



Community Pharmacy Management of Minor Illness



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Abbreviations

Abbreviation	Definition
CASP	Critical Appraisal Skills Programme
CEAC	Cost-effectiveness Acceptability Curve
CI	Confidence Interval
ECC	Emergency Care Centre
ED	Emergency Department
EM	Emergency Medicine
EQ-5D	Euroqol 5 dimensions
EQ VAS	Euroqol Visual Analogue Scale
GP	General Practitioner
HCP	Health Care Professional
ICER	Incremental Cost-effectiveness Ratio
INB	Incremental Net Benefit
IPA	International Pharmaceutical Abstracts
MAS	Minor Ailment Scheme/Service
MCP	Multidisciplinary Consensus Panel
MRC	Medical Research Council
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
OTC	Over-the-Counter
PACT	Prescribing Analysis and Cost Data
PCT	Primary Care Trust
PGD	Patient Group Direction
PIS	Patient Information Sheet
PMAS	Pharmacy-based Minor Ailment Scheme
POM	Prescription Only Medicine
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
QALY	Quality Adjusted Life Year
RCT	Randomised Controlled Trial
ReBIP	Review Body for Interventional Procedures
SD	Standard Deviation
SP	Simulated Patient
UK	United Kingdom

Executive Summary

Aims

The overall purpose of this programme was to derive evidence to inform recommendations regarding the future delivery of community pharmacy-based minor ailments schemes (PMAS) in the UK. The research addressed the following research aims which were to:

1. Identify and summarise empirical evaluations of PMAS in terms of effectiveness (patient outcomes) and cost-effectiveness.
2. Identify the minor ailments that have the highest impact on the workload of high cost services (general practitioners (GPs), Emergency Departments (ED)) using routinely collected data.
3. Seek consensus amongst health professionals in settings where minor ailments are most often treated (in general practice, community pharmacy, ED) about which ailments are regarded as minor ailments.
4. Compare the effectiveness (patient outcomes) and cost-effectiveness of the different models of delivery of care for selected minor ailments in community pharmacy, general practice, and ED.
5. Explore patient triggers for seeking care for selected minor ailments from community pharmacy.
6. Assess the effect of pharmacy staff consultation performance in the management of selected minor ailments on patient outcome.
7. Evaluate pharmacists' consultation performance in the management of selected minor ailments.

Methods

A systematic review was undertaken to identify and summarise data regarding the effectiveness (patient outcomes) and cost-effectiveness of existing PMAS both nationally and internationally (Aim 1). Routinely-collected data were collated and used to identify minor ailments that have the highest impact on the workload of GPs and EDs (Aim 2). A multi-stage consensus process was undertaken about which ailments are regarded as minor ailments (Aim 3). A prospective cohort study was conducted to address Aims 4-6. A study was conducted using covert simulated patient (SP) visits to community pharmacies to evaluate pharmacists' consultation performance in the management of selected minor ailments (Aim 7).

Systematic Review

The systematic review aimed to explore the effect of PMAS on patient health and cost-related outcomes, and their impact on general practice workload. Standard systematic review methods were used including the search of electronic databases e.g. MEDLINE, EMBASE and grey literature from 2001 to 2011 imposing no language or study design restrictions. Reporting was presented in the form recommended in the PRISMA statement and checklist.

Routine Data Analyses and Consensus

Two retrospective analyses were undertaken to estimate the prevalence of presentations in ED and general practice for minor ailments that might be managed in a community pharmacy setting. ED presentations were screened for eligibility; case summaries were assessed by a consensus panel of ED doctors (n=5) and a sub-set of their categorisations was validated by the multidisciplinary consensus panel (MCP) (lay members (n=4), ED (n=8) and non-ED (n=16) health professionals). A similar process was used for general practice presentations.

Case summaries were firstly assessed by a GP consensus panel (n=8). Each consultation was assessed independently by paired GPs. Validation of a sub-set of these cases was undertaken by the MCP. The four minor ailments that presented most frequently in ED and general practice were identified.

Cohort Study

A prospective cohort study was conducted to explore and compare health- and cost-related outcomes associated with the management of minor ailments in community pharmacy, general practice and EDs. In addition, the study explored triggers for seeking care in the chosen setting and explored the effect of satisfaction with the consultation on patient outcome. Patients presenting in participating community pharmacies (n=10), general practices (n=6) and EDs (n=2) in East Anglia, England and Grampian, Scotland, for the management of one or more of the four target conditions identified from the routine data analysis and consensus exercises, were invited to participate. The four target conditions were:

- Musculoskeletal pain: aches or pain in arms or legs or back or hands or feet.
- Eye discomfort.
- Upper respiratory tract-related: Sore throat or cough or cold or sinus problems.
- Gastro-intestinal disturbance: nausea or vomiting or diarrhoea or constipation.

Participants were asked to complete three paper-based questionnaires throughout the study. The questionnaires were:

- Baseline (completed immediately prior to the index consultation)
- Satisfaction (completed immediately after the index consultation)
- Follow-up (completed two weeks after the index consultation)

These self-reported data were used to generate all the health- and cost-related outcome measures for this study. These included: symptom resolution; quality of life; costs; triggers for seeking care in chosen setting; and satisfaction with the index consultation.

Simulated Patient Study

The Simulated Patient (SP) Study evaluated the consultation performance of pharmacy staff in the management of minor ailments. The study was conducted in 18 community pharmacies in East Anglia, England and Grampian, Scotland. Eight SPs made covert visits using scenarios to represent back pain, eye discomfort, vomiting and diarrhoea, and sore throat. The visits were audio-recorded and the SPs completed a data collection form immediately after leaving each pharmacy. The content and outcome of the consultation was assessed against standards defined by the MDP.

Results

The systematic review included 26 studies reported in 31 evaluations. Re-consultation rates in general practice following an index consultation with a PMAS ranged from 2.4% to 23.4%. The proportion of patients reporting complete resolution of symptoms after an index PMAS consultation ranged from 68% to 94%. No study included a full economic evaluation. The mean cost per PMAS consultation ranged from £1.44 to £15.90. The total number of consultations and prescribing for minor ailments at general practices often declined following the introduction of PMAS.

