

ORIGINAL ARTICLE

Factors predicting the guideline compliant supply (or non-supply) of non-prescription medicines in the community pharmacy setting

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Background: The reclassification of prescription only medicines to pharmacy and general sales list medicines (also known as non-prescription medicines) provides the public with greater access to medicines that they can purchase for self-care. There is evidence that non-prescription medicines may be associated with inappropriate supply. This study investigated factors predicting evidence-based (guideline compliant) supply or non-supply of non-prescription medicines.

Method: Secondary analysis of results from a randomised controlled trial of educational interventions to promote the evidence based supply of non-prescription medicines. Ten actors made simulated patient (customer) visits to 60 community pharmacies using seven scenarios reflecting different types of presentations. The dependent variable was appropriate (guideline compliant) supply of antifungal medication for treatment of vaginal candidiasis.

Results: No significant association was shown between guideline compliant behaviour and pharmacy type or location, or with the actor making the visit. The likelihood of guideline compliant outcome was significantly greater with symptom presentations than with condition or product presentations ($p < 0.001$). The likelihood of a guideline compliant outcome increased (a) as more information was exchanged ($p < 0.001$), (b) with the use of WWHAM (a mnemonic frequently used by medicine counter assistants during consultations for non-prescription medicines) ($p < 0.001$); (c) when specific WWHAM questions were used (including “description of symptoms” ($p < 0.001$) and “whether other medication was currently being used” ($p < 0.001$); and (d) in consultations involving solely pharmacists compared with those involving only medicine counter assistants ($p = 0.017$). After adjustment for presentation type, a significant association persisted between appropriate outcome and consultations with WWHAM scores of 2 and ≥ 3 , respectively.

Conclusions: The nature and extent of information exchange between pharmacy staff and customers has a strong influence on the guideline compliant supply of non-prescription medicines. Future interventions to promote the safe and effective use of non-prescription medicines should address the apparent deficit in communication between pharmacy staff in general, and medicine counter assistants in particular, which may reflect both pharmacy staff skills and customer expectations.

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Burgeoning healthcare costs are of worldwide concern. Expenditure on medication in particular is increasing at an unsustainable rate. One strategy adopted by many governments, including the UK, has been the reclassification of medicines originally available only on prescription to legal categories that enable them to be purchased from community pharmacies (pharmacy-only medicines) and from other retail outlets (General Sales List items), thus removing them from national medicine budgets. Reclassification has resulted in medicines of increasing potency becoming available for purchase, including antifungal agents for vaginal candidiasis, H₂-receptor antagonists and proton pump inhibitors and, more recently, statins (in the UK).¹

There are concerns regarding the risks associated with the public's enhanced access to these medicines, as well as with the ability of community pharmacy staff to ensure the safe, effective, and evidence-based supply of reclassified medicines.^{2–5} The inappropriate supply of non-prescription medicines has many implications including misdiagnosis, delayed access to correct treatment, and adverse drug reactions.⁶ It is therefore important to ensure the appropriate supply of these medicines.

Between 2000 and 2001 a randomised controlled trial was conducted in 60 community pharmacies from Grampian,

Scotland to compare the effectiveness and efficiency of two educational strategies as methods of improving the appropriate (guideline compliant) supply of antifungal medicines for the treatment of vaginal candidiasis.⁷ The outcome measure (appropriateness of sale or no sale) was derived using pre- and post-intervention visits from simulated patients (actors) who performed scenarios in each of the participating pharmacies. The training of the actors is presented fully elsewhere.⁸ No statistically significant effect was shown with either intervention, either singly or combined. Possible barriers to the evidence-based supply of non-prescription medicines from community pharmacies were investigated in a qualitative study.⁹ Suboptimal communication was identified as one of the most important barriers to this activity.

The purpose of the study presented here was to conduct a secondary analysis of the data derived from the randomised controlled trial to identify variables predictive of guideline compliant supply (or non-supply) of an antifungal for the treatment of vaginal candidiasis. This was an exploratory study which aimed to maximise the issues that could be investigated from an existing data set.

The objective of this study was to determine whether the following factors were associated with appropriate outcome:

(1) consultation (scenario) characteristics; (2) pharmacy characteristics; and (3) customer characteristics.

