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Examining the Heterogeneity and Cost-Effectiveness of a Complex Intervention by Segmentation of Patients with Chronic Obstructive Pulmonary Disease

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ABSTRACT

Objectives: To examine the heterogeneity in cost-effectiveness analyses of patient-tailored complex interventions. **Methods:** Latent class analysis (LCA) was performed on data from a randomized controlled trial evaluating a patient-tailored case management strategy for patients suffering from chronic obstructive pulmonary disease (COPD). LCA was conducted on detailed process variables representing service variation in the intervention group. Features of the identified latent classes were compared for consistency with baseline demographic, clinical, and economic characteristics for each class. Classes for the control group, corresponding to the identified latent classes for the intervention group, were identified using multinomial logistic regression. Cost-utility analyses were then conducted at the class level, and uncertainty surrounding the point estimates was assessed by probabilistic sensitivity analysis. **Results:** The LCA identified three distinct classes: the psychologically care class, the extensive COPD care class, and the limited COPD care class. Patient baseline characteristics were in line with the features identified in the LCA. Evaluation of cost-effectiveness revealed highly disparate results, and case

management for only the extensive COPD care class appeared cost-effective with an incremental cost-effectiveness ratio of £26,986 per quality-adjusted life-year gained using the threshold value set by the National Institute of Health and Care Excellence. **Conclusions:** Findings indicate that researchers evaluating patient-tailored complex interventions need to address both supply-side variation and demand-side heterogeneity to link findings with outcome. The article specifically proposes the use of LCA because it is believed to have the potential to enable more appropriate targeting of complex care strategies.

Keywords: case management, chronic obstructive pulmonary disease, complex interventions, economic evaluation, heterogeneity, latent class analysis, variability.

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Introduction

Health economic evaluation of complex interventions is still in its infancy and needs to be developed further [1,2]. This article is a contribution to this development.

Health economists evaluating complex interventions are faced with a number of challenges, because complex interventions often 1) consist of multiple components that act both on their own and in conjunction with each other, 2) are provided to a group of patients with different unobservable preferences and needs, and 3) are studied in pragmatic trials in which the provided health care typically varies over time and in patients and providers in contrast to protocol-driven trials (e.g., drug-trials).

A standard health economic evaluation treats patients as a homogeneous group, and the effects and costs of alternatives are

calculated and presented as average point estimates for the group with a given uncertainty. Nevertheless, applying such an approach for interventions containing heterogenic groups of patients might lead to wrongful decisions of funding; for example, an intervention reimbursed on the basis of its average cost-effectiveness for the total population may not be cost-effective for a subgroup of these patients. Health economists taking patient heterogeneity into account typically stratify their analyses according to traditional subgrouping methods. In such analyses patient heterogeneity is assessed using either prespecified subgroups or subgroups identified post hoc on the basis of observable patient characteristics associated with outcome [3,4]. Such subgrouping methods are problematic though, when evaluating complex interventions entailing multiple components and unobservable patient heterogeneity, because they do not address

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the actual differences in patient treatment pathways. Although efforts have been made to guide those evaluating complex interventions, practical advice on how to evaluate and report on patient heterogeneity is described in less detail [1,2,5]. Hence, previous studies of patient heterogeneity in complex interventions have solely focused on reporting differences in frequencies or duration [6,7].

In this article, we propose a new method for analyzing heterogeneity in a randomized controlled trial (RCT) of a complex intervention in health care. We will consider the case with a single provider of health care services delivering a multicomponent intervention to a single group of patients. Context and implementation issues are not included although these issues could probably also be taken into account. The sources of complexity under these circumstances can then be reduced to

1. different types of care (i.e., the different components that the intervention consists of);
2. different levels of intensity of treatment (i.e., the different combinations of components that the individual patient may receive and how much);
3. a selection process, postrandomization, into different types and intensity of treatment (i.e., the selection of the “package” or patient pathway for the individual patient). This selection process is likely to be driven by patients’ needs and preferences (probably unobservable to the analyst and the decision maker) as well as case manager preferences.

