HOW COMPLETE ARE DRUG HISTORY PROFILES THAT ARE BASED ON PUBLIC DRUG BENEFIT CLAIMS?

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ABSTRACT

Background
In Canada, programs are being developed to supply hospital emergency departments and family doctors with electronic access to their patients' drug history profiles. While some of these programs have access to databases that capture information about all out-patient prescriptions that are dispensed to an individual, regardless of payer; others do not, and rely upon claims paid by their provincial drug benefit plans. The completeness of these latter profiles is unknown.

Objectives
To estimate the percentage of Ontario seniors who use private drug insurance (as an indicator of the potential for a 'public' drug history profile to be incomplete) and to describe the kinds of medications for which private insurance is used.

Methods
Cross-sectional time series analysis of Ontario Drug Benefit (ODB) claims and private drug insurance claims for Ontario residents aged 65 years or older (seniors) covering the period January 2000 to December 2005.

Results
During the study period, approximately 95% of Ontario seniors filled at least one prescription paid by the provincial drug benefit plan. By comparison, approximately 15-20% filled a prescription paid by a private insurer. Compared to the 20 drugs most frequently subsidized by the ODB Program (all but one of which had ODB full benefit status), the top privately-purchased drugs were more diverse: 8 had ODB full benefit status; 4 had ODB Limited Use status (which requires that patients meet prespecified clinical criteria for coverage); 3 required individual clinical review (prior authorization) by the ODB Program; and 5 were ODB non-benefits.

Conclusions
Many Ontario seniors are at risk for an incomplete ODB drug history profile. Further research is needed to confirm whether this causes problems for physicians and patients.

Key words: *Drug history profiles, prescription drug insurance, emergency department, drug adverse events*

Concerns about patient safety and drug safety have led to important investments in research and interventions aimed at reducing the incidence of adverse drug events. Older adults, who are more likely to be hospitalized for such events[1], are a primary target of these interventions, including

recent efforts to supply emergency physicians and family doctors with electronic access to patients' drug history profiles. In Canada, several such programs are sponsored by provincial governments and use electronic pharmacy dispensing records as their primary data source.[2-7] While some of these programs have access to databases that capture information about *all* out-patient prescriptions that are dispensed to an individual, regardless of payer;[3-7] others do not, and rely upon claims paid by their provincial drug benefit plans.[2,8] Where public drug plans are comprehensive and clear about the people and drugs they cover, this may not be a problem. If the risk of encountering an incomplete drug profile is small or the drugs that are missing highly predictable, physicians may value access to a partial profile despite its limitations. On the other hand, if information gaps are frequent, large, or highly unpredictable, this could seriously undermine the usefulness of the profiles, or worse, be harmful.

Recently, Ontario's health ministry began providing hospital emergency departments with access to drug history profiles constructed from patients' provincial drug benefit claims.[2] While this was an important step forward[9], we believed that physicians using the profiles could benefit from information about the drugs most likely to be missing from profiles, and how frequently profiles might be incomplete. Accordingly, we set out to answer two questions; 1) what percentage of Ontario seniors use private drug insurance (as an indicator of the potential for an incomplete drug history profile), and 2) for what medications is it used?

METHODS AND CONTEXT

Our study was a cross-sectional time series analysis of Ontario Drug Benefit (ODB) Program claims and private drug insurance claims for Ontario residents covering the period January 2000 to December 2005. Claims for privately-insured drug purchases were obtained from 12 claims administration databases, representing approximately 85% of Ontario's pay-direct private drug insurance business. Subjects were Ontario residents aged 65 years or older (seniors). We focused on seniors because they comprise the majority (70%) of ODB beneficiaries; and because accurate drug histories are frequently difficult to obtain from seniors and therefore are highly valued by emergency physicians.[10] The number of senior claimants appearing in the private claim databases served as an indicator of the number of seniors for whom ODB drug profiles could be missing information. In two of the 12 private plan databases (representing about 30% of beneficiaries), records distinguished between medications that were paid for by the ODB Program and those paid privately. These records were used to describe the types and prevalence of medications that could be absent from a patient's ODB drug profile. Provincial population estimates were obtained from Statistics Canada.[11]

