Results of a national survey on OTC medicines, Part 2: Do pharmacists support switching prescription agents to over-the-counter status?

Lyne Lalonde, BPharm, PhD; Ross T. Tsuyuki, BSc(Pharm), PharmD, MSc; Eric Landry, BSP; Jeff Taylor, BSP, PhD

Introduction

Switching prescribed medications to over- or behind-the-counter status is considered an option to improve accessibility to treatment while insuring appropriate and safe use. For example, in the UK, omeprazole and simvastatin have already been granted over-the-counter (OTC) status, while omeprazole has nonprescription status in the USA.

In Canada, switching prescribed medications to OTC status (Schedule II) can have major implications for pharmacists. The level of care required to ensure safe selection and use may be quite significant. To date, few reports in Canada have dealt with pharmacists' readiness to expand practice in this area. Indeed, some concern has been expressed over the ability of pharmacists to engage in more patient assessment.[1]

In this paper, we explore pharmacists' readiness for switching simvastatin, omeprazole and fluticasone to Schedule II status. We also identify the barriers and facilitators for such a switch.

Methods

The detailed methods for this national survey have been reported previously.[2] Briefly, this was a cross-sectional survey of practising community pharmacists across Canada. Respondents completed a questionnaire covering various aspects of OTC medication. This mail-out survey was conducted using the Dillman method: an advance letter 1 week prior to the main mailing, the mailing of the questionnaire, 2 follow-ups and 1 request for information from nonresponders.

For this part of the survey, pharmacists were asked to consider a Schedule II OTC switch for 3 medications currently available under prescription in Canada: simvastatin for dyslipidemia, omeprazole for heartburn and fluticasone for allergic rhinitis. For each one, they were asked to indicate their level of support to an OTC switch on a 5-point Likert scale ranging from strongly disagree to strongly agree. Those who strongly disagreed or disagreed were asked to state the reason(s) why they would not support a change to Schedule II status. Those who strongly agreed or agreed were asked to state the additional training or working conditions required for them to support such a change. They answered these questions by checking 1 or more options (and adding any not listed in the proposed choices). Response choices were based on previous research[3-5] and experience of the researchers. For those who were unsure, no other questions were asked.

The margin of error was equal to ± 2% when all respondents were considered (*n* = 1764) and ± 7% when the smallest subgroup was considered (*n* = 177), 19 times out of 20.

TABLE 1 Pharmacist agreement with an OTC switch

This agent should be made OTC in Canada, n (%)					
	Strongly disagree	Disagree	Unsure	Agree	Strongly agree
Simvastatin for high cholesterol (n = 1752)	840 (48)	704 (40)	31 (2)	161 (9)	16 (1)
Omeprazole for heartburn (n = 1764)	253 (14)	825 (47)	89 (5)	544 (31)	53 (3)
Fluticasone for allergic rhinitis (n = 1740)	120 (7)	432 (25)	246 (14)	847 (49)	95 (5)

Results

The survey was sent to 5037 pharmacists across Canada. A total of 2305 (46%) were returned and usable. Among those, 1752 (76%), 1764 (76.5%) and 1740 (75.5%) pharmacists completed the question regarding simvastatin, omeprazole and fluticasone, respectively.

The average age of pharmacist respondents was 47 years (SD ± 14 years) and 58% were female. Two-thirds were staff pharmacists and 27% practised in a franchise >1200 square feet, 21% in a chain pharmacy and 21% in an independent pharmacy.

As reported in Table 1, the majority of pharmacists would not support an OTC switch for simvastatin (88%) and omeprazole (61%). In contrast, more pharmacists (54%) would support such a change for fluticasone.

Pharmacists against deregulation reported a mean of 3.1, 2.7 and 2.5 barriers to enacting an OTC switch for simvastatin, omeprazole and fluticasone, respectively. As reported in Table 2, the complexity of disease management was the most prevalent reason to disagree with an OTC switch for each of the 3 drugs; simvastatin (83%), omeprazole (77%) and fluticasone (66%). In addition, the complexity of managing simvastatin and fluticasone was also listed as a main barrier by 62% and 42% of pharmacists, respectively. Other reported barriers for simvastatin included the lack of access to laboratory testing, the required medical follow-up for comorbidities, the potential for drug interactions and the potential negative impact of reducing the number of medical visits.

