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OPINION

Drug Benefit Program Myths

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Fuzzy Logic

Public drug programs have a rather bizarre context. Government announcements appear to be based on the assumptions that drug prices are too high, pharmaceutical firms profits are excessive, new products usually represent minor improve at inappropriately high prices, and that there are other therapies that provide equally effective care at a lower cost.

Government statements that drug prices are increasing is unclear and misleading. It certainly doesn't refer to current prices of products increasing, so it must refer to other products coming to market and replacing products. If so, it is not really a price increase, it is a replacement price which may include advantages leading it to a preferential place in therapy. Fear mongering rather than information seems to be the purpose based on myths accepted as conventional wisdom.

These assumption are supported by press statements to the effect that drug prices are increasing rapidly, drug expenditures are a threat to sustainability (never defined), are unaffordable (the patient will have to pay for them), and money spent on medication could be better used to fund hospitals and physicians. Rarely is any data provided to support these statements and when data is presented it is questionable.

A good measuring post is the experience in other countries. Most European countries have universal drug benefit programs that cover most drugs (in Canada less than 50% of new drugs are covered), the drug prices are similar, European health outcomes are better and despite covering most new drugs the overall health expenditures are less (Canadian rhetoric is that health care would be unaffordable if we covered more new drugs). In the Organization for Economic Co-operation and Development (OECD) health system ranking, Canada is near the bottom because we do not have a universal drug program, we do not have an integrated health care system and we don't have electronic medical records to measure health outcomes. Why do we think our system is better?

Based on the fuzzy logic of the current public drug benefit programs the following myths need to be examined.

1. Restricted formularies provide better health care than open formularies

Studies in the U.S. with managed care (HMO's) showed that open formularies had better patient outcomes. It makes sense that the more you restrict benefits the more patients will be forced to use medication other than the appropriate product. Drug benefit programs often say that by using an expert committee to choose "better" products, prescribing is improved but there is little evidence that this is the case, we just have constrained prescribing often excluding appropriate products.

2. Old drugs are as good as new drugs

In support of this statement, Canadian evidence cites only one paper and it states that 1 in 10 prescriptions for new drugs could be replaced by an equally effective old drug. Many new drugs are the first in class to treat a disease so there is no old drug. While a lot of old drugs are effective many (especially psychoactive products) have side effects that deter patients from being adherent and thereby are not effective.

3. Deductibles reduce financial barriers and improve patient access to medication

Deductibles force patients to pay full price for medication up to the deductible limit. This places a financial barrier at the beginning of therapy and if the price is seen to be excessive for the family disposable income therapy is not initiated. Based on common sense, the notion that a program to reduce financial barriers should require patients paying full price is dumb. In the insurance industry the use of deductibles is to deter people from making claims. This should not be applicable to health programs where you want people to initiate therapy.

4. Monitoring the price of every product is required to control program costs

Drug programs focus on price and set a reimbursement level for every product, often following negotiations with firms. Overall this creates a large complex data base that takes a lot of resources to monitor and results in

a large number of "corrections". In the past reimbursement was at acquisition cost and pharmacists were required to justify this cost. There is a small spread between maximum allowable cost (MAC) and acquisition cost and the question is whether this amount justifies the resources devoted to squeezing every penny out of the reimbursement system. No evidence has been presented to show that it is worthwhile.

5. Patient input into drug benefit decisions is useful and welcome

The literature on patient input is substantive and conclusive that patient input improves health and health care systems. However, most public drug programs do not have patient input into decisions on drug benefits despite the continuing pressure from advocacy groups. Since drug benefit programs claim to be evidence based they should include patient input as part of the evidence otherwise the systematic exclusion of evidence results in a "bias based" system.

