RESEARCH

Delisting of drugs in Ontario

How attitudes and prescribing strategies of family physicians in the Kingston area changed

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OBJECTIVE To assess how attitudes and prescribing strategies of family physicians changed when drugs were delisted from the Ontario Drug Benefit formulary.

DESIGN Mailed, self-administered survey.

SETTING Family physicians' offices in Ontario.

PARTICIPANTS All family physicians practising in the Kingston, Frontenac, Lennox, and Addington Health District.

MAIN OUTCOME MEASURES Physicians were presented with six vignettes involving patients receiving a delisted drug. The choices were to recommend the patient pay for the medication, to substitute a drug still listed on the formulary, to make a special request that the medication be covered for this patient, or to offer another option. As well, the physicians were asked to indicate, on a 5-point Likert scale, their opinions regarding the effect of delisting on themselves and their patients.

RESULTS Physicians were most likely to change to a medication that was still on the formulary. Patient sex and ability to pay were factors in physicians' decisions. Physicians believe that the delistings are not likely to have adversely affected patients' health, that noncompliance is a problem because many once-daily formulations have been removed, that suitable alternatives are not always available, and that physicians should have been consulted more before the changes were made.

CONCLUSIONS Physicians usually substitute listed medications for medications that have been delisted. This is especially true for female patients and patients who are unable to pay.

OBJECTIF Évaluer le changement des attitudes et des stratégies de rédaction des ordonnances chez les médecins de famille lorsque certains médicaments furent radiés de la liste des médicaments assurés par la Régie de l'assurance-maladie de l'Ontario.

CONCEPTION Sondage postal par questionnaire à remplir soi-même.

CONTEXTE Cabinets de médecins de famille de l'Ontario.

PARTICIPANTS Tous les médecins de famille exerçant dans les régions sanitaires de Kingston, Frontenac, Lennox et Addington.

PRINCIPALES MESURES DES RÉSULTATS Présentation aux médecins de six vignettes où les patients recevaient un médicament radié de la liste. Les médecins avaient le choix de recommander au patient de défrayer le coût de sa médication, de substituer pour un médicament encore sur la liste des médicaments assurés, de rédiger une demande spéciale afin que la médication demeure assurée pour ce patient ou d'offrir une autre option. On a également demandé aux médecins d'indiquer, sur l'échelle en 5 points de Likert, leurs opinions concernant les conséquences pour eux-mêmes et leurs patients de la radiation de certains médicaments.

RÉSULTATS Les médecins allaient très probablement substituer pour un médicament encore inscrit sur la liste des médicaments assurés. Le sexe du patient et sa capacité de payer furent des facteurs importants dans la décision du médecin. Les médecins sont d'avis que les radiations de médicaments ne comportent pas nécessairement d'effets négatifs sur la santé du patient, que la non-observance devient un problème parce que beaucoup de médicaments formulés en monodose quotidienne ont été radiés, que les alternatives acceptables ne sont pas toujours disponibles et qu'on aurait dû consulter les médecins avant d'effectuer les changements.

CONCLUSIONS Les médecins vont habituellement substituer les médicaments radiés de la liste par des médicaments encore inscrits. Cette situation s'avère particulièrement vraie dans le cas des femmes et des patients incapables de défrayer les coûts.

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THE ONTARIO MINISTRY OF HEALTH HAS TAKEN steps to control the ever-increasing costs of health care by implementing widespread reforms. These reforms included a critical look at the drugs covered under the formulary of the Ontario Drug Benefit (ODB) program.

