

Seeking Value in Pharmaceutical Care: Balancing Quality, Access and Efficiency



COMMENTARY

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ABSTRACT

Healthcare remains a dominant issue for Canadians. Central to the debate is the dynamic tension among the value, accessibility and affordability of drugs. Simply put, innovative drugs improve health and economic outcomes for individuals and populations. As a result, providers and patients increasingly demand, and expect, these benefits; utilization and expenditures increase. The management challenge is finding the best balance of quality, access and costs. Supply-side strategies, such as restricting access with the intention of controlling isolated costs of drug budgets, are not optimal from a population health view because

they have the adverse impact of limiting the system benefits of innovative drugs. Management strategies emphasizing the demand side of the market are more empowering to providers and patients and, given the increasing knowledge and accountability of these stakeholders, are increasingly feasible. Population health outcomes and efficient resource use may be better served by a combination of strategies. The partnership-measurement model of disease management is a practical example of this approach at the community level; timely and repeated feedback of real-world practices, as well as provider and patient education, drive accountable, cost-efficient and continuously improved outcomes. As we seek the optimal societal strategy for innovative drug therapy, resource allocation decisions have to be made. Widening the debate and informing the debaters will enhance the chances of making choices that achieve the best health for the most people at the best cost.

CONCERN WITH SUSTAINABILITY of the publicly funded health system continues to be a dominant topic of debate in Canada. Pharmaceutical therapies are receiving particular attention of late. Total drug expenditure, including non-prescription drugs and pharmacy distribution costs, represents about 15% of health spending, with patented prescription drugs accounting for 6% (Canadian Institute for Health Information 2002). About 80% of Canadians are currently reported to have good insurance coverage for drugs; 10% are underinsured; and 10% have no insurance for routine or catastrophic drug costs. Canadians least likely to have adequate coverage are young adults, especially women, those with illnesses having a negative effect on employability and/or those with diseases for which newly available therapies are very costly (Applied Management Consultants 2000).

In this issue of *HealthcarePapers*, Morgan and Willison present a comparative evaluation of possible approaches to a national pharmaceutical care policy. Their principal stimulus was the Commission on the Future of Health Care in Canada,

which recommended a universal catastrophic drug benefit, or “last-dollar” pharmaceutical care, in the fall of 2002. The authors benchmark the implications of this recommendation against a “first-dollar” approach, as recommended by the 1997 National Forum on Health.

Morgan and Willison characterize the positive features of the “last-dollar” recommendation as providing an equitable, ongoing subsidy, and avoiding a burden of financial disaster or non-insurability, for patients with chronic and serious diseases. On the negative side, they feel cost-control will be more difficult; and unintended adverse outcomes might ensue if some patients perceive the deductible as a financial disincentive and choose not to follow treatment advice from their doctor. This latter concern is also based on their sense that patients and prescribers may not have an accurate long-term, or “downstream,” view of the net value of treating, or not treating, a disease at the individual and societal levels.

The authors suggest a blend of publicly provided, “first-dollar” and “last-dollar” features for a pharmaceutical care policy that is accessible, equitable and

efficient. Lastly, to strengthen the likelihood of success of the “first-dollar” component in the blended solution, Morgan and Willison recommend further research and development of disease management and systems analysis tools to ensure our future pharmaceutical care policies optimize treatment access and clinical and fiscal outcomes from our dollars spent.

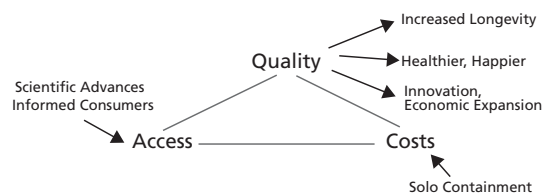
The recommendation for a network of centres of excellence for innovative pharmaceutical policy is an obvious need for Canada, which we strongly support. As well, we commend and support the overall goal of Morgan and Willison in their paper; increasing knowledge of the issues and facilitating an informed debate will contribute to a pharmaceutical care policy that improves health outcomes in a cost-efficient way.

