Research paper

Piloting and validating an innovation to triage patients presenting with cough to community pharmacies in Western Australia

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ABSTRACT

Aim To develop a tool to assist community pharmacists to triage patients presenting with cough and to validate this against an established cough-specific quality of life (QoL) measure.

Methods A decision-support tool, the Pharmacy Cough Assessment Tool (PCAT) was developed with reference to published guidelines and a team of clinical experts. The PCAT was validated against the Leicester Cough Questionnaire (LCQ). It was then administered at four community pharmacies in Perth, Western Australia to assess the scope to recruit and follow up participants, and to estimate the proportion of participants who would be advised to consult a general practitioner (GP). The reported outcomes of the consultations with doctors were also recorded.

Results Ninety-nine subjects were recruited over 12 weeks. Thirty-seven participants were advised to consult a GP for further assessment with reference to the PCAT; seven attended their doctor. The LCQ scores of those referred to their GP were significantly lower, indicating a poorer quality of life (adjusted mean and range 13.16 [11.87, 14.46]; non-referred 15.82 [14.47, 17.18]; $P < 0.001$). Scores of this magnitude have previously been shown to identify patients with chronic respiratory conditions. A smaller group of participants also had a poor quality of life based on LCQ scores but were not referred to their GP. Of the seven participants who made an appointment with their GP, most were prescribed treatment or referred for investigation. There was no significant difference in LCQ score based on gender, or decision to consult a GP.

Conclusions The PCAT identifies patients with cough who might benefit from medical advice and may feasibly be used as an initial screening tool in the community pharmacy setting.

Keywords: cough, decision support tool, pharmacist, triage

How this fits in with quality in primary care

What do we know?
Cough is a common symptom presented to primary care practitioners. People with cough who present to a community pharmacy are not always advised to consult their general practitioner when they might benefit from medical advice.

What does this paper add?
The Pharmacy Cough Assessment Tool (PCAT) identifies patients with cough who may benefit from referral to a general practitioner. Further assessment of these patients may result in therapeutic action for most patients who make an appointment with their doctor.

Introduction

Twelve percent of the general population have a cough on a daily or weekly basis and the worldwide market in cough treatments is several billion US dollars.[1] Patients with cough may be divided into those with acute cough (duration less than three weeks), usually viral illness and those with chronic cough (duration greater than eight weeks).[2] Acute cough represents the largest single cause of consultation in primary care, whereas chronic cough is often the key symptom of many important chronic respiratory diseases, but may be the sole presenting feature of a number of extrapulmonary conditions, in particular upper airway and gastrointestinal disease.[2]

Factors that promote help seeking are predicted by the Health Belief Model and in practice have been found to be: work interference caused by symptoms, duration of symptoms, 'sanctioning' and social emotional interference.[3,4] Some patients appear to seek medical help only when they perceive symptoms as interfering with their capacity to carry out their job. Others are more influenced by the duration of symptoms and will not seek help unless symptoms persist over time. 'Sanctioning' refers to patients whose help seeking seems to need to be 'sanctioned' by others such as work colleagues, pharmacists or family members. A final group appear to be most influenced by emotional factors. They seek help for physical symptoms when other emotional stresses occur, or they seek help when symptoms interfere with their social and emotional relationships. Response styles explain what sometimes seems to be irrational in patients' responses to acute illness.[5] The theory emphasises that 'severity' may not be the main cause of patient help seeking and therefore one would anticipate that there may be people with cough seeking over-the-counter treatments at a community pharmacy who have moderate or even severe symptoms. Duration of symptoms is probably an extremely important cultural norm in Western society. Contact with medical help is not appropriate (according to this norm) unless symp-

toms have lasted for some time.[6] Again, one may anticipate that there may be people in the community living with symptoms that have persisted over several weeks who have not sought advice from a medical practitioner. Finally, a cough with haemoptysis may be indicative of lung cancer, especially in smokers, yet empirical data suggest that some patients with haemoptysis may be less likely to consult a doctor for fear of receiving a diagnosis of cancer.[7] Nonetheless, they may seek to self-medicate for their symptoms and may visit a community pharmacy.

