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LITERATURE REVIEW

De innovatione: The concept of innovation for medical technologies and its implications for healthcare policy-making

Ciani Oriana[a,b,*], Armeni Patrizio[a], Boscolo Paola Roberta[a], Cavazza Marianna[a], Jommi Claudio[a,c], Tarricone Rosanna[a,d]

[a]*CERGAS – Centre for Research on Health and Social Care Management, Bocconi University, Milan, Italy*
[b]*University of Exeter Medical School, Exeter, United Kingdom*
[c]*Department of Pharmaceutical Sciences, Università del Piemonte Orientale, Novara, Italy*
[d]*Department for Institutional Analysis and Public Management, Bocconi University, Milan, Italy*

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Abstract
Innovation is constantly evoked as an imperative to drive growth, however identifying an actionable and agreed upon definition that applies to different settings and purposes is not trivial. In healthcare, innovation has often been described in relation to pharmaceuticals. Defining innovation allows for proper recognition and rewarding, thus fostering present and future innovativeness in the system. Current definitions adopted by payers are focused on therapeutic added value and more specifically include clinically significant benefit, large health gains, and favorable risk-benefit balance at an acceptable cost. However, they may not be fully adequate to assess medical devices. Based on a systematic review of the academic literature in the field, we aim at summarizing acceptable definitions of innovation in relation to medical devices. Based on the innovation management and economics theory, proposed definitions have been classified according to the source of innovation, to the degree of discontinuity introduced and to the impact associated to the technology. They have also been compared with definitions adopted for drugs by main healthcare reimbursement agencies. Decision-making in healthcare often favors static allocative efficiency at the expense of incentives to innovate and obtaining valuable innovation, that is dynamic allocative efficiency. In the long run, this attitude may

*Correspondence to: CERGAS – Centre for Research on Health and Social Care Management, Bocconi University, Via Roentgen 1, 20136 Milan, Italy. Tel.: +390258362605; fax: +390258362598.
E-mail address: oriana.ciani@unibocconi.it (O. Ciani).

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artificially shrink net returns from innovation and rebound on the sustainability of the healthcare systems, an undesirable consequence that a farsighted shared notion of innovation should try to prevent.

Contents

Introduction

The word "innovation" comes from the Latin noun *innŏvātĭo*. In lay language use, it refers to the act or process of introducing new ideas, devices, or methods or to the new ideas, devices, or methods themselves [1]. In business, economics and politics, the term is often evoked as an imperative to drive growth, [2] especially in times of financial crisis for companies, markets and economic institutions in general [3]. Although the subject has risen to the core of the debate in many disciplines, including economics and management theory, and their subfield known as innovation studies, [4-6] identifying an actionable and agreed upon definition that applies to different settings and purposes is not trivial.

In healthcare, the need to define innovation in relation to health technologies comes with the assumption that recognizing and appropriately rewarding innovation will foster present and future innovativeness in the system [7]. In many jurisdictions, health policy initiatives are discussed or in place where innovation is a critical element, often described in relation to pharmaceutical products [8-11]. New target or novel pharmacological mechanism, method of synthesis, pharmacokinetic, pharmacodynamic, pharmacogenetic or therapeutic features are properties of medicinal products that can lead to their innovative status [12]. However, the International Society of Drug Bulletins has explicitly distinguished between innovation that produces therapeutic advance, in terms of efficacy, safety, and convenience to patients, and innovation from a purely commercial (e.g. new molecules that do not produce any added value) and technological (e.g. biotech products *vs* chemical products) viewpoints [13]. More specifically, the Italian Society of Hospital Pharmacists has agreed on three criteria to recognize therapeutic advance. They are evidence from an intervention successful in at least one randomised superiority trial where the control group is treated according to the current best practice and the primary endpoint is clinically relevant [14]. Aronson and colleagues propose an intentional definition for innovation in drug therapy that includes more selective parameters, i.e. clinically significant benefit, large health gains, favorable risk-benefit balance at an acceptable cost [7].

However, health technologies are not to be intended as drugs only. Medical devices have an estimated market of roughly €100 billion in Europe only, and account for about 7.5% of the healthcare expenditure in most publicly funded healthcare systems [15]. Besides the extreme diversity and heterogeneity of products falling under this classification, medical devices are known to differ from drugs in many respects. For instance, for many of them, especially the implantable devices, their performance and use are heavily dependent upon organizational settings, training, competence, and experience of the operator. As long as clinicians and their staff do not reach the plateau of the learning curve, it is difficult to assess the value of new devices. There might be cases when the plateau is never reached. This happens when new devices are quickly replaced by newer generations. Because of their short life cycle, medical devices do not often benefit from patenting. Moreover, due to different regulatory and coverage requirements or unavoidable facts (e.g. difficult, impossible or unethical blinding in clinical trials), the evidence on added value at market launch is less robust than for drugs. The value of devices is also more challenging to assess because they have often multiple indications (e.g. CT-scan, MRI) or are embedded into procedures or services. Devices are often diagnostics and their contribution to final health outcomes depend on how the information provided is treated by the end-users and on what happens to patients afterwards, therefore it is not easy to parcel out the contributions of each single components to final outcomes [16-18].

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