

Patient Outcomes and Hospital Pharmacy Practice

Linda D. MacKeigan

ABSTRACT

A 1995 survey of patient outcome assessment activities in Canadian hospital pharmacies revealed that hospital pharmacy directors (or their designates) do not have a clear understanding of what constitutes a patient outcome and that pharmacy department participation in patient outcomes initiatives is modest. This suggests that hospital pharmacists would benefit from access to continuing education literature and programs on patient outcomes that discuss their meaning and relevance for hospital pharmacy practice. This article provides a first response by explaining the term "patient outcomes", differentiating it from clinical outcomes, health care outcomes, and process indicators. It places patient outcomes within the context of the outcomes movement in health care and discusses the potential applications of patient outcomes in pharmacy practice.

Key Words: outcomes assessment, outcomes management, patient outcomes

RÉSUMÉ

Un sondage mené en 1995 sur les activités d'évaluation des résultats axés sur le patient dans des pharmacies d'hôpitaux canadiens a révélé que les chefs de pharmacie (ou leur représentant) ne comprennent pas bien ce qu'est un résultat axé sur le patient et que la participation des département de pharmacie dans les initiatives reliées aux résultats axés sur le patient était modeste. Cela porte à croire que les pharmaciens d'hôpitaux tireraient un avantage d'avoir accès à de la documentation et à des programmes d'éducation continue sur les résultats axés sur le patient, qui traitent de leur portée et de leur application pour les pharmaciens d'hôpitaux. Cet article fournit une réponse préliminaire en expliquant ce que sont les «résultats axés sur le patient», et en les différenciant des résultats cliniques, des résultats de la prestation des soins et des indicateurs de processus. Il place les résultats thérapeutiques dans le contexte du mouvement centré sur les résultats qui existe dans le domaine des soins de santé et examine les applications possibles des résultats axés sur le patient dans la pratique de la pharmacie.

Mots clés : évaluation des résultats, gestion des résultats, résultats axés sur le patient.

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PATIENT OUTCOMES

Patient outcomes are those end-results of health care that are noteworthy to patients. In other words, they are outcomes that patients experience, interpret, evaluate, and report.^{1,2} They include a person's

health status, health-related quality of life, satisfaction with care, and costs incurred for health care.

One might ask how patient outcomes differ from the more familiar clinical outcomes reported in clinical trials? The differentiating factor is perspective; patient outcomes represent the patient's perspective, and clinical outcomes the physician's perspective. Clinical outcomes encompass both clinical measures and clinical events. Clinical measures are the physical signs (heart sounds, enlarged organs, etc.), symptoms, laboratory values, and radiological images that physicians use to diagnose disease and monitor disease progress. With the exception of symptoms, clinical measures are aspects of physiological function that the patient does not experience. They are important only because they are risk factors (i.e., predictors) for clinical events and the patient outcomes associated with those events. At best, they are intermediate outcomes. For example, a high diastolic blood pressure is a risk factor for myocardial infarction. High blood pressure is an intermediate clinical measure, whereas, a myocardial infarction is a clinical event. A patient outcome associated with myocardial infarction is severe chest pain. If the myocardial infarction were "silent" however, there would have been a clinical event (detected through a subsequent ECG) but no patient outcome.

In the clinical paradigm of health care professionals, emphasis is placed on the pathophysiology of a patient's disease because an understanding of the mechanism of the disease is necessary for rational diagnosis and treatment. Hence, physiological measures assume importance.³ In contrast, in the non-clinical paradigm of

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patients and health care managers, the focus is on how the effects of health care are felt or experienced by the person in terms of ability to function, sense of well-being, or satisfaction with care. With such different focuses, it is not surprising that measures of effectiveness in each paradigm differ. This is not to say, however, that there is not some common ground. Death, the ultimate outcome, is relevant in both paradigms and so are symptoms. Physicians use the patient's symptomatology to assist in diagnosing disease and in monitoring response to treatment. Symptoms, and the discomfort they represent or the disability they produce, are also very important to patients.