Pharmacists may apply the mnemonic WWHAM (Who is the medicine for? What is the medicine for? How long have the symptoms been present? Actions already taken? Medicine taken for other reasons prescribed or otherwise?) as an aide memoire to remind pharmacy staff of the generic questions to be asked and information needed to support every over-the-counter consultation.[8] However, in practice, patients with cough may not be asked all the relevant questions.[9,10] Common reasons cited for not asking all the questions include lack of customer receptiveness and time.[11] Therefore, more effective ways to evaluate patients who may be suffering from significant pathologies and have chosen to buy over-the-counter medicines are urgently required. Despite the encouragement of and focus on the potential health promotion role of community pharmacists, opportunities for this are not often pursued. A recent study from Western Australia further supports the suggestion that people with cough are not always appropriately advised when they present to a community pharmacy.[12]

The aim of this study was to develop a tool to assist the community pharmacist to triage patients presenting with cough and to validate this against an established cough-specific quality of life (QoL) measure.

Methods

This project was conducted with reference to the Medical Research Council's framework for the devel-

opment and evaluation of complex interventions.[13] In this pilot study, we focused on some key elements to assess the scope to recruit and follow up participants; to estimate the proportion of participants with a poor QoL who would be advised to consult a medical practitioner and the proportion who would consult a doctor.

Developing the innovation

A team consisting of two respiratory physicians, a pharmacist and two general practitioners (GPs) was assembled to review a decision-support tool for use in the pharmacy for patients presenting with cough, the Pharmacy Cough Assessment Tool (PCAT). The team focused on developing a 'tick test' self-administered survey based on the recommendations of the British Thoracic Society guidelines for the management of cough in adults and the National Institute for Health and Clinical Excellence referral guidelines for suspected cancer.[1,14] The tool was designed to support the early diagnosis of chronic and life-limiting illness. It was circulated to each member of the team individually to be assessed for content and face validity. After three iterations, the panel of experts agreed that the recommendations to refer a patient with cough to a GP with reference to the PCAT would be clinically justified and that no further details that might assist the pharmacist's decision could be suggested by the expert panel (Figure 1). The validity of the PCAT was then assessed against a validated QoL assessment tool: the Leicester Cough Questionnaire (LCQ).[15] The LCQ is a 19-item questionnaire that assesses cough-related QoL. It has three domains: physical, physiological and social. The total score ranges from 3 to 21 and domain scores range from 1 to 7; a higher scores indicates a better QoL.
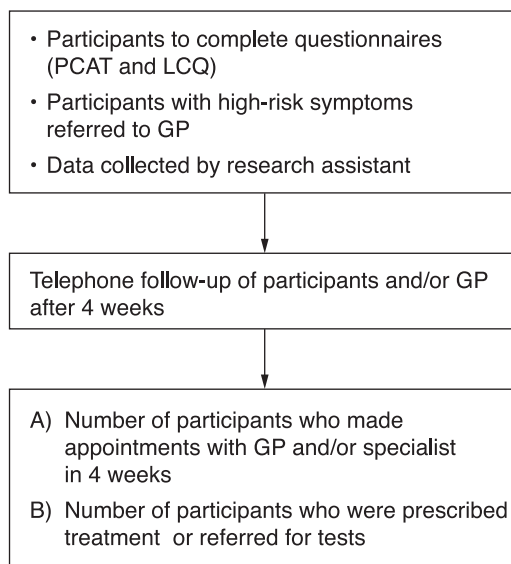
Sample size

Pharmacies were recruited by a research assistant from metropolitan Perth in Western Australia. The main aim of the study was to validate the PCAT and assess the data collection methods. We estimated that at least 10% of the sample would be advised to consult their GP and that these people would have a relatively poor QoL. The mean LCQ score for patients with chronic cough has been estimated as 14.2 (SD 2.7).[16] The mean LCQ score for patients who have been treated for cough is similarly reported to be 19.5 (SD 1.9).[16] Therefore, for 80% power, assuming that at least 10% would be advised to consult their GP, we required 100 participants in total to detect a similar difference in LCQ scores for those advised to consult a GP and those not. We recruited from four pharmacies conveniently located to the research centre and each was asked to recruit 25 people with cough presenting to their outlet.

