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Patient Outcomes: Information Paper on Directing the Pharmacist's Practice toward Health Outcomes (2004)

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PREFACE

This is the 2004 edition of the Canadian Society of Hospital Pharmacists (CSHP) Patient Outcomes: Information Paper on Directing the Pharmacist's Practice toward Health Outcomes. This document was approved under the title of Information Paper on Directing the Pharmacist's Practice Toward Health Outcomes; the title was fine-tuned in 2009.

PRINCIPLES

Hospital pharmacists should orient their daily, weekly, monthly and yearly goals, priorities and routines to achieving outcomes that are concurrent with institutional, professional and patient goals.

Outcomes can be administrative; they can be professional; and they can be health outcomes in patients. They must be specific and measurable and achieved over a targeted time frame.

A series of outcomes for a hospital pharmacy service must be integrated into an overall plan whose first priority is to maximize health outcomes for the patients. In this hierarchy, all other outcomes are secondary but should be related to the first priority of optimizing patient health outcomes. Prioritization of activities, workflow and expenditures should be based on their ability to affect patient health outcomes.

Pharmacists and pharmacy departments need to establish indices (markers) of their work relating to health outcomes. These should be reviewed regularly, readjusted and reprioritized as necessary in order to participate in and to achieve optimised patient health outcomes.

1. INTRODUCTION

Measuring and comparing health outcomes and using such data to manage health services have become, over a decade, the major influence on health budgets for determining which services will be offered, continued or abandoned. As a vital health profession, pharmacy has no choice but to participate in this new endeavour and indeed, to develop its own criteria, its own studies and to develop easy methods to incorporate the philosophy into everyday activities, both administrative and clinical.

This information paper is a starting point for planning and discussion of pharmacists' responsibility for patients'/clients' health outcomes. It looks at the origin and definition of health outcomes, their importance in health care, how they fit with pharmacy practice, what studies have shown about pharmacy practice and drug use, and how to do outcomes management and develop an outcomes-oriented practice.

2. WHAT IS AN OUTCOME?

Health outcome is defined as "a change in a patient's current and future health status that can be related to previous health care".[1] Health outcomes are consequences in a patient's life. They are end results such as morbidity or mortality, length of illness, incidence of side effects and quality of life.

There are three types of outcomes, according to the ECHO model developed by Kozma and colleagues at the University of Southern California in 1993.[2] The first type is economic outcomes such as costs of care and altered costs of living. The second type of outcome is clinical which is best illustrated by measures such as mortality or morbidity, but we often seek "surrogates", which are easier to measure but which have been shown to relate to real health outcomes. For example, blood pressure is not an outcome but it has been shown to be good surrogate measure in studies because it has been shown to predict the incidence of several cardiovascular outcomes (myocardial infarction, etc.). Finally, there are humanistic outcomes, such as quality of life or functionality in life.

All three types of outcomes are important; indeed, they often inter-relate. For instance, certain asthma interventions have been shown to not only improve the number of pneumonias (clinical), but also to improve quality of life (humanistic) and to lead to decreased health care costs (economic).

Part of the development of the field over the last decade has led to consensus not only on the identity of the outcomes for a particular disease, but also the extent of change expected. For years we have used general quality of life scales such as the SF-36.[3] For most diseases we now also have one or more disease-specific quality of life scales that have been validated and published.

3. WHY ORIENT TO HEALTH OUTCOMES?

The simple answer is that there is little choice. The entire health care system has been put up for evaluation ever since the early 1990s. At that time, the western world faced a significant slowdown in the economy. Governments that were paying for health services sought tools to measure the health output of the various components of the health care system. Provincial budget administrators, hospital administrators, as well as health insurance companies, sought to fund those services that provided high health value and to cut back on those that did not. The fields of health economics and more particularly pharmacoeconomics experienced geometric growth because of these new demands. They developed and tested tools to measure health outcomes and often initiated studies to measure various services. Pharmacy would have suffered significant financial cutbacks if we had not participated not only in the development of the tools, but also in the testing of our services for their impact.

