Triaging consumers who present bowel symptoms to community pharmacies: a pilot study of two interventions

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Abstract

Introduction: A significant proportion of pharmacy consumers who develop symptoms of any illness do not consult a doctor. Community pharmacists have been identified as the professionals that consumers would consult about their lower bowel symptoms.

Methods: Consumers presenting to community pharmacies with lower bowel symptoms were recruited to receive one of two interventions in two sequential studies over 14 weeks:

1. a 'tick test' administered by the pharmacy staff to consumers with bowel symptoms. And
2. a 60-domain self-completion questionnaire (Patient Consultation Questionnaire or PCQ) of colorectal symptoms, medical and family history.

Results: A convenience sample of 16 pharmacies were recruited in the Perth metropolitan area, Western Australia. The majority (75%) of the pharmacies were located in metropolitan shopping centres. The pharmacies were seeing an average of 1300 customers per week, and dispensing just over 1000 prescriptions. Approximately one in three eligible consumers who presented to the pharmacy with lower GI symptoms were recruited into the study. TICK TEST: Over an eight week period 59 consumers (54% [32] female/46% [27] male) were recruited from eight tick test study pharmacies. Of these 74% [44] were aged 60 years or younger. Six consumers (overall referral rate 10.2%, referral rate range 0–22%) were referred to their GP. PCQ: Over a six week period 50 consumers (54% [27] female/42% [21] male – gender not recorded in two cases) were recruited from 16 pharmacies using the PCQ. The mean age of the consumers was 45 years (+19 years). Twelve consumers (23.5%, 95% CI 14%–37 %) had PCQ scores over 50. All of the latter were advised to consult their general practitioner (GP).

Discussion: The data suggest that more consumers are likely to be referred to their GP with the PCQ intervention than are likely to be selected for referral by structured questioning by a community pharmacist. However as this is an underpowered pilot study these data need to be confirmed in a formal and appropriately powered randomised control trial.

Introduction

A significant number of symptomatic consumers do not consult a doctor. It is generally accepted that in a population of 1000 adults, in an average month, 750 report an illness, 250 consult a physician, nine are hospitalised, five are referred to another physician, and one is referred to a university medical centre.[1] These proportions have not altered over many decades.[2] In our survey in Western Australia we reported that many consumers are unaware of the significance of lower bowel symptoms even when they may be indicative of serious pathology and therefore would delay making appointments.[3] Delayed diagnosis of life threatening conditions may be a consequence of such procrastination. Crosland and Jones found that consumers who had not consulted their general practitioner (GP) when experiencing rectal bleeding believe their symptoms are due to haemorrhoids or constipation.[4] Such consumers are more likely to consult a pharmacist. It is also recognised that in practice most cases of colorectal cancer will be diagnosed not by screening asymptomatic consumers but only after consumers have consulted a medical practitioner about symptoms.[5] Significant colorectal conditions have pathognomic features on history which may be identified by an objective symptom scoring tool. Detection of these

conditions at an early stage has the potential to improve prognosis significantly.[6]

Pharmacists were listed most often as the health professionals who might advise consumers about bowel symptoms in a West Australian survey, echoing the findings of a survey of community pharmacy customers conducted in an Australia-wide study, which concluded that 30% of Australian consumers had consulted pharmacy staff about their symptoms as a prelude to making an appointment with a doctor.[3,7] Almost one in three respondents said they would use the pharmacy for health screening and monitoring. These findings support a growing interest in the most effective ways to involve community pharmacists in health promotion and chronic diseases management.[8,9]

However several issues require investigation before conducting a definitive randomised controlled trial of an intervention focused on consumers with lower bowel symptoms presenting to community pharmacies. Several estimates are required:

1. The number of consumers who present to community pharmacies with the index symptoms.
2. The proportion of these who would benefit from a medical assessment.
3. The proportion of these who would be willing to participate in a study in which they would be questioned about potentially embarrassing symptoms in the context of a visit to their pharmacy, and
4. The number of these consumers who would be available for follow up by researchers.

Additionally the feasibility of conducting this research within the community pharmacy setting needs to be demonstrated. In this pilot study we sought to estimate these numbers and to field test two interventions aimed at identifying the subjects in the sample frame. The 'Tick test' intervention was developed by the team in consultation with colleagues in community pharmacy and designed to reflect current 'best practice', this includes systematically questioning consumers about their medical history before selling them the requested product. The second intervention the Patient Consultation Questionnaire or PCQ was selected following a review of the literature for validated, reliable survey instruments which link symptoms to outcomes of clinical tests. The PCQ does not require the pharmacy staff to ask any additional or embarrassing questions but allows that data to be collected for review and included in the assessment of the consumers problem.