At each pharmacy, participants were recruited by a pharmacy assistant and invited to complete the questionnaires (PCAT and LCQ) before being advised by a pharmacist. Those with high-risk symptoms were then advised to consult a GP and provided with a letter from the pharmacist as well as a copy of the PCAT. High-risk groups included the following:

- cough of more than three weeks' duration with no GP consultation (undiagnosed acute cough)
- cough of more than eight weeks' duration with no GP consultation (undiagnosed chronic cough)

- Participants to complete questionnaires (PCAT and LCQ)
- Participants with high-risk symptoms referred to GP
- Data collected by research assistant

Telephone follow-up of participants and/or GP after 4 weeks

A) Number of participants who made appointments with GP and/or specialist in 4 weeks
B) Number of participants who were prescribed treatment or referred for tests

Figure 1 Project schema

- cough with any of the following: haemoptysis, weight loss, chest pain, shoulder pain, breathlessness, fever, sweating, or hoarseness with cough of at least three weeks' duration.

All data were collected by a research assistant. Participants and/or GPs were then followed up by telephone by the research assistant after four weeks. We noted the number of participants who made appointments with a GP and/or specialist within these four weeks and the number of participants who were prescribed treatment or referred for tests.

Inclusion criteria included adults aged 18 years or older, those requesting advice regarding a cough or to purchase a cough medicine and able to give informed consent.

PCAT

The participants were considered at risk and strongly recommended to consult a GP if they had a symptom profile that warranted referral based on the PCAT. All others were asked to consult a GP if they remained concerned about their symptoms or they remained concerned for any other reason. For all patients who were advised to consult a GP, a copy of the questionnaire was sent to the GP.

The outcome measures were as follows:

- the proportion of people who presented to a GP following visiting a pharmacy
- the proportion of people who were referred to a respiratory physician/chest clinic by their GP
- the LCQ score for patients who were referred and not referred with reference to the PCAT.

Statistical analysis

Differences in the demography of the sample of the three PACT groups (not referred and not at high risk, not referred but at high risk, and referred and high risk) were tested by one-way analysis of variance (ANOVA) for age (continuous variable) and chi-square test for gender. The normality of the outcome variable, LCQ scores, were examined by the construction of a histogram. Differences in LCQ score across the three PACT groups, which reflect the referral decision, were tested by analysis of covariance (ANCOVA) with adjustment for participant gender. The adjusted mean of LCQ scores and 95% confidence intervals (CIs) are reported. The reason for adjusting for the gender of the participants in this model is because there was slightly unbalanced, although statistically insignificant, distribution of gender ($P = 0.06$) across the three PCAT groups. Two-way interactions between PACT groups and gender of participants were included the primary model and excluded from the final model because of statistically insignificant data. Differences

in LCQ score between participants who attended their GP and those did not were tested by two-sample *t*-test among those who were referred ($n = 37$). Owing to the small number, gender of participant was not adjusted in the analysis. Mean and 95% CIs are reported. The gender differences in LCQ score among those being referred were tested by two-sample *t*-test and mean and 95% CIs are reported.

All analyses were performed using Stata software v. 11.0 (StataCorp LP, College Station, TX, USA). All tests are two-sided and a *P*-value < 0.05 is considered to be significant.

Results

The decision-support tool prepared for the study is presented in Figure 2. Part one of the tool was developed to prompt pharmacists to screen for risk factors of chronic and life-limiting illness, including cigarette smoking, past medical history of chronic respiratory or cardiac disease, asbestos exposure and current medication. Part two focused specifically on the cough; duration, associated symptoms, haemoptysis and weight loss. The team recommended that patients were considered for referral to their GP with high-risk symptoms as outlined above. Ninety-nine patients were recruited over 12 weeks. The available literature suggests that each pharmacy would see three patients per week presenting with cough.[17] Therefore, over 12 weeks they could have recruited up to a total of 144 participants or 36 per pharmacy. Pharmacy A recruited the most participants and Pharmacy B the fewest. Informal feedback from the pharmacies suggested that in some pharmacies the length of the LCQ was off-putting and some staff did not recruit actively because they believed it would inconvenience their customers and potential participants. Of the 99 participants, 44 were not referred. Eighteen of the remaining participants appeared to qualify for referral based on responses to the PCAT but were not referred following further questioning by the pharmacist. The remaining 37 patients were referred. The numbers recruited per pharmacy are as shown in Table 1.