Pharmacists who were in favour of deregulation reported a mean of 2.6, 1.9 and 1.7 facilitators for simvastatin, omeprazole and fluticasone, respectively. For each of these 3 drugs, additional training on the initial assessment and the monitoring of the condition were considered important by most pharmacists (Table 3). Having access to clinical information, such as laboratory test results,

TABLE 2 Perceived barriers to OTC switch as reported by pharmacists who *Strongly Disagreed* or *Disagreed* with OTC status

Number of times each reason was selected (%)*			
Reason(s)	Simvastatin (n = 1544)	Omeprazole (n = 1078)	Fluticasone (n = 552)
The condition is too complex to manage without medical care	1286 (83)	831 (77)	362 (66)
The drug is too complex to manage without medical care	953 (62)	244 (23)	233 (42)
The potential for liability is higher	567 (37)	236 (22)	118 (21)
A loss of drug plan coverage would occur	558 (36)	446 (41)	186 (34)
Pharmacists are not paid for this task	375 (24)	172 (16)	106 (19)
We don't have the staffing to add this task to our day	328 (21)	134 (12)	77 (14)
Such a move would jeopardize pharmacist-physician relations	230 (15)	67 (6)	67 (12)
A lack of privacy in the pharmacy	95 (6)	50 (5)	26 (5)
Existing OTC agents should be sufficient to control most cases we would see	23 (1)	617 (57)	128 (23)
Other	296 (19)	156 (14)	65 (12)

*Pharmacists could select more than 1 reason.

was reported to be important in order to provide such service.

Discussion

This large national survey shows that pharmacists do not support the deregulation of simvastatin or omeprazole and only moderately support an OTC switch for fluticasone. The complexity of disease and drug management was listed as the main barrier by those who were against such a switch, while additional training on the initial assessment and monitoring of these conditions was deemed necessary by pharmacists who would agree with such legislative change. Access to laboratory test results, liability issues and loss of drug plan coverage were also listed as important issues. Lack of remuneration and the need for a reorganized dispensary floorplan were not perceived by most pharmacists as an important barrier and facilitator, respectively. These findings highlight the complexity of issues surrounding the deregulation of prescribed medications. Clearly, such legislative changes cannot be envisioned without insuring the appropriate support and working environment to provide safe and efficient treatment.

Canadian pharmacists' views on an OTC switch for simvastatin seem to differ from pharmacists in the UK; pharmacists there were more in agreement with a switch. Just after the switch in Great Britain (2004), a survey of 100 community pharmacists revealed that 40% agreed with the deregulation, 36% were unsure and 24% disagreed.[6] However, as in our survey, UK pharmacists were more inclined to consider omeprazole as a welcome OTC addi-

tion.[7] Omeprazole is indicated for self-medication for short-term (14 days) treatment and symptomatic relief of frequent (2 or more days a week) heartburn.[8] In contrast, simvastatin should only be used on a long-term basis. With simvastatin, UK pharmacists had concerns regarding cardiovascular risk assessment, adverse drug reactions and likelihood of patients not committing to therapy.[7] A few years after the switch of simvastatin, the majority of primary care physicians still did not support the supply of OTC simvastatin by community pharmacists.[9] They were particularly concerned by the lack of cholesterol and blood pressure data in cardiovascular disease risk assessment prior to sale. In a recent US survey, community pharmacists indicated highest support for an OTC switch for selected agents within smoking cessation therapy (85%), nasal corticosteroids for allergies (81%) and vaccines (75%). However, they were much less supportive of a switch for statins (42%) and antihypertensives (38%).[10]

TABLE 3 Perceived facilitators to OTC switch as reported by pharmacists who *Strongly Agreed* or *Agreed* with OTC status