The ODB, established in 1974, provides coverage for prescription drugs and several over-the-counter (OTC) drug products to people age 65 and older, home care clients, residents of long-term care facilities, people receiving social assistance, and some people with specific chronic diseases.[1] The ODB covers approximately 2.4 million people and has an annual cost of about $1.2 billion.[2]

In 1990 the Pharmaceutical Inquiry of Ontario (Lowy Inquiry) reported on the accelerating costs of the ODB program. The report estimated that from 1976-1977 to 1988-1989, ODB expenditure increased 313.8%.[3]

In February 1992, the Drug Programs Reform Secretariat was established by the Ministry of Health, with a 2-year mandate to "achieve comprehensive reform of the government's drug program."[1] One of the initiatives of the Drug Programs Reform Secretariat included a review by the Drug Quality and Therapeutics Committee of all remaining OTC products covered by the ODB and extended-release dosage form (ERDF) drugs (ie, drugs that allow at least a twofold reduction in dose frequency as compared with the conventional form). The goal was to ensure that removal of a product would not have a life-threatening impact or increase costs to the program.[2]

In September 1993, Health Minister Ruth Grier announced changes to the ODB program that were estimated to save taxpayers $40 million yearly. As of September 16, 1993, 134 drug products were removed from the formulary, including 94 OTC products and 37 long-acting or ERDF products.[4]

Experience elsewhere

Other health care systems have used drug delisting to control rising health care costs. In 1972 Hammel[5] compared data from states without a drug formulary or with an unrestricted formulary with states with a restrictive formulary. Hammel's data did not indicate any association between using a closed formulary and expenditure reductions.

In 1986 Reilly et al[6] surveyed general practitioners in Scotland regarding their attitudes toward delisting certain medications from the National Health Service formulary. Sixty percent of physicians were against the limited list scheme, and they expressed the opinion that it had been introduced without sufficient consultation with physicians. They also thought it would have undesirable effects on clinical freedom.[6]

In 1984 Smith and McKercher[7] looked at the clinical and economic impact of delisting selected drugs from the Michigan Medicaid benefit program. The study concluded that 46% of patients discontinued therapy, 23% were prescribed an alternative drug (which often cost more than the original drug), and more than 30% continued therapy at their own expense. The economic savings due to the delisting were reported to be a 15% reduction in prescription claims and an annual saving of more than $10 million.[7] Although this study showed lower costs for prescription drugs, it did not address any reciprocal increase in other health care expenditures.

Bloom and Jacobs,[8] in 1985, examined the effects of a closed formulary on Medicaid expenditures for peptic ulcer disease. Data were collected relating to the total Medicaid costs for peptic ulcer treatment before and after the removal of cimetidine from the Medicaid formulary. While this study found that pharmaceutical costs decreased, it also found that monthly physician payments and inpatient hospital costs increased. The authors thought that the small, short-term savings could be negated by increased expenditures later when sicker patients, previously denied peptic ulcer drug treatment, would reenter the Medicaid system in need of expensive hospital treatment.

A large, controlled study by Soumerai and associates[9] in 1990 used a time-series design to

study the effects of the government's ceasing to pay for 12 categories of drugs of questionable efficacy in a random sample of the New Jersey Medicaid population and in four cohorts of regular users of the delisted products.[9] Increased costs due to the use of replacement therapies approximately equalled the savings made from delisting the drugs. An important issue addressed by the study was physician and patient education. The authors suggested that effective drug delisting reforms be accompanied by educational programs for physicians to encourage use of appropriate replacement therapies, if replacements are indicated.

Ferrando et al[10] in 1987 looked at how removing OTC preparations (antacids, antihistamines, cough and cold preparations, and simple analgesics) from the General Medical Services formulary in the Republic of Ireland affected medical and pharmaceutical services use. They reported an association between implementation of delisting and increased prescriptions for retained drugs. Many of the substituted drugs cost more than the ones delisted. The authors concluded that the delisting neither saved as much as initially projected nor improved prescribing habits.

We were unable to find a report of the effects of delisting drugs from a formulary in Canada.

Questions

This study, carried out in the Kingston, Frontenac, Lennox, and Addington (KFLA) Health District, assesses the effects of delisting OTC and ERDF drugs by the ODB program on the stated practices, beliefs, and attitudes of family physicians in the area. More specifically, the study addressed the following questions.