Analysis of routine data showed that the prevalence of ED and general practice consultations deemed to involve minor ailments suitable for management in community pharmacy was 5.3% (95% CI, 3.4% to 7.1%) and 13.2% (95% CI 10.2% to 16.1%), respectively. There was generally low agreement amongst the ED doctors as well as amongst GPs regarding which presentations may be considered as a minor ailment suitable for management in a community pharmacy. Good agreement was achieved between the multidisciplinary panels and the MCP. Presentations for musculoskeletal pain were most prevalent in ED and also occurred frequently in general practice. Symptoms suggestive of upper respiratory tract infection were the most prevalent type of minor ailment in general practice but rarely presented in ED.

In total, 377 patients were recruited during the cohort study; 94.3% of the target sample size (n=400). Of these, 134, 162 and 81 patients were recruited from community pharmacies, general practices and EDs, respectively. Symptom presentation differed between sites with more patients seeking care for musculoskeletal aches and pains at EDs compared with other sites. Musculoskeletal pain (46.4%) was the most common symptom across all settings. At presentation, just over half the participants (52.8%) felt their symptoms were somewhat serious and just under half (47.2%) felt they needed to visit their site of choice within 24 hours. Symptom resolution at two-week follow-up was similar across settings i.e. pharmacy, general practice, ED. Quality of life measured at follow-up using the EQ-5D was highest for participants who had visited a pharmacy but differences between sites were not statistically significant. The mean overall costs (for the index visit and any subsequent illness-related costs in the next two weeks) were estimated to be significantly lower in the pharmacy (£29.30 (37.81)) setting, compared with general practice (£82.34 (104.16)) and ED (£147.09 (74.96)). After adjusting for differences between settings, there was no significant difference in Quality Adjusted Life Years between the three settings. The trigger ranked first for seeking care from any of the three settings was convenient location. Not having to travel too far was ranked second by pharmacy participants and third for general practice and ED participants. Factors that ranked second with non-pharmacy participants were: perceiving that the illness was not serious enough to visit an ED (general practice participants); and having to wait longer for an appointment with a GP (ED participants). Perceiving that the illness was not serious enough to visit a doctor was ranked third for pharmacy participants. Overall satisfaction with the index consultation i.e. MISS-21 total score, differed significantly across the three settings and was highest (indicating higher satisfaction) for general practice consultations and lowest for community pharmacy consultations. Of the four sub-scales within this measure, the lowest scores (indicating lower satisfaction) were consistently for pharmacy participants. Symptom resolution was significantly associated with participant satisfaction (baseline MISS-21 total score) for all settings combined.

For the SP Study, audiotaped data were available for 68 of the 72 completed visits. Seven visits achieved a “basic” standard: back pain (4), and one each for the remaining scenarios. No visit achieved a “good” standard. The majority of consultations resulted in the sale of a medicinal product; advice alone was the outcome in three consultations. All the back pain and sore throat visits achieved appropriate outcomes. General professionalism was rated highly, as was SP satisfaction with their consultations. Overall, the scenarios involving back pain and sore throat were better-managed than those involving eye discomfort and vomiting and diarrhoea.

Discussion

The results of the systematic review in terms of low re-consultation rates and high symptom resolution rates suggest that minor ailments are being dealt with appropriately by PMAS.

This suggests that PMASs provide a suitable alternative to general practice consultations. Where evaluated, PMAS consultations were less expensive than consultations with GPs. The extent to which these schemes shift demand for minor ailment management away from high cost settings has not been determined. Evidence from economic evaluations is needed to inform the future delivery of PMAS. There was a lack of agreement amongst health professionals regarding which symptoms and conditions are minor ailments suitable for management in community pharmacies. The routine data analyses confirmed that patients with minor ailments suitable for management in community pharmacies continue to present in EDs and general practices. Many of these presentations were associated with musculoskeletal pain, particularly in ED. Patterns of minor ailments that present in ED differ from general practice. The routine data collection and consensus studies were conducted using data derived from Scotland, where a national Minor Ailment Scheme has existed since 2006. Despite this, over one in 10 GP consultations in this study were for a minor ailment that might be treated in a community pharmacy.

The results of the cohort study showed that costs of managing minor ailments were lower in the pharmacy setting and no significant differences were shown in outcomes across the three settings. Whilst this suggests that community pharmacies provide a suitable alternative to general practice and ED care for the conditions evaluated in this study, this finding should be interpreted with caution because the severity of similar symptoms may have varied across settings. The main triggers for seeking care from a community pharmacy were convenient location, not having to travel too far and perceiving that the illness was not serious enough to visit a doctor.

Patient satisfaction with their index consultation was significantly associated with symptom resolution. This reinforces the importance of maximising the consultation skills of healthcare professionals in general, and community pharmacists and their staff in particular. The evidence from the wider literature as well as from the SP study shows that pharmacy staff's communication and counselling behaviour is often sub-optimal and variable across conditions.

Conclusion

Consultations for minor ailments continue to be a burden on high cost service providers. The lack of consensus amongst healthcare professionals regarding what constitutes a minor ailment suitable for treatment in the community pharmacy setting requires further exploration: if these professionals are unsure of the suitability of conditions for community pharmacy treatment then it is likely that the public has a greater degree of uncertainty. The systematic review derived evidence that suggests that providing community pharmacy-based MAS is an effective and cost-effective strategy for managing patients. The cohort study confirmed equivalence of health-related outcomes for pharmacy-managed patients presenting with symptoms similar to those in high cost settings. The lower costs associated with the management of these symptoms in pharmacies compared with the other settings provides further evidence of the suitability of pharmacies to manage these conditions.

However, health professionals and patients need to be confident in the ability of pharmacists and their staff to manage minor ailments. As such, there is an urgent need to address the deficiencies in consultation skills and communication behaviour identified by the simulated patient study. Future initiatives to shift demand from high cost settings to community pharmacy should adopt an interdisciplinary approach to explore and address patient decision-making behaviour. The management of musculoskeletal pain currently represents a major burden on high cost services and as such, future initiatives should target this condition.

1 INTRODUCTION

Currently, in the UK, minor ailments are managed in general practice (by general practitioners (GPs), practice nurses), Emergency Departments (EDs), community pharmacies, NHS walk-in centres, by telephone help lines (e.g. NHS 24), local out-of-hours services, as well as with the provision of information using the internet, information booklets or leaflets. These services have been implemented either nationally or by local negotiation.