Administrators continue to seek information on relative spending advantages of one health service over another, because of the many demands for increased funding. Moreover, the decade has witnessed a trend towards greater accountability of providers, in that all of those who provide care must accept the responsibility of meeting society's goal of high quality care at an affordable price. Therefore it is important that we continue to develop measurement of our health impact and that we incorporate easy measures in our departmental management as well as in our daily practice. It therefore becomes part of modern quality assurance to assure that our precious resources, both personnel and drugs, are directed to achieving the maximum health outcomes of our patients for the least cost.

4. DOES PROCESS NO LONGER COUNT?

For years, the teaching in management theory has been on the three-stage model of Problem – Process – Result (or outcome). We have become focused on process and not on evidence of what processes lead to the best outcomes. Pharmacists have historically refined the process of distribution and endeavoured to improve its quality with concerns over safety, errors, and legal considerations, but rarely have been concerned with health outcomes. We were concerned with doing a good job, often involving quality assurance programs, and with product quality, distribution and safe preparation. Even the prescription verification process of checking dosages is based on an average dose (a sort of safety check) and not on optimizing the patient's individual health outcomes.

This orientation is changing as we weigh evidence of which processes count, in terms of optimal health outcomes, and as we shift pharmacists' priorities to exercising influence, supported by evidence in the literature, which will lead to better outcomes. The first changes came when pharmacists became more involved with the patient in counselling them about their medications; unfortunately there have been few studies done to show health impact. Many of the recent studies on counselling show only modest,

if any, impact on health and, given the tremendous amount of time that such activity requires, we clearly need more research to show us which type of counselling interventions improve outcomes. In addition, we became clinically active with other health professionals, particularly in advising or intervening with physicians about prescribing. Similarly, because of the significant time involvement required to conduct this activity, we have sought evidence to assure that health outcomes are altered. Indeed, the last decade has slowly revealed a series of studies where health outcomes have been positively altered through such clinical activity.[4] Finally, the most recent model of pharmacist activity, the pharmaceutical care model, has required that pharmacists actually take responsibility for health outcomes related to drug therapy.[5] This is a major step but clearly causes us to constantly pose the question: Am I doing what has been shown to count?

5. WHAT DOES THE RESEARCH TELL US?

Evidence is mounting to guide us towards organizational and practice models which have the most impact on outcomes. Considering "process", research on error rates tells us that pharmacy technicians do as well, and often better, in purchasing, inventory management, preparation and distribution (especially unit dose) of pharmaceuticals. Research also tells us that pharmacists can, and in some practices do, have significant influence on health outcomes. It has been shown that we can have an effect on the incidence of adverse drug reactions, the length of stay in hospital, the drug budget, the quality of life and the disease benefits in most major chronic diseases.(4) The Clinical Pharmacy Services Study (CPSS) showed that we had influence on the benefits, the risk reduction and the costs of drug therapy, and that this influence was agreed to by prescribers (who had often been asked to change prescribing, based on pharmacists' interventions).[6]

Unfortunately, our impact remains potential only because it is not universally applied. As a result, our patients continue to have significant drug-related problems (DRPs) and therefore continue to cost the health care system a fortune! Let us examine some simple outcomes resulting from DRPs, with and without the influence of pharmaceutical care, as documented by Bootman and Johnson, using estimates provided by several Canadian authors:[7,8]

Annual Costs of Drug-Related Problems –
CA$ for 2000

	WITHOUT PC	WITH PC
Health Care Costs	10 billion $	4.1 billion $
Deaths	25,000	9,900
Hospitalizations	100,000	39,700

According to these estimates, the costs of DRPs are higher than the actual drug costs. The application of pharmaceutical care could reduce these costs, as well as reducing hospitalizations and deaths, by approximately 60%.