The ODB Program

Drug Coverage

The ODB Program subsidizes over 3,400 medications in three categories: General Benefit; Limited Use; and Section 8.[12] General Benefit drugs are reimbursed for all beneficiaries, without restrictions. Limited Use drugs are reimbursed only for patients who meet certain prespecified clinical criteria. Physicians must confirm that patients meet these criteria by signing a special prescription and entering a number that corresponds to the relevant criterion. Drugs outside these categories are not reimbursed by the province unless requested of the drug plan in writing. Such requests are reviewed by drug plan staff based on clinical criteria set by an expert panel or by an external medical consultant, and a decision regarding reimbursement is reached. This latter process is known as the Individual Clinical Review mechanism or Section 8. As a matter of policy, both 'lifestyle' drugs (e.g., those for erectile dysfunction and weight loss) and drugs that are available over-the-counter are typically not subsidized by the province. We refer to these drugs as having 'non-benefit' status.

Cost Sharing

Throughout the study period the ODB Program required lower-income seniors (those with a net annual income of $16,018 for singles or $24,175 for couples – about 30% of senior beneficiaries) to pay a per-prescription co-payment of $2. All others paid an annual deductible of $100, plus a per-prescription co-payment of $6.11. For those

with private insurance, prescription claims would normally be sent to the ODB Program first and any ineligible or deductible drug costs or co-payments would then be reimbursed by the private plan. Our analysis excluded private claims for ODB co-payments. Though prescriptions dispensed during the deductible period are not paid by the ODB Program, they are recorded in the ODB database to ensure proper tracking of payments toward the annual deductible. For patients who have private insurance, such costs are typically covered by the private plan, resulting in a second, duplicate claim recorded by the private payer. Thus, although purchases toward annual deductibles would normally appear in a patient's ODB drug profile (which is desirable), we left the duplicate private claims for these purchases in the private payer database to illustrate the impact of the deductibles upon the private drug plans.

RESULTS

Between 2000 and 2005, approximately 95% of Ontario seniors filled at least one prescription paid by the provincial drug plan (Table 1). By comparison, 15-20% filled a prescription paid by a private insurer. During this time, the number of ODB claimants grew by approximately 12%, compared to nearly 70% for those with private drug insurance.

The cohort for whom we had valid information about the primary payer grew by about 35% over the study period (Table 2). In recent years, the ratio of pubic-to-private drug claims has remained relatively stable in this group – about 3.8. Table 3 lists their most frequently reimbursed drugs by payer. With the exception of Omeprazole, all of the publicly-paid claims were for drugs with General Benefit status, and most were for the treatment of cardiovascular disease. The 20 most frequently prescribed drugs accounted for about 40% of the group's claims overall. Compared to the publicly-subsidized medications, the top privately-purchased drugs were more diverse: 8 had ODB General Benefit status; 4 had Limited Use status; 3 had Section 8 status; and 5 were Non-benefits (Table 3). Several drugs, namely ASA, Lorazepam, Nitroglycerin, and Atorvastatin (all with General Benefit status) appeared on both lists, reflecting their high prevalence of use. As mentioned, ODB General Benefit products that were present in the private claims database are likely to represent payments towards the ODB annual deductible. Of the 1,383 distinct drug products present in the database, 46% appeared only in the private claims. This group included a broad mix of old and new prescription drugs, as well as a long list of products available without prescription (e.g., cold preparations, gastric acid suppressants, and vitamins and minerals).

TABLE 1 Estimated number and percentage of Ontario seniors using public and private drug insurance by year, 2000-2005

Measure	Year					
	2000	2001	2002	2003	2004	2005
Number of senior residents[1]	1,463,899	1,489,294	1,520,070	1,550,327	1,581,250	1,608,698
Number of ODB program claimants[2] (% of residents)	1,364,167 (93.2)	1,397,849 (93.9)	1,463,403 (96.3)	1,429,949 (92.2)	1,498,156 (94.7)	1,532,388 (95.3)
Number of private drug plan claimants[3] (% of residents, % of ODB claimants)	197,413 (13.5, 14.5)	220,049 (14.8, 15.7)	253,034 (16.6, 17.3)	293,039 (18.9, 20.5)	303,814 (19.2, 20.3)	334,935 (20.8, 21.9)

Sources: 1) Statistics Canada; 2) Ontario Drug Benefit Program Database; 3) Brogan Inc.

