VALUE IN HEALTH ▮ (2016) ▮▮▮–▮▮▮

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Incorporating Budget Impact Analysis in the Implementation of Complex Interventions: A Case of an Integrated Intervention for Multimorbid Patients within the CareWell Study

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ABSTRACT

Objectives: To develop a framework for the management of complex health care interventions within the Deming continuous improvement cycle and to test the framework in the case of an integrated intervention for multimorbid patients in the Basque Country within the CareWell project. **Methods:** Statistical analysis alone, although necessary, may not always represent the practical significance of the intervention. Thus, to ascertain the true economic impact of the intervention, the statistical results can be integrated into the budget impact analysis. The intervention of the case study consisted of a comprehensive approach that integrated new provider roles and new technological infrastructure for multimorbid patients, with the aim of reducing patient decompensations by 10% over 5 years. The study period was 2012 to 2020. **Results:** Given the aging of the general population, the conventional scenario predicts an increase of 21% in the health care budget for care of multimorbid patients during the study period. With a successful intervention, this figure should drop to 18%. The statistical analysis, however, showed no significant differences in costs either in primary care or in hospital care between 2012 and 2014. The real costs in 2014 were by far closer to those in the conventional scenario than to the reductions expected in the objective scenario. The present implementation should be reappraised, because the present expenditure did not move closer to the objective budget. **Conclusions:** This work demonstrates the capacity of budget impact analysis to enhance the implementation of complex interventions. Its integration in the context of the continuous improvement cycle is transferable to other contexts in which implementation depth and time are important.

Keywords: Deming cycle, discrete event simulation, integrated health care, planning.

Introduction

The increasing prevalence of chronic diseases mainly because of an aging population has led to a profound change in the paradigm of health care. Approximately one in four adults have two or more chronic conditions, and half of older adults have three or more [1]. Therefore, health systems have changed in perspective, and health care organizations previously concerned mainly with treating acute problems are now focused on a continuum-of-care approach [2]. That implies profound organizational changes [3,4]. Nevertheless, organizations are dynamic, and interventions that require behavioral changes are difficult to implement. As first shown in 1943, the adoption curve of an innovation has an S shape, with a slow early phase affecting very few people, a rapid middle phase spreading widely, and a slow third phase ending with incomplete penetration [5]. This means that a substantial "steady-state" period during which the intervention could be evaluated is unlikely to be attained quickly [6].

Furthermore, the impact of organizational changes depends not only on the intervention content but also on their implementation. This is similar in pharmacoeconomics to the relationship of the efficacy of drugs to adherence to treatment [7]. Nevertheless, adherence can be managed in randomized controlled trials to study the effectiveness of the drug, whereas the deployment of an organizational change relates to personal behavior. Implementing behavioral changes is not insurmountable, but it makes the economic evaluation of interventions aimed at modifying organizational models challenging [8].

The Deming cycle, also known as the Plan-Do-Check-Act (PDCA) cycle, is an iterative four-step management method used for the control and continuous improvement of processes and products. A fundamental principle of the scientific method and

Conflicts of interest: The authors have indicated that they have no conflicts of interest with regard to the content of this article.

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1098-3015$36.00 – see front matter http://dx.doi.org/10.1016/j.jval.2016.08.002

PDCA is iteration—once a hypothesis is confirmed (or negated), executing the cycle again will extend the knowledge further. Repeating the PDCA cycle can bring the goal closer [9], and the process itself helps to create a culture of critical thinkers [10]. Compared with more traditional health care research methods, the PDCA cycle presents a pragmatic scientific method to address the implementation of organizational changes [9].

The objective of the present study was to develop a framework for the management of complex interventions within the continuous improvement cycle over the long-term. The approach, although adaptable to other contexts and diseases, was tested with the case of an integrated health care intervention for multimorbid patients in the Donostialdea county in the Basque Country.

Methods

The Framework

The transferability of randomized controlled trials in the context of complex interventions has arisen in the literature in recent years [11]. Unlike in the field of pharmacoeconomics, the implementation of the intervention in this study depends on behavioral changes, and therefore the need to assess them in the daily routine emerges. Administrative claims databases can prove to be very useful in measuring resource use and costs [12]. Furthermore, behavioral changes occur slowly, which implies that the designed framework needs to cover the mid- to long-term vision.