Previous estimates suggest that between 18% and 37% of GP consultations are for minor ailments, many of which may be managed in other ways, including self-care supported by community pharmacists^{1, 2}. A study in one ED showed that 19% and 8% of consultations were suitable for management by a GP³ or a community pharmacist, respectively. The number of consultations in general practices and EDs is increasing annually⁴⁻⁶. A proportion of this increase is likely to be due to presentations for minor ailments.

1.1 Management of Minor Ailments in Community Pharmacy

In 2002, a review was published of community pharmacy NHS minor ailment schemes⁷, but, since then, there has been no systematic collation of the evidence of effectiveness or cost-effectiveness of these schemes, despite increasing numbers of services being provided throughout England as well as the introduction of the national service in Scotland (eMAS). Analysis has shown variation in patient uptake of eMAS across different Scottish Health Boards⁸ and this may be associated with deprivation and waiting times to see GP. Between April 2011 and March 2013, over two million items were dispensed by community pharmacists under the scheme. Paracetamol was the most frequently prescribed item in both years, followed by ibuprofen and simple linctus⁸. The top 10 items accounted for 53% of all prescribing by volume.

Evidence is needed of the effectiveness and cost-effectiveness of community pharmacy based management of minor ailments.

This report presents the results of a 27-month* research programme to address the five key points outlined in the commissioning brief for “Pharmacist intervention in the treatment of minor ailments:

- A systematic review of published and non-published data;
- Identification of ailments that appear to have the highest impact on the workload of high cost services (GPs, EDs);
- Evaluation of different models of delivery of care, which compares both costs and patient outcomes;
- Research into the triggers to seeking care for minor ailments from pharmacies; and,
- Evaluation of pharmacists’ consultation skills in these areas and their impact on patient outcomes.”

[*The research programme commenced 1st April 2011 and ended 30th June 2013. A no-cost extension was subsequently granted by the PPRT to 31st March 2014 to facilitate the revision of the final report to reflect feedback from the Steering Group, prepare manuscripts for submission to peer reviewed journals as well as briefing papers for relevant policy makers, organisations and individuals.]

The overall purpose of this programme was to derive evidence to inform recommendations regarding the future delivery of minor ailments services in community pharmacies (PMAS) in the UK. The research programme comprised several inter-linked components, each of which addressed one or more of the research aims which were to:

1. Identify and summarise empirical evaluations of PMAS in terms of effectiveness (patient outcomes) and cost-effectiveness.
2. Identify the minor ailments that have the highest impact on the workload of high cost services (GPs, ED) using routinely collected data.
3. Seek consensus amongst health professionals in settings where minor ailments are most often treated (i.e. general practice, community pharmacy, ED) about which ailments are regarded as minor ailments.

4. Compare the effectiveness (patient outcomes) and cost-effectiveness of the different models of delivery of care for selected minor ailments in community pharmacy, general practice, and ED.
5. Explore patient triggers for seeking care for selected minor ailments from community pharmacy.
6. Assess the effect of pharmacy staff** consultation performance in the management of selected minor ailments on patient outcome.
7. Evaluate pharmacists' consultation performance in the management of selected minor ailments.

[** The original PPRT brief required pharmacists' consultation and diagnostic performance to be assessed. However, the authorised research proposal included the performance of non-pharmacist staff as it was not possible to target pharmacists without adversely affecting study design and also, this is a more accurate reflection of the types of members of staff involved in these consultations. Furthermore, "diagnostic" performance per se was not assessed; only consultation performance of pharmacists or pharmacy staff was assessed.]

The research programme was devised following the Medical Research Council's (MRC's) Framework for Complex Interventions⁹, which comprises four key elements: development; feasibility and piloting; evaluation; and implementation. The research programme addresses the first three of these elements with three distinct components: Data Synthesis; a Cohort Study; and, a Simulated Patient Study.

The background and rationale for this research programme are described in the original grant application. The definition of minor ailment that was used throughout this programme was: *A common or self-limiting or uncomplicated condition that may be diagnosed and managed without medical (i.e. doctor) intervention.* This definition was derived by the research team, informed by other published definitions. This report comprises separate summary chapters for each research component.

1.2 DATA SYNTHESIS

The data synthesis component comprised a systematic review, the analysis of routinely collected data, and a consensus exercise. The *systematic review* was undertaken using standard methods to identify and summarise data regarding the effectiveness (patient outcomes) and cost-effectiveness of existing MAS, both nationally and internationally (Aim 1). *Routinely-collected data* were collated and used to identify minor ailments that have the highest impact on the workload of GPs and EDs (Aim 2). A multi-stage *consensus process* was undertaken to identify the four most commonly occurring minor ailments (Aim 3).

1.3 COHORT STUDY

A prospective cohort study was conducted to address Aims 4-6.

1.4 SIMULATED PATIENT STUDY

A study was conducted using covert simulated patient (SP) visits to community pharmacies, to evaluate pharmacy personnel consultation performance in the management of selected minor ailments (Aim 7).

2 DATA SYNTHESIS

2.1 Systematic review: Are pharmacy-based Minor Ailment Schemes a substitute for other service providers?

The systematic review is summarised below and has been published in the British Journal of General Practice¹⁰.

2.1.1 Aim

The systematic review aimed to:

- Identify and summarise empirical evaluations of PMAS in terms of effectiveness (patient outcomes) and cost-effectiveness.

It explored the effect of PMAS on patient health and cost-related outcomes, and their impact on general practice workload.

2.1.2 Method

Standard systematic review methods were used including the search of electronic databases e.g. MEDLINE, EMBASE and grey literature from 2001 to 2011 imposing no language or study design restrictions. Reporting was presented in the form recommended in the PRISMA¹¹ statement and checklist.

2.1.3 Results

Thirty-one evaluations were included from 3,308 titles identified. Re-consultation rates in general practice, following an index consultation with a PMAS, ranged from 2.4% to 23.4%. The proportion of patients reporting complete resolution of symptoms after an index PMAS consultation, ranged from 68% to 94%. No study included a full economic evaluation. The mean cost per PMAS consultation ranged from £1.44 to £15.90. The total number of consultations and prescribing for minor ailments at general practices often declined following the introduction of PMAS. Most stakeholders had favourable opinions of the schemes.

