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Emergency supply of prescription-only medicines to patients by community pharmacists: a mixed methods evaluation incorporating patient, pharmacist and GP perspectives

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ABSTRACT

Objective: To evaluate and inform emergency supply of prescription-only medicines by community pharmacists (CPs), including how the service could form an integral component of established healthcare provision to maximise adherence.

Design: Mixed methods. 4 phases: prospective audit of emergency supply requests for prescribed medicines (October–November 2012 and April 2013); interviews with CPs (February–April 2013); follow-up interviews with patients (April–May 2013); interactive feedback sessions with general practice teams (October–November 2013).

Setting: 22 community pharmacies and 6 general practices in Northwest England.

Participants: 27 CPs with experience of dealing with requests for emergency supplies; 25 patients who received an emergency supply of a prescribed medicine; 58 staff at 6 general practices.

Results: Clinical audit in 22 pharmacies over two 4-week periods reported that 526 medicines were requested by 450 patients. Requests peaked over a bank holiday and around weekends. A significant number of supplies were made during practice opening hours. Most requests were for older patients and for medicines used in long-term conditions. Difficulty in renewing repeat medication (forgetting to order, or prescription delays) was the major reason for requests. The majority of medicines were 'loaned' in advance of a National Health Service (NHS) prescription. Interviews with CPs and patients indicated that continuous supply had a positive impact on medicines adherence, removing the need to access urgent care. General practice staff were surprised and concerned by the extent of emergency supply episodes.

Conclusions: CPs regularly provide emergency supplies to patients who run out of their repeat medication, including during practice opening hours. This may aid adherence. There is currently no feedback loop, however, to general practice. Patient care and interprofessional communication may be better served by the introduction of a formally structured and funded NHS emergency supply service from community pharmacies, with ongoing optimisation of repeat prescribing.

Strengths and limitations of this study

- This paper expands the sparse literature about the occurrence and characteristics of emergency supplies of prescription-only medicines made through community pharmacies to patients.
- This paper examines the perspectives of the three major stakeholder groups—patients, pharmacists and general practice staff.
- The participants were self-selected and this may introduce bias.
- The number of participants in each stakeholder group was modest.
- The study has generated useful underpinning information for further practice and policy development in this field.

INTRODUCTION

The Medicines Act 1968, and latterly the Human Medicines Regulations 2012, permit community pharmacists (CPs) to supply prescription-only medicines (POMs) without a prescription in an emergency when requested by either a prescriber or the patient.[1] This enables pharmacists to use their professional judgement to ensure continuous supply of medicines. Pharmacists '*must be satisfied*' that there is an '*immediate need*' for the medicine, while also considering the patient's well-being and any consequences of not supplying (box 1).[2] In this paper, the term 'emergency supply' refers to both the supply of medicines where a charge is made directly to the patient, and to the 'loan' of medication made by CPs where no

Box 1 Emergency supply at the request of a patient

Interview: the pharmacist must interview the patient, preferably face to face
Immediate need: the pharmacist must be satisfied that there is an immediate need for the prescription-only medicine (POM) and that it is not practical for the patient to obtain a prescription without undue delay
Previous treatment: the POM requested must previously have been used as a treatment and prescribed by a relevant prescriber
Dose: the pharmacist must be satisfied of knowing the dose that the patient needs to take
Not for controlled drugs, except phenobarbital: medicinal products cannot be supplied if they consist of or contain any schedule 1, 2 or 3 controlled drugs; phenobarbital can be supplied to patients of UK-registered prescribers for the purpose of treating epilepsy
Length of treatment: if the emergency supply is for a controlled drug (ie, phenobarbital or schedule 4 or 5 controlled drug), the maximum quantity that can be supplied is for 5 days' treatment. For any other POM, no more than 30 days can be supplied except:

- If the POM is insulin, an ointment, a cream or an inhaler for asthma (ie, the packs cannot be broken), the smallest pack available in the pharmacy should be supplied;
- If the POM is an oral contraceptive, a full treatment cycle should be supplied;
- If the POM is an antibiotic in liquid form for oral administration, the smallest quantity that will provide a full course of treatment should be supplied.

Records kept: an entry must be made in the POM register on the day of the supply (or, if impractical, on the following day). The entry needs to include: date supplied; name (including strength and form where appropriate) and quantity of medicine supplied; name and address of patient; and information on nature of emergency
Labelling: in addition to standard labelling requirements, the words 'Emergency Supply' need to be added to the dispensing label

charge is made to the patient and the supply is subsequently reconciled against a future National Health Service (NHS) prescription. Emergency supplies may also be made at the request of a prescriber, but those are not included in this paper. For loans in anticipation of a future NHS prescription, the additional work (ie, clinical check, determining evidence of previous supply, dispensing and documentation) undertaken by the pharmacists is not remunerated, either by the patient or the NHS. For an emergency supply where a future NHS prescription is unlikely to be obtained, usually for outside visitors to the locality, a charge is made to the patient to cover the medicine costs, and a discretionary small amount for administration.