METHODS

The randomised controlled trial from which these data were derived is presented in full elsewhere.⁷ The pharmacies were stratified by type (independent, small chain, and large chain) and location (rural, town, urban) and then randomised into four trial groups (control, educational outreach, continuing professional development, and educational outreach with continuing professional development). Nine actors conducted 384 simulated patient visits to 60 community pharmacies. The data for a tenth actor were excluded from all analyses because of doubts about its veracity. This decision was made before any analyses were undertaken. The excluded visits comprised 9% of the total available data. Seven scenarios were presented in each pharmacy during the study. Of these, three represented product requests (for example, “*I would like a tube of Canesten*”), two were condition presentations (for example, “*I need something for thrush*”), and two scenarios represented symptom presentations (for example, “*I have an itch down below*”). None of the actors gave all seven scenarios.

Immediately after each visit the actor completed a 15-item data collection form, indicating which questions had been asked or information elicited by pharmacy staff during the consultation. Each question that was asked/item of information elicited received a score of 1, with a maximum possible score of 15. This was defined as the “total information score”. Within the pharmacy profession there is an established framework called WWHAM^{10–11} which has been promoted as a decision aid for the supply of non-prescription medicines. WWHAM stands for **W**ho is it for?; **W**hat are the symptoms?; **H**ow long have the symptoms been present?; **A**ny other medication being used at present?; and **W**hat **M**edication has been tried already? Four of the 15 items on the actors’ data collection forms were WWHAM questions. The question concerning duration of symptoms was not recorded on the form (due to an oversight). Each question that was asked/item of information elicited received a score of 1, with a maximum possible score of 4. This was defined as the “WWHAM score”.

Analysis of data

Statistical analyses were performed using SPSS version 11.5. The primary outcome measure was “appropriate outcome”—that is, the outcome complied with evidence-based guidelines for the treatment of vaginal candidiasis.¹² For example, the guidelines recommended that antifungal medicines should not be sold to treat pregnant women so, if an antifungal was sold to the actor during the “pregnancy” scenario, this was deemed to be a non-compliant (or inappropriate) outcome. The total information score and WWHAM score were analysed as continuous variables using non-parametric methods. χ^2 tests were performed to assess the association between two categorical factors. The “scenario” variable was

reduced from seven to three categories representing product, condition, and symptom consultations. Pharmacies were categorised by type (single, small chain (n = 2–9), large chain (n > 9)) and location (rural (<4000 inhabitants), town (4000–9000), urban (>9000)). Logistic regression was performed to identify independent predictors of appropriate outcomes only. Variables that showed a statistically significant association (i.e. p < 0.05) with an appropriate outcome in the univariate analyses were combined in these analyses.

RESULTS

Consultation characteristics

Significant differences (p < 0.001) were shown with guideline compliance across the seven individual scenarios, as well as across the three types of presentation (symptom, condition, and product presentations). Symptom presentation scenarios were most likely to result in an appropriate outcome. The total information score and WWHAM score were calculated for 327 (85.2%) and 351 (91.4%) visits, respectively, due to missing data with some of their components. Symptom presentations had higher WWHAM scores and total information scores than condition or product presentations (p < 0.001, table 1). A highly significant positive association (p < 0.001) was also shown between the total information score and appropriate outcome. Condition presentations also had significantly higher WWHAM scores than product presentations (p < 0.001).

A highly significant positive association was shown between the WWHAM score and guideline compliance (appropriate outcome) (p < 0.001, table 2). Guideline compliance was also associated with specific questions (table 3). Achieving an appropriate outcome was 1.4–4.5 times more likely depending on the specific question that was asked or information elicited. WWHAM scores varied significantly across all scenarios (p < 0.001). Significant variation (p < 0.001) was also shown across the seven scenarios for three of the four individual WWHAM questions. No significant difference was shown with “treatment tried already” (p > 0.05; data not shown).

After adjustment for the WWHAM score, consultations involving symptom presentations had over twice the chance of an appropriate outcome (OR 2.15, 95% CI 1.20 to 3.85) compared with other consultations. After adjusting for scenario type, consultations with a WWHAM score of 2 (OR 3.23, 95% CI 1.73 to 6.10) or a WWHAM score of 3 or 4 (OR 5.56, 95% CI 2.46 to 12.56) were significantly more likely to result in an appropriate outcome (data not shown).