2.1.4 Conclusion

Low re-consultation rates and high symptom resolution rates suggest that minor ailments are being dealt with appropriately by PMAS. This evidence suggests that PMAS provide a suitable alternative to general practice consultations. PMAS consultations were less expensive than consultations with GPs. The extent to which these schemes shift demand for minor ailment management away from high costs settings could not be determined. Evidence from economic evaluations is needed to inform the future delivery of PMAS.

2.2 Routinely Collected Data: Assessing the prevalence of minor ailments in an Emergency Department (ED).

A paper giving a more detailed description of this element of the study is in preparation and will be submitted for publication in a peer reviewed journal in due course.

2.2.1 Aim

The routine data collection exercise aimed to:

- Seek consensus amongst health professionals in settings where minor ailments are most often treated (in this case, ED) about which ailments are regarded as minor ailments.
- Identify the minor ailments that have the highest impact on the workload of high cost services (general practitioners (GPs), Emergency Departments (ED)) using routinely collected data

This element of the exercise estimated the prevalence of presentations in ED for minor ailments that could have been managed in a community pharmacy setting.

2.2.2 Methods

A retrospective analysis of adult presentations to a single ED from Monday–Saturday 9am - 6pm (typical community pharmacy opening times, referred to hereafter as “in hours”), in February 2012. Presentations were screened for eligibility and excluded if they involved: patients who died whilst in the ED; patients admitted to hospital; patients who deliberately self-harmed (DSH) (as they were automatically referred for assessment by Liaison

Psychiatry); patients with injury e.g. fracture; follow-up; referral; technical procedure e.g. suturing.

Case summaries were assessed by a consensus panel of ED doctors to identify those occurring due to minor ailments (using the definition provided in 1.1), and may be managed in a community pharmacy. Validation of a sub-set of consultations was performed by a multidisciplinary consensus panel (MCP), comprising lay members, ED and non-ED health professionals.

2.2.3 Results

During the study period, there were 550 adult presentations “in hours”. Following application of exclusion criteria, 219/550 were included in the ED consensus process: 15.1% (33) were categorised as minor ailments, and 13.2% (29) were suitable for management in a community pharmacy. The prevalence of consultations for minor ailments that could be treated in a community pharmacy was 29/550 (5.3% (95% CI, 3.4% to 7.1%) of ED consultations. ED doctors’ classification of presenting conditions as minor ailments ranged from 3.2% to 46.6% (kappa 0.178) and for minor ailments that could be managed in a community pharmacy, 3.2% to 42.5% (kappa 0.223). There was, however, very good agreement (kappa 0.857) within the MCP for what could be classified as a minor ailment within the validation subset. The most commonly occurring ailments that presented in the ED and were deemed suitable for management in a community pharmacy were: musculoskeletal pain (72.4%); eye discomfort (10.3%); gastro-intestinal conditions (6.9%); minor head injury (3.4%); dental pain (3.4%); and sore throat (2.4%).

2.2.4 Conclusion

Consultations for minor ailments continue to present in EDs, albeit with a lower prevalence than reported in previous studies. Redesigning initial management of musculoskeletal pain has the potential to shift demand away from ED to community pharmacies. Little is known why patients choose to seek care from different healthcare providers. Evidence is needed regarding patients’ decision-making behaviour so that interventions can be developed to change this behaviour where appropriate and encourage treatment seeking from community pharmacies.

2.3 Routinely Collected Data: Assessing the prevalence of minor ailments in general practice.

A paper giving a more detailed description of this element of the study is in preparation and will be submitted for publication in a peer reviewed journal in due course.

2.3.1 Aim

The routine data collection exercise aimed to:

- Seek consensus amongst health professionals in settings where minor ailments are most often treated (in this case, general practice) about which ailments are regarded as minor ailments.
- Identify the minor ailments that have the highest impact on the workload of high cost services (general practitioners (GPs), Emergency Departments (ED)) using routinely collected data

This element of the exercise estimated the prevalence of presentations in general practice for minor ailments that might have been managed in a community pharmacy setting.

2.3.2 Method

A retrospective analysis and a two-stage consensus panel process was conducted of adult (≥ 18 years) consultations, in two general practices in Grampian, occurring during one week (between Monday–Friday 9am–6pm, i.e. typical community pharmacy opening times, hereafter referred to as “in hours”), in March 2012. Consultations were excluded if they were obviously non-minor e.g. injections, blood tests. Two consensus panels were convened, one unidisciplinary (GPs) and one multidisciplinary (health professionals and lay members). Case summaries were firstly assessed by the GP consensus panel, comprising eight academic GPs from the University of Aberdeen, to identify those occurring due to minor ailments and may be managed in a community pharmacy. Each consultation was assessed independently by paired GPs. Disagreement was resolved by the involvement of a third GP. Validation of a sub-set of these cases was undertaken by the MCP.

2.3.3 Results

Of the 494 consultations occurring “in hours” within the study period, 353 were eligible for inclusion in the GP consensus process; 31.2% (n=110) were categorised as minor ailments, of

which 59.1% (n=65) were considered treatable in a community pharmacy. The prevalence of consultations for minor ailments that could be treated in a community pharmacy, was 65/494 (13.2%, 95% CI 10.2% to 16.1%). The most common minor ailments were upper respiratory tract infection (44.6%), pain-related conditions (26.2%) and skin problems (10.8%). There was poor to fair agreement ($\kappa < 0.4$) amongst GP pairs. There was good agreement within the MCP for what could be classified as a minor ailment within the validation subset ($\kappa = 0.651$).

2.3.4 Conclusions

This study was conducted in Scotland, where a national Minor Ailment Scheme has existed since 2006. Despite this, over one in 10 GP consultations were for a minor ailment that might have been treated in a community pharmacy. This suggests a need to increase awareness amongst patients about which minor ailments may be managed effectively in community pharmacies with non-prescription medicines and other methods of medicine supply e.g. pharmacist prescribing, patient group directions, or advice. Further research is needed regarding the wide variation in the intra-professional interpretation of case summaries and perceptions about definitions of minor ailments and their suitability for management in a community pharmacy. More research is also needed to identify patients' reasons for choosing to go a general practice instead of a community pharmacy for these conditions. Different approaches to changing patient behaviour and decision making could then be developed and evaluated.