If we accept that "what people value is their health status, rather than their disease status",⁴ then the evaluation of care must focus on measures of health and well-being as perceived by patients, i.e., patient outcomes. The purpose of measuring patient outcomes is not to supplant the traditional clinical measures (these are very important to physicians and other health professionals) but to supplement them because, in addition to determining whether health care has resulted in progress against disease, it is important to determine whether health care has resulted in a meaningful difference in people's lives, and only patients can assess that. Some examples of patient outcomes are provided in Table I.

A reader of the current medical literature may encounter several other outcome based terms. Medical outcomes are outcomes resulting from medical care. Similarly, pharmaceutical outcomes are outcomes resulting from treatment with pharmaceuticals and/or pharmaceutical care. Health care outcomes encompass both medical and pharmaceutical outcomes, as well as those from other types of health care. Health outcomes are effects on health, whether defined by physiological measures or by measures of functioning and well-being. Unfortunately, the term patient outcome is often used when one of the other outcome terms would be more precise.

Outcome measures are sometimes confused with process measures. A good example is patient compliance,

an "outcome" that is often reported in the pharmacy literature. Compliance with medications is a behaviour that, in theory, leads to better health outcomes. It is, thus, an intermediary process between the prescribing of a drug and any change in health status. Similarly, appropriate prescribing (adherence with drug therapy criteria) is a process measure.

The ECHO (Economic, Clinical, and Humanistic Outcomes) model has been put forth in the pharmacy literature to describe the relationship between different types of health care outcomes (Figure 1).^{5,6} Clinical outcomes are defined as "medical events that occur as a result of disease or treatment";⁵ these include events such as

Table I: Examples of Patient Outcomes and Patient Outcome Measures

Patient Outcomes	Patient Outcome Measures
Death	Mortality rate or years of survival
Functional status (Disability): physical, mental or social	Health status or quality of life questionnaire
Symptoms (Discomfort and Distress) Specific to the disease and the side effects of the drugs used, e.g., pain, anxiety, nausea, fatigue, shortness of breath, tremor	Elicited from the patient using a symptom checklist or scales that rate frequency and/or severity of symptoms
Overall well-being	Health status or quality of life questionnaire
Satisfaction with care and/or health outcomes	Patient satisfaction questionnaire