- What alternatives are family physicians choosing when faced with patients receiving drugs that have been delisted?
- Do certain patient or physician factors affect the choices physicians make when faced with patients taking drugs that have been delisted?
- How do family physicians think delisting affects their patients, and what do they think of the process by which delisting was instituted?

METHODS

The survey was carried out between June and August 1994. The study population consisted of all family physicians in the area served by the KFLA Health Unit. Physicians were identified from a list maintained by the KFLA Health Unit that was cross-checked for accuracy using the telephone directory and a list maintained at the Family Medicine Centre of Queen's University. One hundred fifty physicians were identified as being in active full-time or part-time general practice in the study area at the time the study was carried out. The total population of the study area is approximately 166 000 people; of these, 116 000 are located in the greater Kingston area, the tertiary care centre for the region. The remaining people live in towns ranging from a few hundred to 5000 people, or on farms.

The Dillman method,[11] which consists of an initial mailing followed by mailings to nonrespondents 3 and 8 weeks later, was used to maximize the response rate.

The questionnaire consisted of three parts. Part A presented respondents with six vignettes (*Table 1*) involving situations where a decision had to be made about a drug no longer covered by the ODB. The vignettes were chosen based on the two types of medications that had been delisted, namely OTC medications and ERDF medications. Patients' sex and their ability to pay for their own medication were two factors included in the vignettes. Vignettes 1, 2, 5, and 6 had female patients and vignettes 3 and 4 had male patients. Vignettes 2 and 3 represented people who could pay for their medications while vignettes 1, 4, 5, and 6 represented people with limited resources who would likely be perceived as unable to pay for their own medications.

Physicians could choose to recommend that patients stay on the drug and pay for it themselves; to prescribe a different drug, or different formulation of the same drug, that was covered by the ODB; to use a procedure called Section 8

to request, in writing, that the ODB consider paying for the delisted drug for a particular patient; or to offer some other option, which was left open-ended.

Part B of the questionnaire consisted of statements that the physicians were asked to respond to on a 5-point Likert scale indicating their degree of agreement or disagreement with the statement. The statements were designed to determine the physicians' beliefs and attitudes about the effect of the delistings on their practices. Part C collected demographic data on the physicians. Descriptive analysis of the data was done using Epi Info, version 6.[12]

RESULTS

One hundred nine of the 150 family physicians completed the questionnaire for a response rate of 73%. There were proportionally more female physicians in the responder group (40%) than in the nonresponder group (22%). There was no difference in year of graduation, location of practice, or university of graduation between responder and nonresponder groups.

Table 2 shows the characteristics of responding physicians. Female physicians were more likely to be practising part time and to have graduated after 1979.

Table 1. **Vignettes presented to respondents:** *Physicians were asked to make decisions about management.*

VIGNETTE 1
A 67-year-old woman, who has received 120 mg daily of propranolol (Inderal-LA) for 5 years to treat supraventricular tachycardia, comes in for a regular follow-up visit. Her tachycardia is well controlled. Her pulse is 64 and regular. She reports that the pharmacist informed her that the medication was no longer covered by the Ontario Drug Benefit (ODB) program and that she would either have to switch to an alternative that you might recommend or else pay $90 monthly for the drug. She is a widow who lives alone in a poor part of town. The only relative you are aware of is a son who visits occasionally.
VIGNETTE 2
The scenario is the same as vignette 1 except the woman is the wife of a wealthy, retired business man. They go to Florida for the winter each year. They have three children, all of whom are professionals.
VIGNETTE 3
A 70-year-old man who has been taking magaldrate (Riopan) for epigastric distress complains that he now must pay for antacids, as the drug is no longer covered by the government drug plan. He is a retired executive with a good pension.
VIGNETTE 4
A 34-year-old unemployed man has a history of alcoholism, codeine abuse, and a peptic ulcer with a major bleed 2 years ago. He has abstained from alcohol use for 3 months and codeine for a year. He is doing well except that his chronic back pain has flared up again after several months of quiescence. He has tried a heating pad and plain acetaminophen at home with little help. You prescribed acetaminophen and methocarbamol (Robaxacet), forgetting that it is no longer covered by the ODB. The pharmacist calls to say the patient is unable to afford the prescription.
VIGNETTE 5
Your practice, which is located in a poor area of town, includes many people in a low socioeconomic class. A 24-year-old single parent is pregnant for the second time. Your policy is to give pregnant women in your practice multivitamins because of the high likelihood of a poor diet. Multivitamins have been delisted from the ODB formulary.
VIGNETTE 6
A 66-year-old woman with osteoarthritis in her back, knees, hips, and wrists has been fairly well controlled on naproxen (Naprosyn-SR) for about a year. Her supply of medication ran out, and when she went to the pharmacy for refills, she discovered it was no longer covered by ODB. She lives with her husband and receives an old age pension.