A budget impact analysis (BIA) projects the burden of the target population in the conventional or baseline scenario and analyzes how this burden would change if the intervention achieved the organizationally defined goal. First, the BIA provides the long-term perspective. This approach also lends understanding of the economic burden of the disease, which is important for estimating future expenditures, especially in environments in which an aging population will make a difference. Finally, it helps explore the potential impact of the intervention [13,14] (Plan stage). Although a BIA can be carried out more simply than by dynamic simulation modeling, this technique is advantageous for representing the complexities of health systems [15]. Because discrete event simulation (DES) modeling handles time explicitly [16], we think it is the most suitable dynamic model for carrying out BIA. Once the intervention is deployed (Do stage), a statistical analysis is needed to ascertain any changes in resource consumption in the subsequent years (Check stage). In addition, the real costs, together with the objective cost fixed in the Plan stage, will determine whether the trend is positive. The statistical analysis alone, although necessary, may not always represent the practical significance of the intervention. Thus, the true economic impact of the intervention can be ascertained by integrating the statistical results in the BIA. This approach provides direct and understandable information for the stakeholders [17]. If the intervention achieves the objective, then that becomes the new standard (baseline) for the organization's actions going forward. On the contrary, if the Check stage shows no improvement, then the existing standard remains and adjustments or correction actions should be done (Act stage). Figure 1 shows graphically the proposed framework for assessing complex interventions. It combines statistical analysis with the analysis of trends on the basis of what would have occurred 1) in the baseline scenario and 2) in an objective scenario.

Case Study: Integrated Health Care Intervention for Multimorbid Patients in the Basque Country

An integrated care approach supported by information and communication technologies is being applied to determine how to best respond to the complex needs of multimorbid patients in the Basque Country as well as in six other European pilot sites participating in the CareWell project [18]. The Basque Country approach is focused on a vertical integrated model of health care that refers to the delivery of primary and specialized care in a single health care organization [19,20]. This is described in depth in Supplemental Materials found at 10.1016/j.jval.2016.08.002.

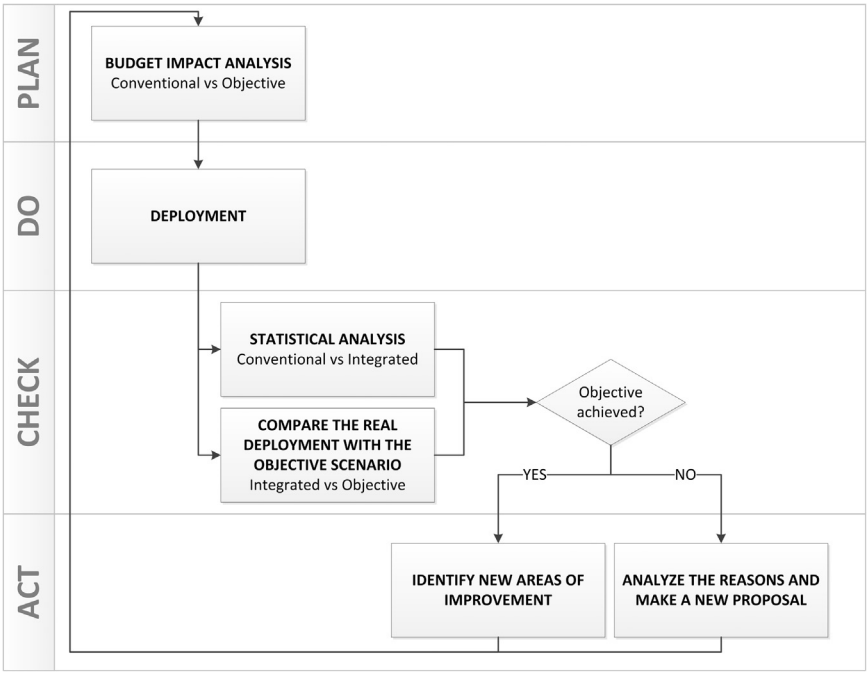

Fig. 1 – Description of the approach that integrates simulation modeling and statistical analysis in Deming's continuous improvement cycle.