Overall, there were 57 males (57.6%) recruited into the study. Thirty-seven participants were advised to consult their GP. As can be seen in Table 2, females were disproportionately represented in the group advised to consult (74.5%).

For patients who were not referred despite high-risk symptoms on the PCAT, the following reasons were recorded: symptoms mild or improving ($n = 7$), patient seen GP recently or due to see GP soon ($n = 6$) or no reason for non-referral recorded ($n = 5$). The numbers advised to consult a GP with reference to the PCAT are shown in Figure 3.

Part 1

1. Have you had a cold in the past 3 weeks?
☐ Yes   ☐ No

2. Are you a smoker?
☐ Yes   ☐ Never smoked   ☐ Ex-smoker

If yes how many cigarettes do you smoke daily?................................

3. Do you suffer from any of the following conditions:
☐ Asthma   ☐ COPD/Bronchitis   ☐ Emphysema
☐ Heart Failure   ☐ Gastroesophageal Reflux Disease (GORD)   ☐ Not sure

4. Have you ever been exposed to asbestos in your life?
☐ Yes   ☐ No   ☐ Not sure

5. What medication are you currently taking?
…………………………………………………………………………………
…………………………………………………………………………………

6. Are you attending a hospital or private medical specialist about a chest or heart condition?
☐ Yes   ☐ No

If yes date of last appointment, if known.................................

Part 2

7. How long have you been coughing?
a. ☐ Less than 3 weeks
b. ☐ **More than 3 weeks**
c. ☐ **More than 8 weeks**
Have you consulted your GP about your cough?
☐Yes
☐ No*

8. Since starting to cough do you suffer from any of the following symptoms
a. ☐ Chest pain and or shoulder pain*
b. ☐ Breathlessness*
c. ☐ Fever*
d. ☐ Hoarse voice

Have you been hoarse for more than 3 weeks?
☐Yes*   ☐No

e. ☐ Sweating especially at night*

9. Have you coughed up blood?
☐ Yes*   ☐ No

If yes when?...

10. Have you lost weight since you started coughing?
☐ Yes *   ☐ No   ☐Not sure

If yes how much?.................................
Over how many weeks?.................................

To Pharmacist-please discuss referral to GP for any participants who have ticked the boxes marked thus ☐. *

Figure 2 Pharmacy cough assessment tool (PCAT)

Table 1 Recruitment and referral rates per pharmacy

Pharmacy	Number recruited	Number referred (%)
A	64	29 (45.3)
B	7	2 (28.6)
C	15	3 (20.0)
D	12	2 (16.7)
Unknown	1	1 (100)
Total	99	37 (37.4)

Table 2 Participant demographics including numbers referred and numbers with high risk as per the PCAT

	Number	Mean age (years) (range)	Statistics	Number male (%)	Statistics
Not referred – not high risk	44	42 (19–80)	$F = 0.32$, $df = 2$, $P = 0.72$	26 (55)	Pearson Chi-square = 5.78, $df = 2$, $P = 0.06$
Not referred – high risk	18	39 (18–64)		9 (19.2)	
Referred – high risk	37	43 (18–75)		12 (25.5)	
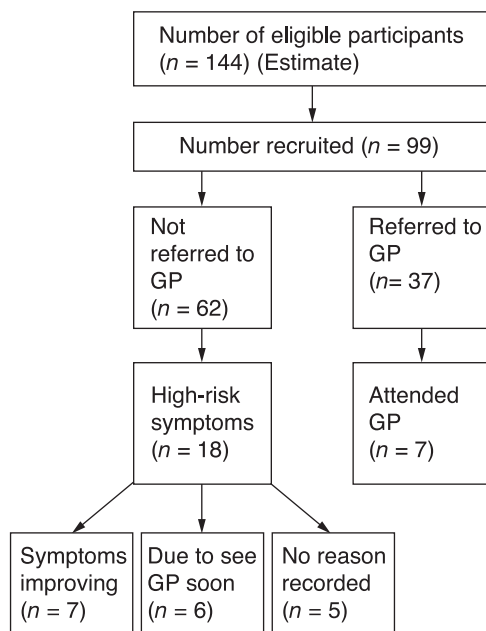
Figure 3 Numbers advised to consult a GP with reference to the PCAT

