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Using Resource Use Logs to Reduce the Amount of Missing Data in Economic Evaluations Alongside Trials

Elsa Marques, PhD[1,*], *Emma C. Johnson, PhD*[2], *Rachael Gooberman-Hill, PhD*[2], *Ashley W. Blom, MD, PhD, FRCS*[2], *Sian Noble, PhD*[1]

[1]*School of Social and Community Medicine, University of Bristol, Bristol, UK, and* [2]*Musculoskeletal Research Unit, School of Clinical Sciences, University of Bristol, Bristol, UK*

ABSTRACT

Objectives: Economic evaluations alongside randomized controlled trials that collect data using patient-completed questionnaires are prone to missing data. Our objective was to determine whether giving patients a resource use log (RUL) at baseline would improve the odds of completing questions in a follow-up resource use questionnaire (RUQ) and to identify patients' views on RUL's usefulness and acceptability. **Methods:** The RUL study was a randomized controlled trial and qualitative study nested within a larger randomized controlled trial (the Arthroplasty Pain Experience Study trial). Eighty-five patients were randomized at baseline to receive or not receive an RUL. At 3-month follow-up, all participants received a postal RUQ. We created dummy variables for 13 resource use categories indicating whether complete information had been given for each category. We compared the completion rates between arms by using descriptive statistics and logistic regression. We explored patients' experience of using the RUL by interviewing a different subsample of Arthroplasty Pain Experience Study patients (n = 24) at 2- to 4-week follow-up. **Results:** At 3 months, 74 of the 85 (87% in each arm) patients returned the RUQ. Patients in the RUL arm were 3.5 times more likely to complete the National Health Service community-based services category ($P = 0.08$). The RUL was positively received by patients and was generally seen as a useful memory aid. **Conclusions:** The RUL is a useful and acceptable tool in reducing the amount of missing data for some types of resource use.

Keywords: data collection, economic evaluation, missing data, patient-reported outcome measures, questionnaire, randomized controlled tria, resource use, resource use log.

Introduction

Economic evaluations conducted alongside randomized controlled trials (RCTs) are often susceptible to missing data. In an economic evaluation, total patient cost is the sum of the cost of individual resource use items; hence, if one item of resource use is missing, the total cost for the patient will also be missing. This is compounded by the possibility of missing health outcome data. There are statistical methods available to deal with missing data such as simple and multiple imputation and regression approaches [1–5], but the skewed nature of cost distributions [6] may impose additional computational problems for health economists [7]. Improving data collection methods could lead to more complete sets of data for analyses [8], which would improve the power of the evaluation and decrease the risk of biased results.

Resources can be collected in a number of ways and the greater the complexity of a trial, the greater the number of data collection methods that are used [9]. When the perspective of the study is limited to the health care payer, then medical or administrative records could potentially provide a solution to

The data used for this research are property of the North Bristol NHS Trust, sponsors of the Arthroplasty Pain Experience Study (APEX) trial, currently taking place at Southmead Hospital, Bristol, UK, and are not available for reproduction at this time. The resource use log and questionnaire that this article refers to are available online at the Data Instruments for Resource Use Measurement (DIRUM) database and freely dowloadable from http://www.dirum.org/instruments/details/54 and http://www.dirum.org/instruments/details/55, respectively. Ethics: The study was approved by Southampton and South West Hampshire Research Ethics Committee (B) (09/H0504/94), and all participants provided informed, written consent, in line with the Helsinki Declaration of 1975, as revised in 1983. The trial has been registered with EudraCT (2009-013817-93) and Current Controlled Trials (ISRCTN96095682). The trial is also registered as a Clinical Trial of an Investigational Medicinal Produce with the Medicine Healthcare and Regulatory Authority (18524/0215/001-0001).

Conflicts of interest: All authors have no financial or personal relationships between themselves and others that could bias the work. All authors declare no conflicts of interest.

* *Address correspondence to:* Elsa Marques, School of Social and Community Medicine, University of Bristol, Canynge Hall, 39 Whatley Road, Bristol BS8 2PS, UK.

E-mail: e.marques@bristol.ac.uk.

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collect patient health resources. This is more likely to be the case in a private or an insurance-based system in which data might be more accessible and more readily available in an electronic format than in publicly funded health care systems. When it is too burdensome to collect resource use from records because of limited accessibility and/or electronic format, or a broader perspective is taken for the economic analysis, requiring the collection of resource use data beyond that of the health care payer, then trials often need to rely on patient-reported information.

Patient-reported information can be collected through interviews, diaries, or patient-completed questionnaires [10]. Patient-completed resource use questionnaires (RUQs) are cheap and easy to administer [11], thereby a frequently used data collection method in trials [12]. They are, however, subject to recall bias and prone to missing data [13,14]. Interviews either face to face or by telephone are less susceptible to missing data [15]. On the other hand, they are more expensive to administer and subject to self-report and interviewer bias [16,17]. Diaries overcome the issue of recall bias and are generally considered more accurate [18], yet there are concerns over patient burden, which leads to incomplete data [19].

