Measuring the impact of medicines information services on patient care: methodological considerations

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Abstract
Introduction: Medicines information services (MISs) aim to promote the safe, effective and economic use of medicines. Results from published studies suggest that they provide effective information, which in many cases results in improved patient outcome. However, there are several methodological issues that are important in the interpretation of such studies.
Aim: To address methodological issues in the evaluation of MISs
Objectives: To carry out a critical appraisal of papers assessing the impact on patient outcome of passive information given to health care professionals, to identify the key methodological issues and to make recommendations for future research in Europe.
Methods: Literature search to identify relevant papers meeting the inclusion criteria, critical evaluation of the methods used
Results: Most studies have been conducted in the United States. Various methodological considerations were identified: study design, sampling, data collection, choice of outcome measures, and validity. The results of each study are interpreted in view of the methods used. In addition, the implications of the methods selected on the validity, reliability and generalisability of the results are discussed. Finally, suggestions for future studies are provided, in order to maximise validity and reliability.

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Introduction

The first medicines information services (MISs; previously known as drug information services) were established in the United States in the 1960s [1] and in the United Kingdom in the 1970s [2]. Their aims were to help problem-solving related to the use of medicines and to develop best practice in medicines' use. A UK national survey published by Cotter et al. [3] showed that 60% of all NHS hospital pharmacies had an on-site pharmacy MIS with specifically assigned pharmacists. A Europe-wide survey revealed that few hospitals had MISs, with the exceptions of Denmark and Britain [4]. However, since the average response rate for each country was only 32.7% in this study, these results must be interpreted with caution.

MISs aim to promote the safe, effective and economic use of medicines. Centres may provide information passively (in response to users' queries), or actively (newsletters or bulletins), at local, regional or national levels. Requests for information generally come from health care professionals (HCPs) in both primary and secondary care. In some cases, patients are also direct users of MISs.

Few studies have been conducted in Europe to evaluate the effectiveness of MISs, and not all potential outcomes have been assessed. Overall, the earliest studies focussed on active information provided for patients in a primary care setting [5–7], while later studies have assessed MISs provided for HCPs [8,9]. In terms of the general impact of MISs, studies have mainly focussed on identifying improvements in the safety and effectiveness of drug therapy.

The aim of this review article was to address methodological issues in the evaluation of MISs. Our objectives were to carry out a critical appraisal of papers assessing the impact on patient outcome of passive information given to HCPs, to identify the key methodological issues and to make recommendations for future research in Europe.

Methods

Relevant literature was identified by searching the *Medline* database (1970–2001 through Ovid), *EMBASE* database (1970–2001 through Ovid) and the *International Pharmaceutical Abstracts (IPA)* database (1970–2001). Keywords used were "drug information", "drug information services", "impact", "usefulness", "effectiveness", "evaluation studies", "assessment" and "patient outcome". Papers identified were not restricted to the English language. The reference list of each relevant paper found was also reviewed.

Research papers on the following topics were not included: active information, information provided directly to patients, global evaluations of clinical pharmacy services, economic evaluations, evaluations related to specific groups of drugs.

Results

Nine papers that assessed the impact of passive information given to HCPs were identified [10–18]. Only two studies were performed in Europe; both were from the United Kingdom [16,18]. Amerson and Wallingford [19] also reviewed the development of drug information centres in the United States, as well as the criteria used for measuring their usefulness and their quality.

Results from available studies indicate that MISs provide effective information to HCPs, which in many cases results in improved patient outcome.

The main methodological features of each research study are shown in Table 1. All studies were descriptive rather than experimental and no comparison groups were used. Most studies used a retrospective design.