Dispensing services around the world are likely to identify with the issues of emergency supply or owing/loaning medication outlined above. Where prescription medicine supply is tightly regulated—like in the UK, the USA, Europe, Canada and Australasia—an emergency supply service similar to the England version prevails. In countries where more prescription medicines are sold in pharmacies, like the Middle and Far East, patients are able to purchase these medicines directly, although evidence of previous use (such as old medicine packets) may be required. There are also some countries where no provision for pharmacy emergency supply exists and where the patient would have to visit a doctor for a prescription.

A 1998 survey of CPs by O'Neill *et al*[3] demonstrated that requests for emergency supplies and medicine loans were being made on a frequent basis: at least monthly for three-quarters of respondents, at least weekly for half, and at least daily for 1 in 10. Respondents perceived emergency supplies as an important service, but over three-quarters felt it was open to misuse. Other studies in this field suggest variability in professional decision-making processes and justifications, and there remains no clear definition as to what constitutes 'immediate need'.[4–8] While pharmacists identify themselves as acting in the patient's best interests, previous studies have not explored what impact supply or refusal might have on patient adherence to treatment. A significant number of emergency medicine requests are being made to urgent care services. Urgent Care 24 (UC24), a local provider of general practitioner (GP) out-of-hours services in Liverpool, reported that a total of 5156 repeat medication requests out-of-hours were received by the service in the period of September 2012–September 2013,[9] for a patient population of approximately 750 000.

NHS England's *Call to Action* highlighted challenges regarding more patients with long-term conditions and increasing patient expectations.[10] CPs are named among healthcare professionals who can support patients in managing long-term conditions in primary care. A Royal Pharmaceutical Society (RPS) report on future models of care for pharmacy[11] highlights the potential of community pharmacy in GP out-of-hours services and urgent care. Joint work between NHS England and the Pharmaceutical Services Negotiating Committee has explored extending pharmacy services to relieve pressure on accident and emergency (A&E) departments while maintaining standards of care, including amendments which permit NHS England Area Teams (regional commissioners) to commission 'Emergency Supply at NHS expense' as an Enhanced Service from community pharmacies.[12–14] A review of the literature has identified only a few studies that have explored emergency supplies by community pharmacies in depth; the majority were based in the UK.[3–8] Moreover, there is a need for a holistic examination, incorporating multiple viewpoints, of how the emergency supply service at community pharmacies may best fit within current and established health and social care provision in order to best support patient care. This evaluation aims to describe the current profile of emergency supply activity in community pharmacies to explore and inform future practice.

METHODS

This study used a mixed methods approach over four consecutive phases. Data collection was undertaken by practising CPs in North West England alongside the research team. Participants in all phases gave informed consent before taking part. An overview of the multiphased study is provided in table 1 (Research Protocol v1).

Phase 1: Clinical audit data of emergency supplies in participating pharmacies across North West England, over two 4-week collection periods. Pharmacies were purposively sampled via a recruitment pack, containing study information and consent forms, posted to them by the local Primary Care Research Network and Liverpool John Moores University (LJMU). Through this process, diversity in pharmacy ownership (independent vs corporate), setting and opening hours—and pharmacist gender and practice experience—was maximised. CPs in the participating pharmacies were asked to document the characteristics of all emergency supplies of prescribed medicines over two 4-week periods (October/November 2012 and April 2013). A pad of preprinted paper audit forms was supplied to each pharmacy. The form was created, piloted and validated by the practising CPs on the research team (GBP and NM) (phase 1—data capture form—1 October 2012.pdf (v1.0)—see online supplementary file). Details captured for each episode included: the day/date of the request; patient age and postcode; the quantity, name, dosage form and dose given of the medicine; the reason for the request, and whether the supply was made. No identifiable information was recorded on those forms.

Phase 2: Semistructured telephone interviews with CPs working at pharmacies across North West England. A subgroup of specially trained CPs who volunteered from the phase 1 audit cohort interviewed the other pharmacists, who were based in pharmacies with diverse locations, settings, opening hours and ownership type. Pharmacies who had participated in the phase 1 audit were invited to take part, and other pharmacists were recruited via local professional networks. Recruitment packs containing information and consent forms were provided to potential participants (phase 2—participant information sheet—1 Oct 2012.pdf (v1.0)—see online supplementary file). Those who returned a completed consent form were interviewed. These telephone interviews (undertaken February/April 2013) explored pharmacists' experiences and opinions in relation to requests for emergency supplies and loans (phase 2—interview schedule—1 Oct 2012.pdf (v1.0)—see online supplementary file). It also explored their reflections on challenges encountered and their resolution strategies. Peer-to-peer interviewing facilitated effective probing of responses to elicit details of difficult situations through shared professional insight into the dilemmas described. This technique has been utilised previously during interviews conducted by GPs with fellow practitioners;[15] these respondents recognised the interviewer as a fellow clinician, resulting in broader and more personal accounts of their attitudes and behaviour in clinical practice. Interviews were audio recorded with consent from interviewees.