Tick test

A checklist based on the UK NICE cancer referral guidelines, and Rutter and Newby's 'Community pharmacy symptoms, diagnosis and treatment', was designed as a vehicle to question consumers systematically at the time of presenting to the pharmacy counter.[10,11] The tick test was therefore based on a 'gold standard' or 'best practice' assessment of consumers presenting to community pharmacies with lower bowel symptoms. (See Figure 1.) A referral letter pro forma was also developed for use by the pharmacist clearly indicating the grounds for referral to the GP.

Figure 1. Tick test

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Please tick the relevant box below after asking the client the following question: ***"Have you had any of the following symptoms recently, and if so, for how many weeks?"***

		Number of weeks of persistent symptoms		
Bleeding from the back passage	No ☐	1 ☐	3 ☐	6 ☐
Bloating	No ☐	1 ☐	3 ☐	6 ☐
Constipation	No ☐	1 ☐	3 ☐	6 ☐
Loose bowel motions	No ☐	1 ☐	3 ☐	6 ☐
Pain in your tummy (abdomen)	No ☐	1 ☐	3 ☐	6 ☐
Pain when passing a stool	No ☐	1 ☐	3 ☐	6 ☐
Unusual stools (e.g. mucus)	No ☐	1 ☐	3 ☐	6 ☐

Have you already seen a Doctor about these symptoms?
No☐ Yes☐ If *yes*, how long ago?
1 week ☐ 1 month ☐ 2 - 5 months ☐ 6+ months ☐

Have you already tried something to treat the symptoms?
No ☐ Yes ☐ If *yes*, did it help? No☐ Yes☐

Do you take any medications regularly? No☐ Yes☐
Do you have any medical conditions? No☐ Yes☐

What is your age? _____ years (Under 60☐ 60+☐)

Patient Consultation Questionnaire (PCQ)

The PCQ is a formally validated 60-item questionnaire of colorectal symptoms (combination of symptoms, if any, their duration and their progression), and medical and family history.[6] Each symptom is given a score (based on clinical experience), the value of which depends on factors such as age, type of bleeding, frequency and duration. There is an additional weighting for symptom complexes (more than one symptom). A previous study described 4253 patients with distal colonic symptoms, referred by GPs, who completed a PCQ.[12] A weighted numerical score (WNS) based on the symptoms reported on the PCQ was derived for each patient. Patients underwent flexible sigmoidoscopy and a diagnostic outcome was recorded. Early and advanced colorectal cancers were separated and PCQ derived symptom profiles compared. A total of 183 patients had cancer; 55 (30%) were Dukes' A early colorectal cancers, 112 were

advanced colorectal cancers (Dukes' B-D) and 16 could not be staged. Early colorectal cancers had significant symptoms and comparable profile to advanced colorectal cancers. The tendency in advanced colorectal cancers was towards greater symptom prevalence for only a few primary and systemic symptoms, as reflected by a higher WNS of 75 ($P = 0.001$).[6,12] Data from the PCQ studies lead to the conclusion that the risk for colorectal cancer with a PCQ in the range 50–59 is (1:19) rising dramatically to a risk of 1:5 for patients with a score at or above 70.[13] Australians have a one in 21 lifetime risk of developing colorectal cancer.[14] The PCQ has advantages over the tick test insofar as patient privacy is maintained by not having to answer embarrassing questions at a shop counter. This has previously been shown to inhibit symptom presentation at pharmacies.[15] The PCQ was recently administered to 47 pharmacy consumers presenting with lower bowel symptoms. One in five consumers presented with symptoms that merited referral to a medical practitioner.[16]

The objectives of this pilot study were therefore to collect the following data:

1. The number of consumers who present to pharmacies with colorectal symptoms in a 12 week period.
2. The proportion of eligible consumers who would consent to participating in a study focused on their symptoms.
3. A comparison of the proportion of consumers who would be advised to consult their doctor after each of the two interventions.

Method

Ethics approval was obtained from the Curtin University Human Research Ethics Committee (RD-56-07 and HR115/2008).