How physicians responded as a group to the six vignettes is presented in *Table 3*. Physicians were more likely to choose the option of changing to an alternate drug that is still covered by the ODB formulary. For all six vignettes, this option was chosen a mean of 61% of the time. This choice was significantly more likely if the patient was female ($P < 0.001$), if the patient was perceived as unable to pay ($P < 0.001$), or if the drug in question was an ERDF rather than an OTC medication ($P < 0.001$). Overall, physician characteristics, such as age, sex, location and type of practice, year of graduation, and percentage of practice covered by ODB, did not affect physicians' choices. However, when patients were grouped by their ability to pay, female physicians were more likely to suggest that those better able to pay should pay for their own medications, whereas older physicians were more likely to suggest that those less able to pay should pay for their own medications.

The final part of the questionnaire examined physicians' attitudes and beliefs about the ODB's delisting of drugs (*Table 4*). The 5-point Likert scale was collapsed into three groups with "strongly agree" and "agree" indicating agreement, "strongly disagree" and "disagree" indicating disagreement, and "uncertain" comprising the third group.

Responses suggest that most physicians believe that ODB changes are not resulting in second-class treatment for the poor, nor do they think their patients have been adversely affected. They believe that compliance is lower when a patient has to change from a once daily formulation to a three times daily formulation and also that the government should have consulted more with physicians before deciding which drugs to delist. They do not agree that suitable alternatives are always available, nor do they agree that the ODB currently covers all drugs that are essential. Physicians claim that they infrequently use the Section 8 option, which involves a written physician request to the ODB, and that they write fewer prescriptions since the delistings. They consider pharmacists helpful in making suggestions for alternate medications.

Table 2. **Characteristics of responding physicians (N = 109)**

PHYSICIAN CHARACTERISTICS	%
Male	60
Female	40
CLINICAL LOAD	
Full-time practice	73
Part-time practice	27
PRACTICE TYPE	
Group practice	66
Solo practice	34
PRACTICE LOCATION	
Kingston area	85
Rural	15
TIME IN PRACTICE	
Graduated before 1979	51
Graduated 1979 or later	49
PERCENTAGE OF PRACTICE COVERED BY ODB	
>50	37
≤50	63

DISCUSSION

Responses to the vignettes suggest that physicians, when faced with a situation where a patient's drug has been delisted, are most likely to prescribe a different medication that is still on the formulary. For ERDF drugs, this probably results in a reduced cost to the system; for OTC medications, it could result in a higher cost, although alternatives for many delisted ODB drugs are not approved for the formulary (eg, calcium, multivitamins). Economic analysis of the ODB drug delistings cannot be made from this study, however; whether the expected $40 million annual savings will actually be realized remains to be determined.