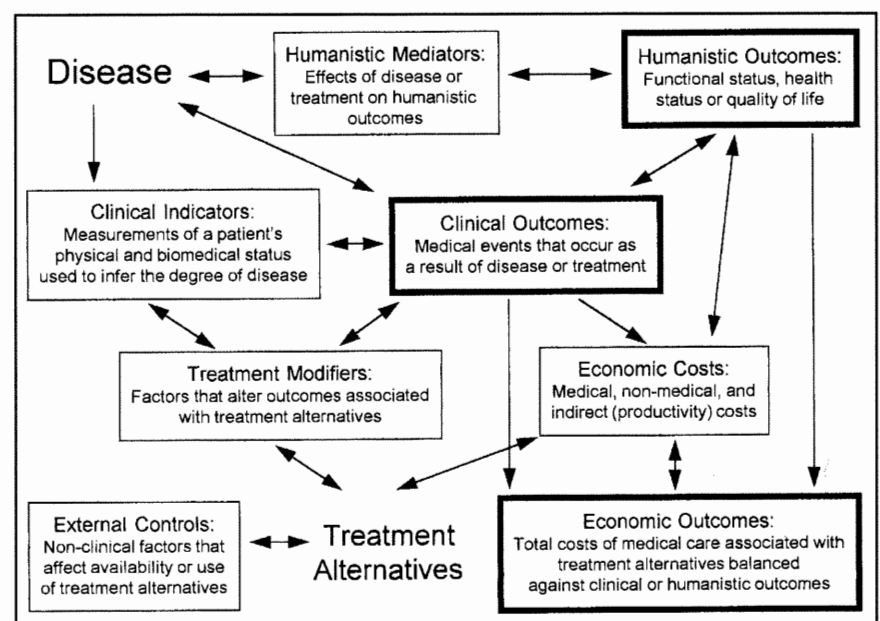


Figure 1: The ECHO (Economic, Clinical, and Humanistic Outcomes) Model of Health Care Outcomes. (Adapted with permission from reference 5; copyright University of South Carolina Center for Outcomes Research and Evaluation)

death, cure of infection, and heart attacks. Humanistic outcomes include functional status, health status, health-related quality of life, and satisfaction with care and/or health. Economic costs and outcomes include medical, nonmedical and productivity costs associated with the provision or consequences of health care. The model also includes mediating variables (or what some might call process variables, indicators, or surrogates). These include clinical indicators or end-points (such as blood pressure), "humanistic intermediaries" (such as drug side effects), and "treatment modifiers" (such as medication compliance or prescribing appropriateness).

Patient outcomes, in this model, would include humanistic outcomes and those economic outcomes that are borne by the patient. Economic outcomes for the provider or insurer are not patient outcomes.

Patient Outcomes Assessment in Pharmacy

The phrase "patient outcomes" is a current buzzword in the medical and health services literature. Originally advocated as a concept (and set of measures) that would bring the patient's perspective to quality assessment, patient outcomes are now also being used to assess the effectiveness of health care technologies and services. For instance, numerous studies in the medical literature report on the use of health-related quality of life measures such as the Quality of Well-Being Questionnaire, the SF-36, and the Functional Living Index - Cancer to assess the effectiveness of pharmaceuticals.

Patient outcomes are considered to be the centrepiece of a movement in health care called outcomes management.^{7,8} Outcomes management involves maintaining system-wide databases of health care outcomes in routine clinical practice and providing each decision maker with access to data analyses that are relevant to the health care choices he/she must make. Its intent is to improve the quality of health care choices by providing better insight into the effect of these choices on the patient's life. Basically, it is a method of continuous quality improvement. This concept is achieving growing acceptance in managed care;⁹ it is, thus, important to pharmacists working within organized systems of care.

One could also assert that patient outcomes are the centrepiece of pharmaceutical care: "the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life".¹⁰ Since quality of life is a patient outcome, patient outcomes would seem to be the ultimate validators of the effectiveness of pharmaceutical care. However, a recent review of the literature found only a handful of studies that evaluated pharmaceutical care interventions in terms of patient outcomes.¹ Furthermore, these studies were limited in terms of their research design and the nature

of the pharmaceutical care intervention evaluated. Fortunately, several important studies are currently underway (e.g., an outcomes-based evaluation of pharmaceutical care for children with asthma).¹ Until more results are available, however, the impact of pharmaceutical care on patient outcomes is uncertain.

Hospital pharmacists may want to learn about patient outcomes because of a need or desire to interpret studies that report patient outcomes, because they want to conduct evaluations of their own services using these measures (they may be the most credible measures to administrators and other important decision makers within the hospital), or simply because they have heard others in their institution talking about patient outcomes and they do not wish to appear uninformed nor to be left behind. Patient outcomes assessment was of sufficient interest to Canadian hospital pharmacists to have been suggested by the readership, and selected by the editorial board, of the annual Canadian hospital pharmacy report as its special topic for the 1994/1995 survey.¹¹ Some of the findings of that survey demonstrate that there is a need for hospital pharmacists to learn more about patient outcomes.