When individual WWHAM questions were included in the logistic model with scenario type, “description of symptoms” (OR 4.45, 95% CI 2.80 to 7.07) and “taking other medication” (OR 3.85, 95% CI 2.26 to 6.58) remained significant predictors of an appropriate outcome. Furthermore, significance persisted with these two WWHAM components when the logistic model comprised all four WWHAM items and

Table 1 Effect of type of presentation and guideline compliant behaviour on WWHAM and total information scores

Type of presentation	Appropriate outcome, n (%)	Total WWHAM score Median (IQR)	Total information score Median (IQR)
Product	47 (28.0)	0.00 [0.00–1.00]	1.00 [0.00–3.00]
Condition	30 (31.3)	1.00 [0.00–2.00]	4.00 [1.00–6.00]
Symptom	69 (57.5)	2.00 [1.00–2.00]	6.00 [4.00–7.00]
p value*	<0.001*	<0.001**	<0.001**

IQR, interquartile range.

* χ^2 or Kruskal-Wallis tests showing significance of difference in appropriate outcome, total WWHAM score, and total information score across the three types of presentation.

Table 2 Association between WWHAM score and appropriate (guideline compliant) outcome

WWHAM score	Appropriate outcome, n (%)	Total (n)	Odds ratio	95% CI
0	27 (21.1)	128	–	–
1	28 (29.5)	95	1.56	0.85 to 2.88
2	46 (52.3)	88	4.10	2.26 to 7.45
3	21 (61.8)	34	6.95*	3.20 to 15.10
4	5 (83.3)	6		

*Categories 3 and 4 combined due to small numbers.

scenario type (table 4), although the magnitude of the odds ratio was reduced.

Pharmacy characteristics

No significant association was shown between pharmacy type or location in terms of appropriate outcome. Of the 384 visits, 36 (9.4%) were perceived by the actors to involve only a pharmacist, 140 (36.5%) to involve solely a medicine counter assistant, and 77 (20.1%) to involve both a pharmacist and a medicine counter assistant. The member of staff could not be identified in 131 (34.1%) visits. The analysis of staff member and appropriateness was limited to 171 visits (pharmacist or medicine counter assistant only), and 253 visits when visits involving both a pharmacist and medicine counter assistant were included.

A highly significant difference ($p < 0.001$) was shown with WWHAM score and total information score and the member of pharmacy staff involved in the consultation, with pharmacists asking significantly more questions or eliciting more information than medicine counter assistants. Consultations involving only pharmacists were significantly more likely to be guideline compliant than those with medicine counter assistants only (52.8% ($n = 19$) v 31.4% ($n = 44$), $p = 0.017$), and consultations involving both medicine counter assistants and pharmacists were also significantly more likely to be guideline compliant than those involving medicine counter assistants only (61.0% ($n = 47$) v 31.4% ($n = 44$), $p < 0.001$).

Pharmacists asked more WWHAM questions (or elicited information relating to these questions) than medicine counter assistants ($p < 0.001$). The type of information elicited by pharmacists and medicine counter assistants varied, with statistically significant differences being shown for 10 of the 15 questions or types of information elicited (table 5). These significant associations between staff member and guideline compliance did not persist after adjusting for the effect of scenario type and the number of WWHAM questions asked or information elicited (data not shown).

Customer characteristics

No significant association was shown between the nine actors and appropriate outcome. However, significant variation was shown across some (but not all) scenarios, depending on the actor who presented them. For example, with scenario 7, three of the four actors' visits all resulted in appropriate outcomes while, with the remaining actor (actor 9) only two visits (16.7%) resulted in an appropriate outcome (data not shown).

DISCUSSION

The likelihood of guideline compliant behaviour was influenced by the way in which customers present in the pharmacy, which affected the extent of information exchange between the customer and pharmacy staff. Guideline compliant behaviour was least likely to occur with product presentations. It may be easier to engage in