6. All products in a reference based pricing group are equivalent

Products in a reference based pricing arrangement are said to be similar. They usually have the same mechanism of action and similar effectiveness. However, there is a large patient to patient variation in response to medication with the result that an effective response to one product in the group is not proof that the same response would be seen from another product. In the case of enteric coated proton pump inhibitor (PPI) products they form results in a range of release patterns that influence effectiveness. When a drug program claims that the products are all equally effective this is generally true as a guide in initiating therapy but it is not valid in changing therapy. Without head to head studies there is no evidence for "equally effective" therapy.

7. Cost sharing by patients is required for program sustainability

Sustainability is a commonly used term in drug benefit programs that is rarely defined and appears to be

used for fear mongering rather than understanding. Sustainability for a drug program could mean exceeding the drug budget which would lead to the issue of whether there is evidence that the drug budget is appropriate for the needs of the patient. Or, whether it means that the health budget for government would be exceeded to the point where substantive reductions in all services would be necessary. This latter issue is unlikely as drug expenditures in the public sector represent only 8% of the health budget and pharmaceuticals have been growing at a slower rate than other, larger programs such as hospitals and physicians.

8. Cost effective decisions are scientific and based on evidence

Cost effectiveness is usually measured in clinical trials which have a select patient population that does not reflect the population as a whole, particularly the elderly who are on several medications. For the patient population studied the results may be cost effective but this cannot be generalized to other populations, particularly the elderly. Additionally, decisions on benefits should include patient input, if it is missing, there is a gap in the evidence used and the results are bias based rather than evidence based. Finally, only government expenditures are measured ignoring patient expenditure and choice.

9. Programs should have maximum limits

Drug benefit programs, particularly in the private sector, are using expenditure caps either on an annual basis or on a cumulative basis which lead to patients "Maxing out" and no longer entitled to further benefits. This approach is to the benefit of drug programs since patients using expensive or multiple drugs are excluded although they are the ones in greatest need of financial support. Greater use of caps is counterproductive as it reduces health outcomes and denies benefits for the patients most in need.

10. Income based programs are more equitable

Benefits linked to income appear on the surface to be equitable but gross income for an income band is variable in terms of disposable

income. A large family with several chronically ill patients faces not only high drug expense but a variety of other health and social expenditures. Also, income based programs use deductibles to determine the financial contribution of the program. On an annual basis a family would have to pay full price up to the deductible before receiving any assistance. If they have little disposable income they face a major financial barrier; this is not equitable.

11. Pharmaceutical firms are able to afford large price reductions

Research based firms' viability is based on the constant marketing of new products. This requires a large income flow to fund research and to pay dividends to attract investors. The more prices are reduced the less firms can accumulate for funding new products. Innovation has become extremely expensive ($1-2 billion) and requires multi-centre research sites. Regulatory requirements inflate the research costs and growing administrative costs are also a constraint. With governments acting to reduce prices the profitability of firms is declining as is shown by their standing on the stock exchanges. Other areas of health care are becoming more profitable than drugs, such as devices and software. In general, governments' actions in drug benefit programs tend to reduce their contribution to research compared to other payers although they are the major beneficiaries.

12. The input from drug wholesale firms is not important in program decisions

The role of the wholesaler is to make a wide range of products immediately available which enables retailers to stock more products, increase inventory turnover and generate more income. When this role is neglected in drug benefit programs by setting reimbursement levels at the manufacturer level rather than the wholesale level, retailers are forced into dealing with more suppliers and to reduce inventory turnover. The opposite impact occurs when drug programs reimburse on the basis of wholesale price which induces retailers to take on a wholesale function and get reimbursed for it. In both instances there are consequences that need to be examined with the wholesale stakeholder. Recent reductions in

generic prices have had a major impact on drug wholesale firms and this affects the services they provide.

13. Substantial savings in drug expenditures are not offset by other health care costs

Drugs are part of a treatment plan. When the appropriate medication is not available the treatment plan may use less effective medication, more diagnostic tests, more physician visits and most importantly, more hospital services (with long wait times). Some of these factors are considered in cost effectiveness studies but not in drug benefit programs where only the impact on budget is measured. Generally, medication is a less expensive form of therapy and for new drugs the end of patent validity provides a substantial reduction in expense while providing the same level of health value.