2.4 Multidisciplinary Consensus Panel (MCP)

2.4.1 Aim

The MCP aimed to:

- Seek consensus amongst health professionals in settings where minor ailments are most often treated (in general practice, community pharmacy, ED) and lay people, about which ailments are regarded as minor ailments.

Identify consultation characteristics that represent components of basic/good standards of practice for each of the four scenarios that were used during the simulated patient (SP) study.

2.4.2 Method

The MCP comprised 28 members recruited from Scotland, England, Northern Ireland and Wales who were identified and recruited using personal contacts of the research team and membership lists of relevant professional organisations. The panel comprised one GP, one practice nurse, two community pharmacists, one ED consultant, one Emergency Nurse Practitioner and one lay member from each country. The MCP assessed a random sample of the anonymised case summaries, already categorised by the two uni-disciplinary panels, using the same criteria. They were also provided with an initial list of consultation components for each of the four scenarios to be used in the Simulated Patient Study (Section 4 of this report) and asked to add items which they perceived to be relevant or important. Each panel member was asked to identify which of these components they considered to represent “basic” and “good” practice; components reaching 60% agreement were included in a composite list, to be used by the research team to assess consultations in the Simulated Patient study.

2.4.3 Results

Agreement was achieved between the uni-disciplinary panels and the MCP for 28/30 ED cases ($\kappa = 0.857$; very good) and 25/30 GP cases ($\kappa = 0.651$; good). The consultation components agreed by the MCP that would be required to meet basic standard of practice for consultations involving each of the four minor ailments are presented

Table 1: Consultation components required for basic standard of practice

	Back pain	Eye discomfort	Vomiting & diarrhoea	Sore throat
Information gathering				
What are the symptoms?	yes	yes	yes	yes
Who is the patient?	yes	no	yes	no
How long have the symptoms been present?	yes	yes	yes	yes
Are any other medications being used (for other conditions)?	yes	no	yes	yes
Does the patient have other medical conditions?	yes	no	yes	no
Is this patient a contact lens wearer?		yes		
Has the patient stopped taking oral fluids?			yes	
Advice provision				
Advise re. symptoms and action if symptoms continue	yes	yes	yes	yes
Ensure advice re no contact lenses until condition resolved and ensure good cleaning of lenses if not disposable		yes		
Advise re hydration/fluids			yes	
Dosage instructions (if medication has been recommended)	yes	yes	yes	no
Timescale defined (no improvement after x period referral advised)	no	yes	no	yes
MCP outcome	Simple analgesic (89%)	No sale but give advice (61%)	No sale but give advice (61%)	Simple pain relief (89%)
	No sale but give advice (61%)	Antibacterial eye drops (54%)	Oral rehydration sachet (61%)	

3 COHORT STUDY

A paper giving a more detailed description of this element of the study is in preparation and will be submitted for publication in a peer reviewed journal in due course.

3.1 Aims

The aims of the cohort study were to:

- Compare the effectiveness (patient outcomes) and cost-effectiveness of the different models of delivery of care for selected minor ailments in community pharmacy, general practice, and ED.
- Explore patient triggers for seeking care for selected minor ailments from community pharmacy.

It explored and compared health- and cost-related outcomes associated with the management of minor ailments in the three types of health care settings. In addition, the study explored triggers for seeking care in the chosen setting and explored the effect of satisfaction with the consultation on patient outcome.

3.2 Method

A prospective cohort study was conducted. Patients presenting in participating community pharmacies (n=10), general practices (n=6) and EDs (n=2) in East Anglia, England and Grampian, Scotland, for the management of one or more of the target conditions (see below) and who fulfilled the inclusion criteria for the study, were invited to participate. This presentation is referred to hereafter as the “index consultation”.

The four symptom groups representing the minor ailments presenting most frequently in general practice and ED, were:

- Musculoskeletal pain: aches or pain in arms or legs or back or hands or feet.
- Eye discomfort.
- Gastro-intestinal disturbance: nausea or vomiting or diarrhoea or constipation.
- Upper respiratory tract-related: Sore throat or cough or cold or sinus problems.

[NB: Groups of symptoms were chosen rather than single symptoms or conditions e.g. diarrhoea only, to ensure relevance across all settings as well as to maximise the likelihood of recruiting sufficient numbers of participants to the study.]

Target recruitment was 400 participants: 160 each from community pharmacies and general practices, and 80 from the EDs. Participants were asked to complete three paper-based questionnaires throughout the study. The questionnaires were:

- Baseline (completed immediately prior to the index consultation)
- Satisfaction (completed immediately after the index consultation)
- Follow-up (completed two weeks after the index consultation)

Data collected included: triggers for seeking care; outcome of/satisfaction with consultation; symptom resolution; and any reconsultations. These self-reported data were used to generate all the health- and cost-related outcome measures for this study.

3.3 Results

In total, 377 patients (94.3% of target) were recruited, most of whom were seeking treatment for musculoskeletal aches and pains (46.4%) or upper respiratory tract problems (e.g. sore throats/coughs/colds) (28.9%). Symptom presentation differed between sites with more patients seeking care for musculoskeletal aches and pains at the EDs (81.5%) compared to pharmacies (37.3%) and general practices (36.4%). At presentation, just over half the participants (52.8%) felt their symptoms were “somewhat serious” with highly significant variation in perception of seriousness occurring across settings. Just under half the participants (47.2%) felt they needed to visit their site of choice within 24 hours and this was also associated with highly significant variation across the settings; 64.2% of ED participants stated this timeframe for treatment compared with 37.3% of community pharmacy participants.

The duration of waiting prior to receiving their consultation varied across settings with pharmacy participants having the shortest wait (median 1 (IQR 0,1) minute) and having the shortest duration of consultations (median 2 (IQR 1,3) minutes). Symptom resolution at follow-up was similar across settings i.e. pharmacy (44.3%), general practice (35.7%), ED (37.3%) and setting was not a significant predictor of symptom resolution. Quality of life measured at follow-up by the EQ-5D was highest for participants who had visited a pharmacy but differences between sites were not statistically significant. Mean (SD) overall costs (for the index visit and any subsequent illness related costs in the next two weeks) were estimated

to be significantly lower in the pharmacy (£29.30 (37.81)) setting, compared with general practice (£82.34 (104.16)) and ED (£147.09 (74.96)). After adjusting for differences between settings, there was no significant difference in Quality Adjusted Life Years between the three settings.

