

Is non-prescription oseltamivir availability under strict criteria workable? A qualitative study in New Zealand

Natalie Gauld^{1*}, Fiona Kelly² and John Shaw²

¹Department of General Practice and Primary Healthcare, University of Auckland, Private Bag 92019, Auckland Mail Centre, New Zealand;

²School of Pharmacy, University of Auckland, Private Bag 92019, Auckland Mail Centre, New Zealand

*Corresponding author. Department of General Practice and Primary Healthcare, University of Auckland, Private Bag 92019, Auckland Mail Centre, Auckland 1142, New Zealand. Tel: +64-9-9239340; E-mail: n.gauld@auckland.ac.nz

Received 20 May 2010; returned 19 July 2010; revised 16 September 2010; accepted 6 October 2010

Objectives: In 2007, New Zealand became the first country to make oseltamivir (Tamiflu®) available off prescription. Strict rules for supply were developed to ensure that potential public health benefits were balanced against possible risks. We wished to explore the success of implementing this unique decision through elucidating pharmacists' attitudes to and experiences of non-prescription supply of oseltamivir.

Methods: Semi-structured interviews with a maximum variation sample of 26 community pharmacists were conducted and analysed using a framework approach.

Results: Most participants were positive about non-prescription availability of oseltamivir with the majority appearing to apply the rules successfully. However, some rules were difficult to recall and/or frustrating. Supply did not appear to be driven by potential for commercial gain and the inappropriate requests were manageable. Some of these were driven by other health professionals. Pharmacists valued the manufacturer-supplied 'Pharmacist Protocol' and 'Consultation Record' and kept them ready for use. Certain rules potentially restricted consumer access and pharmacists were generally conservative about recommending the medicine.

Conclusions: While pharmacists welcomed non-prescription oseltamivir, the rules for supply frustrated pharmacists and limited potential public health benefits. If medicines are reclassified with various rules of supply, multiple reminders of the rules for supply to pharmacists and other health professionals are desirable along with the rationale for such rules. Protocols and/or consultation pads for use at time of supply are likely to be valued and are an important aid where there is a risk of faulty recall of rules. Research in the first year of availability may highlight issues to address.

Keywords: non-prescription drugs, pharmacists, self-medication, human influenza

Introduction

Antimicrobials are part of the move for reclassification from prescription to non-prescription availability,¹ e.g. azithromycin and chloramphenicol in the UK.²

Neuraminidase inhibitors have been mooted for reclassification in the UK.³ However, New Zealand (NZ) was the first country to reclassify these medicines in 2007.⁴ Concerns including potential misdiagnosis, raised resistance and internet sales were uniquely addressed through an exemption to prescription availability under set rules (Table 1), which included pharmacist-only supply and the influenza sufferer to present in person.⁴ Roche supplied an educational pack to community pharmacies.

Little research has been done to establish what happens to antimicrobial supply after reclassification and whether non-prescription supply criteria successfully address existing

concerns.⁵ The main aim of this research was to elucidate how non-prescription supply of oseltamivir under specific rules worked in practice and whether improvements were necessary.

Methods

Following ethics approval (MEC/07/59/EXP) and with informed consent, N. G. interviewed pharmacists during October 2007. The maximum variation sample was purposively selected for diversity of pharmacy or pharmacist attributes, from a list of all 903 NZ community pharmacies. Pharmacy attributes considered included size, dispensing/retail mix, socio-economic area, ownership and geographical location. Pharmacist attributes considered included age, gender, ethnicity, job title and experience. The pharmacists received a NZ\$50 (~UK£20) honorarium.

Eleven pharmacies were selected from high socio-economic or central business district locations (where supply was indicated to be more likely)

as a primary aim was to gain information on pharmacist experience of non-prescription provision and requests.

Interviewing was 'iterative' with earlier interviews shaping ongoing data collection.⁶ Content of the semi-structured interviews included opinions and recall of the non-prescription availability of oseltamivir, use of educational and consultation material and experiences during consultations. Interviewing finished when data saturation had occurred and no new themes emerged.

Verbatim transcripts were read repeatedly by two authors who separately coded them with NVIVO version 7 using a framework approach.⁶ The authors discussed content and emerging themes on multiple occasions. Constant comparison was used to look for similarities and differences in the data.⁶

The interviewer took a neutral approach in the interviews, asking open questions and prompting if necessary for a variety of opinions. She used reflexive bracketing in her analysis,⁷ and analysis by the second author helped manage the possible perception of researcher bias.⁶

Results

Participants

Twenty-six pharmacists were interviewed by telephone (n=22) or face to face (n=4) for 20–35 min. One participant declined audiotaping and interview notes were taken. Sample characteristics are provided in Table 2.

Awareness of oseltamivir availability

All participants were aware of oseltamivir non-prescription availability, although two had been unaware early in the season.

All participants had seen at least part of the educational pack. The protocol and/or consultation pads were valued and used during most oseltamivir supplies. Other sources of education were used by seven pharmacists.