Given these treatment features, heterogeneity in treatment efficacy and costs may arise from

1. the type of care: one component of the care may be more cost-effective in itself than other components, regardless of patients’ characteristics;
2. the level of intensity of care (i.e., the number of treatment components provided and how much may drive efficacy and costs regardless of the type of care);
3. the selection on returns: patients may respond better to some type/intensity of treatment because of unobservable health characteristics, preferences, or needs and may select themselves (or are selected by the health care provider) accordingly.

For simplicity, we will use the term “demand-side heterogeneity” to describe observable and unobservable patient characteristics associated with heterogeneity in costs and efficacy of treatment. The term “supply-side variation” will be used to describe the different types of care and different levels of intensity of care provided to the patients.

As an alternative method to identify subgroups within a heterogeneous sample/patient group, latent class analysis (LCA) has been performed in this study. The method has widely been applied in marketing research, in which it is used to classify consumers into underlying segments with the purpose of maximizing within-segment homogeneity and between-segment heterogeneity according to similarities in response patterns [8]. In LCA, unobserved latent variables are inferred from observed measures usually on the basis of individual responses from multivariate categorical data [9]. In the field of health economics, LCA has previously been used to examine unobserved patterns in demand for, access to, and utilization of health care [10–13], and to quantify patient preferences for treatment [14,15]. Nevertheless, to our knowledge, the use of LCA in the field of health economic evaluation is yet to be explored.

In this article, we propose the use of LCA not as a segmentation tool based on traditional customer/patient differences, but as a tool for identifying patterns of interaction between supply-side

variation and demand-side heterogeneity in the evaluation of complex interventions. The method is illustrated using data from a complex RCT of case management for patients suffering from chronic obstructive pulmonary disease (COPD) [16,17]. The intervention contained both supply-side variation and demand-side heterogeneity, because the patients could receive different types of care and at varying intensities in response to each individual’s needs and preferences for care. The process of care selection was conducted after randomization, and care was continuously adjusted throughout the trial on the basis of changing health status and patient preferences. This article focuses on demonstrating the use of LCA as a tool for investigating service variation and patient heterogeneity in cost-effectiveness analyses of complex interventions. The purpose of the study was specifically to 1) identify latent classes on the basis of different patterns of service provision in the case management of COPD, 2) examine the heterogeneity of patient characteristics of the identified classes, and 3) estimate cost-effectiveness at the class level.

Methods

The RCT was conducted in a large Danish municipality from 2012 to 2014. The study had an intervention period of 12 months and included 150 patients with COPD. Patients were eligible for participation if they had been referred by their general practitioner or by hospital respiratory specialists for pulmonary rehabilitation at the local rehabilitation center in 2011. The patients were randomly assigned to either an intervention group or a control group. A thorough description of the study design can be found elsewhere [16].

Control

Patients in the control group received usual care as according to most recent evidence-based guidelines [18]. In the intervention period, the control group had no contact with the case manager.

Intervention

Patients assigned to the intervention group received community-based case management in addition to usual care, and the program was delivered by an experienced COPD nurse. The case manager was not supposed to take over the role and responsibility of other health care providers but to serve as an advisor and support person. The focus of the intervention was to develop and support the autonomy and self-care of the patients so that the patients would be better equipped to handle their disease. The case manager used motivational dialogue and positive performance feedback in her work.

The intervention consisted of a total of eight components. All patients were provided with the knowledge of COPD, its associated consequences, and advice on the incorporation of physical activities in daily life. In addition, the patients were educated in how to manage exacerbations; they were trained in correct inhalation and coughing techniques, and they received an introduction on why, when, and how to take their COPD medication correctly. Advice on proper diet was provided, and smokers received support for smoking cessation. The case manager prepared the patients for appointments with other health professionals through formulation of issues and questions to address, and she provided general counseling and support throughout the intervention. Tailored care plans were formulated together with each patient on the basis of what was relevant for the individual, and the health status and needs of each patient were continuously monitored through regular telephone calls and face-to-face meetings. The multicomponent nature of the

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