Canadian Hospital Pharmacy Directors' Knowledge of and Experience with Patient Outcome Assessment

The Canadian hospital pharmacy survey¹¹ is a comprehensive survey of pharmacy services and operations mailed annually to directors of pharmacy in Canadian hospitals of more than 100 beds. The 1994/1995 survey, which achieved a 45% response rate (151 respondents), included a special section on patient outcomes. Three of its objectives were of particular interest to this paper:

- To determine pharmacy managers' understanding of the term "patient outcomes";
- To determine the extent to which hospital pharmacies are currently gathering patient outcome measures; and
- To determine reasons for not participating, or limiting participation, in patient outcomes assessment initiatives.

To test understanding we asked each respondent to provide three examples of patient outcome measures. Twenty-three percent of respondents (35/151) offered no examples at all. Of the 319 examples offered, 33% were measures that were consistent with the definition of a patient outcome as an end-result of health care that is experienced, interpreted, evaluated, and reported by the patient, that is, they were valid examples. The key criteria for a valid example were that it: 1) be something that could be measured; 2) measure an outcome, that is, an end-result (versus a process or an intermediary result) of care; and 3) incorporate the patient's perspective,

that is, measure something that a patient experiences or feels.

Fifteen percent of the valid examples were health status measures such as death, cure of infection, specific symptomatology, or quality of life; 16% were health care utilization measures that could serve as a proxies for health status outcomes (e.g., length of stay, readmission rate); and 2% were patient satisfaction measures. Thirty-four percent of the examples did not qualify as patient outcome measures. Sixteen percent were process measures such as patient knowledge of, or adherence to, medication regimens and physician adherence to DUE criteria; 11% were clinical indicators such as laboratory measures; and 7% were utilization measures (economic costs) such as number of lab tests and drugs. Thirty-three percent of examples were not evaluable, either because it was not apparent how they pertained to the question asked or because they did not identify something that could be measured. The breakdown of responses is summarized in Figure 2. Additional detail is provided in the survey report.¹¹

Only 36 (24%) of respondents reported that they had participated in a patient outcome assessment initiative in the prior year. However, when the patient outcomes measures used in these reported initiatives were evaluated, none of the examples cited by 15 respondents were valid patient outcome measures. Thus, the proportion participating in a true patient outcomes initiative was only 14%. Respondents who presented invalid examples seemed to be assuming that any evaluative measure was a patient outcome measure. For example, while serum drug levels are an evaluative measure they are not patient outcomes because they are not experienced by the patient. Neither are they outcome measures because they are not an end-result of care.

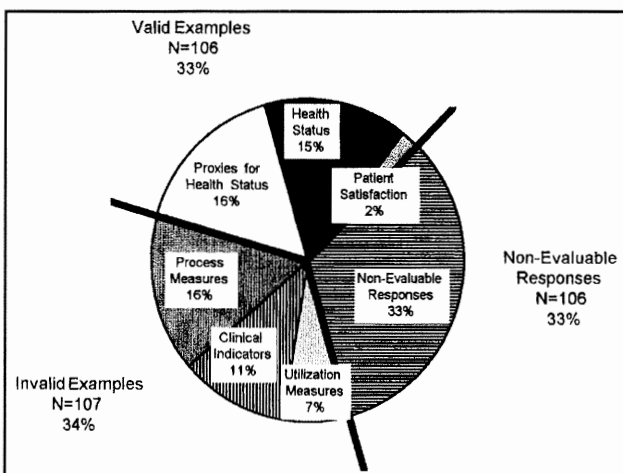


Figure 2: Hospital Pharmacists' Examples of Patient Outcome Measures (N=319). (See text for explanation of each category)

Factors identified as limiting pharmacy participation in patient outcomes assessment included not having sufficient resources to collect and compile the data (56%), difficulty identifying the appropriate measures to collect (14%), and not having considered the issue yet (13%). The latter two responses suggest that pharmacists may not be familiar with the trend to assess the patient outcomes resulting from health care or, in spite of familiarity, not fully understand the precise meaning of a "patient outcome".

