AIES 2018 Abstract Submission

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Background

What drives the adoption and diffusion of technological innovations in healthcare is a major topic of interest for both decision makers, who strive to balance cost containment pressures and access to innovative and effective technologies, and scholars, who try to understand the factors that act as facilitating or inhibiting forces in the adoption of innovations. Within this broad literature, a particular interest of scholars has been on the use of scientific evidence in adoption and diffusion decisions of healthcare innovation. Understanding the role of RCTs in the adoption and diffusion decisions is especially stimulating in the field of medical devices. The growing body of literature challenges the "supremacy" of RCTs in the evaluation of medical devices given their intrinsic differences with other technologies, namely pharmaceuticals. Moreover, there is increasing recognition that, in the case of medical devices, RCTs might be less relevant than real-world data to making policy decisions. Given this background, it becomes

increasingly important to investigate what role RCTs actually have in the diffusion of medical devices in Europe. Addressing this issue in a systematic way could improve the understanding of the diffusion process for both new and established medical devices.

Objective

The aim of this study is empirically investigate the role of clinical evidence (i.e. RCTs) in the diffusion of medical devices in one of the largest EU markets. More specifically, we aim to test the hypothesis that, despite the importance of evidence-based decision-making claimed by policymakers, physicians and scholars, the diffusion process of medical devices often starts and gains momentum in the absence of RCTs.

Methods

The database was a panel, structured at the product class level with repeated yearly observations on 11 years (2007-2017).The unit of observation was the number of devices launched in the focal year within a same product class. The analysis was restriced to high-risk devices (Class-III, 93/42/EEC Directive) in three major therapeutic areas: cardiovascular apparatus, active implantable devices and implantable prostheses. The Italian case was chosen due to the peculiar system of classification, where each device is categorized in technologically homogeneous classes. 36 product classes were identified and 1,889 devices were launched in the observed period. We tested for i) differences in the number of launches between classes with and without clinical evidence published before the end of the observed period, studied using a Poisson regression model; ii) differences in the number of launches in a class before and after the publication of clinical evidence, where available, studied using a regression discontinuity design.

Results

The analysis showed that simply belonging to a class with available evidence does not affect the launches of new products based on the same technology and, after controlling for the number of competitor products, the publication of clinical evidence can even slow-down the pattern of new launches. Such result was robust across two different specifications of the dependent variable. The in-depth analysis of possible differences before and after the publication of clinical evidence showed that the year when a RCT on the focal technology is published a higher number of launches is generally expected. However, the effect was not significant when looking at the cumulative number of devices launched in a class, confirming the slow-down effect of competition. The regression-discontinuity design showed that the effect of the publication of evidence on the number of launches is barely significant and not lasting.

Discussion

The presence of a RCT acts as a barrier to entry only if the technological class is already crowded with products, supporting our hypothesis. Patients are then exposed to the implant of devices whose efficacy is not supported by the presence of clinical trials. Such results underline the urge of identifying, producing and accepting prompter forms of evidence (such as real world evidence) to support medical and coverage-related decision-making in the field of medical devices. Deciding with no evidence is worse than deciding based on real-world evidence.