The trigger ranked first for seeking care from any of the three settings was convenient location. Not having to travel too far was ranked second by pharmacy participants and third for general practice and ED participants. Factors that ranked second with non-pharmacy participants were: perceiving that the illness was not serious enough to visit an ED (general practice participants); and having to wait longer for an appointment with a GP (ED participants). Perceiving that the illness was not serious enough to visit a doctor was ranked third for pharmacy participants. Other factors influencing seeking care from a community pharmacy included, being “comfortable discussing my illness with ‘staff’ here”, having “previously successfully used [the] ‘site’ to treat this illness”, and being able to access “treatment/advice at [the] ‘site’ without [an] appointment.

Overall satisfaction with the index consultation i.e. MISS-21 total score¹², differed significantly across the three settings and was highest (indicating higher satisfaction) for general practice consultations and lowest for community pharmacy consultations. Of the four sub-scales within this measure, the lowest scores (indicating lower satisfaction) were consistently from pharmacy participants. Symptom resolution was significantly associated with participant satisfaction (baseline MISS-21 total score) for all settings combined.

3.4 Conclusion

The cohort study suggested equivalence of health-related outcomes for pharmacy-managed patients presenting with symptoms, with those in high cost settings. The lower costs associated with the management of these symptoms in pharmacies compared with the other settings provides further evidence of the suitability of pharmacies to manage these conditions. The association between patient satisfaction and the resolution of symptoms is an important finding relevant to all health professions.

4 SIMULATED PATIENT STUDY

A paper giving a more detailed description of this element of the study is in preparation and will be submitted for publication in a peer reviewed journal in due course.

4.1 Aims

The aims of the simulated patient study were to:

- Assess the effect of pharmacist or pharmacy staff consultation performance in the management of selected minor ailments on patient outcome.

4.2 Method

This was an observational study using simulated patients (SPs). It was conducted in 18 community pharmacies in East Anglia (England) and Grampian (North East Scotland). SPs were trained to make covert visits. Four standardised scenarios were developed for back pain, vomiting and diarrhoea, sore throat and eye discomfort. Scenario development was undertaken by the research team and the 28-person multidisciplinary consensus panel (MCP). The MCP members were provided with the scenario outlines and asked to decide what information gathering/advice provision and outcomes reflected “basic” and “good” standards of practice. Two rounds were conducted and consensus was defined as 60% agreement.

Ten SPs (one per scenario plus one reserve per centre) were recruited and attended a four hour training session that focused on the delivery of a standardised performance. Each participating pharmacy was scheduled to receive one visit from each of the four SPs in their location (i.e. Grampian or East Anglia). Visits were audio-recorded by the SP. On completion of each visit, the SP completed a data collection form (DCF).

Outcome measures were derived from the digital recordings and DCF data. Two researchers verified the data in the DCF against the digital recordings, and three researchers assessed all the digital recordings according to the criteria established by the MCP. The SPs’ assessment of professionalism was reported on a 5-point scale (exceptional interaction/not professional at

all). The SPs also reported overall satisfaction with the consultation on a 5-point Likert scale (very satisfied)/not at all satisfied).

4.3 Results

Audiotaped data were available for 68 of the 72 completed visits. No visit achieved a “good” standard. A “basic” standard was achieved with four back pain visits and one each for the three other scenarios. The majority (n=65) of consultations resulted in the sale of a medicinal product; advice alone was the outcome in only three of the consultations. Every visit involving the back pain and sore throat scenarios resulted in an appropriate outcome. Two visits, one of each involving the eye discomfort and vomiting and diarrhoea scenarios, achieved appropriate outcomes. General professionalism was rated highly, as was SP satisfaction with the consultation. Most SPs were either very satisfied or satisfied with their consultations (64/72).

4.4 Conclusion

There is considerable scope for improvement regarding the management of consultations for minor ailments in community pharmacy settings. Pharmacists and their staff need to have effective communication skills to ensure that relevant information is gathered and provided in order to make safe and effective recommendations to their patients. There is an urgent need to increase the competency of pharmacy staff with regard to these skills particularly if a convincing argument is to be made that community pharmacy is a suitable setting for the management of minor ailments, whether part of a formal Minor Ailment Scheme or as a traditional over-the-counter consultation.

5 GENERAL DISCUSSION

This was a novel research programme which used a range of research methods and data sources to address the seven research aims. The following discussion is based upon the full findings of all the components of the programme.

5.1 Strengths and Limitations

The systematic review was reported according to the PRISMA Standard¹¹ and was registered with PROSPERO¹³. It was published in the British Journal of General Practice¹⁰. It is the most comprehensive evaluation of PMASs to be undertaken to date. However, many of the evaluations were limited and the methodological quality was often sub-optimal. No non-UK data were identified.

The routine data collection component was limited to one ED and two general practices in Grampian. As such, these data may not be representative of the wider population. Data collection was limited to one week and, as such, any seasonal effect cannot be quantified.

There was considerable variation amongst the ED doctors regarding which consultations constituted a minor ailment suitable for management in a community pharmacy. The level of agreement amongst GPs was also low. The MCP was a novel approach to validating the results of the multidisciplinary panels, as well as identifying components which constitute basic and good practice in terms of the content and outcome of consultations for specific minor ailments.

The cohort study was a unique exploration of the health- and cost-related outcomes of managing similar symptoms in different healthcare settings, as well as of the triggers to seeking care from specific health settings and the association between consultation satisfaction and health outcome. The study was conducted across two regions in Scotland and England to increase the generalisability of the results. These regions are not necessarily representative of each country. The study achieved 94% of the target sample size. There was slight under-recruitment from community pharmacies in East Anglia, but all other targets were met. All outcome measures for this study were derived from patient self-reported data,

which were not validated against a second source. Similar symptoms may be experienced but which are due to very different aetiology. For example, one participant presented with leg pain (musculoskeletal pain) but was ultimately diagnosed with a deep vein thrombosis (DVT). No specific diagnosis was sought for any of the participants because this would not have been available from individuals recruited from community pharmacies. In addition, no assessment of severity of condition was used; only patient's perception of "seriousness" was assessed. As such, it is possible that the aetiology and severity of similar symptoms might have varied across settings. The two-week follow-up rate was 70%. Symptom resolution was measured at this point. Whilst some symptoms had resolved, it is possible that there was later resolution of some symptoms for some participants. Despite best intentions, follow-up was not always achieved at exactly two weeks post-index consultation.