Phase 3: Telephone interviews undertaken by the research assistant (ECS) with patients who received emergency supplies/loans of POMs. Over 6 weeks in April/May 2013, patients requesting emergency supplies or loans of POMs at participating pharmacies were invited to participate in a follow-up telephone interview after using the service. At the end of the supply, they were given a recruitment pack by the pharmacist and replied direct to the research assistant (RA) (phase 3—participant information sheet—28 November 2012.pdf (v3.0)—see online supplementary file). No demographic data were collected. These semistructured telephone interviews explored patients' views, experiences and prior knowledge of the service, as well as the perceived impact of the emergency supply on the continuity of their medicines' supply and adherence (phase 3—interview schedule—1 Oct 2012.pdf (v1.0)—see online supplementary file). Interviews were completed within 2 weeks of the initial request and were audiorecorded with patient consent and transcribed verbatim.

Phase 4: Qualitative interactive feedback sessions with medical practice teams. A subgroup of CPs volunteered from the phase 1 cohort to do this work and received further training from the research team and, with support from the RA, presented interim findings from phases 1–3 to their local general practice team. Sessions took place in October/November 2013, and explored practice staff's views and experiences regarding the emergency supply service and its impact on, and relevance to, their workflow and patient well-being (phase 4—practice staff feedback session discussion schedule.pdf (v1.0)—see online supplementary file). Practice staff provided written informed consent to take part in the

Table 1 Overview of study phases

Project phases
Phase 1: Clinical audit of emergency supplies in participating pharmacies over two 4-week collection periods October–November 2012 and April 2013
Phase 2: Semistructured telephone interviews with pharmacists working at pharmacies across North West England February–April 2013
Phase 3: Follow-up telephone interviews with service users who received emergency supplies/loans of prescription-only medicines April–May 2013
Phase 4: Qualitative interactive feedback sessions with medical practice teams October–November 2013

session (phase 4—participant information sheet—1 Oct 2012.pdf (v1.0)—see online supplementary file). To protect patient anonymity, CPs began sessions by explaining that the findings were from multiple study sites across North West England and incorporated many patients who were not registered at that practice. Field notes were taken during the discussions by the RA and consent to participate was obtained from all attendees.

Data analysis

Data were entered from the forms into IBM SPSS V.21 statistical software, where it was subjected to basic descriptive analysis. Qualitative data from all other phases were transcribed verbatim and thematically analysed for emergent themes, using NVivo V.10 software (QSR International). A 'directed content analysis' approach was used.[16] Primary attention was directed at identifying broad categories of data, followed by specific line-by-line categorisation. The study objectives provided a clear source of categories with which to organise participants' responses, while allowing other themes to emerge. Analysis examined commonalities between participants as well as contrasting perceptions of the emergency supply process. Members of the project team, and the CPs who conducted the interviews, further reviewed emergent themes to ensure robustness regarding coding and reconstruction.

Data from all phases were then triangulated to provide an understanding of the service from multiple perspectives, enhancing the validity and reliability of the study outcomes.

RESULTS

Participants in each phase of the project

Phase 1 audit: Twenty-two pharmacies took part in the phase 1 audit (table 2). Diversity in pharmacist experience, gender and length of time since registration was seen. Sites were most frequently located in small parades of neighbourhood shops (9/22) or within or adjacent to the health centre (8/22) (table 2). Fourteen pharmacies (63.6%) were closed at weekends, and three (13.6%) opened for 100 h over 7 days.

Phase 2 CP interviews: Following training in telephone interview techniques by the research team, five pharmacist researchers (PRs) completed recorded semistructured peer telephone interviews with 26 CPs working at pharmacies across North West England. Interviewees were based in pharmacies with diverse locations, settings, opening hours and ownership type, that is, independent, small/medium chain and nationwide multiple. Nineteen of the pharmacists interviewed had been involved in phase 1 of the study with the remainder being directly recruited by the PRs via professional networks. Interviews lasted between 7 and 36 min (mean 14 min).

Phase 3 patient interviews: From the 191 recruitment packs distributed by 22 pharmacies, 30 responses were received from patients at 9 pharmacies (16% response rate). Semistructured interviews were completed with 25 patients (2 declined to take part when contacted and 3 could not be contacted). Interviews lasted between 3 and 9 min (mean 5 min).