Why Is Pharmaceutical Care a Major Topic of Debate?

There are four essential factors underlying the debate. First, people are concerned for the quality of their health, and drugs, particularly new drugs, are recognized as very valuable in achieving quality health outcomes. Second, this widely perceived value, an aging population and newer therapies are driving an increasing use of drugs and an accompanying increasing cumulative cost for payers. Third, major precepts of medicare, particularly universal access to core physician and hospital services, with no user fees, have become deeply embedded in public expectations and beliefs of what it means to be Canadian. They are part of the fabric of our society. But, fourth, contrary to the value recognition of drugs and the cultural expectations of universal access, prescrip-

tion drugs are not systematically provided, or funded, under current medicare policies. These factors have led to tension among demand for access to new drugs, their positive impact on health quality and the willingness, or ability, to pay their costs (see Figure 1).

Figure 1. The major driving forces in health-care are in dynamic tension. As demand for access rises, driving improved health and economic outcomes, cumulative costs also rise. To contain costs, policy-makers restrict access, in turn producing perceptions of decreased quality of care.



In terms of the medicare template and culture, the debate on pharmaceutical care may distill to a discussion on whether drugs are an essential service, justifying a status of universal access and insurance coverage; and, given this, what trade-off choices individual citizens, or governments, are willing to make to provide supporting funds. In this case, then, two important questions arise: What is the societal value of drugs? And what can be done to optimize the return on investment for drug spending?

Drugs: The Value Proposition

The health value of many drugs is very apparent. For example, immunizations and antibiotics have great individual efficacy and population effectiveness. More recently, adoption of randomized clinical trials (RCT) methodology has allowed the causal recognition of smaller

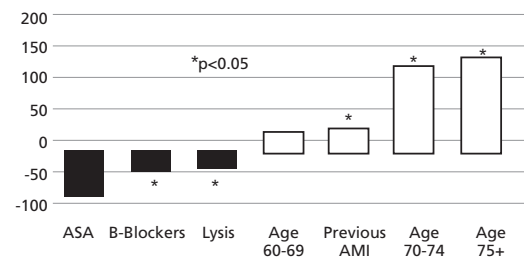
degrees of drug efficacy in disease states with a large burden of illness, such as heart disease, arthritis and asthma.

In high-burden areas such as coronary heart disease, where there is now a large body of accumulated RCT data, important consistencies in the efficacy evidence have emerged. These include the principle that efficacious drugs are efficacious in all clinically relevant patient subgroups; there are no qualitative interactions (SOLVD 1991; McAlister et al. 1999; Jong et al. 2003). However, there are some quantitative interactions. One is that efficacious drugs tend to have greater impact in higher risk patients (McAlister et al. 1999). Another is that the strength of the efficacious intervention may be time-related; for example, differences between the control and intervention groups in outcomes such as survival may continuously increase over time (SOLVD 1991) and persist for prolonged periods (Jong et al. 2003).

Based on the weight of available evidence, it is a reasonable assumption that the benefit of proven efficacious drugs also extends to the health outcomes of whole populations. For example, repeated univariate and multivariate analyses from the Clinical Quality Improvement Network (CQIN), of thousands of consecutive patients with acute myocardial infarction and congestive heart failure in real-world community and academic settings, consistently demonstrated the positive association of proven drug use with decreased mortality risk (Tsuyuki et al. 1994; CQIN 1996; McAlister et al. 1999). Results from a CQIN cohort of 2,070 infarction patients are shown in Figure 2.

A subsequent analysis of a cohort of

Figure 2. Multivariate analysis of clinical and demographic variables, relative to in-hospital mortality risk, for 2,070 consecutive patients with acute myocardial infarction (AMI) admitted to four hospitals of the Clinical Quality Improvement Network, 1987-1992. Acetylsalicylic acid (ASA), beta blockers (B-Blockers) and thrombolytic therapy (Lysis) were associated with decreased relative risk of dying; previous history of AMI and older age were associated with increased mortality risk. Adapted, with permission, from *CHEST* (Tsuyuki et al. 1994).