Recruitment

Pharmacies

Pharmacies approached to participate in the pilot study by the research team included pharmacies previously involved in research or teaching students from the Curtin University of Technology, School of Pharmacy. Eight pharmacies were recruited for the tick test study and 16 participated in the PCQ component. Formal sample size calculations were not done for this pilot study. As the PCQ component of the study was conducted in December a much greater number of pharmacies were recruited for this component because December is when retail pharmacies traditionally have fewer available staff resources.

Participants

Consumers were invited to participate in the study if they:

1. were 18 years of age,
2. were able to provide informed consent, and
3. had presented at one of the participating pharmacies with lower bowel symptoms (rectal bleeding, constipation and/or diarrhoea); and/or
4. had requested a product for such conditions

The exclusion criteria for the study were:

1. Consumers who had consulted a GP in the previous two weeks and or were attending the pharmacy to purchase the product on medical advice.
2. Consumers who were purchasing the product as a precaution before travelling abroad.
3. Consumers who were purchasing the product for someone else.
4. Pregnant women.

Design

Tick test study

When consumers attended a community pharmacy with symptoms and/or to request haemorrhoid and/or anti-diarrhoeal products, they were asked if they wished to participate in the study and, if yes, informed consent was sought. In the first eight weeks all consenting consumers who met the inclusion criteria were questioned about their symptoms using the tick test. This procedure required the pharmacy team to adopt a systematic approach and to coordinate the responses of the pharmacy assistant and the duty pharmacist to the consumers.

Each pharmacy was supported by the research co-ordinator in order to ensure study protocols were followed appropriately and that recruitment was ongoing. The pharmacists and pharmacy assistants were given the opportunity to become familiar with the tick test and the need for privacy when questioning consumers was emphasised. Those consumers who merited a referral to their GP were asked to nominate their usual GP and given a letter explaining the reason for the referral. Consent was sought for a researcher to contact the client after four weeks to ascertain if he/she had visited the GP.

PCQ Study

The PCQ was administered to all consenting eligible consumers. Completed PCQs were collected by the research co-ordinator and the scores calculated at the research centre. The scores were then relayed to both the client and the client's nominated GP by registered post within one week of completing the questionnaire. All consumers were asked to contact their GP if their symptoms were persistent or causing concern for any other reason. Those presenting with PCQ scores above 50, i.e. those at higher risk of significant colorectal pathology, were advised to contact their GP sooner rather than later. All consumers who completed the PCQ also consented to follow up to ascertain if they had consulted their GP.

Table 1. Characteristics of participating pharmacies.

Pharmacy Id 9 (Group: A = TT &PCQ, B = PCQ only)	Pharmacy location (shopping centre = A, stand alone = B)	Weekly customer numbers (Mean, SD: 1322, 475)	Weekly prescription Numbers (Mean, SD: 1051, 357)	Number of full time equivalent (FTE) pharmacists (Mean: 2)
1 A	B	2000	1100	4
2 A	A	1500	1500	3
3 A	A	1400	1050	1
4 A	A	800	750	1
5 A	A	1400	1200	2
6 A	B	2000	1800	4
7 A	A	1500	1200	2
8 A	B	1000	1000	2
9 B	A	1750	1050	4
10 B	A	700	800	1
11 B	A	900	900	2
12 B	A	1000	1200	2
13 B	B	600	360	1
14 B	A	1600	1400	2
15 B	A	1000	1000	2
16 B	A	2000	500	1

Table 2. Recruitment and outcomes of tick test intervention.

Pharmacy ID	Number of eligible clients	Number recruited (% of eligible clients)	Number recommended to consult a GP	Number who presented to a GP
1A	30	13 (43%)	2	2
2A	25	11 (44%)	1	1
3A	20	10 (50%)	1	1
4A	23	9 (39%)	2	2
5A	16	6 (37.5%)	0	0
6A	19	4 (21%)	0	0
7A	18	4 (22%)	0	0
8A	20	2 (10%)	0	0
Total	**171**	**59 (34.5%)**	**6**	**6**

Results

The characteristics of the participating pharmacies are shown in Table 1. The majority (75%) of the pharmacies which participated in the study were located in shopping centres. The pharmacies were seeing an average of 1300 customers per week, and dispensing just over 1000 prescriptions. This was based on information received in a survey of participating pharmacies. These data were collected to offer readers the profiles of the participating pharmacies.