Phase 4 general practice feedback sessions: Fourteen general practice teams were invited to take part in this phase, of which six agreed. Reasons given for non-participation included: introduction of Electronic Prescription Service (EPS) occupying staff time; and a policy of refusing meetings with external parties. In some cases, practice teams appeared comfortable with meeting to hear the study findings, but were reticent about their opinions being captured. The length of time made available for the meeting varied between practices; some added the discussion to their monthly staff meeting agenda and others arranged a separate, full-length discussion. Different general practice staff categories were represented at the feedback sessions, which took place in October/November 2013. They included 5 practice managers; 25 GPs; 12 practice nurses; 10

Table 2 Characteristics of participating pharmacies

Characteristic	Number of pharmacies	Percentage of total pharmacies (n=22)
Type of pharmacy ownership		
Single independent pharmacy	4	18.2
Small group of 2–5 pharmacies	3	13.6
Local group of more than 5 pharmacies	11	50.0
National group of over 100 pharmacies	4	18.2
Location of pharmacy		
Local parade of shops	9	40.5
Health centre	8	36.4
Town centre/high street	3	13.6
Other	2	9.5
Standard days open		
Monday–Friday	14	63.6
Monday–Saturday	5	22.8
Monday–Sunday	3	13.6

reception and administration staff; 2 healthcare assistants; 2 district nurses; 1 phlebotomist; and 1 health visitor. Attendance ranged from 2 (the lead GP partner and practice manager) at one surgery to 17 team members at another. The duration of the six sessions ranged from 18 to 62 min (mean 36 min).

The results of the study are presented in an integrated approach by theme, across methods.

Frequency and characteristics of emergency supplies

Emergency supply requests were made for a total of 526 medicine items by 450 patients at 22 community pharmacies over the two 4-week audit collection periods. Most requests were for single items (405/450 occasions; 90%) with three or more items requested on 17 occasions (4%).

A higher proportion of requests were recorded on either side of the weekend (Mondays and Fridays) than on other days, with around a quarter of items requested (123/526; 23%) on a Friday (figure 1). In the eight pharmacies open during weekends (3 open both days; 2 all day Saturday; and 3 Saturday morning only), emergency supply requests were made for 65 items during this period, reflecting a higher rate per pharmacy in comparison to any of the weekdays.

Almost two-thirds (16/26) of CPs interviewed in phase 2 reported normally receiving requests at least daily, with four describing multiple requests per day, although requests rates were often variable. At phase 4 feedback sessions, some participants, including GPs and practice managers, were surprised to find that requests were received across the week; they regarded emergency supplies as something that should only happen outside practice opening times.

Emergency supply requests in phase 1 occurred for patients aged from 3 months to 92 years, with 13 (3%) for children under the age of 12 years. Although there was a trend towards more requests from older patients, a substantial number were made by young and middle-aged adults (figure 2).

Over two-thirds (18/26) of CP interviewees in phase 2 highlighted older people as the client group most frequently requesting emergency supplies. Some respondents (6/26) felt that this group had more difficulties in ordering their repeat prescriptions than younger people, but others (3/26) felt that this was simply

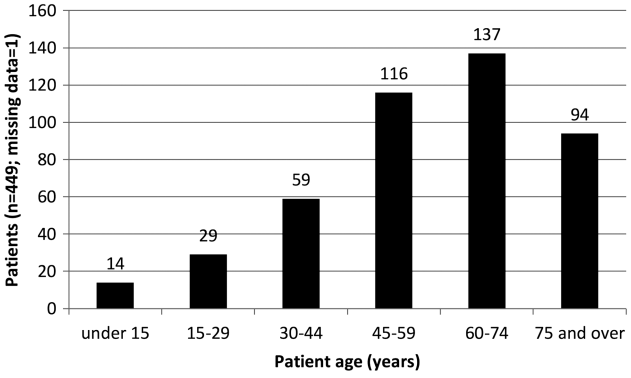

Figure 2 Distribution of emergency supply requests by patient age category (n=449; missing=1).

related to the more frequent use of medicines in this group. Younger and middle-age groups were thought by three interviewees to be likely to request emergency supplies due to other commitments, such as working or caring for others.

Most requests in phase 1 were for medicines used in long-term conditions and the therapeutic areas broadly mirrored national prescribing profiles.[17] The most commonly requested medicines were used for cardiovascular (32%, 169/526), respiratory (13%, 70/526), endocrine (12%, 63/452) and gastrointestinal conditions (11%, 56/526). Specific medicines that might lead to a risk of adverse clinical implications if a supply was not provided included treatment for a renal transplant (azathioprine) and cancer (letrozole). The wide range of medicines involved was confirmed by CPs in phase 2, with most stating that the majority of requests were for medicines for long-term conditions.

Reasons for requests

Difficulties associated with renewing repeat medication were the major reason recorded in phase 1 audit for emergency requests, including patients having 'forgotten to order' (364/526; 69%), delays with prescriptions being issued (16/526; 3%); ordered items missed off prescriptions (14/526; 3%); and errors in ordering repeat supplies via the pharmacy, for example, incorrect strength (8/526; 2%). Patient interviewees in phase 3 also reported repeat medication ordering as a cause for their emergency supply request, particularly at the end