Supply of oseltamivir

Fourteen pharmacists supplied non-prescription oseltamivir in 2007 (usually one or two packs). Non-supply resulted from lack

of recommendation by pharmacists, lack of requests, rules preventing supply, a mild influenza season and pharmacists' perceptions of affordability for some consumers.

Pharmacists who considered that oseltamivir was beneficial, would definitely take it themselves and who had higher socio-economic clientele supplied most oseltamivir. However, few were proactive in looking for influenza or informing pharmacy assistants about oseltamivir. The most proactive pharmacist had used oseltamivir personally and her 10 sales were from recommendation not request. Her pharmacy was small, with one pharmacy assistant, which may have assisted the pharmacist to overhear conversations and intervene.

High non-prescription sales in another pharmacy (n=40) were primarily driven by the referral to the pharmacy of people about to travel, by nearby doctors. Prescription supplies of oseltamivir were also reported to be usually in advance of need, mainly for people travelling in 2007 and due to the avian influenza threat in 2006.

Pharmacists who supplied oseltamivir recalled presenting symptoms, particularly fever, lethargy, sudden onset and sometimes cough. Several mentioned previous contact with an influenza sufferer.

Opinions of oseltamivir non-prescription availability

Pharmacists were usually positive about non-prescription availability of oseltamivir, although many were frustrated by the rules of supply.

Two older male pharmacy owners preferred not to supply—one due to perceptions around effectiveness and affordability for those who needed it most. The second preferred people to visit the nearby walk-in doctor clinic for diagnosis. A young female pharmacist was ambivalent on cost and effectiveness grounds, despite previously having oseltamivir prescribed at her request. These pharmacists did not supply non-prescription oseltamivir.

Table 1. Recall, opinion of, and compliance with requirements for supply

Requirement		Recall	Opinion	Excursions reported
Pharmacist sale Between May and September inclusive		all aware	no disagreement	none
		high recall of seasonality (one unaware); difficulty with recalling exact dates	minority wanted change due to date confusion, potential late influenza season and travellers from northern hemisphere	one supply possibly in October
Treatment of seasonal influenza		very high awareness	some wanted availability in advance of need, e.g. for travellers, rural people, household contacts	supplies from one pharmacy in advance of need (travellers) on doctor referral
≥12 years of age		recall difficulties, but no risk of inadvertent sales to <12-year-olds	no disagreement	none
Presenting in a pharmacy with early symptoms of influenza		very high awareness; one unaware, another unsure; one thought oseltamivir could be used up to 72 h after symptom onset	almost all wanted this changed to allow the sufferer to stay at home	none

Table 2. Pharmacist and pharmacy characteristics

No.	Job title	Years of experience	Gender	Pharmacy location ^a	Clientele socio-economic status ^b	Oseltamivir packs supplied from the pharmacy
20	owner	11–15	M	CBD	middle to high	2 OTC; 1 Rx
7	owner	21–25	M	suburban city	higher middle	40 OTC; 13 Rx
24	owner	21–25	M	suburban city	mixed	2 OTC; 4 Rx
10	owner	>30	F	suburban city	low	2 OTC; ~2 Rx
6	owner	>30	F	inner city suburb	high	~10 OTC; 0 Rx
13	owner	>30	M	city mall	high	~6 OTC; ~9–14 Rx
26	owner	11–15	F	centre city mall	high	1 OTC; 1 Rx
22	owner	16–20	M	city mall	mixed	3 OTC; unknown Rx
8	owner	26–30	M	CBD	high	2 OTC; 2 Rx
25	owner	26–30	M	rural	middle	0 OTC; 1 Rx
12	owner	>30	M	suburban city	middle	0 OTC; 1–2 Rx
21	owner/part-timer	>30	F	rural	low	0 OTC; 0 Rx
3	manager	≤5	M	city mall	middle	1 OTC; 1 Rx
18	manager	6–10	F	CBD	middle to high	9 OTC; 2 Rx
15	manager	≤5	F	CBD	high	6 OTC; ~2–4 Rx
5	manager	≤5	F	suburban city	low	1 OTC; ~1 or 2 Rx
9	manager	≤5	F	rural town	middle	3 OTC; 2 Rx
1	manager	6–10	F	CBD	mixed	0 OTC; 0 Rx
4	employee	≤5	F	inner city suburb	mixed	6 OTC; 0 Rx
16	employee	≤5	F	tourist town	middle to high	0 OTC; unknown Rx
17	employee	≤5	F	town	mixed	0 OTC; 0 Rx
23	part-timer	11–15	F	tourist town	higher	unknown
19	part-timer	11–15	F	inner city	mixed	2 OTC; small number Rx
11	part-timer	21–25	F	rural town	middle	0 OTC; 0 Rx
14	locum	>30	F	suburban city	low/mixed	NA locum
2	locum	≤5	M	suburban city	middle	NA locum

M, male; F, female; OTC, over the counter, supplies without a prescription; Rx, prescription supplies; NA, not applicable; CBD, central business district.

^aAuthors' descriptors.

^bAccording to participant.

Criteria for non-prescription supply of oseltamivir

Nearly all interviewees considered that rules for supply had been communicated well, but recall varied. Most pharmacists disagreed with aspects of the rules (Table 1). Recall may be overstated where information was reviewed for the interview.