The application of pharmacoeconomics[7] is changing the entire system of drug use and pharmacy services in our health care facilities. Over the last twenty years, we have gone from emphasis on "drug use control", to improving the provision of pharmacists' interventional educational services in the wards, to the acceptance by pharmacists of their responsibility for patient outcomes. Much of the thrust for these changes has been on the basis of sound pharmacoeconomic research, which by its very nature attempts to evaluate the costs of outcomes. This research and the subsequent changes in pharmacy practice have led to many questions about the value of various models of pharmacy practice.

6. WHAT IS OUTCOMES MANAGEMENT?

Outcomes management is the use of tools of management directed toward optimizing health outcomes. Ellwood described outcomes management as a "technology of patient experience" designed to help patients, payers and providers make rational choices guided by better insight into the effect of those choices on patients' lives.[9] Over the last few decades we have witnessed efforts to manage health care using a variety of influences to improve outcomes; such efforts include formulary controls, care plans, managed care, therapeutic reviews and case costing reviews. The major new influence on these efforts has been the development of evidence-based medicine (EBM).

For over forty years, health care facilities, and more recently, health care system payers or regional bodies, have developed formularies or approved drug lists developed by Pharmacy and Therapeutics (P&T) Committees or similar expert bodies. Much of the motivation for formulary development has been economic, that is, to control the release or conditions of use of therapies that are more expensive than others. Review of the literature on formulary policies shows definite reductions in drug costs; however, evidence is lacking on the influence of formularies on health outcomes. More recently, the application of institutional formulary policies has been suggested to be responsible for confusion of patients about their medications, leading to an unmeasured level of drug-related problems. Others suggest that efforts by expert committees on formulary policies should be extended to a more positive role of fostering better drug use through disease or drug category guidelines.

Care plans have been developed to standardize and optimize care for certain conditions and problems. Care plans have been developed within health care facilities, regions or even provinces, for such areas as: pre- and post-operative care for various surgeries, acute myocardial infarction, cardiac arrest, prevention of constipation, prevention of deep vein thromboses, and many more. Care plans should be developed by a multidisciplinary team and be approved by the P&T Committee or other body responsible for care. It is imperative that they be prepared using available guidelines and strong evidence from the literature. Once prepared, they need to be promulgated through educational campaigns, because in many settings, they may not be compulsory. Finally, they require periodic review as the evidence and experience in their use changes. Pharmacists should be routinely involved with the development of care plans which involve drug therapy. Although there is little literature evaluating the influence of care plans on outcomes, that which exists is positive.

Managed Care is a system of health care, frequently under one payer, where efforts are made to optimize care according to the best evidence to ensure the achievement of desired health and economic outcomes. In such systems of health care, interventions are frequently monitored as are the costs in the system; some systems also monitor health and economic outcomes.

Managed care systems usually use a process or disease state management which is an approach to patient care that coordinates resources across the entire health care delivery system; it takes a systemic approach, focusing on the patient with a disease as the relevant unit of management, with an emphasis on quality as well as cost. Such organizations often publish guidelines, which may be employed more or less rigidly for treatment methods and algorithmic sequences of interventions recommended, including drug therapy selection with individual doses, length of therapy and methods of evaluation. Expert committees that review the published evidence usually create these guidelines. Some pharmacy organizations have created disease-specific modules of care which delineate not only the desirable drug therapy but also the methods of pharmacist care to improve compliance, help understanding and attain better outcomes.

At the core of the outcomes movement, and especially in the area of rational therapeutics, has been the development of evidence-based medicine. Sackett has defined EBM as the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients.[10] The practice of EBM means integrating individual clinical expertise with the best available external clinical evidence from systematic research. By individual clinical expertise we mean the proficiency and judgement that individual clinicians acquire through clinical experience and clinical practice. It involves tracking down the best external evidence with which to answer our clinical questions. Because the randomised trial, and especially the systematic review of several randomised trials (such as meta analysis), is so much more likely to inform us and so much less likely to mislead us, it has become the "gold standard" for judging whether a treatment does more good than harm. However, some questions about therapy do not require randomised trials (e.g., successful interventions for otherwise fatal conditions) or cannot wait for the trials to be conducted. And if no randomised trial has been carried out for our patient's predicament, we follow the trail to the next best external evidence and work from there.