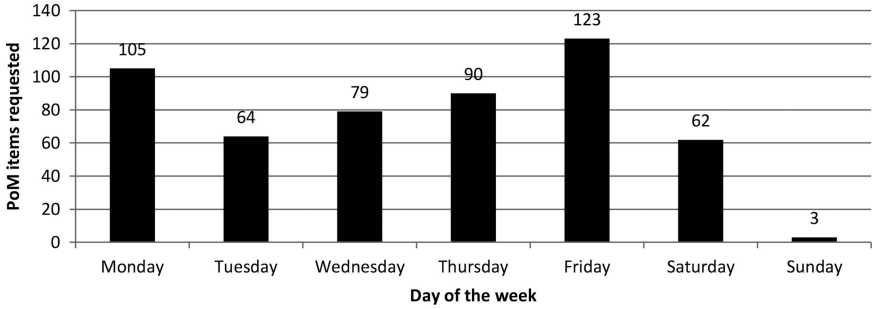

Figure 1 Distribution of emergency supply requests: days of the week (n=526) (POM, prescription-only medicine).

of a week where a supply was needed to cover the weekend. Some patients admitted that this was often an oversight on their part, but others mentioned life circumstances contributing to their problems with the ordering systems, including a 24 h carer and those who worked full-time. Other reasons for requests recorded in phase 1 were: insufficient quantities prescribed (24/526; 5%); requests following increases in the prescribed dose leading to shortages (7/526; 1%); and prescribed quantities of medicines being out-of-sync with multiple repeat dates (30/526; 6%). Problems with unsynchronised medicines prescribing, that is, where one or more additional medicines are started at a different time to other medicines, were also reported as the cause of the problem for five of the phase 3 patients.

Responding to requests

The majority (489/526; 93%) of item requests in phase 1 related to medicines 'loaned' to the patient in anticipation of an NHS prescription. In the few cases (17/526; 3%) where a charge was made, this was usually because the patient was on holiday and had forgotten their medicines and it would not have been practical to obtain a prescription. In all of the emergency supplies made to the 25 phase 3 patients, medicines had been supplied as a loan, with a subsequent NHS prescription being requested by the pharmacist to claim payment.

When prompted about payment, phase 3 patients were largely unaware that the service was not a standard aspect of the NHS supply service and, in many cases, felt that they should not have to pay as they were exempt from prescription charges. In the phase 4 feedback sessions, practice staff also considered loans the more appropriate mechanism (rather than charging the patient), since the majority of requests related to repeat medication from the patient's regular pharmacy. However, one GP commented that charging patients may act as a deterrent to the patient making a future emergency supply request, suggesting that some individuals may use the loan mechanism in preference to the standard procedure.

Impact on medicines adherence

Over half of the phase 2 CPs (15/26) described the emergency supply of medicines as a mechanism to ensure continuity of treatment as having a positive influence on adherence. Additionally, seven described it as a 'safety net' and a further two described its importance where there were delays in the processing of a prescription. Respondents also speculated that, without emergency supplies being available, some patients would simply stop their treatment until the medicines were available again.

Four of the phase 2 CPs considered the emergency supply service to have little or no impact on patient adherence. Nine expressed frustration that, although they saw the benefits in genuine emergencies, some patients abused the system, rather than managing their medicines properly. However, emergency supply requests were considered to provide opportunities to engage such patients over adherence and managing their medicines via informal discussion or through Medicines Use Reviews, an NHS-funded service for pharmacists to discuss broad issues of medicine-taking with their patients.[18]

Some phase 2 CPs and phase 4 GPs agreed that, while certain medicines did not need to be supplied urgently, if emergency supplies were refused in such cases, this might give patients mixed messages about the importance of adherence (box 2). In addition, some GPs highlighted that failure to supply could be interpreted as negligence if a patient were to experience an adverse health event owing to the interruption in treatment.

Phase 3 patients were asked to reflect on the impact of this emergency supply on the management of their medicines and condition. Many respondents explained that the supply had maintained their use of medicines as prescribed and one-third (8/25) said that this gave them peace of mind with respect to their treatment. Two-thirds of patients (16/25) emphasised the importance of an uninterrupted supply of medicines, describing the possible impact that they believed a missed dose might have (box 3). Patients also recognised that emergency supplies should not be a routine mechanism for them to obtain medicines, and one respondent described how the incident had made her more vigilant about ordering medication on time to ensure that she had a continuing supply.

Phase 3 patients described possible alternative actions that they would have taken in the absence of an emergency supply. Half (12/25) said they would speak to their GP or the surgery receptionist in the first instance, although some were unsure whether an appointment would be possible at short notice. Using the walk-in centre, the A&E department or GP out-of-hours service was also mentioned by four respondents.

Around a quarter of phase 3 patients (7/25) said that they would have just done without their medicines until their prescription was ready. In some cases, participants felt that, although this would not be ideal, it would not cause any particular harm. However, others commented that this might have a negative impact on them. Four respondents described purchasing over-the-counter medicines as a possibility, although they felt that these would be less effective than their usual medication. One service user reported having previously borrowed medicines from friends (warfarin) when he ran out. Practice staff were not surprised by the alternative actions that patients described in the phase 3 interviews, including even this case of the individual who borrowed warfarin from his friend, as they recognised such behaviour from their own patients.