Table 1 *Characteristics of studies having assessed the impact of passive drug information given to health care professionals*

Reference	*Country*	*Drug information requests*	*Endpoint measures*	*Evaluator (+instrument)*
Pearson et al. 1975 [10]	US	– Random sample of all requests (n = 551) – Requests from all HCPs*	(P): accuracy, relevance, timeliness, adequacy, usefulness (O): use of information	– Multidisciplinary committee – Inquirers (through questionnaire)
Cardoni and Thompson 1978 [11]	US	– All patient-specific requests (n = 350) – Requests from all HCPs*	(O): use of information, action taken, patient outcome	Inquirers (through phone interview)
Baker and Gallo 1984 [12]	US	– Random sample of all requests (n = 77) – Requests from nurses and physicians	(P): accuracy, clarity, timeliness, completeness (O): use of information, action taken	Inquirers (through questionnaire)
Repchinsky and Masuhara 1987 [13]	Canada	– All requests (n = 158) – Requests from all HCPs*	(P): timeliness, accuracy, objectivity, completeness (O): use of information	Inquirers (through questionnaire)
Golightly et al. 1988 [14]	US	– All requests (n = 11424) – Requests from all HCPs*	(O): outcome of case (not detailed)	Physician
Moody 1990 [15]	US	– Random sample of all requests – Requests from physicians	(P): correctness, completeness, timeliness, appropriateness	Director of clinical services
Stubbington et al. 1998 [16]	UK	– All adverse-event related requests (n = 161) – Requests from all HCPs*	(O): use of information, action taken, patient outcome	Inquirers (through questionnaire)
Melnyk et al. 2000 [17]	Canada	– All patient-specific requests (n = 98) – Requests from all HCPs*	(P): timeliness, objectivity, appropriateness (O): action taken, patient outcome	– Inquirer (through phone interview) – Expert panel
Shah et al. 2000 [18]	UK	– All patient-specific requests (n = 27) – Requests from all HCPs*	(O): use of information, action taken, patient outcome	Ward pharmacist

Abbreviations: HCP: health care professional; (P): process measure; (O): outcome measure; UK: United Kingdom; US: United States.
* "All HCPs" include: pharmacists, doctors, nurses and other health care professionals.

Discussion

Important factors to be considered when evaluating studies of MISs are summarised in Figure 1 and include: study design, sampling, collecting and evaluating data, choice of endpoint measures, and validity. Each of these will be addressed in turn.

1. Study design

Evaluation of the impact of any service should ideally be performed experimentally by comparing outcomes either before and after the introduction of the service, or in similar environments with and without the service [20]. Both approaches are difficult to apply: ethical and practical considerations mean that HCPs cannot be allocated to receive or not receive information. Moreover the majority of hospitals in the United States and in the United Kingdom have access to a MIS. Therefore, descriptive methods of evaluation have been used instead.

All nine studies identified were descriptive rather than experimental. In contrast to the United States and the United Kingdom, MISs are not widely provided in European hospitals [4]. This means that future studies evaluating the impact of a new MIS could be experimental rather than descriptive.

Descriptive studies can be either prospective or retrospective. In prospective studies, data are collected forwards in time from the start of the study. In retrospective studies, data refer to past events, and may be acquired from existing sources. Retrospective studies are less demanding in terms of workload. However, prospective studies give the investigator more control over the data collected. Only one study used a prospective design [17].