To ascertain whether the PCAT results provide an indication of patient suffering, an assessment of each participant's QoL was undertaken using the LCQ. The LCQ scores are shown in Table 3. As expected, those patients who had high-risk symptoms had lower LCQ scores compared with those which the PCAT ident-

Table 3 LCQ scores and referral to GP

	Adjusted mean (95% CI)[a]			
	LCQ overall	LCQ physical	LCQ physiological	LCQ social
PCAT groups				
Not referred (44)[b]	15.82 (14.47, 17.18)	5.14 (4.75, 5.53)	5.58 (5.07, 6.09)	5.10 (4.51, 5.70)
Not referred but high risk (18)[c]	12.23 (10.46, 14.00)	3.87 (3.37, 4.38)	4.30 (3.63, 4.97)	4.06 (3.28, 4.83)
Referred (37)[d]	13.16 (11.87, 14.46)	4.27 (3.90, 4.64)	4.52 (4.04, 5.01)	4.37 (3.80, 4.94)
F-statistics for groups ($df = 2$)	$F = 8.87$, $P < 0.001$	$F = 12.73$, $P < 0.001$	$F = 8.78$, $P < 0.001$	$F = 3.72$, $P = 0.028$
F-statistics for gender ($df = 1$)	$F = 0.35$, $P = 0.26$	$F = 0.00$, $P = 0.96$	$F = 1.72$, $P = 0.19$	$F = 0.03$, $P = 0.85$

[a] LCQ scores by PCAT groups were derived from ANCOVA adjusted for gender of participants. F-statistics were derived from an ANCOVA model which included two factors, PCAT group and gender. [b] Data missing for two participants. [c] Data missing for two participants. [d] Data missing for six participants. Higher LCQ scores indicate a better quality of life.

Table 4 Comparison of LCQ scores of GP attendees and non-attendees

	Mean (95% CI)			
	LCQ overall	LCQ physical	LCQ physiological	LCQ social
Did not attended GP (28)	13.02 (11.93, 14.12)	4.30 (4.00, 4.60)	4.42 (3.95, 4.89)	4.30 (3.77, 4.83)
Attend GP (7)	12.97 (9.26, 16.67)	4.16 (3.13, 5.19)	4.31 (3.04, 5.58)	4.50 (2.76, 6.24)
P-value of t-test	0.97	0.70	0.82	0.75

Total referred $n = 37$; there were six missing LCQ values in the 'did not attended GP' group which were excluded from the analyses.

ified as not requiring referral. Of the 37 participants who were referred to their GP, only seven could be confirmed as having done so. Of these, two were prescribed antibiotics, one was referred for a chest X-ray and one was referred to a specialist. Of the remaining 30, we were unable to confirm whether 12 (32%) of the participants consulted a doctor. LCQ scores for those who attended their GP did not differ from LCQ scores for those who did not (Table 4). Similarly, the LCQ for female participants who were referred was not different from male participants who were referred (Table 5).