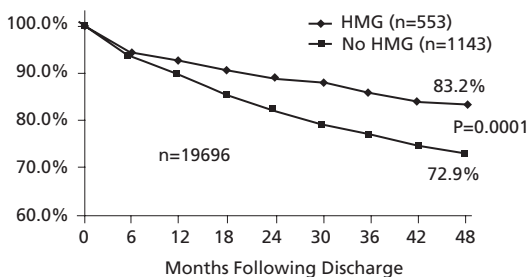


7,070 consecutive patients with acute myocardial infarction confirmed that the uses of ASA (odds ratio [OR] 3.1; $p < 0.001$), beta blockers (OR 3.0; $p < 0.001$) and thrombolytic therapy (OR 1.1; $p = .35$) were associated with improved hospital survival (McAlister et al. 1999). Reflective of RCT results, the drop in mortality rate over the decade these studies occurred was greater in the older higher-risk patients (McAlister 1999).

More recently, the Improving Cardiovascular Outcomes in Nova Scotia (ICONS) investigators, also using multivariate analyses, demonstrated an important positive relation between use of proven medications, specifically angiotensin-converting enzyme inhibitors, beta blockers and lipid-lowering statins, and 30-day and one-year mortality protection for patients with acute myocardial infarction (Mitnitski, 2003). In addition, also reflective of the RCT results, data from ICONS suggest

the population effectiveness of proven therapies may also be time-related, with increasing impact over time (see Figure 3).

Figure 3. Differences in survival of consecutive patients with acute myocardial infarction admitted to Nova Scotia hospitals in 1997 and 1998, according to whether they received lipid-lowering medications. The degree of difference associated with the intervention (HMG = lipid-lowering statin medications) continued to increase over the four-year post-discharge period. Adapted, with permission, from *Hospital Quarterly* (Montague et al. 2003).



Moving beyond single disease states, econometric analyses have assessed the relation of drug use across many diseases and whole countries and, most recently, groups of countries. The results of these studies, which derive primarily from the arena of economics, as opposed to health-care, are very consistent with the more clinically oriented studies. Analyzing data from 52 developed and undeveloped countries between 1986 and 2000, Lichtenberg found an average increase in life expectancy of 1.96 years (Lichtenberg, forthcoming). He estimated that the introduction of new drugs into these countries accounted for 40% of the longevity increase. Interestingly, introduction of multiple-source, or older, drugs was not associated with longevity benefit.

In a previous analysis of the U.S. market, Lichtenberg found a similar

relation between the introduction of new drugs and longevity (Lichtenberg 2003). There was an incremental impact of 11,200 life-years saved per year for the average new drug launched during the study interval 1970 to 1991. These findings relating new drug use and population longevity gains are supported by econometric analyses of other investigators (Cutler and McClellan 2001), including results from a recent Canadian study (Analysis Group/Economics 2003).

In a cost-effectiveness analysis from the 1996 Medical Expenditure Panel Survey (MEPS), Lichtenberg also concluded that patients taking newer drugs were significantly less likely to die, and also to have less work-loss days, lower non-drug costs and a net reduction in total treatment costs of a given condition, compared to patients taking older drugs (Lichtenberg 2001).

The weight of the econometric data is consistent with the quality ladder model of innovation, which suggests innovative products are better than older products because they provide more services. Or, put another way, an underlying driver of the value proposition of innovative drugs is inherent in their “newness,” as opposed to “firstness” or “sameness.” At a national level, the return on investment for drug-related gains in health outcomes such as longevity has been estimated to be associated with economic growth that is twice as large as the traditionally calculated growth unadjusted for the longevity benefit (Nordhaus 2003).

Optimizing Patient Care

To optimize both the clinical and cost effectiveness of new drugs, and gain the greatest societal benefit of their innovative

value, their appropriate use must extend to whole populations. In other words, cost may not be the most appropriate focal point in determining cost-effectiveness. Rather, the issue is population effectiveness of the drugs. Can it be optimized?