All of these influences have led to the publication of clinical practice guidelines by expert national groups. In Canada, most of these guidelines are filtered and reproduced on the Canadian Medical Association web site (http://www.cma.ca/cpgs/index.asp). Reviewers of drug therapy have been disappointed however in the overall utilisation of these guidelines in practice. The literature suggests, for instance, that the use of beta-blockers and aspirin post myocardial infarction, despite the overwhelming evidence of efficacy is used in less than half of cases. This is much lower than the expected number of contraindications (diabetes, asthma etc.). Researchers have found that there is still a process of adoption which is operative in most regions. Initiation by a series of respected specialists is often necessary.

Pharmacists' intervention has sometimes been successful, sometimes not. The barriers are significant, including a classical medical disdain for "cook-book medicine". The philosophic argument is also proposed that the evidence from randomized controlled trials provides support of efficacy only, but not necessarily of effectiveness in the so-called "real world". Trials rarely take into account extremes in age or patients with multiple major diseases or with multiple drug therapies. Nonetheless, the attempted use of evidence weighting and guidelines is still redeemable because there is no better approach available.

Another interesting exercise, particularly in the institutional setting, is that of case costing and its review by pertinent groups. Case costing involves assembling all of the major costs in the treatment of specific disease or diagnostic categories, including health professional costs, laboratory, drugs and per diem hospital overhead. Availability of these data in a facility's computer databases is critical to the development of case costing analysis. The most interesting aspect of case costing is the comparison of per case costs of particular diagnostic entities among similar facilities or among individual physicians. The review of such data according to the constituent contributors, especially the "outliers", can lead not only to an understanding of patient differences, of surgical habits, but also to changes in prescribing – demonstrable by subsequent audits. In order for such a tool to be effective, it must be trusted by its users and analysed with professionalism.

7. IS THERE EVIDENCE FOR ONE MODEL OF PHARMACY PRACTICE OVER ANOTHER?

In the old distribution model most of our activities and interventions were retrospective, occurring after the medication order was written. We had little or no responsibility or even knowledge of patient diagnoses or problems. Nor did we have any feedback on whether drugs were effective or not. Only if there was a grave error were we "measured" in terms of quality. Subsequently, we used drug use evaluations to document how prescribing measured up to pre-determined criteria, but they shed little if any light on the effects of our interventions on patient care. We spent a lot of time checking patient profiles for drug interactions.

In the clinical pharmacy model, we took a more prospective view of drug therapy by going on medical rounds, making suggestions and by providing drug information. Our ability to affect drug therapy decisions was enhanced. We focused on optimizing drug therapy and increasingly documented our interventions. We would spend hours providing drug information to patients without knowing whether it was wanted, understood or usable. Evidence was lacking; follow-up was not part of that model.

In the new model of health outcomes practice, we have come to accept some responsibility for the outcomes of drug therapy in our patients. We have adopted the principles of pharmaceutical care and involved patients in decision making. This orientation means that:

1. Drug therapy will be used only when there are clear benefits, that is, when it improves health outcomes. Unneeded drugs have no value and increase the risk of drug-related problems.
2. Drugs are used in a preventive manner where demonstrated to improve outcomes.
3. We do everything possible to reduce or eliminate drug-related problems.

A model of practice that requires pharmacists to accept responsibility for health outcomes is highly desirable. Many pharmacy practitioners have embraced the new orientation; however, the majority have not and there are huge barriers to developing this level of practice amongst present practitioners. Nevertheless if you believe in the power of the outcomes movement, pharmacists may have no choice but to undertake this change with or without the support they require.