The SP Study was conducted successfully with all but four visits eligible for analysis. Digital recordings do not enable non-verbal communication to be assessed. Non-verbal communication is considered to be a more powerful communication method than verbal. Whilst few SP visits achieved a high standard based upon verbal communication, all were rated very highly in terms of satisfaction by the SPs. This suggests that the non-verbal component of these interactions was important in these consultations. SP visits represent interactions between a human and the environment and as such, busy pharmacies and staff not wishing to ask too many questions to maintain the customer's privacy may have reduced the extent of verbal interaction in this study. The appropriateness of the consultation performance was judged against a gold standard agreed by the MCP. As such, this represented a peer comparison rather than comparison with a traditional evidence-based standard.

The following section is presented according to the aims that were addressed by the research programme.

5.2 To identify and summarise empirical evaluations of community pharmacy-based minor ailments services in terms of effectiveness (patient outcomes) and cost-effectiveness.

Evidence from the systematic review suggests that PMAS provide a suitable alternative to general practice consultations. Evidence from economic evaluations is needed to inform the future delivery of PMAS. Few evaluations included clinical outcomes e.g. symptom resolution. To date, there has been no definitive trial of the effectiveness and cost-effectiveness of pharmacy management of minor ailments. It is likely that the provision of PMAS has led to an expansion of care for minor ailments rather than complete substitution i.e. where all consultations for minor ailments would be managed in community pharmacy rather than general practices or EDs. The low rates of reconsultation, and high rates of symptom resolution, suggest that PMASs provide equivalent management of these conditions compared with the higher cost settings.

5.3 To identify the minor ailments that have the highest impact on the work load of high cost services (GPs, ED) using routinely collected data.

The routine data analyses identified the types of minor ailments, which present in ED and general practices. The prevalence of ED and general practice consultations deemed to involve minor ailments suitable for management in community pharmacy was 5.3% (95% CI, 3.4% to 7.1%) and 13.2% (95% CI 10.2% to 16.1%), respectively, which is similar to previous estimates^{2, 3}. All these data were derived from consultations which had been undertaken during standard community pharmacy opening hours.

Musculoskeletal pain was the dominant ailment presenting in ED and was the second most common type of minor ailment in general practice. Symptoms suggestive of upper respiratory tract infections were the most common minor ailment in general practice. Globally, pain is the most common reason for presenting to an ED^{14, 15}. In one prospective study of pain management in 20 US/Canadian EDs¹⁴, 506 of the 842 included patients

received analgesia during their ED attendance. Of these, the analgesics administered included ibuprofen (127), paracetamol (53), codeine/paracetamol (12), and naproxen (9), all of which are available without prescription in the UK. Analgesics are the most commonly purchased over-the-counter (OTC) medicines in Scotland, the UK and Europe¹⁶ and the most frequently supplied medicines via PMASS^{10,8}. As such, any future strategy to reduce ED consultations should focus upon the management of pain and accessing advice and effective analgesia from community pharmacies.

5.4 To seek consensus amongst health professionals, in settings where minor ailments are most often treated (general practice, ED, community pharmacy), on which ailments should be regarded as minor ailments.

Generally, there was low agreement amongst ED doctors and amongst GPs regarding which consultations were minor ailments, and may be managed in a community pharmacy. Much higher agreement was achieved between the unidisciplinary panels and the subset of consultations considered by the MCP. Whilst this variation may have been due to the interpretation of the term “minor ailment”, it may also reflect risk management considerations regarding what may be treated in community pharmacies. Other health professionals may lack confidence regarding the appropriate management of specific conditions in community pharmacies¹⁷. GPs and ED doctors may also lack awareness of the range of options available from pharmacies for the management of these conditions.

5.5 To compare the effectiveness (patient outcomes) and cost-effectiveness (cost-related outcomes) of the different models of delivery of care for selected minor ailments in community pharmacy, general practice, and ED.

The results of the cohort study suggested that equivalent health-related outcomes were achieved across all settings. Costs were significantly lower in the pharmacy setting. This suggests that community pharmacies provide a suitable alternative to general practice and ED care for the conditions targeted in this study. However, it is important to note that the severity of symptoms presenting across different sites is likely to have varied. It cannot be assumed that all presentations were equivalent across the three settings for similar symptoms.

For example, musculoskeletal pain presentations in ED might have been more severe than those presenting in the other settings.

5.6 To explore patient triggers for seeking care for selected minor ailments from community pharmacies.

“Convenience” was the major influence on choice of site for seeking care for cohort participants with 79%, 69% and 52% of patients in pharmacy, general practice and ED, respectively. Distance to travel was ranked as one of the top three influences across all three types of site. The second most highly ranked influence on patients, who presented in ED, was that they would have needed to wait longer for a GP appointment. Community pharmacies can fulfil the requirements of convenience and travel time for the majority of the population in the UK, yet the results of the cohort study suggest that despite this, other factors must be influencing the decision-making process regarding where to seek care.

Patients who sought care in the ED were significantly more likely to perceive their illness to be somewhat or very serious, compared with clients presenting in other sites. These findings suggest that providing convenient and accessible care for conditions is a major influence on patients’ care-seeking behaviour, and that patients assess the seriousness of their condition prior to selecting their site of choice. The co-location of pharmacies and general practice services with EDs should be explored and has been highlighted as a possible solution to reduce the burden of demand on EDs in the UK¹⁸.

5.7 To assess the effect of pharmacy staff’s [originally pharmacists’] consultation performance in the management of selected minor ailments on patient outcome.

The significant association across all consultations between the MISS-21 score and symptom resolution is an important finding. Participants recruited in community pharmacies, who reported symptom resolution at follow-up, had higher MISS-21 scores at baseline (indicating higher levels of satisfaction with their index consultation) than participants whose symptom had not resolved. Whilst the pharmacy results were not statistically significant the overall

results demonstrate the importance of good consultation management and performance. These results are of particular relevance when considered with those from the SP Study.