Changes to practice

Phase 2 CPs highlighted that the numbers of loans currently supplied were a small, but important, facet of the existing NHS supply arrangements and structuring these supplies as a funded NHS service would be helpful

Box 2 Phase 4 practice staff quotes

The challenges of emergency supply

I think the number of steps involved it sounds easy from the outside. The patient gives in the script and he expects it to happen like that, but there are so many steps involved in it coming to the doctor and going to the pharmacist…They come at three o'clock and they want a script by five o'clock before you close. So I need to drop everything what I'm doing to do the script so it puts a lot of pressure on the service. You just need two or three people to unbalance the whole thing. (Pract1, GP)

I know from experience on a Friday everybody needs that medication because they can't wait the two days till Monday…we know what it's like but it's hard for us to know what is urgent and, you know, what can wait till Monday. (Pract3, Receptionist)

Promoting adherence

Even though we know realistically somebody's blood pressure isn't going to shoot up and somebody's not going to suddenly have a stroke, psychologically trying to convince patients of that is very difficult…and if something adverse did happen, they would blame the fact that they didn't have the medication. It's, it's hard to get the balance right…'You can miss it every now and then. It doesn't matter'. Yes you're sending a contradictory message…If you start saying, 'Well that doesn't matter that much', people will stop taking medication regularly or might stop it altogether. (Pract5, GP)

It's not ideal but…you can't leave the patient without any medication and that's the decision you've got to make…you're put in a difficult position but[you have to do] what's in the patient's best interests, I suppose. (Pract2, GP)

Communication and relationships

I've worked in practices where there's very often been a pharmacist like you who you get to know personally…The problem is when requests are coming for prescriptions to pay back tablets that have been lent out from a chemist that you're not really that familiar with, and we start to wonder about what the patient's up to. (Pract5, GP)

The thing is I think the problem is because they[patients] can, they can actually access you and bypass us. The whole problem stems from that. If you say everything has to come through the GP and they have to come here for the repeat prescriptions that problem doesn't arise…So those incidents should not happen. (Pract1, GP)

Changes to practice

We do get reports from Out-of-Hours services that people present at Out-of-Hours services requesting prescriptions for inhalers or blood pressure or heart medications etc. and clearly that's using out-of-hours resources which isn't appropriate. So if the pharmacist is able to do that, then it's going to save pressure on the Out-of-Hours services. (Pract6, GP)

There's a few[patients] who would misuse it so we need to identify those…I think it[feedback to GP] gives you a bit more confidence doesn't it? As a pharmacist: 'I've done this, I've let the GP know' and there's a safety net somewhere that would pick up a problem if there was an issue. I think that's not a bad idea. (Pract1, GP)

If we were informed who was using the service we could explore what were the reasons and maybe reduce that.' (Pract3, practice nurse)

I for the life of me don't understand why we have to spend so many hours a week writing prescriptions for things that people know that they should be on all the time. And I've got no understanding as to why we don't do that through pharmacies.[…] I think pharmacies would be far better at actually monitoring the number of prescriptions that have gone through. (Pract5, GP)

Ninety-nine percent of patients are taking charge or responsibility for their prescriptions; we are going after that one percent. Are we going to throw so many resources at this one per cent? (Pract1, GP)

(box 4). It was suggested that this could operate as an advanced service (nationally commissioned), such as Medicines Use Reviews, or an enhanced service (locally commissioned), such as the minor ailments service in operation in the study area. Respondents felt that such a service would need clear and transparent terms of service and associated fees to provide recognition of the additional workload for the CP and the expertise involved in providing the service. A national service specification was also considered important to ensure a consistent service, which would be useful for patients and other health professionals in understanding and referring to the service.

The importance of patients accessing care in the right place (GP/out-of-hours service/A&E/Community pharmacy, etc.) for their needs was also emphasised. Pharmacists and GPs identified the role that CPs could have in removing unnecessary demand from GP out-of-hours services regarding medicines supply and that this could be a driver for change to a funded emergency supply service in community pharmacies. This provision was considered to be likely to be comparatively cost-effective, directing limited NHS resources to be used in the best way. A coordinated approach to promoting such a service was preferred, with other relevant NHS service providers having clear pathways for referral. One GP contextualised the emergency supply issue as part of the broader challenge of supplying long-term repeat prescriptions, and felt that the pharmacist might take a greater facilitating role that would reduce the need for practice staff administration. In contrast, another GP felt that emergency supplies were being requested by only a small proportion of the patient population and questioned whether the resource could be justified.