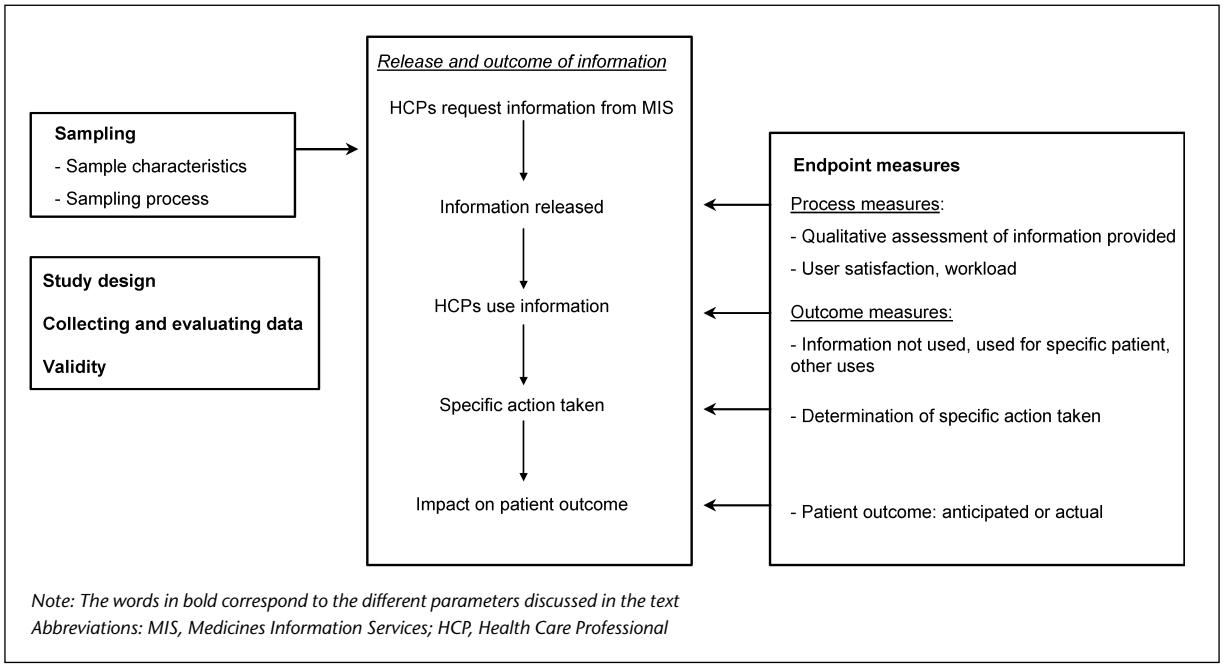
2. Sampling

2.1. Sampling process

Three ways of sampling information requests have been used. The first two aim to obtain a sample representative of all requests, whereas the third aims to select a more specific category of requests.

First, a random sample of MI requests over a certain period of time may be used: Pearson et al. [10] selected every twentieth request each month; Baker and Gallo [12] and Moody [15] selected enquiries accounting for 25% and 10% of MI requests respectively but did not describe the randomisation process used. Representativeness of the sample was assessed in only one of the three studies mentioned above [15]: the distribution of types of question selected for committee review was compared to the total sample data from a published study. Reasonable similarity was shown. The lack of information regarding randomisation and representativeness in many studies could potentially hide a source of bias.

Second, the sample may include all requests received over a relatively short period of time (four weeks and two years in the studies conducted by Repchinsky and Masuhara [13] and Golightly et al. [14] respectively). While bias related to any randomisation or selection process is avoided, the large variability of requests within the sample may make it difficult to set evaluation criteria applicable to every request.



Note: The words in bold correspond to the different parameters discussed in the text
Abbreviations: MIS, Medicines Information Services; HCP, Health Care Professional

Figure 1 *The impact on patient outcome of passive information given to HCPs: parameters evaluated in the critical appraisal process*

Finally, a specific type of MI request can be selected. This allows a more coherent analysis but may bias the results. For example, Cardoni and Thompson [11], Melnyk et al. [17] and Shah [18] used only patient-specific requests. However, Cardoni and Thompson [11] showed that questions appearing to be of a general nature were often patient-specific.

Consequently, it is difficult to ensure reproducibility in the sample because it depends upon the capability of the MIS employee to detect more patient-specific problems. Additionally, information not affecting a specific patient at the time of the request might affect future behaviour of the practitioner [11], and excluding those requests may bias the results.

In conclusion, each sampling process makes sense. However, the representativeness of samples should be demonstrated and any conclusions drawn should take into account the sampling process used.

2.2. Sample characteristics

This review article focuses on enquiries from HCPs (doctors, pharmacists and nurses). However, the proportion of each class of HCP varies among the studies, and this may affect the results.