14. Product listing agreements reduce drug prices

Product Listing Agreements are often listed as one of the measures to reduce drug prices. In fact, by their very nature they do NOT reduce the price of the drug. The agreement is confidential as to the amount pharmaceutical firms secretly kick back to government in lieu of not publically reducing the price in the marketplace. The money paid to government goes to general revenue not to the drug budget. The result is that government gets more revenue, the drug benefit program lists a drug product which incurs more expenditure increasing budget pressure, and governments then need to initiate more expenditure reduction actions to compensate for the budget increase.

15. All generics are of equal quality

There is a long list of studies showing that the quality of drug products varies from firm to firm. The view that every generic product on the market is of equal or superior quality than the original product is wrong. One can assume that most generics on the market meet compendial standards for disintegration and dissolution but the pattern of release varies and has an impact on patient response. As more research is done on drug absorption and distribution on the body it is clear that the variation is more substantive than generally recognized. An underlying problem with assuming all products

equal is that there will be a variation among patients with different products. To maintain consistent therapeutic results patients should have continuity with one product. Generally the original product has the most continuity as it was first on the market.

16. Administrative costs are not important in drug benefit programs

Savings from changes in drug benefit programs rarely include the increase in administrative costs. It is obvious that a shift to an income based program where the income of every patient must be known is a huge data system that has continual changes and inconsistencies that need to be dealt with requires more resources. Drug benefit programs staffing has increased faster than the increase in drug benefit expenditures.

17. Program changes should link to past practices rather than future options

Public drug programs continue to rely on past practices such as using generic drugs (60 years) and bulk purchasing (40 years). Canadian provinces tend to look at the programs in other provinces for change options rather than best practices. The shift in the market to biologicals and specialty products with a small patient pool no longer respond to old methods. Recent meetings on reimbursement have now declared this as the current situation needing new approaches. Meetings of public drug program administrators to conspire in fixing prices are not a path to better patient care.

18. Best practices are not applicable to drug benefit programs

Use of medication to improve health is linked to best practices. In public drug programs the focus is on budget impact rather than health impact. In public programs there is no measure of health outcomes and no required use of clinical guidelines.

19. Frequent audits of pharmacy billings are required to control costs

Linked to the use of price management of every benefit product is the assessment of billings for excessive prices. Duplication of

medication is also monitored as a measure of excessive use and expense. In each case there is intervention and clarification, a process that demands resources by pharmacies and drug plan managers. All of this is done without assessment of the savings and costs (cost benefit analysis).

20. Patient appeal procedures are open to abuse and increase administrative cost

Some public programs have an appeal mechanism for patients who require medication not on the benefit list. This process normally requires a physicians' input and may or may not have guidelines. Where this process is part of the normal operating procedure there tends to be a large number of appeals. Rather than considering this as an indication of a need for program change, programs initiate measures to minimize the number and nature of appeals on the basis that they are unimportant or frivolous. There is neither transparency nor accountability in hiding appeal processes.

Conclusion

The presentation of these issues as myths is based on the lack of evidence by programs on their procedures and assumptions. While some of the issues have truthful elements, generally there is not enough truth to justify their use as absolutes in patient care. A major problem is that the programs are not transparent or accountable and do not have patient input in to decision making, a key element in have an "evidence based" system.

The U.K. (NICE) has a number of full time staff devoted to assisting patient input to improve decisions. This should be considered as a best practice and utilized in Canadian systems. There is no Canadian evidence to that show that restricting patient input improves care.

Pharmaceuticals represent only 8% of health care costs in the public sector and have been growing at a slower pace than most other programs over the past decade. Major changes in drug programs divert attention from programs having greater financial impact.

The lack of transparency and accountability of drug programs, as well as a lack of performance indicators, should be of more interest to the public than drug prices as they have a major impact on health.