See the CSHP Information Paper on Pharmaceutical Care: Responsibility for Outcomes.[11]

Research to date on the PC model proves its positive influence and improvement in health services.[4] However, there is much to be investigated on the particulars of the model in various types of health care facilities and how it can be integrated with the patient in community care. Gaps in the transition to and from institutional care have been identified, but presumably our orientation to outcomes will cause us to assure continuity in the care of our patients – to make it "seamless".

Questions remain about certification of pharmacists as disease specialists, about the required education of pharmacists to serve as therapeutic advisors and about the minimal requirements for pharmacy graduates to serve in general practice. The overall pressure within the health care community will push the search for answers to these questions and for the best models of practice that will result in cost-effective care. We must assure that we continue to subject our models to the research evaluation required to answer these questions.

8. WHAT HAS BEEN SHOWN IN STUDIES ABOUT THE PHARMACIST'S ABILITY TO INFLUENCE OUTCOMES?

A number of review articles have now publicized the evidence of pharmacists' impact on health outcomes.[4,12,13] Unfortunately, the literature has also

provided many anecdotes: testimonial claims of impact and tales of positive experiences rather than studies of evidence-based outcomes. Nevertheless there is an increasing number of controlled trials comparing pharmacists' services and measuring health outcomes. Overall the impact has been rather positive over a wide variety of diseases and clinical situations. Disease states or conditions include hypertension, asthma, diabetes, mental illnesses, the elderly, intensive care, cardiac care, infections, hyperlipidemia, rheumatology, thromboses, and more. You are referred to reviews in the reference list and bibliography for further details. One could summarize by saying that pharmacists, in identifying and resolving DRPs according to a PC model, have been shown to improve outcomes in a variety of diseases by:

a) reduced drug costs;
b) reduced adverse drug reactions;
c) reduced hospitalizations;
d) increased quality of life;
e) improved disease indicators; and
f) reduced overall health care costs.

Although the calibre of research is not always the best, evidence is overwhelming that pharmacists can influence health outcomes. These are often "efficacy" trials, that is, they are special arrangement highly controlled and are not always adapted to general practice. The question that remains is whether pharmacists will impact health outcomes routinely in the care of their patients. As the question sits and as research studies are being designed to study our "effectiveness", the models for pharmacists to routinely orient themselves to outcomes, both administratively and clinically, are now developing rapidly. Let us examine how outcomes can be adapted to every pharmacist's practice.

9. HOW CAN THE PRACTISING PHARMACIST ADAPT TO THE OUTCOMES MOVEMENT?

Progressive pharmacists have become accustomed to change in their career. Less progressive pharmacists may not have kept up with the changes and will have difficulty adapting to the health outcomes movement. But no matter where you are on the spectrum of adaptability to change, the first decision has to be a conscious one, namely to invest the time and stress necessary to make the change successfully. On the positive side, there is certainly a great deal of professional satisfaction in being up-to-date; practising PC or outcomes-oriented pharmacy is very rewarding in itself: to accompany patients in their resolution of DRPs and in their improvement in health as measured by outcomes.

For many pharmacists, an investment in education is necessary to make the change. Two areas require upgrading: one is therapeutic knowledge (particularly related to the specialty areas or diseases that one is working with) and the other is clinical skills. Therapeutic knowledge can be obtained from texts, correspondence courses and specialty programs that are offered for various common diseases. A visit to a pharmacist who is specialized in your area is well worth the minor expense. Once you have been brought up-to-date, you should then keep current by subscribing to sources of therapeutics in your specialities; several specialty services are available on the web. Remember, the pharmacist should be as knowledgeable as the physician in terms of therapeutics, if not more so.

The other area that may require upgrading is pharmacists' clinical skills. PC requires a different approach to the patient than previous models and requires adaptation and practice. There are a number of clinical skills programs that are available by correspondence. Certainly pre-reading about the

philosophy and approach of PC is essential to understand the basics and help orient you to this practice. CSHP's Pharmaceutical Care Education modules are ideal: "Direct Patient Care: A curriculum for learning", modules 1-5.[15] Some pharmacists have also organized themselves around the basis of a PC practice (e.g., professional specialty groups (PSGs) or professional specialty networks (PSNs) and they sometimes offer educational modules. Finally, a very useful option is a small sabbatical to a site where PC is practised and where there is a preceptor willing to train you.