A resource use log (RUL) is in essence a diary that is given to patients at baseline for them to prospectively record resources used. Unlike a diary, data in the RUL are neither collected nor used for analysis. It is designed as a memory aid, to assist patients in the completion of an RUQ at follow-up. The use of RULs is not common and is rarely reported. In one methodological study, however, Cooper et al. [20] described the creation of an RUQ and used RULs to aid participants in their completion of a subsequent RUQ. Patients found the RUL useful as a memory aid.

We conducted a nested RCT within a larger RCT (the Arthroplasty Pain Experience Study [APEX] trial) to test whether giving patients an RUL at the start of the follow-up period to prospectively record resource use would decrease the amount of missing data in a patient-completed RUQ administered at 3-month follow-up. We then conducted a qualitative study on a different subsample of APEX patients, to explore participants' experiences of using the RUL, including views on their acceptability and usefulness in assisting the completion of RUQs. This would identify whether any increase in completion rates of the RUQ was not at the expense of additional patient burden.

Methods

Setting

The RUL study included a RCT and a qualitative study embedded within the APEX trial that is taking place at Southmead Hospital, North Bristol National Health Service (NHS) Trust, Bristol, UK (ISCTRN 96095684). The aim of the APEX trial is to determine whether using local wound infiltration in addition to the standard anesthetic regimen significantly reduces joint pain at 1 year after total hip replacement (THR) and total knee replacement (TKR) [21]. The APEX trial included a pilot stage to assess patients' acceptance of the trial and pilot data collection methods. The RUL RCT was nested within this pilot stage. Patients were preoperatively randomized to receive standard analgesia or intervention analgesia as per the APEX protocol [21], and then subsequently randomized to receive or not receive the RUL. The qualitative study was embedded within the main APEX trial and aimed to explore patients' experiences of surgery and postoperative recovery. It involved in-depth interviews with patients 2 to 4 weeks postsurgery. As part of these interviews, patients were asked to describe their experience of the RUL. Ethical approval for the APEX trial, which included the nested RUL RCT and qualitative study, was obtained from the Southampton and South West Hampshire Research Ethics Committee (B) (09/H0504/94).

Patient Recruitment Into the RUL Study: Trial and Qualitative Study

The RUL trial took place between November 20, 2009, and April 1, 2010. Randomization was stratified by type of joint replacement and allocated arm in the APEX trial and performed on the remote randomization system of the Bristol Randomised Trials Collaboration.

At hospital discharge, a research nurse completed a discharge questionnaire for all patients and explained that at 3-month follow-up they would receive a postal questionnaire in which they would be asked to complete questions about their pain, function, and quality of life, as well as health services use and expenses incurred in relation to their joint replacement. The research nurse was encouraged to discuss the contents of the forms, including the resource use questions, with patients in both arms, to promote uptake and response rates for the APEX trial. For patients randomized into the RUL arm, the research nurse gave the patient an RUL, described how to use it, and explained that it was designed to help patients remember resource use and expenses, as an aid to the completion of the 3-month follow-up questionnaire. At 3 months, we administered the patient-completed follow-up postal questionnaire, which included the RUQ. The last 3-month questionnaire was administered on August 1, 2010, and received on September 15, 2010. After the pilot phase, all patients in the main APEX trial received an RUL at hospital discharge.

All participants in the main APEX trial were asked whether they were willing to be contacted about taking part in a qualitative interview. Of those who indicated that they were willing to be contacted, a purposive sample was drawn. The sample included men and women, a range of ages, and a balance of hip and knee replacement surgical procedures. Twenty-four participants were interviewed, at which point recruitment was stopped because saturation had been reached, with no new insights being achieved [22]. The qualitative study only included participants taking part in the APEX trial after the RUL RCT was completed. This meant that all participants in the qualitative study had received an RUL, which enabled the qualitative study to explore views about the acceptability and use of the RUL.

Design of the RUL and RUQ

The RUL [23] was designed to replicate the content and order of the 3-month follow-up RUQ [24]. Both instruments are available online on the Data Instruments for Resource Use Measurement database [25]. In the RUL, patients could prospectively record their use of health services and expenses by using tick boxes and open questions for the 3 months from hospital discharge.

The RUQ included 13 resource use categories and asked patients about UK NHS services; patient expenses (e.g., travel and medication costs); use of social services (e.g., home care worker); and other costs such as informal care time and time off work to enable a societal perspective to be taken for the economic evaluation. Each category included several questions, the first being a filter yes/no question of whether that category of resource was used. Resources used by the patient from the intervention hospital were not collected, as these were obtained from the patient's medical records.

Analysis for the RUL Trial

We categorized patients' baseline characteristics (sex, marital status, living situation, ethnicity, education, and working status) into dummy variables and described them in addition to age for both arms of the RUL trial. We compared the return rate of the 3-month follow-up questionnaire between trial arms by using a chi-square test.