The short answer is yes. However, to attain this goal, impediments to appropriate diagnosis of disease and to prescription, compliance and access of medications have to be removed, or minimized, for everyone in the population at risk from the disease for which efficacious therapy is available. Modern disease management theories and practice go a long way toward realizing these goals.

Disease management can be broadly defined as a focused application of resources to identify patients at risk from specific disease(s) and to intervene to improve their outcomes. The contemporary use of the term often refers to a patient-centred, population approach to the prevention, diagnosis, therapy and monitoring of disease/health states. It considers drug and non-drug therapy, measurement and feedback of practices and stakeholder and patient education, with attempts at coordinating specific interventions across the healthcare system. The working premise is that care and outcomes can be better improved.

Effectiveness of Interventions in Health and Disease Management

In a recent issue of the *British Medical Journal*, Weingarten and colleagues published a comprehensive evaluation of the efficacy of interventions used in disease management programs. In this formal, systematic review, 118 programs were analyzed, covering common and important disease burdens such as asthma,

coronary disease, depression, diabetes, hypertension and chronic pain (Weingarten et al. 2002).

Patient education was the most common intervention in these programs, followed by stakeholder/provider education and feedback, with most programs using a combination of interventions. At the provider level, the investigators found all interventions to be associated with significant improvements in adherence to guidelines (effect size range, 44 to 61%) and disease control (effect size range, 17 to 35%). At the patient level, several interventions were also associated with significant positive increments in disease control, including education (24%), reminders (27%) and financial incentives (40%).

These conclusions are very compatible with recent Canadian data on the effectiveness of education and stakeholder feedback in driving improved patient outcomes as part of disease management initiatives (CQIN 1998; McAlister et al. 1999; McAlister et al. 2001; Montague et al. 1995; Montague et al. 1996; Montague et al. 1997; Montague et al. 2003; Young et al. 2003).

Key features of this model of disease management are community-based partnerships and use of repeated measurement and feedback of practices and outcomes to generate a continuous quality improvement loop (Montague et al. 2003). The most advanced case study of the model is the ICONS project, which was a province-wide program designed to use a broad-based partnership and a combination of measurement/feedback and other interventions to drive improvements in care for patients with acute ischemic syndromes, congestive heart failure and atrial fibrillation (Montague et al. 2003).

Perhaps the most distinguishing feature of ICONS was the broad community involvement of physicians, nurses, pharmacists and patients. This connectedness of the health teams in Nova Scotia created an accountable forum for receipt of practice and outcomes data and stimulation of a Hawthorne effect (White 1993). This phenomenon appears widespread in healthcare. It is probably, at least in part, related to stakeholders caring about the quality of practices and outcomes (White 1993). At the community level in Nova Scotia, that caring, supplemented by measurement and communication, drove continuing improvement in practices and outcomes across the whole province (Montague et al. 2003).

Another successful Canadian example of the partnership-measurement model of disease management is the SCRIP partnership. The SCRIP studies utilized randomized controlled trials and cross-sectional analyses, to demonstrate the value of a community-based collaboration of physicians, pharmacists and patients in improving the care and outcomes for high-risk cardiac patients (Tsuyuki et al. 2002; Olson and Tsuyuki 2003). The SCRIP projects also demonstrated the feasibility of patient identification and recruitment at the pharmacy point-of-care.

Conclusion

In summary, there is a strong evidence base underlying the increasing demand for new drug therapies in our society.

Innovative drugs bring significant and quantifiable value, in clinical and fiscal terms, in the short and long terms. The degree of certainty around best return on dollars spent can be ensured through modern disease management principles,

which foster community buy-in and accountability around appropriate use.

The primary implication for insurers is that optimal drug coverage should reflect the current best evidence for drug use and its impact on population health and fiscal outcomes. From a government's perspective, concern for the economic productivity and well-being of its citizens should embrace the evidence that application and support of innovative products will have positive economic benefits beyond those achieved in the health system alone.

With improved access, improved use and outcomes will follow. We have the knowledge and the tools to make it so. Things can be better!

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