessions among the research team led to the final framework that was validated by feedback from experts at the end. The conceptual framework describes the impact from in-silico technologies along the product development cycle of implantable medical devices through impact channels up to socioeconomic endpoints referring to firm, market, health system and society. Since the whole conceptual framework has multiple complex impact channels that create a kind of network, each impact channel is explained with its ramifications. One channel reveals that underrepresented patient groups in clinical trials might benefit from in-silico models by enabling to model rarer anatomical configurations and leading to medical device development for a broader range of population. The conceptual framework provides the basis for the quantification of the impacts of in-silico models that is expected to increase the acceptance of these models among different stakeholders. The potential benefits as well as disadvantages can be better estimated and classified from different perspectives. The use of in-silico models is expected to enable access to implantable devices faster and to a larger population group.

Key messages:

- The framework reveals opportunities of in-silico models for different stakeholders, e.g., entrepreneurs, regulators, that might lead to an increased development, use and acceptance of such models.
- The framework indicates that in-silico models are expected to accelerate implantable medical device development, increase patient safety, and gain faster access for larger population groups.