Facilitator(s)	Number of times each reason was selected(%)*		
	Simvastatin (*n* = 177)	Omeprazole (*n* = 597)	Fluticasone (*n* = 942)
More training on the drug	40 (23)	83 (14)	216 (23)
More training on initially assessing the condition	103 (58)	381 (64)	658 (70)
More training on monitoring the condition	106 (60)	351 (59)	518 (55)
Changes to dispensary floorplan	13 (7)	72 (12)	82 (9)
Changes to pharmacy staffing	20 (11)	45 (8)	78 (8)
Access to information such as lab values	156 (88)	115 (19)	55 (6)
Other	26 (15)	53 (9)	61 (6)

*Pharmacists could select more than 1 facilitator.

POINTS CLÉS 🔑

- Les pharmaciens ne sont pas en faveur de la déréglementation de la simvastatine ou de l'oméprazole et ne sont que modérément en faveur de la mise en vente libre du fluticasone.
- La complexité de la maladie et de la prise en charge pharmaceutique a été citée comme principal motif d'opposition à la mise en vente libre.
- On estime qu'une formation supplémentaire serait nécessaire pour faciliter le reclassement du produit parmi les médicaments en vente libre.
- Parmi les autres questions soulevées, mentionnons l'accès aux résultats d'analyses de laboratoire, les questions de responsabilité et le retrait du régime d'assurance-médicaments.

These results suggest that pharmacists do not consider these particular OTC switches to be a valuable alternative for improving the management of chronic conditions. In fact, ensuring optimal management of chronic conditions is complex and requires long-term engagement[11]; adherence to and persistence with pharmacotherapy are generally low and convincing people to adopt and maintain a healthy lifestyle is very challenging.[12-17] In addition, other alternatives exist to improve both the accessibility and quality of care, including the provision of prescription privileges to pharmacists, the use of individual prescriptions with dosage adjustments by pharmacists, as well as collective prescriptions (as applied in Quebec). On the other hand, a majority of pharmacists would welcome OTC switches for non-chronic conditions that are relatively easy to self-diagnose, often require little or no follow-up, and whose medications have low potential for harm.

To optimize OTC medication use, the majority of pharmacists reported the need for additional training, including appropriate clinical tools. In the Blenkinsopp et al. survey, all respondents agreed there should be a protocol and guidelines in place for the supply of OTC statins.[6] Nearly all agreed that training would be an integral part of a successful switch. In a survey by Stewart et al., most responders disagreed that the education they received failed to meet their needs for OTC simvastatin and omeprazole.[7] In follow-up work, 60.7% of those reported having a protocol in place for the sale of omeprazole.[18] In Quebec, the TEAM study has showed that after a short period of training,[19] community pharmacists can effectively and safely monitor and adjust statin dosage.[20] However, a lack of time was perceived as a major barrier to the provision of such services in current pharmacy practice.[21]

Limitations

Although the response rate was relatively high for this survey, about one-quarter of those surveyed did not answer the questions regarding OTC switches. There may have been some respondent bias, selecting those who are most interested in OTC medications. As for any survey, social desirability bias may have influenced the results.

More importantly, our survey questions were very general. We did not underline the conditions regulating the OTC sale (e.g., target patient population, treatment duration and dosage). For perspective, in the UK, OTC simvastatin is for the 10 mg strength only and sales are restricted to individuals who are at least at moderate cardiovascular risk. Having stated these conditions may have changed the results.

Conclusion

Under the current practice conditions, most Canadian pharmacists do not support the switch of these 3 prescribed medications to OTC status (Schedule II status), particularly for a chronic condition like dyslipidemia. Before implementing such legislative changes, successful conditions would need to be put in place, including appropriate training, access to laboratory tests and drug plan coverage for patients. ∎

From the Faculty of Pharmacy, Université de Montréal (Lalonde), Montreal, Quebec; the COMPRIS/EPICORE Centre (Tsuyuki), Faculty of Medicine and Dentistry, University of Alberta, Edmonton, Alberta; and the College of Pharmacy and Nutrition (Landry, Taylor), University of Saskatchewan, Saskatoon, Saskatchewan. Contact lyne.lalonde@umontreal.ca.