Discussion

The PCAT has been validated insofar as it assists in identifying patients with cough who may benefit from referral to their GP. The mean overall LCQ score of participants not referred to a GP was 15.82. The difference in LCQ scores between those referred and those not referred was > 1.3, which has previously been estimated as the minimal important difference (MID) for patients who would benefit from clinical intervention.[18] We note significant differences in all three domains measured on the LCQ. In a separate study, it has also been demonstrated that poor QoL, as estimated by the LCQ, is correlated with four common chronic respiratory conditions: chronic cough, asthma, chronic obstructive pulmonary disease and bronchiectasis.[19]

Table 5 LCQ score and gender

| | Mean (95% CI) | | | |
	LCQ overall	LCQ physical	LCQ physiological	LCQ social
Female (20)	12.96 (11.59, 14.33)	4.20 (3.83, 4.57)	4.47 (3.89, 5.05)	4.29 (3.62, 4.95)
Male (11)	13.10 (11.12, 15.09)	4.39 (3.82, 4.96)	4.26 (3.56, 4.96)	4.45 (3.53, 5.38)
P-value of *t*-test	0.90	0.55	0.64	0.75

Total referred *n* = 37; there were six missing values (respondents who did not state their gender) which were excluded from the analyses.

Approximately one in three patients who appeared to have high-risk symptoms were not referred to their GP. On closer questioning, there were plausible reasons for non-referral in most cases. Of those who were referred to their GP, there was a tendency for a significantly greater proportion to be female. However, in this small study, there was no difference in the LCQ comparing genders either among those referred or overall in the sample. This is consistent with previous reports suggesting that history taking is an important adjunct to the LCQ score because 'Health status questionnaires are designed to quantify quality of life numerically using the least number of questions. They are not a substitute for taking a good history'.[20] We note that 18 of the 53 patients identified by the PCAT were not referred to a GP despite their low (poor) LCQ scores; in most cases further history taken by a pharmacist concluded that referral was not necessary. In six of 18 cases the patient had recently, or had already, made an appointment to consult a doctor; we recommend that this is an exclusion criterion in future research with this instrument.

Only seven of the 37 participants advised to consult a GP made an appointment to discuss their symptoms. Of these, four received an antibiotic, investigation or referral. This suggests that the PCAT would not lead to an overburdening of GPs because patients may choose not to consult a doctor. However, of those who do consult, most in this sample (4/7) would be offered further interventions. In this study of 99 participants over 12 weeks, 7 (95% CI 3–14) made appointments to see a GP.

The pharmacies in this project recruited at least 25% of eligible participants based on an estimate of three eligible patients per pharmacy per week. This proportion varied during the same period over four pharmacies. One pharmacy exceeded recruitment targets, whereas the others did not achieve the target. This may have been a reflection of the size of the outlet and the demography served by the pharmacies. However, recruitment in this setting is dependent on the commitment of the pharmacy owners to the project.[21]

Although the project was endorsed by the proprietors of the hosting outlets, informal feedback was that the combined instruments (PCAT and LCQ) required more time than some staff were willing to request from participants. A shortened survey instrument, for example the PCAT alone, may facilitate recruitment in future.

Limitations

As noted above, recruitment to this study may have been influenced by the willingness of pharmacy staff to request that participants spend time giving informed consent and completing the surveys. In the case of those who were most unwell, those who were referred to their GP, there is a suggestion that participants were less willing to complete the full survey pack. For example, for those referred in this setting, the LCQ data were missing for six of 37 participants compared with four of 62 for the non-referred participants. Although the LCQ has been developed as a short survey tool, its combination with the PCAT and the need to read an information sheet, agree to follow-up calls from a researcher and sign a consent form may have deterred some participants.

Conclusions

The PCAT, with or without the LCQ, identifies patients who may benefit from consulting a GP and may feasibly be used as an initial screening tool in the community pharmacy setting. The data suggest that pharmacists are able to recruit most eligible patients and that the tool is completed in most cases. The data implies that the QoL based on the LCQ results for those patients who are referred may be significantly impaired, hence providing validation that the PCAT identifies those patients with significant suffering, and

hence may benefit for medical review. Research is now required to confirm that this new tool can identify patients who are at risk of significant chronic and life-limiting respiratory illness.

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ETHICS

This project was approved by the Curtin University Human Ethics Committee. Approval number HR 63/2011.

PEER REVIEW

Not commissioned; externally peer reviewed.

CONFLICTS OF INTEREST

None.

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