TABLE 2 Number of public vs. private drug claims among senior beneficiaries of two private drug plans, 2000-2005

Measure	Year					
	2000	2001	2002	2003	2004	2005
Number of claimants	60,734	66,283	68,296	72,841	79,396	82,467
Number of ODB claims (per claimant)	1,150,404 (18.9)	1,324,414 (20.0)	1,562,130 (22.9)	1,760,274 (24.2)	2,027,103 (25.5)	2,196,447 (26.6)
Number of private claims (per claimant)	352,654 (5.8)	388,335 (5.9)	398,483 (5.8)	448,794 (6.2)	532,263 (6.7)	575,762 (7.0)
Ratio of number of public-to-private claims	3.3	3.4	3.9	3.9	3.8	3.8

TABLE 3 Twenty most frequently reimbursed drugs by payer among senior beneficiaries of two private drug plans, 2000-2005

Payer and Drug	ODB Coverage Status[1]	Mean Annual Number of Claims (per 100 claimants)[2]	Percentage of Payer's Claims
ODB Program			
Levothyroxine	GB	83.2	3.0
Atorvastatin	GB	82.6	3.0
Ramipril	GB	81.5	3.0
Furosemide	GB	78.4	2.9
ASA	GB	66.9	2.4
Acetaminophen-Caffeine-Codeine	GB	63.3	2.3
Hydrochlorothiazide	GB	61.4	2.2
Amlodipine	GB	53.8	2.0
Lorazepam	GB	51.7	1.9
Warfarin	GB	50.5	1.8
Metformin	GB	50.4	1.8
Metoprolol	GB	45.9	1.7
Atenolol	GB	45.9	1.7
Ranitidine	GB	45.0	1.6
Simvastatin	GB	42.4	1.5
Diabetes test strips	GB	42.3	1.5
Glyburide	GB	37.6	1.4
Diltiazem	GB	37.5	1.4
Nitroglycerin	GB	37.2	1.4
Omeprazole	LU	28.4	1.0
Total			39.5
Private Insurers			
ASA	GB	44.2	6.0
Calcium Carbonate	NB	30.5	4.1
Omeprazole	LU	26.5	3.6
Clopidogrel	S8 to LU	22.1	3.0
Potassium Chloride	GB	22.0	3.0
Zopiclone	S8	19.6	2.6

Payer and Drug	ODB Coverage Status[1]	Mean Annual Number of Claims (per 100 claimants)[2]	Percentage of Payer's Claims
Celecoxib	LU	16.4	2.2
Needle/Syringe/Lancet	NB	13.9	1.9
Fluticasone	GB	13.3	1.8
Quinine Sulfate	GB	9.4	1.3
Sildenafil	NB	9.3	1.3
Lorazepam	GB	8.3	1.1
Calcium Carbonate-Vitamin D	NB	8.2	1.1
Mometasone	GB	7.7	1.0
Pantoprazole	LU	7.7	1.0
Nitroglycerin	GB	7.5	1.0
Rosiglitazone	S8	6.9	0.9
Rofecoxib	LU to withdrawal	6.1	0.8
Atorvastatin	GB	4.8	0.6
Vitamin D	NB	4.7	0.6
Total			39.0

[1]GB = General Benefit, LU = Limited Use, S8 = Section 8, NB = Non-benefit [2]Using the number of claimants in 2000 as the denominator