Increasingly, evidence and experience are accumulating to show the importance of recognizing the psychological components of influence in dealing with both physicians and patients. The use of assessing the stage of "Readiness for Change"[15], for instance, has been shown to improve compliance in smoking cessation and other major therapeutic interventions. Pharmacists are encouraged to ally with clinical psychology colleagues in learning more about areas where behaviour modification is implicated.

10. HOW DOES A PHARMACY DEPARTMENT ORIENT ITSELF TO THE OUTCOMES MOVEMENT?

As any change in management philosophy, in order to be successful, must be adopted at the top and spread enthusiastically throughout the department to all employees. Such change may be best brought about through a departmental retreat and/or a series of staff meetings on the significance of the change. During this process, it is useful to identify barriers to the change and to propose solutions to overcome these impediments. All of this should result in a plan and a commitment by the department to the new direction.

Some of the key ingredients in the re-orientation would be:

a) invite outside expertise as necessary;
b) commit to a plan with specifics and deadlines;
c) seek funds, if needed, for personnel, perhaps with promised outcomes of economic savings and better therapy;
d) bring administration and medicine (through the P&T Committee) onside;
e) delegate all pharmacists' technical duties to technicians – with training as needed;
f) officially make pharmacists responsible for outcomes;
g) mark the accomplishment of objectives with celebration; and
h) communicate the accomplishments, tracking and reporting various outcomes indicators, to senior hospital management.

You do not have to wait until the department has all of the plans made. You can start today in your daily practice.

11. LEAVE A TRACE OF YOUR INFLUENCE – DOCUMENT!

Your review of patients will involve the establishment of goals in certain measurable monitoring parameters (e.g., blood pressure, serum glucose, # of attacks, pain scale reading). It is important to document the goals, the progress towards them and changes made to achieve them. These notes will become very important to your fellow pharmacists as well as to nursing, medical and other health professionals who are involved.

You will also need to keep statistics of the outcomes achievements for your boss, who can then use them collectively with other statistics to show the achievements of the department to others at an administrative level. Such data collection is becoming increasingly facilitated through electronic aids. This information is proof-positive that the department is outcomes-oriented.

At an administrative level, it is critical to seek only the important data from staff on their involvement.

The data collection process should be facilitated as much as possible to ensure the prompt submission of such data and to ensure its accuracy. Electronic aids and short forms can facilitate this collection. Sharing data summaries with all of the staff will reinforce their importance. As an administrative tool, it may be most useful to look at where the highest incidence of DRPs exist, the percent resolved, the types of DRPs, and the percent achievement of outcomes goals. It may also be interesting to compare your data with other health care facilities. See CSHP's Information Paper on Documentation for ideas.[16]

12. SOME FINAL QUESTIONS AS TO YOUR ORIENTATION

1. Do you have a responsibility other than providing a safe product at an average dose? If so, what is it?
2. What is the real purpose of your patient's prescriptions?
3. What is your real purpose professionally?
4. What can you do to assure that your patients medications work best?
5. Do you want to improve your patients' care?

In short, our involvement in assuming responsibility for patient outcomes in drug therapy:

a) assures a better level of health for our clients,
b) gives a better recognition of our contribution to the care process, and
c) provides more satisfaction to ourselves and our patients.

13. CONCLUSIONS

The hospital pharmacist needs to orient him/herself to the outcomes philosophy. The need for this is absolute in the present climate of constant review of health economics and continuing research on health outcomes. Orienting one's practice to outcomes is necessary on the clinical side and on the management side of the department. The individual pharmacist needs to constantly aim to serve his/her patients by setting goals and achieving optimal outcomes. Similarly the Pharmacy Department collectively needs to accomplish goals which are the achievement of outcomes agreed upon for patient care.

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