Table 3 Association between information exchange on appropriateness of outcome

	Appropriate outcome (n (%))		Odds ratio	95% CI
	Information not elicited	Information elicited		
Whether pregnant	127 (37.1)	19 (45.2)	1.40	0.73 to 2.67
Whether any treatment tried currently	133 (37.2)	12 (48.0)	1.56	0.69 to 3.52
Whether GP had diagnosed thrush previously	105 (34.7)	39 (50.0)	1.89	1.14 to 3.12
Frequency of thrush in previous 6 months	102 (33.9)	42 (52.5)	2.16	1.31 to 3.55
Which previous treatment for thrush	92 (33.1)	54 (51.9)	2.18	1.38 to 3.45
Treatment of sexual partner	142 (37.7)	4 (57.1)	2.21	0.49 to 10.00
Who treatment for	35 (25.5)	95 (43.4)	2.23	1.40 to 3.56
Whether had thrush before	52 (27.8)	90 (48.9)	2.49	1.62 to 3.83
Whether vaginal odour a symptom	129 (36.0)	15 (62.5)	2.96	1.26 to 6.95
Whether itch was a symptom	58 (26.7)	69 (52.7)	3.05	1.93 to 4.81
Whether taking other medication	99 (31.9)	47 (64.4)	3.85	2.26 to 6.58
Recommendation to consult GP	70 (27.1)	74 (59.7)	3.99	2.53 to 6.25
Whether vaginal discharge a symptom	94 (30.8)	51 (65.4)	4.24	2.51 to 7.18
Description of symptoms	71 (26.9)	72 (62.1)	4.45	2.80 to 7.07
Preparation sold for sexual partner	142 (37.5)	3 (75.0)	5.00	0.52 to 48.60

Table 4 Association between scenario type, individual WWHAM item, and appropriate outcome

WWHAM item	Product n (%)	Condition n (%)	Symptom n (%)	p value	OR*	95% CI	OR _{adj} †	95% CI
Who for	75 (44.6)	70 (74.5)	74 (78.7)	<0.001	2.23	1.40 to 3.56	0.95	0.52 to 1.73
Description of symptoms	28 (16.8)	21 (21.9)	67 (57.3)	<0.001	4.45	2.80 to 7.07	2.94	1.60 to 5.42
Other medication taken	19 (11.3)	19 (20.0)	35 (29.2)	0.001	3.85	2.26 to 6.58	3.39	1.77 to 6.48
Treatment tried already	5 (3.0)	7 (7.3)	13 (10.9)	0.026	1.56	0.69 to 3.52	0.72	0.25 to 2.04

*Logistic model includes each individual WWHAM question and scenario type.

†Logistic model includes all four WWHAM questions and scenario type.

information exchange (communication) with customers making non-product requests (that is, advice) as pharmacy staff can discuss different treatment options in response to a clear request for advice. Product requests may be perceived as having fewer opportunities to enter into discussion with customers, as well as being more intimidating and difficult.¹³ Customer resistance to questioning and perceived limited ability of medicine counter assistants in information gathering and advice provision has been reported previously.^{13, 14} Variation has also been shown with patient counselling by pharmacists for patients receiving prescribed medications, with the extent of information exchange varying depending on whether the prescription is acute (that is, a newly prescribed medicine) or a refill (that is, chronic or repeat medication).¹⁵ Deficiencies with information gathering by community pharmacists and simulated patients consultations have been shown,^{16–18} as well as problems with tailoring advice to customers and patients in pharmacy settings.^{19, 20}

Pressure to maintain good relationships with customers may influence pharmacy staff decisions to supply non-prescription medicines, as has been shown with general practitioners and their decision to prescribe for their patients.²¹ Perceived patient demand has also been shown to influence the extent to which general practitioners intend to comply with prescribing guidelines.²² The previous use of a prescribed medicine may also encourage patients to demand or expect similar treatment in the future (regardless of its clinical appropriateness),²³ and this may also occur with the supply of non-prescription medicines from community pharmacies.

Healthcare professionals and communication skills

Patient satisfaction has been shown to be influenced by doctor-patient communication,²⁴ and it is likely that customer satisfaction will also be affected by the communication skills of pharmacy staff. However, it is not only the number of questions that are asked nor items of information elicited that are important in achieving guideline compliant behaviour, but the specific information that is elicited. In this study the “description of symptoms” was the WWHAM item most strongly associated with an appropriate outcome. In addition, establishing whether the customer was using other medication concurrently was also strongly associated with an appropriate outcome. In this study, pharmacists were also more likely to elicit this information than medicine counter assistants. Furthermore, customers who report using concurrent medication may be more likely to be referred to the pharmacist, and this in turn may increase the chance of achieving an appropriate outcome. A review of communication between patients and healthcare professionals in relation to medicines showed that interventions which encourage patients to ask questions about their treatment may be partially effective.²⁵ A review of communication skills training for health professionals (which did not include pharmacists or their staff) showed that training increased the process and content of consultations with anxious and depressed patients, but did not enhance patient satisfaction or patient outcomes.²⁶

Consultations that solely involved pharmacists were significantly more likely to be guideline compliant than those involving only medicine counter assistants. This is