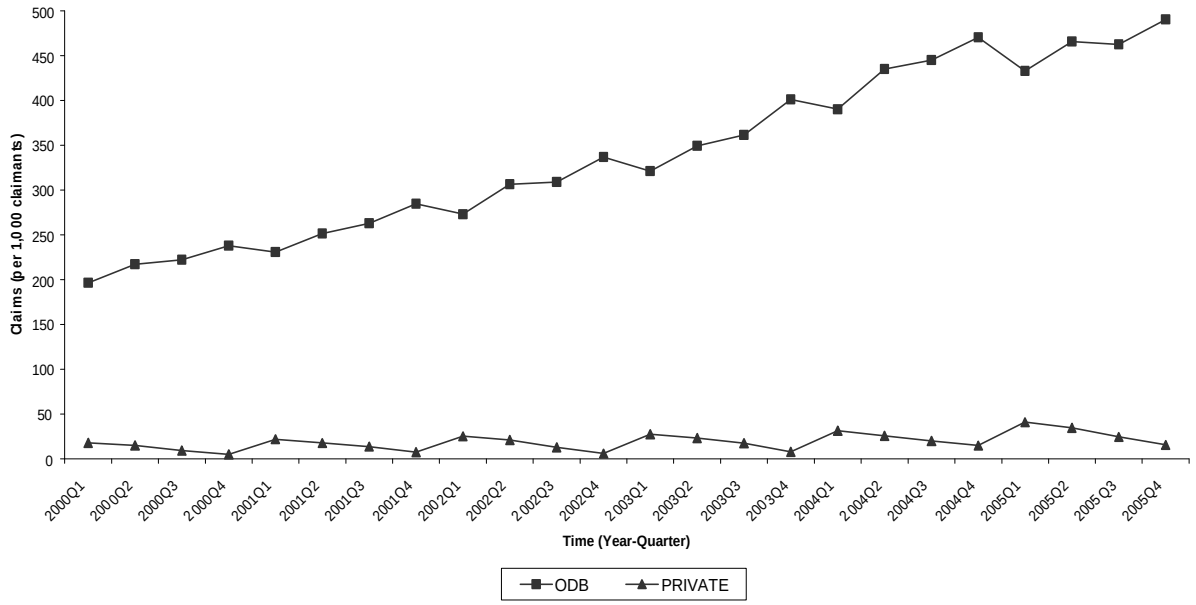
Case Studies

Figures 1-4 show patterns of public and private drug claim activity for prominent drugs within the four ODB coverage categories.

General Benefit Status: Statins (Figure 1)

General Benefit products, such as statins, generate relatively low, predictable levels of private drug plan activity due to payments for ODB deductibles. As such claims are also recorded in the ODB database, these drugs do not present a risk for users of ODB drug profiles.

Figure 1. Public and private drug claim activity for Statins (ODB General Benefit status throughout)



Restricted Access Categories - Limited Use and Section 8: Cyclooxygenase Inhibitors (Figure 2) and Clopidogrel (Figure 3)

Because new drugs are heavily promoted at the time of licensing, delays and restrictions to public coverage can profoundly affect private payers. Many seniors were exposed to these LU and Section 8 products before public reimbursement, but many remained or became private payers despite public coverage. Products with which we have the least experience - new drugs - are represented disproportionately in private drug claims; making it more likely they will be missing from ODB drug profiles.

Non-benefit Status: Erectile dysfunction agents, Orlistat, and the Triptans (Figure 4)

ODB Non-benefit therapies were diverse and had relatively high rates of use among seniors. Access to private insurance may put seniors at increased risk for 'undocumented' exposure to 'lifestyle' drugs, which, like many Section 8 products, can have limited safety data. Non-prescription drugs, such as cold preparations and non-steroidal anti-inflammatory drugs, were also well represented in the private drug claims. These medicines are considered high risk for ADRs.[1] Not knowing whether a particular drug is reimbursable under the public drug plan (i.e., whether it is a Section 8 or a Non-benefit product) makes its presence in an ODB drug profile unpredictable.

Figure 2. Public and private drug claim activity for Cyclooxygenase Inhibitors (which were launched as ODB Limited Use in Q2 2000, except Meloxicam which was General Benefit throughout)