Although it was recognised that there would always be a cohort of patients who would request this type of supply, it was strongly felt that a formal service should not support patients who repeatedly forgot to order repeat prescriptions and may be considered to be abusing the system. Continued patient education at each point of access to the service, together with appropriate action by pharmacists/GPs (eg, synchronisation of

Box 3 Phase 3 patient quotes

Importance of uninterrupted supply

She has to take it every day…she has brittle asthma and she's been in the paediatric ICU on occasion. She had been poorly and she absolutely does need it. It's vital for her. (Mother who requested emergency supply of an inhaler for her daughter aged 11)

This resident is dependent on this medication on a daily basis. It's to do with her mental health issue. It was important that we made sure that she took her medication otherwise there would be relapses. (Member of staff at supported living home for people with learning disabilities who requested emergency supply of medicines prescribed for a tenant's mental health condition)

It was on a loan because obviously I was picking my full prescription up the next day so it was just to tide me over for that one day. (Female who experienced delay in repeat prescription being forthcoming due to staff shortage at the GP's surgery)

Use of urgent care services

I probably would have had to have gone Out-of-Hours or maybe up to A&E or drop in centre—probably explain my situation from that point of view…So yeah, it would have been far more complicated and far more awkward to be able to resolve the situation, the predicament that I was in. (Male, requested emergency supply as he had left regular medication at holiday home after weekend visit)

Well I probably would have demanded to see the doctor and then if not, I would have called the Out-of-Hours probably if I was in a mood…Depends what type of mood I'm in but I really was needing them because if I haven't had them for a few days I start getting really bad. (Female, requested emergency supply of medication to control symptoms of anxiety)

Box 4 Phase 2 community pharmacist quotes

Communication and relationships

I've had a dilemma fairly recently on someone wanting an emergency supply…she was taking something differently from what was recorded on the computer…It was lucky the surgery was open so I could get in touch…She was taking sertraline[anti-depressant medication] and she was taking two times 100 milligrams where in fact it had been reduced. She did initially take that, but it had been reduced…she got a bit confused. (P3)

I had a guy the other day who was overusing his Airomir (salbutamol) inhaler. He was going through one every two weeks and I was saying, "You shouldn't be using that much" because I can tell by looking at him he's not that ill in a sense, you know, he's in his fifties but he wasn't collapsing on the floor with breathing difficulties or anything. So I ended up phoning the doctors and they actually got him in to see the nurse. (P1)

Changes to practice

Well I think it should become part [of] the pharmacy contract. An emergency supply really is no different from Care of the Chemist, the minor ailments scheme. So the minor ailments scheme attracts a fee and a consultation fee so why could we not have something similar for the emergency supply scenario? (CP20)

It would be nice if we could package up some sort of service across particular boundaries or groups so we [pharmacists and practice staff] all work together and we don't have the confusion for the patient really.[…] Yes more structure and a more robust system that we could all adhere to, which would be patient friendly. (CP7)

medications, review of asthma inhaler use, etc), was considered to be preferable and, over time, likely to lead to fewer patients making repeated requests. Formalised feedback to the GP about the emergency supply made might also help to improve appropriate use of the service and was supported by CP, GP and nurse participants.

DISCUSSION

Results indicate that CPs are supporting continuity of medicines use by supplying them to patients without prescription on an occasional, but routine, basis. This is particularly prevalent around times when other health services are not available, such as weekends and bank holidays, but also happens 'in-hours' during the week. Many requests are from elderly patients and individuals with long-term conditions, but all age groups are represented and a wide range of medications involved. Practice staff seemed unaware of the extent of emergency supply, especially during the week when practices were open. Practice staff acknowledged, however, that patients made requests for medication that they needed more quickly than the standard 48 h wait. GPs and reception staff experienced pressure and disruption from such requests. While the systems in place for managing repeat medication seemed to work well for the majority of patients, there were issues faced by a significant minority, which were related to multiple factors. These included: practice opening hours; forgetfulness; process errors; and competing priorities. If patients had not accessed the emergency supply service, many would have stopped taking their medication or accessed urgent care services, which was considered inappropriate by pharmacists and practice staff. Practice staff and GPs recognised the potential for mixed messages about adherence to have an impact on future medicine-taking.

The methodology used in this study brought a number of benefits and inevitable limitations. The multiphased, mixed methods nature of this study involved collation of data from multiple perspectives and provided a holistic view of the provision of emergency supplies of POMs through community pharmacies. Sufficient data were collected in all qualitative phases to reach theoretical saturation. Peer-to-peer interviewing has been shown to enable interviewees to be more open about issues encountered in practice, with interviewers better placed to probe answers using their professional experience.[15] Any inconsistencies across interviewers were minimised by group training and a review of transcripts by the RA

and individual interviewer. The experiences of the group of CPs who were involved as researchers in this multiphased study are published in a separate paper.[19] This paper provides more detail about the methodological training and data collection techniques provided to the group. CPs' existing rapport with their local general practice team also enhanced the feedback sessions in phase 4, with open dialogue giving greater understanding of the practice team perspective. However, data were not routinely collected in phase 1 regarding requests for supplies that were refused, and it is not known how many patients were referred to other services to obtain medicines. Moreover, no patient interviews undertaken in phase 3 of the study involved requests for emergency supply of POMs that had been refused. Additionally, the time of request was not recorded, so it is not possible to determine the activity in the 'out-of-hours' period other than at weekends. The response rate among patients was disappointing, and it is likely that there was a self-selection bias, although the impact of this on the data is unclear.