Table 3. **Physicians' recommendations about management in the six vignettes (N = 109)**

VIGNETTE SUMMARIES	PHYSICIAN RESPONDENT RECOMMENDATIONS			
	Patient should change to drug covered by ODB (%)	Patient should continue medication and pay for it (%)	Special request to ODB to cover drug cost (%)	Physician chose other treatment (%)
VIGNETTE 1: ERDF drug; woman; unable to pay	90.8	0.0	4.6	4.6
VIGNETTE 2: ERDF drug; woman; able to pay	50.0	32.4	0.0	17.6
VIGNETTE 3: OTC drug; man; able to pay	12.4	81.9	1.0	4.8
VIGNETTE 4: OTC drug; man; unable to pay	57.0	22.4	0.9	19.6
VIGNETTE 5: OTC drug; woman; unable to pay	72.2	7.4	8.3	12.0
VIGNETTE 6: ERDF drug; woman; unable to pay	86.1	1.9	2.8	9.3
MEAN FOR ALL VIGNETTES	61.0	24.1	2.7	5.6

Physicians recommended that patients pay for their medication rather than changing in 24% of cases. However, most of these recommendations were for elderly patients who had ODB coverage and were described as being in a higher socioeconomic class and likely able to afford the medications. Patients perceived as unable to pay were almost always prescribed another drug listed by ODB. Is the delisting creating two classes of coverage or is this just a more equitable distribution of scarce resources?

Family physicians believe that their patients are not being adversely affected. This is probably because they have learned to cope by finding suitable alternatives that are covered by the program. Despite this belief, they express concern that compliance could be impaired, that at times they have difficulty finding an appropriate alternative, and that some drugs they consider essential are not listed in the formulary.

The literature suggests that education programs for both patients and physicians should be a part of any delisting process.[9] The delisting of OTC and ERDF drugs that occurred in the fall of 1993 in Ontario was not combined with an effective education program.

The process by which physicians could be included in future decision making and the type of education programs required is unclear. Perhaps this should be the focus of future study; otherwise education programs that are not based on the needs of physicians and consultation processes will still not be considered satisfactory.

Limitations

It is important to recognize the limitations and weaknesses of this study. It is a survey of physicians' beliefs and attitudes, and it relies on physicians saying what they think they would do in given situations. As well, this study was carried out in a small area of Ontario; although it included physicians from a tertiary care setting as well as rural areas, and although physicians of a variety of ages, different practice types, and both sexes were included, it is impossible to know whether the results can be generalized beyond this population. More than half (52.3%) the physicians in this study believed they were writing fewer prescriptions since the ODB delistings. If this is the case, it

is possible that costs will decrease despite the fact that responses to the vignettes suggest otherwise.

Conclusion

The goal of delisting was to remove coverage of certain products without having a life-threatening impact and simultaneously to reduce cost to the system. It is highly unlikely that the drugs removed would have a life-threatening impact. Physicians in this survey do not see any notable negative effect on patient health. The eventual effect on overall cost will be known only when the Ministry of Health analyzes and reports the full results of the delisting on expenditures. Delisting OTC and ERDF drugs in Ontario could result in patients having to take medications three times daily instead of once, in physicians feeling that the government has once again imposed changes without sufficient consultation, and in a system wherein people who can afford it pay for their own medication. ■

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Table 4. **Responses to statements on attitudes and beliefs**

STATEMENT	AGREE (%)	UNCERTAIN (%)	DISAGREE (%)
Pharmacists are helpful in making suggestions for alternate medications.	78.0	7.3	14.7
Compliance decreases greatly when medications have to be used three times rather than once daily.	82.6	6.4	11.0
Delisting OTC drugs will result in second-class treatment for the poor.	21.1	22.9	56.0
Delisting extended-release medications will result in second-class treatment for the poor.	17.4	19.3	63.3
Equally effective and less expensive drugs are available for delisted extended-release drugs.	13.7	10.1	76.2
Government did not sufficiently consult physicians before delisting medications.	54.1	27.5	18.4
I use the Section 8 option to request payment for delisted drugs I consider necessary for a patient.	12.8	11.0	76.2
The ODB should pay for essential drugs only.	14.9	14.0	71.1
Currently all essential drugs are available under ODB.	32.7	21.5	45.8
When a drug was delisted, suitable alternatives were almost always listed in the formulary.	29.6	21.3	49.1
Delisting of drugs by the ODB has had an adverse effect on the health of my patients.	13.8	27.5	58.7
I write fewer prescriptions since the delistings by ODB.	52.3	19.3	28.4

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