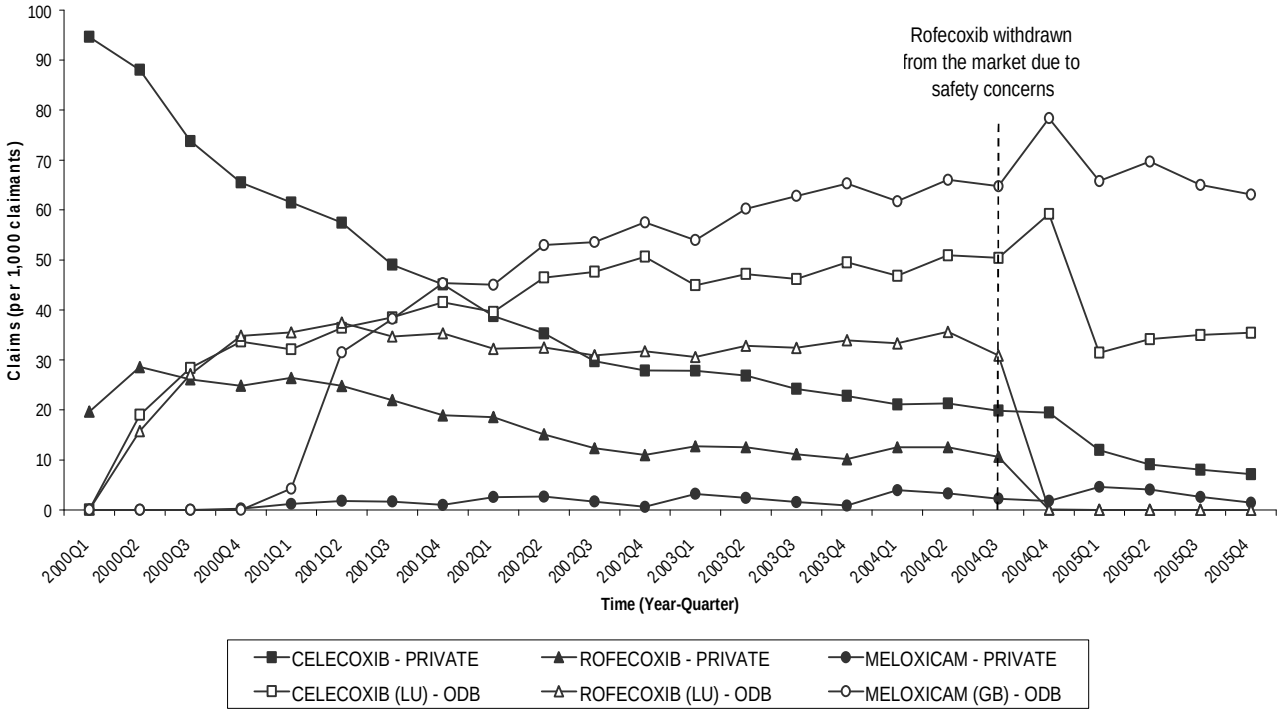


Figure 3. Public and private drug claim activity for Clopidogrel (which was moved from ODB Section 8 to Limited Use in Q3 2003)

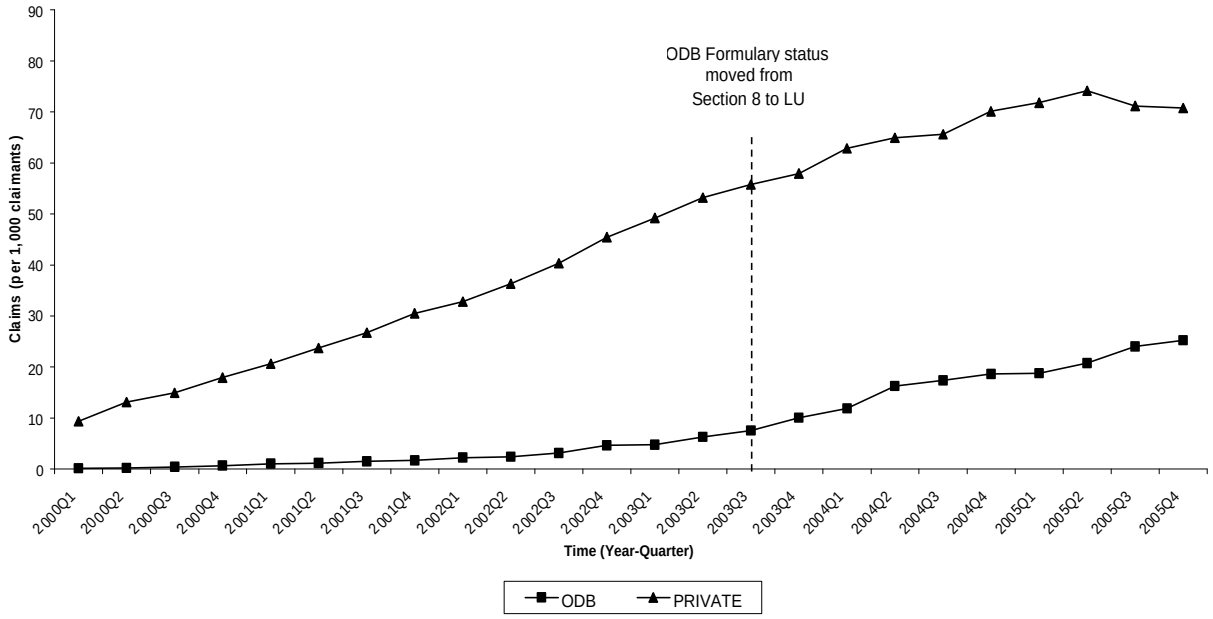
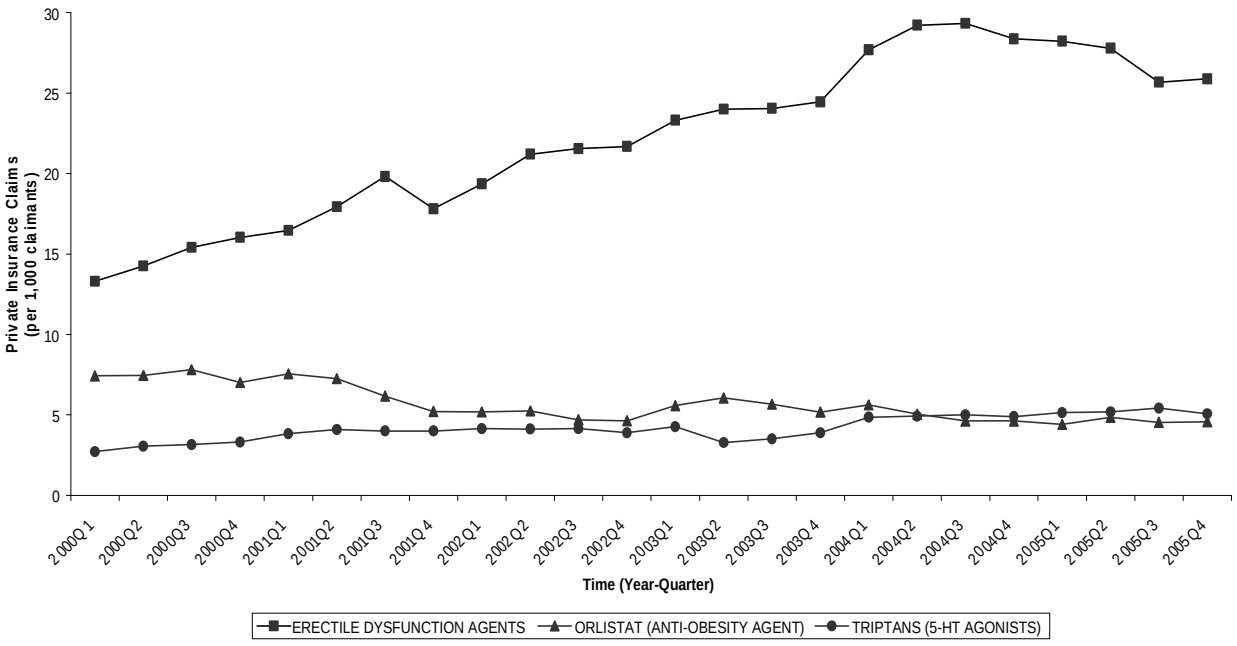