Pearson et al. [21] showed that information provided to physicians altered a particular patient's therapy in 56.4% of cases, compared to 40.8% for pharmacists and 35% for nurses. Interestingly, 95.5% of nurses and 83.1% of pharmacists disseminated the information to colleagues, compared to 75% of the physicians' group. Cardoni and Thompson [11] showed that 75% of pharmacists' requests and 50% of nurses' requests resulted in specific drug herapy recommendations, indicating that these health professionals do influence prescribing. Studies should therefore consider results according to the different categories of HCP. Transmission of information from non prescribers to prescribers should also be considered.

3. Data collection and evaluation

Using questionnaires was the most common way of collecting data. Only two studies used interviews [11,17]. Absence of anonymity may be a limitation with interviews, although interviews do allow more follow up of responses.

In both questionnaires and interviews, questions may be open and/or closed. Responses to closed questions are easier to analyse. Open questions may be of interest but present limitations of observer and subject bias. Melnyk et al. [17] minimised this by allowing only one investigator, a member of the MIS staff but not one who was answering queries, to assess the inquirer's opinion of the service.

Evaluators of patient outcome can be the inquirers themselves or an external person/panel. First, the *inquirer* is certainly an appropriate evaluator. However, status of the inquirer may be significant, since their relative competence, experience and contact with the patient may lead to differences in evaluation of patient outcome. Moreover, there may be a lack of objectivity because different people are carrying out the assessments. These drawbacks can be minimised by using explicit rather than implicit criteria to avoid judgmental and subjective interpretations, for example by asking respondents to tick the specific action taken for the patient. Second, the use of an *external panel* is associated with objectivity, expertise and uniformity [10]. Time is a significant limitation. However, Melnyk et al. [17] used an external panel to assess appropriateness of the answers and the impact of recommendations on outcomes.

In the study conducted by Cardoni and Thompson [11], 78% of requests had positive effects on patient outcome, compared to 47% described by Melnyk et al. [17]. This difference is likely to be due to the fact that the measure of the impact on patient outcome was based either on the inquirer's judgment in one case [11], and on an independent panel in the other [17].

4. Choice of endpoint measures

The most widely used taxonomy of health-care quality assessment is that of Donabedian [22]. He believes that quality of health care can be assessed by

focussing on structure, process, or outcome. However, there is little evidence for a relationship between structure and quality [23].

4.1. Process measures

In this context, process measures refer to the daily operation of producing information. Classification of information provided, workload, timeliness, accuracy and appropriateness of information are all process measures. For example, in the study published by Pearson et al. [21], most users felt that the information provided was relevant (89.4%), adequate (88.8%), quick (89.7%), and accurate (95.8%).

The advantage of process standards is that they are relatively easy to measure. But there is a major drawback when considering them as a measure of patient care: they are based on the assumption that they directly affect patient outcome. However, the process–outcome relationships that are believed to exist often do not [24].

Moody [15] related the accuracy and timeliness of information to the provision of high quality health care by nurses and physicians. However, the author did not mention the danger of using only process measures in a study aiming to focus on patient outcome. Melnyk et al. [17] used process indicators in addition to outcome measures. They mentioned that if an HCP's input was considered a link in the chain of care, process and the end point to that process could be measured with the assumption that improvement in one link should lead to improvement in global outcome.

4.2. Outcome measures

Outcome focuses on the result of the process. In our context, outcome refers to how information was used and to what finally happened to the patient. Three main questions can be asked.

1. Did the HCP use the information?

This question was used in most studies. In two studies [10,13] it was the only parameter considered. There are three possible answers to the question: not used, used for specific patient, other uses (teaching, research, personal knowledge). It may seem logical that information is more likely to have an impact on a patient when asked in relation to a specific patient. However, Melnyk et al. [17] report that 54.1% of the HCPs believed the MIS benefited the patient even where the intervention was not used. However, there is no explanation for this given by the authors. Furthermore, information not used immediately can be used in future patient care [13]. In conclusion, although answers to this question can give some useful information, it may not be a valid indicator of impact on patient outcome.

2.What action was taken?