Tick test study

Over an eight week period 59 consumers (32 (54%) female and 27 (46%) male) were recruited from eight pharmacies, as shown in Table 2. Numbers of eligible consumers and numbers recruited were recorded in a diary provided for the purpose at each pharmacy. This demonstrated that approximately one in three eligible consumers, who presented to the pharmacy with lower GI symptoms, could be recruited to the study. Of these 74% were 60 years or younger and 26% were over 60 years of age. Exact ages were not reliably documented in this arm of the study. Six consumers (overall referral rate 10.2%, range 0–22%) were referred to their GP with their symptoms and we confirmed that all of these consumers saw their GP. Informal feedback from the participating pharmacists indicated that some consumers found the protocol cumbersome and time consuming. Some highlighted, as anticipated, that the questions were intrusive and potentially embarrassing.

PCQ study

Over a six week period 50 consumers were recruited from 16 pharmacies. The mean (±SD) age of the consumers was 45 years (19 years), with 27 females and 21 males; Gender was not recorded in two cases. The recruitment was hampered during the busy period during the months of December 2008 and January 2009. However we estimate that less than one in three consumers were recruited. We were unable to confirm this formally as the data with respect to the eligibility of consumers and recruitment figures were not consistently maintained at all the pharmacies and were therefore unreliable.

The data with respect to the PCQ scores indicated that the mean score was 32.7 + 24.5, range 0–98. Twelve consumers (24%, 95% CI 14%–38%) had PCQ scores in excess of 50. All of the latter were advised to consult their GP. At follow-up seven of these consumers had consulted their GP, three were not planning to see their GP and two could not be contacted.

Discussion

The data from this pilot study indicate that it is possible to recruit one in three consumers who present to a community pharmacy with lower bowel symptoms. Of these, approximately one in three would be advised to consult a medical practitioner about their symptoms. We were able to demonstrate in this study that the majority of consumers who are advised to do so would consult a doctor. This study indicates that it is possible to introduce this intervention successfully into a community pharmacy setting. The data also suggest that more consumers with lower bowel symptoms are likely to be referred to their GP with the PCQ intervention than are likely to be selected for referral by structured questioning by a community pharmacist (23.5% versus 10.2%). The PCQ has previously been shown to be acceptable to consumers and highly sensitive for significant chronic and life threatening bowel pathology.[12,16] The data also support the results of our recent structured vignette survey of patients in general practice which demonstrated that consumers do not always recognise the symptoms of significant bowel disease and may procrastinate, self medicate and present to a community pharmacy rather than

a medical practitioner.[3] Our approach suggests that such consumers should be invited to give a detailed history using a robust approach that has been shown to identify significant numbers of consumers at risk of pathology.

We have also identified some challenges to a large study of this intervention. These include the engagement of community pharmacies in recruiting eligible consumers. It will be important to avoid launching any such study during the busy periods leading up to holiday periods as consumers are likely to be attending their pharmacy in significant numbers for a variety of reasons. Staff will inevitably be focused on serving consumers rather than recruiting for research. Whilst this is not a new finding it has important implications for recruitment and its importance cannot be underestimated. It may also be particularly important to employ a dedicated project officer to maintain contact with the pharmacy and to support participant recruitment for the project.

We also note that consumers did not object to completing the survey, although a small number were reticent to give their telephone details to the researcher. It may be possible to allay this anxiety by offering telephone follow up by a member of the pharmacy staff. In this study 18 out of 100 consumers were referred to their GP. Therefore the majority of symptomatic consumers would still be managed within the pharmacy setting. It is important in a follow up study to confirm the diagnosis in the referred group in order to demonstrate that a significant proportion of these consumers have a treatable pathology. If these benefits are confirmed, we could offer this information to potential participants to encourage them to participate in the study.

Limitations

The limitations of this pilot study can be addressed in a larger scale study. In this pilot study we were unable to confirm the diagnosis following referral to the medical practitioner. However we estimate that a significant number will be diagnosed with treatable colorectal pathologies. We were also only able to estimate the number of eligible consumers who would be recruited to the study. However our estimates were consistent in both the tick test and the PCQ component. It is possible, given that the PCQ maintains client privacy and has minimal involvement of the pharmacy staff in formal questioning, that recruitment to a larger study will be more successful than the conservative estimates we present in this paper. It would also be important to conduct the study as a cluster randomised multicentre project in order to minimise the effect of confounding variables including the demography of the population served by the pharmacy.

Conclusions

It is possible to conduct a study within the community pharmacy setting to identify consumers with significant symptoms of lower bowel disease who should be referred to their GP. Careful consideration would need to be given to three aspects: the recruitment strategy within the community pharmacy setting; the arrangements for follow up of participants; and the development of strategies for maintaining the momentum in a multicentre cluster randomised trial.

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