References

1. Taylor J, Berger B, Anderson-Harper H, Grimley D. Pharmacists' readiness to assess consumers' over-the-counter product selections. *J Am Pharm Assoc* (Wash) 2000;40:487-94.

2. Taylor J, Landry E, Lalonde L, Tsuyuki RT. Results of a national survey on over-the-counter medicines, Part 1: Pharmacist opinion on current scheduling status. *Can Pharm J* 2012;145:40-4.

3. Madhaven S. Factors influencing pharmacists' preference for the legal classification of Rx-to-OTC switched drug products. *J Clin Pharm Ther* 1993;18:281-90.

4. Shefcheck SL, Thomas J. Consumers' perceptions of access to medications and attitudes toward regulatory options. *J Soc Adm Pharm* 1998;15:149-63.

5. Isacson D, Bingefors C. On Rx switches and access to over-the-counter drugs in Sweden. *J Soc Adm Pharm* 1999;16:13-25.

6. Blenkinsopp J, Gathoga L, O'Connell K, et al. OTC simvastatin supply: what changes in practice and education do pharmacists want? *Pharm J* 2004;273(7311):191-3.

7. Stewart D, John D, Cunningham S, et al. A comparison of community pharmacists' views of over-the-counter omeprazole and simvastatin. *Pharmacoepidemiol Drug Saf* 2007;16:1290-7.

8. Prilosec OTC monograph. Available: www.accessdata.fda.gov (accessed June 2010).

9. Stewart D, Cunningham IT, Hansford D, et al. General practitioners' views and experiences of over-the-counter simvastatin in Scotland. *Br J Clin Pharmacol* 2010;70:356-9.

10. Hunt TL, Culbertson VL, Erramouspe J, Casperson K. Perceptions of practicing pharmacists in Idaho about a potential behind-the-counter drug program. *Ann Pharmacother* 2010;44:1403-9.

11. Tsai AC, Morton SC, Keeler EB. A meta-analysis of interventions to improve chronic illness care. A RAND Health Program; 2005. Available: www.rand.org/pubs/working_papers/ WR290.html (accessed July 13, 2010).

12. Avorn J, Monette J, Lacour A, et al. Persistence of use of lipid-lowering medications. A cross-national study. *JAMA* 1998;279:1458-62.

13. Morell RW, Park DC, Kidder DP, Martin M. Adherence to antihypertensive therapy medications across life span. *Gerontologist* 1997;37:609-19.

14. Joffres MR, Ghadirian P, Fodor JG, et al. Awareness, treatment, and control of hypertension in Canada. *Am J Hypertens* 1997;10(10 Pt 1):1097-102.

15. Jackevicius CA, Mamdani M, Tu JV. Adherence with statin therapy in elderly patients with and without acute coronary syndromes. *JAMA* 2002;288:462-7.

16. Barham AH, Goff DC Jr., Chen H, et al. Appropriateness of cholesterol management in primary care by sex and level of cardiovascular risk. *Prev Cardiol* 2009;12:95-101.

17. Hackam DG, Leiter LA, Yan AT, et al. Missed opportunities for the secondary prevention of cardiovascular disease in Canada. *Can J Cardiol* 2007;23:1124-30.

18. McCaig D, Hansford D, John D, et al. Reclassification of omeprazole: a survey of community early experiences and views. *Int J Pharm Pract* 2008;16:23-8.

19. Villeneuve J, Lamarre D, Lussier MT, et al. Physician-pharmacist collaborative care for dyslipidemia patients: knowledge and skills of community pharmacists. *J Contin Educ Health Prof* 2009;29:201-8.

20. Villeneuve J, Genest J, Blais L, et al. A cluster randomized controlled Trial to Evaluate an Ambulatory primary care Management program for patients with dyslipidemia: the TEAM study. *CMAJ* 2010;182:447-55.

21. Lalonde L, Hudon E, Goudreau J, et al. Physician-pharmacist collaborative care in dyslipidemia management: the perception of clinicians and patients. *Res Social Adm Pharm* 2011;7:233-45.