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REVIEW ARTICLE

A narrative review shows the unvalidated use of self-report questionnaires for individual medication as outcome measures

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Abstract

Objective: Accurate individualized data on drug consumption is required for a number of purposes. While electronic medication event monitoring is the best objective measure available, self-report tools would be a useful alternative in certain situations. We searched for validated self-completion questionnaires suitable for measuring change in medication.

Methods: A systematic search of the English language literature since 1980, and a narrative literature review.

Results: Few articles described the development or use of self-report methods to measure change in medication over time. We found no questionnaire that was commonly used for this purpose, nor one that had been evaluated and published. Considerable work has been undertaken to develop questionnaires or diaries for individual projects, but because these tools and their validation are rarely published, they are not available for other researchers to use, and comparison across studies is difficult. Some work has been done developing diary formats and the Medication Quantification Scale converts complex medication change data to a single numerical score.

Conclusion: Medication change is rarely considered as an outcome, and when it is measured, nonstandardized methods are used. More attention needs to be given to developing self-report tools and validating them across a range of criteria.

Keywords: Outcome; Medication; Medication diary; Questionnaire; Literature search; Literature review

1. Introduction

Researchers collect data on people's drug consumption for a number of purposes. Epidemiologic surveys measure drug use in particular populations at one point in time. Measurement of compliance, or adherence to medication, is important in clinical areas that depend on patients taking their medication regularly. In clinical drug trials medication usage is measured to evaluate "patient compliance" with the drug being tested. In clinical trials of nonpharmacologic interventions change in symptom–control medication, as a proxy for illness severity, may be a primary or secondary outcome measure. Economic evaluations may measure medication as a component of cost. Change in medication is also monitored when new prescribing guidelines and initiatives are evaluated.

In all these situations a clear distinction must be drawn between medications that are prescribed, medications that are dispensed, and medications that are actually taken. About one in seven prescriptions are not cashed in and dispensed [1], and nonadherence to prescription instructions, both intentional and nonintentional, is widespread [2,3]. Consequently, while prescribing data is easy to collect, it rarely accurately reflects what is actually taken, and it is most useful for population-based studies and for medication intended for long-term nondiscretionary use [4]. Pharmacy refill data is likely to be a much more accurate representation of what is actually taken, especially for long-term medication that is measured over many months. This data is available in managed care situations, such as within Health Maintenance Organisations in the United States, or where patient's prescriptions are automatically sent to one pharmacy, or linked pharmacies, to be dispensed. In other situations, or when medication is taken episodically for symptom relief, or in short courses, research requires methods that record accurately and in detail the medication that individuals actually take. It is collecting this individualized data that we address in this article.

The type of medication data that is collected depends on the purpose of the research. The investigation of adherence,

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both in everyday practice and in clinical drug trials, usually requires individualized data on one or two particular medications, and often as a snapshot at one point in time is sufficient. Accurate data on both what is prescribed and what is taken is required, as well as information about individual beliefs and behaviors around medication taking. When change in medication use is being measured as an outcome or cost component, accurate and detailed individualized data about a wider range of medication usage on two or more occasions, or for two or more periods, is required. For example, a trial of physiotherapy for back pain may specify a reduction in a wide range of prescribed and over-the-counter medication (analgesics, antidepressants, muscle relaxants, hypnotics) as a primary or secondary outcome measure. Evaluations of prescribing initiatives need to include both intended and unintended medication change, and again, both prescribed and over-the-counter drugs may need to be considered.

These different purposes require accurate tools that have been validated for that purpose and, if possible, for the particular population. The tools commonly used for the purposes outlined above are pharmacologic tracers, residual pill counts, electronic medication event monitoring, and self-report using structured interviews, questionnaires, or diaries. In clinical trials, pill counts and pharmacologic tracers have been the customary measures of drug consumption, but both methods have drawbacks. Pharmacologic tracers are expensive, they often reflect a short period of time, and patients may alter their medication-taking behavior shortly before giving a sample [5]. Residual tablet counts grossly overestimate drug consumption [6,7] and, unless they are performed very frequently, they fail to capture the marked intersubject and intrasubject variability [8,9]). Electronic medication event monitoring using the medication events monitoring system (MEMS) [10] has been shown to be more accurate than other methods [7], and has become a useful "gold standard" [11]. Tools for collecting self-reported data have been especially popular in investigating adherence to medication in clinical settings where they may not only be easier to use than MEMS, but also provide an opportunity to explore beliefs and behaviors that may be barriers to adherence [12–15]. For example, the Brief Medication Questionnaire requires people to list the medications taken in the last week, with details of dose, missed pills, reason for medication, and opinion about how well it "works for you"; and then to list any medications that are "bothering you" and answer five questions about common problems with medication such as remembering to take the pills. The Compliance-Questionnaire-Rheumatology consists of 19 items about drug-taking behavior that respondents score on an agree/disagree Likert scale. The performance of both of these questionnaires in predicting and detecting nonadherence to prescribed medication was validated using MEMS data as a gold standard [12,15].

In contrast to these validated self-report questionnaires for measuring adherence, there were not, to our knowledge, any commonly used or well-validated self-report methods for measuring medication change as an outcome. This requires detailed medication data at repeated points in time. The adherence questionnaires are not designed or validated to demonstrate change in medication use over time, and include questions on attitudes, beliefs, and behaviors that are unnecessary for this purpose. They are also based on assumptions about patients "doing as they are told," which may not be the best basis for asking patients to be partners in assessing their own medication use. A preliminary search of standard texts on outcome questionnaires [16–18] did not find any questionnaires that focused on medication, and questions on medication use are rarely included in quality-of-life and problem-specific questionnaires. A few questionnaires contain a single medication question. For example, the arthritis questionnaire, AIMS2, includes the question "During the past month, how often have you had to take medication for your arthritis?," and offers five response options from "all days" to "no days" [19]. The Measure Yourself Medical Outcome Profile, MYMOP, has been adapted to include a medication question [20], but an in-depth evaluation using interviews suggests that this does not perform very well [21].

If it is true that there are no suitable self-report measures, then MEMS is the only tool that has been validated for collecting accurate individualized data about medication use over time. There are a number of practical difficulties in using MEMS, most particularly its cost and availability [5], and in situations where data is required for a wide range of concurrent medication, including both prescribed and over-the-counter items, an alternative tool would be advantageous.

This article reports on a systematic literature search for methods of collecting individualized self-report medication data. The primary aim of the literature search was to find any published, evaluated, or commonly used tools for measuring self-reported "change in medication use." This includes cross-sectional measures that can be repeated over time. The search raised questions about how such tools are validated, and validation methods are described and are returned to in the discussion.

2. Method

The topic of the literature search was defined as "Is there an evaluated or commonly used self-completion questionnaire or diary for measuring change in medication use? If not, what work has been done in this area?" It included books, journal papers, and a little of the unpublished, or "grey," literature. Sources searched were the electronic databases Medline, Science and Social Science Citation Index, PsycINFO, and Biosis (all limited to 1980 onwards and the English language); the journals *Quality-of-Life Research* and *Journal of Clinical Epidemiology* from 1999–2003; standard quality-of-life texts; and the Bristol University Library Catalogue and relevant shelves and chapters of books. Secondary references and citation searching from relevant papers were carried out. Initial keywords and search strategies were extended during the study by checking for more keywords