Table 5 Relationship between information exchange and member of staff (pharmacist or medicine counter assistant) (n = 171 * visits)

	Pharmacist n (%)	Medicine counter assistant n (%)	Odds ratio	95% CI
Treatment of sexual partner	0	5 (3.6)	–	–
Preparation sold for sexual partner	0 (0)	1 (0.7)	–	–
Whether GP had diagnosed thrush previously	6 (16.7)	17 (12.2)	1.44	0.52 to 3.95
Whether pregnant	5 (13.9)	14 (10.0)	1.45	0.49 to 4.34
Frequency of thrush in previous 6 months	8 (22.9)	21 (15.1)	1.67	0.67 to 4.16
Which previous treatment for thrush	13 (36.1)	24 (17.1)	2.73	1.22 to 6.14
Whether itch a symptom	19 (54.3)	34 (25.8)	3.42	1.58 to 7.40
Whether had thrush before	23 (63.9)	42 (30.4)	4.04	1.87 to 8.74
Whether vaginal discharge a symptom	13 (36.1)	16 (11.5)	4.35	1.85 to 10.23
Whether vaginal odour a symptom	5 (13.9)	4 (2.9)	5.44	1.38 to 21.46
Recommendation to consult GP	22 (61.1)	22 (15.7)	8.43	3.75 to 18.95
WWHAM questions				
“Whether taking other medication?”	9 (25.0)	16 (11.5)	2.56	1.03 to 6.41
“Who treatment for?”	25 (73.5)†	59 (43.1)	3.67	1.60 to 8.45
“Any treatment tried currently?”	6 (16.7)	5 (3.6)	5.40	1.55 to 18.87
“Description of symptoms?”	18 (51.4)	20 (14.4)	6.30	2.79 to 14.23

*Missing data (n = 5).

†25 (73.5%) of the 34 visits where a pharmacist was solely involved were associated with an appropriate outcome and 59 (43.1%) of the 137 visits where a medicine counter assistant was solely involved were associated with an appropriate outcome.

unsurprising, considering that pharmacists are highly trained professionals and their activities are regulated by the Royal Pharmaceutical Society of Great Britain. In the UK medicine counter assistants must have successfully completed an accredited medicine counter assistant qualification within 3 years of commencing their employment,²⁷ but they are currently unregulated and unregistered. As such, there is no single organisation responsible for the provision of ongoing training to these individuals. The pharmacist in charge of a pharmacy is responsible for ensuring that the staff are appropriately trained and that their ongoing training needs are identified and addressed.^{28, 29}

Limitations of the study

The data recorded by the actors on the data collection forms were not validated. One method that could be adopted in future studies of this type to overcome this limitation would be the inclusion of covert audiotaping of the consultations (with ethical approval).

This study referred only to the supply of antifungal medicines for the treatment of vaginal candidiasis, so the results may not be generalisable to all non-prescription medicines. Indeed, this condition and requests for products for its treatment may represent one end of the spectrum of non-prescription medicine consultations because this is an intimate infection and therefore a potentially sensitive topic. Pharmacy staff may feel less able to access the type of information that they would normally explore when informing their decision to supply a non-prescription medicine. However, this is the first study of its type to explore measurable factors and their effect on the appropriate supply of antifungal agents, and the findings could be considered in relation to the supply of all non-prescription medicine in general.

The type of staff member could not be identified in 131 (34%) visits; therefore, when analyses were limited to visits where the staff member was identifiable the statistical power was reduced.

Implications of findings for health systems

The reclassification of medicines is an ongoing process, so mechanisms are needed to enhance their appropriate supply. This study shows the importance of information gathering to inform the decision to supply non-prescription medicines. As such, strategies to enhance information gathering may result in the more appropriate supply of these medicines. Interventions that encourage customers to present symptoms or which improve information provided by pharmacists and medicine counter assistants might also be effective.

Future research

If, as these results suggest, the main influence on the appropriate supply of non-prescription medicines is the nature and extent of information exchange between pharmacy staff and customers, then future interventions should address the apparent deficit in communication skills of pharmacy staff in general, and medicine counter assistants in particular. Future initiatives could also explore strategies to enhance the public's awareness and understanding of the need for pharmacy staff to have information about them when buying a non-prescription medicine. These results are being used to inform ongoing research into promoting the evidence-based supply of non-prescription medicines from community pharmacies.

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