Pearson et al. [21] asked whether or not an action was taken, but did not record what the action was. In contrast, the other authors did specify particular actions. For example, specific outcomes of 157 requests that produced positive effects in patients were categorised as follows [11]: drug started (38.2%), drug discontinued or changed (6.4% each), dose changed (4%), schedule changed (1%), no change (14%) and others (29%). This measurement is objective and understandable. Nevertheless, it is important to be aware that information provided is only one component, however relevant, in the decision-making process and resulting actions.

3. What was the impact on the patient?

First, outcomes can be long-term or short-term. Since outcome must reflect the pharmacist's contribution, the use of short-term outcomes is more logical than a global outcome [13]. Second, outcome may be anticipated or actual. Cardoni and Thompson [11] used anticipated outcomes. Conclusions were based on the inquirer's opinion of patient outcome. Similarly, Golightly et al. [14] did not specifically evaluate patient outcomes, but documented an apparent beneficial effect on patient therapy. The subjectivity and poor accuracy of this indicator significantly impairs its validity as a measure of the impact of MISs on patient outcome.

In contrast, the three most recent studies reviewed here documented the actual impact of information by carrying out patient follow-up. In one study [16], the outcome of replies to enquiries involving adverse events was assessed by the inquirer. A period of 12 weeks was allowed for respondents to reply, in order to optimise the chances of the respondent being able to identify and comment on outcome. The possibilities were: patient improved, deteriorated, died, under ongoing review, progress not known, no information given. This last possibility represented 40% of cases (because original inquirer was remote from the patient, or because the patient was transferred to another ward or care setting). This illustrates the difficulty in following-up patients in this context. In another study [17], an investigator collected information on actual patient outcome over a 6-week period. On the basis of this information, an expert panel determined the final impact on the patient. Forty-seven percent of the accepted interventions lead to a positive patient outcome and 4% to a negative outcome. For the remainder, there was insufficient information available, which again reveals the difficulty in assessing actual patient outcome.

In conclusion, while carrying out patient follow-up is more appropriate than anticipating patient outcome, practical difficulties may also impair the validity of the results.

5. Validity

Validity of data refers to the extent to which it is an accurate reflection of the phenomena that are the subject of the research [25].

The impact on patient outcome has been assessed by using process and/or outcome measures. Process data are easy to collect but difficult to validate because they are not directly related to patient outcome. Validation of outcome measures is not easy either because many factors other than the MIS can affect patient outcome. Hence validity is improved by using a combination of research methods.

Conclusions and recommendations for future research

There has been an interesting evolution in studies assessing the effectiveness of MISs on patient outcome. The first studies investigated the process ele-

Table 2 *Suggestions for future studies*

1. A pilot study should be carried out to ensure that the research question can be addressed.
2. Whenever possible, outcomes should be compared either before and after the introduction of the service, or in similar environments with and without the service.
3. If the sample is a random sample of all requests, its representativeness should be demonstrated. If patient-specific inquiries are selected, the authors should be aware that they have excluded other requests with a potential impact on patient outcome.
4. If different categories of HCPs take part in the study, their respective effect on patient outcome should be displayed and compared.
5. In order to minimise false positive feedback, questionnaires should be anonymous, and interviews should not be conducted by the MI employee that answered the enquiry.
6. External reviewers assessing patient outcome provide unbiased and accurate evaluations. When time and money restrictions do not allow it, evaluators should be the inquirers themselves, and evaluation criteria should be explicit to avoid judgmental and subjective interpretations.
7. There is no indicator with a maximum validity, sensitivity and specificity. Studies should therefore rely on a combination of process and outcome measures to demonstrate the impact of the service on patient outcome.

ments of MISs, as these are relatively easy to measure. Subsequently, outcome measures were introduced, while validity of process indicators was questioned. Outcome measurements evolved from non-specific considerations to more detailed questions on precise actions taken. Finally, the most recent papers assessed the actual impact on patient by carrying out patient follow-ups. The focus point of measures has therefore moved from the information itself to the patient.

There is no ideal way to design a study assessing the impact of MISs on patient outcome. However, several suggestions could be made for future studies. These are summarised in Table 2. Taking these suggestions into consideration in the context of European research on MISs will reinforce the validity of the results.

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