Figure 4. Private drug claim activity for several products with ODB Non-benefit Status (for which no ODB claims were recorded)



DISCUSSION

Our analysis suggests that over one in five Ontario seniors are currently using private drug insurance, and that this number is rising. In addition, products with which we have the least experience - newer therapies with restricted public access - were heavily represented in the private drug claims, making it more likely they would be missing from ODB drug profiles. Though these findings need to be confirmed by other studies, they are important for the physicians and nurses currently using ODB profiles, and may have implications for similar programs in other jurisdictions.[10,13-15]

Study Limitations

Our study has important limitations. Although our data represent an estimated 85% of privately-insured pay-direct drug purchases, not all were captured; and we had no information about out-of-pocket purchases or drugs administered in hospital. Thus, our estimates of potential exposure to an incomplete drug profile are likely to be low. Second, information about payment source for individual prescriptions was available for only a third of subjects; and, beyond demographics, it is not possible to confirm the generalizability of our results. We are reassured, however, that the drugs most frequently used by our subjects are used similarly by Ontario seniors as a whole.[16] Third, and most important, we made no attempt to confirm or validate our assumptions about ODB drug profiles in terms of their actual completeness or accuracy, physicians' perceptions of the usefulness of the profiles, or outcomes; all of which are worth exploring.

Implications

Our findings suggest some possible options for drug profile initiatives that use public drug benefit claims. Although such programs are important, our results show that users need to be reminded that the drug profiles are potentially incomplete, and that non-benefit, new, and restricted drugs are the ones most likely to be missing. In Ontario, access to ODB drug profiles requires a physician's written acknowledgement of the potential for missing information. Not knowing which non-formulary products are subsidized through the province's Individual Clinical Review (Section 8) mechanism may make their presence in a drug profile unpredictable. Reviewing drug profiles with patients to identify missing drugs, while theoretically possible, may be impractical on a routine basis. Granting all drugs General Benefit status would improve the completeness of drug history profiles. However, a preferable option is a database that captures all prescriptions regardless of payer.[3-7] The advantages of such systems extend beyond the potential safety and efficiency gains of drug history profiles to improved coordination of health insurance benefits and better evidence regarding the population-health impacts of drugs and drug formulary policies.[17,18]