5.8 To evaluate pharmacists' consultation performance in the management of selected minor ailments.

The SP Study identified wide variation and sub-optimal consultation performance in, the management of the four minor ailment groups. Whilst disappointing, these results are not unexpected. Many studies have been conducted in the UK and internationally to assess the management of consultations in community pharmacies for the management of symptom presentations and/or the supply of medicines^{19, 20}. Almost without exception and irrespective of the country of origin or medicine/symptom involved, the results have identified sub-optimal practice.

6 CONCLUSION

Consultations for minor ailments continue to be a burden on high cost service providers. The lack of consensus amongst healthcare professionals regarding what constitutes a minor ailment suitable for treatment in the community pharmacy setting requires further exploration: if these professionals are unsure of the suitability of conditions for community pharmacy treatment then it is likely that the public has a greater degree of uncertainty.

The systematic review derived evidence that suggests that community pharmacy-based Minor Ailment Schemes are an effective and cost-effective strategy for managing patients. The cohort study suggested equivalence of health-related outcomes for pharmacy-managed patients presenting with symptoms similar to those in high cost settings. The lower costs associated with the management of these symptoms in pharmacies compared with the other settings provides further evidence of the suitability of pharmacies to manage these conditions.

However, health professionals and patients need to be confident in the ability of pharmacists and their staff to manage minor ailments. As such, there is an urgent need to address the deficiencies in consultation skills and communication behaviour identified by the simulated patient study. Inadequate information gathering in particular needs to be addressed. Whilst this will require behaviour change by pharmacists and their pharmacy staff, interventions or strategies may also be required to enhance patient engagement with proactive information provision.

Future initiatives to shift demand from high cost settings to community pharmacy should adopt an interdisciplinary approach to explore and address patient decision-making behaviour. The management of musculoskeletal pain currently represents a major burden on high costs services and as such, future initiatives should target this condition.

7 RECOMMENDATIONS FOR POLICY, PRACTICE AND RESEARCH

Government policy is already promoting community pharmacy as the preferred setting for the management of minor ailments²¹. There is evidence from other countries where similar policies have been introduced that patient behaviour has changed and demand on high cost settings has declined^{22,23}. Service redesign should also be considered including the co-location of pharmacies alongside EDs and general practices. Due to the burden which musculoskeletal pain incurs on high costs settings, it would seem an appropriate topic to address using a multi-disciplinary approach. There is a need to ensure that patients and health professionals recognise the ailments that are appropriate for management in a community pharmacy. Campaigns should be considered to promote awareness regarding the treatment options available. Campaigns should also be considered to increase public awareness of community pharmacy Minor Ailment Schemes, to encourage uptake of this service from (where available) their local pharmacies thus reflecting the findings regarding the importance of convenience in patients' care-seeking behaviour.

There is an urgent need to address the deficiencies in communication skills amongst pharmacists and their staff during consultations for minor ailments. This is an area which requires local, national and professional intervention.

The patient decision making process needs further exploration with regard to health seeking behaviour for symptoms suggestive of minor ailments. This should include their knowledge of community pharmacy as a care provider for these conditions, and an exploration of barriers and facilitators to the use of community pharmacies for the management of these conditions. In addition, this research should explore what "added benefit" patients perceive they derive from seeking care from their chosen service provider compared with others.

Currently, there is a lack of evidence regarding the extent to which pharmacy-based minor ailment schemes shift demand from other health service providers. There is also a general lack of robust evaluation of existing schemes. Research is needed to address this lack of evidence.

8 OUTPUT

PUBLICATIONS

Full

Paudyal V, Watson MC, Sach T, Porteous TH, Bond CM, Wright D, Cleland J, Barton G & Holland R. 'Are pharmacy-based Minor Ailment Schemes a substitute for other service providers?: A systematic review'. Br J Gen Pract (in press).

Abstracts

Paudyal V, Watson MC, Sach T, Bond C, Wright D, Cleland J, Holland R, Porteous T. Health and Cost-related outcomes of pharmacy-based minor ailments schemes. Int J Pharm Pract 2012;20 (Suppl 2): 17-18.

Watson MC, Paudyal V, Sach TH, Bond C, Wright D, Cleland J, Holland R, Porteous T. How prevalent are minor ailment consultations? A consensus exercise with emergency medicine (EM) doctors and general practitioners (GPs). Int. J. of Pharm. Pract. 2012;20 (Suppl 2): 51-52. [Poster]

8.1 ORAL PRESENTATIONS

Burr J, Watson MC, Fielding S, Inch J, Barton G, Bond C, Blyth A, Cleland J, Ferguson J, Holland R, Maskrey V, Paudyal V, Porteous TH, Sach T, and Wright D. A cohort study to explore the use of different health care settings for managing symptoms suggestive of minor ailment. RPS Conference September, Birmingham 2013.

Inch J, Watson MC, Cleland J, Fielding S, Burr J, Barton G, Bond CM, Blyth A, Ferguson J, Holland R, Maskrey V, Paudyal V, Porteous TH, Sach T, and Wright D. How are common minor ailments managed in community pharmacies? The MINA Study. RPS Conference September, Birmingham 2013.

Paudyal V, Watson MC, Bond CM, Wright D, Cleland J, Holland R, Porteous T, Sach T. How effective and cost effective are pharmacy-based minor ailments schemes? A systematic review. SAPC Conference Abstracts, Section 3B6, pp 67. Glasgow, October 2012.

Paudyal V, Watson MC, Sach T, Bond C, Wright D, Cleland J, Holland R, Porteous T. Health and Cost-related outcomes of pharmacy-based minor ailments schemes. RPS Conference September, Birmingham 2012.

Paudyal V, Watson MC, Bond CM, Wright D, Cleland J, Holland R, Porteous T, Sach T. How effective and cost effective are pharmacy-based minor ailments schemes? A systematic review. ADEGS Annual Conference, Dundee, 2012.

Paudyal V. The Management of Minor Ailments. Centre of Academic Primary Care, University of Aberdeen, November 2011.

POSTER PRESENTATIONS

Watson MC, Paudyal V, Sach TH, Bond C, Wright D, Cleland J, Holland R, Porteous T. How prevalent are minor ailment consultations? A consensus exercise with emergency medicine (EM) doctors and general practitioners (GPs). RPS Conference September, Birmingham 2012.

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