Overall, survey respondents did not appear to have a complete understanding of patient outcomes as indicated by the proportion of respondents failing to provide examples of patient outcomes, the high proportion of invalid examples, and the proportion who had not considered the issue or who cited difficulty identifying appropriate measures as a limitation to participation in outcomes assessment. Difficulty understanding what constitutes a patient outcome is understandable in light of confusion even amongst researchers^{1,2} and in light of the survey respondents' relative inexperience with patient outcomes. Results were not much different in the subsample of pharmacists who stated that they had experience; only 29% of patient outcome measures reported met our definition. Overall, the survey responses indicate that many hospital pharmacists think of assessment in terms of traditional process-based measures such as compliance with DUE criteria or compliance with the prescribed medication. Also, the frequent citation of utilization measures suggests that controlling resource usage, that is, cost containment, continues to preoccupy hospital pharmacists. It is interesting that a 1992 survey of hospital pharmacy managers in the U.S. reported similar findings. Familiarity with outcomes research was high but understanding was relatively low.¹²

Recommendations for Hospital Pharmacists

What pharmacists need to know about patient outcomes depends on their opportunities to use the information. All pharmacists need to be able to understand the literature that evaluates pharmaceutical products and services so that they can judge the worth of these innovations for their practice. Increasingly this literature is including patient outcomes.

Some pharmacists may need to conduct evaluations of their services in order to establish their value to administrators and obtain continued support. In this case, the pharmacist will need to understand not only which patient outcome measures to select and how to measure them, but also how to design the evaluation so that reliable and valid results are obtained. Unfortunately, there is no "cookbook" for conducting evaluative studies. Similarly, there is no set of universal patient outcome measures. In selecting a patient outcome measure the

evaluator must consider the relationship between the drug or service being evaluated and the expected outcomes of the clinical condition to which the drug or service is being applied. For instance, since pharmacists on oncology units often focus on the supportive treatment of the cancer patient, one might expect them to have a greater impact on pain control, nausea and vomiting, and appetite than on the patient's length of life. Thus, a quality of life index would be a more appropriate patient outcome measure for assessing the pharmacist's impact than would mortality rate or length of survival.

When patient outcomes are measured in order to assess the impact of a pharmacy service, the challenge for the evaluator is to design the evaluation such that the impact of pharmacy services can be isolated from the impact of other services.¹³ With many factors influencing patient outcomes (including the attributes of individual patients, the care received from other members of the health care team, and the different therapies applied) it is often difficult to establish that any one service or therapy was responsible for the outcomes.¹⁴ Issues such as the need for a concurrent control group, stratification of subjects, identification of process measures that should accompany the outcome measures, and selection of statistical tests must be addressed. Thus, the challenge of designing the evaluation may require that the pharmacist practitioner collaborate with a health services researcher.

When patient outcomes are assessed for quality improvement purposes, there may be less need to definitively establish the source of the improvement. Since many interventions to enhance the quality of drug use in a health care institution are inherently multidisciplinary (e.g., a formulary system, prescribing guidelines), it is often more appropriate to assess the impact of the overall program rather than the contribution of any one group. Indeed, the majority of outcomes initiatives reported in the Canadian hospital pharmacy survey were multidisciplinary, with the most common target of evaluation being physician prescribing.

In conclusion, patient outcomes bring the patient's perspective to the assessment of quality and effectiveness in health care. Patient outcomes play a central role in the outcomes management movement in health care and a growing role in establishing the effectiveness of health care technologies such as pharmaceuticals. Many Canadian hospital pharmacy directors are aware of the impor-

tance of patient outcomes in the evaluation of health care and are curious about their application in pharmacy. However, only 24% of respondents to a recent national survey reported that they had participated in a patient outcomes initiative in the prior year. More importantly, only a third were able to provide valid examples of patient outcomes measures. These findings suggest that hospital pharmacists would benefit from access to continuing education literature and programs on patient outcomes that explain their meaning, relevance, and implementation in hospital pharmacy practice. ☒

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