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REFERENCES

1. Budnitz DS, Pollock DA, Weidenbach KN, Mendelsohn AB, Schroeder TJ, Annest JL. National surveillance of emergency department visits for outpatient adverse drug events. JAMA 2006;296:1858-66.
2. Ontario Ministry of Health and Long-term Care. Bulletin Number 4424. Emergency department access to drug claims histories of Ontario Drug Benefit Program and Trillium Drug Program recipients. July 4, 2005. Accessed September 19, 2007 at http://www.health.gov.on.ca/english/providers/program/ohip/bulletins/4000/bul4424.pdf.
3. British Columbia Ministry of Health. Emergency Department Access to PharmaNet. Accessed September 19, 2007 at http://www.health.gov.bc.ca/das/emerg.html

4. British Columbia Ministry of Health. Medical Practice Access to PharmaNet. Accessed September 19, 2007 at http://www.health.gov.bc.ca/das/medpract.html
5. Saskatchewan Health. Pharmaceutical Information Program. Accessed September 19, 2007 at http://www.health.gov.sk.ca/pip
6. Alberta Netcare Electronic Health Record. Pharmaceutical Information Network. Accessed September 19, 2007 at http://www.albertanetcare.ca/210.htm
7. Manitoba Government. Manitoba Government News Release. January 30, 1998. Health Information Network Activated at Thompson. Thompson General Joins Pilot Program: Praznik. Accessed September 19, 2007 at http://www.gov.mb.ca/chc/press/top/1998/01/1998-01-30-01.html
8. Tamblyn R, Huang A, Perreault R, et el. The medical office of the 21st century (MOXXI): effectiveness of computerized decision-making support in reducing inappropriate prescribing in primary care. CMAJ 2003;169:549-56.
9. Middlesex Hospital Alliance. Media Release. November 13, 2006. Emergency Departments Connect with Provincial Drug Information. Accessed September 19, 2007 at http://www.mhalliance.on.ca/cms/page_complement/75/MHA_EDs_Connect_with_Provincial_Drug_Information.pdf
10. Gottlieb LK, Stone EM, Stone D, Dunbrack LA, Calladine J. Regulatory and policy barriers to effective clinical data exchange: lessons learned from MedsInfo-ED. Health Aff 2005;24:1197-204.
11. Statistics Canada. Annual Demographic Statistics, 2005. Catalogue no. 91-213-XIB. Accessed July 12, 2006 at http://www.statcan.ca/english/ads/91-213-XPB/index.htm.
12. Ontario Ministry of Health and Long-term Care. Ontario Drug Benefit Formulary/Comparative Drug Index. Accessed January 31, 2007 at http://www.health.gov.on.ca/english/providers/program/drugs/odbf_mn.html
13. Halamka J, Fournier GA. MA-SHARE MedsInfo-ED medication history pilot. Am J Med Qual 2006;21:296-8.
14. Department for Medicaid Services. Medicaid Transformation Grant Proposal: Kentucky Health Information Partnership. Accessed September 19, 2007 at http://www.volunteer-ehealth.org/frisse/docs/Medicaid/KY_1.pdf
15. eHealth Initiative. Emerging Trends and Issues in Health Information Exchange. Selected findings from the eHealth Initiative Foundation's Second Annual Survey of State, Regional and Community-Based Health Information Exchange Initiatives and Organizations, 2005. Accessed September 19, 2007 at http://ccbh.ehealthinitiative.org/assets/documents/2005_HIE_Survey_Results.pdf
16. Ontario Ministry of Health and Long-term Care. ODB Annual Reports for 2000/01-2004/05. Accessed at http://health.gov.on.ca/english/public/pub/ministry_reports/odb_report03/odb_rpt_03_04.pdf
17. Laupacis A, Paterson JM, Mamdani M, Rostom A, Anderson GM. Gaps in the evaluation and monitoring of new pharmaceuticals: proposal for a different approach. CMAJ 2003;169:1167-70.
18. Paterson JM, Laupacis A, Bassett K, Anderson GM. Using pharmacoepidemiology to inform drug coverage policy: initial lessons from a two-province collaborative. Health Aff 2006;25:1436-43.