Many pharmacists wanted supply allowed to a third party on behalf of the sufferer (usually with telephone contact) to help the patient and reduce transmission. Illustrating the difficulty of presenting in person, two interviewees were bedridden with influenza in 2007. Despite both being positive about oseltamivir and having sold it, one did not access oseltamivir, and the other had delayed access. Another pharmacist did a home visit then persuaded the sufferer to visit the pharmacy to enable legal supply.

'I cannot see why it cannot be done on the telephone. Having had a bad dose of the flu you just want to go home to bed and die. So the very last thing you want to do is...get out of bed and get down to the local pharmacy and cough and splutter over the pharmacist to prove that you've actually got the flu.' (Interview 13—a male owner of a suburban pharmacy.)

Some pharmacists wanted to be able to sell in advance of need, e.g. to a household contact or travellers. While a few were concerned about inappropriate use for colds or the

potential for missing a serious condition, a couple of pharmacists noted that the risk was no greater than the currently occurring advance prescribing by doctors.

Implementation of the requirements for non-prescription supply

The majority reported requests for oseltamivir outside of the rules, primarily in advance of need (e.g. for travel or stockpiling for avian influenza) or for likely cold symptoms. While there was occasional consumer pressure, usually the refusal to supply was reported to be handled well by the consumer.

Doctors referred people to buy oseltamivir outside of the rules, including in advance of need and purchase outside the season. One interviewee reported an inappropriate supply by a recently qualified pharmacist colleague under considerable pressure by another health professional.

Discussion

This reclassification was intended to improve timely access to oseltamivir, while minimizing risk through specific non-prescription rules.

We found little reported pharmacist-driven or consumer-driven overuse or inappropriate use, achieving the aim to minimize risk. Like other research on reclassified medicines,⁸ we found that educational material and protocols are utilized by pharmacists. This supports the recommendation for protocols by the working party report on antibacterials for reclassification.¹

Seemingly inappropriate supplies to people without influenza occurred in one pharmacy on doctor referral. Multiple communications to health professionals on the rules of supply are recommended. Including the rationale might mitigate pharmacists' frustration.

Some rules caused non-provision of oseltamivir to people with likely influenza. Presentation of the sufferer in the pharmacy is incongruous with public health advice to stay at home. Self-management of influenza is common in NZ,⁹ and a telephone consultation with a pharmacist for oseltamivir may provide a useful triage that would not otherwise occur. Reconsideration of this rule occurred in 2009 allowing non-prescription supply without presentation in the pharmacy.¹⁰

Potential for misdiagnosis was an important reclassification concern.⁴ Few participants expressed concerns about misdiagnosis, even when prompted, possibly because they are used to cold and influenza consultations, because they updated themselves and/or because they saw greater risk with advance prescribing of oseltamivir by doctors. Perhaps pharmacy needs to become more diagnosis based.

The commercial environment of a community pharmacy did not appear to detract from the professional role, in fact cost concerns prevented some recommendations. While many participants did not supply oseltamivir, this was typical of community pharmacy non-prescription oseltamivir supplies in NZ in 2007 (S. Knight, Roche Products New Zealand Ltd, personal communication, 14 November 2007).

The potential benefits to public health—enabling faster access to oseltamivir and minimizing transmission in doctors' waiting rooms—have not yet been realized, with generally low uptake. Further public health benefits may come in time and pharmacy could also play a greater role in this area through provision of influenza vaccination.

Strengths and limitations of the research

The interviews were conducted with a well-diversified sample and allowed areas to be explored in depth.

Advance notice of the interview allowed revision. Our research showed recall problems of the rules despite some revising, but inadvertent inappropriate supply would usually be avoided with the protocol or consultation pad.

We relied on self-reporting. Pharmacists were assured of confidentiality and encouraged to provide whatever opinion they had. There was no personal gain in omitting information or being misleading.

Recall errors were minimized by collecting data just after the first season; additionally oseltamivir consultations were new for pharmacists and few in number so probably memorable. Participants commonly confirmed prescription and non-prescription sales data on the computer.

Further research after multiple seasons of oseltamivir non-prescription availability, and consumer research are desirable and mystery shopping at pharmacies may be useful.

Conclusions and implications

Despite pharmacists being positive about non-prescription oseltamivir availability and educating themselves, the goal of increasing early access to this medicine has not yet been realized. The rules of supply appeared to address the reclassification concerns, and overuse was not a problem. Exemption to prescription sale under defined circumstances is workable with provision of protocols.

When medicines are reclassified with special requirements research is necessary to find out whether these rules work.

Acknowledgements

The involvement of the participants is appreciated.

Funding

This work was supported by Roche Products New Zealand Limited.

Transparency declarations

N. G. received funding to attend conferences from Roche Products New Zealand Limited in 2008. The other two authors have nothing to declare.

Author contributions

The idea for the research came from the authors, who were all involved in planning and reporting. N. G. and F. K. prepared the interview guide and performed analysis and N. G. collected the data.

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