The frequency and characteristics of emergency supply requests were broadly similar to those found in the 1998 study by O'Neill *et al*.[3] Comparisons with Health and Social Care Information Centre (HSCIC) data[17] on prescriptions dispensed in the community suggest that cardiovascular, endocrine and gastrointestinal medicines were requested in proportions that broadly reflect their prescribed usages. However, medicines for respiratory conditions were over-represented among the requests, with 13% of requests being from this category, when they only account for 6% of prescribed items nationwide. In line with previous general studies of medicine dispensing,[4–7] pharmacists and practice staff struggled with the issue of what constituted 'immediate need'. This study extended the field by examining the patient and GP perspective.

The interactions with patients that arise from emergency supplies provide opportunities for CPs to engage with patients around medicines use and adherence. Changes to current practice were supported by CPs and GPs in this study. One approach would be to formalise the current service, remunerating CPs for the extra work involved. It was felt that such a service would have clear benefits in reducing pressure on other services, providing better structure and support for patients and supporting patients in adhering to their treatment to maximise the benefit from this. It should also include a feedback loop between the pharmacy and practice through which repeated requests, and to ensure any inappropriate requests (eg, bypassing a practice medicines review by going to the pharmacy), can be discussed and joint action taken. Technological advances regarding electronic prescribing and access to electronic patient records might also assist in the effective handling of emergency supply requests, although the impact of these advances is currently unclear.

A uniform service may also reduce patient frustration arising from the current pharmacist-level decision-making regarding whether or not an emergency supply or loan is made. However, this may be seen as reducing professional autonomy, which may impact on clinical outcomes for individual patients. A similar service is already commissioned in Scotland,[20] and the specification for an English scheme has been developed.[14] The RPS report *Now or Never*,[11] regarding new models of care for pharmacy, has emphasised the opportunity for community pharmacy to become a first point of call for patients, thus reducing pressure on other NHS services. Investment in pharmacy services would be justified by the ensuing efficiency savings. Jointly, general practice and community pharmacy would benefit from discussing ways to improve the repeat prescribing process. This may involve formalisation of the emergency supply or loan process in the short term, coupled with medium-term exploration of pharmacy-based repeat prescription management. These practice changes need to be underpinned by open communication and good relationships between the professions; this study shows that emergency supply is a shared challenge to stimulate positive joint working.

Non-adherence can reduce the benefits of medicines,[21] leading to therapeutic failure with consequential additional economic costs arising from further treatment needs. It was notable that patients did not necessarily perceive missing doses of their medicines to be a problem, and this should be addressed as appropriate during counselling. Furthermore, the opportunity for patients to circumvent the repeat prescribing process by going straight to the pharmacy and requesting a loan may result in dilemmas and discomfort for GPs and pharmacists alike. It has recently been announced that all community pharmacies in England will audit emergency supply of medicines in 2014/2015 as part of their NHS funding settlement.[22] Further complementary work to examine the patient pathway up to, and following, an emergency supply would help GPs and pharmacists to implement systems to ensure continuous treatment.

CONCLUSION

CPs regularly provide emergency supplies to patients who have run out of their repeat medication, including during practice opening hours. This may aid adherence, but there is currently no feedback loop to general practice. Patient care and interprofessional communication may be better served by the introduction of a formally structured and funded NHS emergency supply service from community pharmacies, with ongoing optimisation of repeat prescribing. This could form a more coordinated component of better integrated health and social care pathways, thus ensuring that patients benefit from being able to maintain adherence to their prescribed medicines regime.

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Collaborators Clive Moss-Barclay initiated the collaborative project and advised on pharmacy training and policy.

Contributors CWM designed data collection tools, monitored data collection for the whole trial, supervised the research assistant and ran training days, wrote the analysis plan, and drafted and revised the manuscript. He is the guarantor. AJM implemented the study, supervised the research assistant and ran training days, analysed the data, and drafted and revised the manuscript. ECS undertook fieldwork, supervised pharmacists to collect data, analysed the data and drafted and revised the manuscript. DMA revised data collection tools, monitored data collection and analysis, and revised the draft manuscript. SEW revised data collection tools, monitored data collection and analysis, and revised the draft manuscript. NM created and piloted the audit tool, developed the audit analysis plan, monitored data collection and analysis, and revised the draft manuscript. GBP created and piloted the audit tool, developed the audit analysis plan, monitored data collection and analysis, and revised the draft manuscript. NJG initiated the collaborative project, revised data collection tools, monitored data collection and analysis for the whole trial, and drafted and revised the manuscript. All authors designed the study.

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RESEARCH PROTOCOL:

AN EVALUATION OF THE ROLE OF COMMUNITY PHARMACISTS IN OPTIMISING SAFE AND APPROPRIATE MEDICINES USE IN RESPONSE TO PATIENT REQUESTS FOR EMERGENCY SUPPLIES.

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INTRODUCTION

Emergency supply of prescription only medicines

Medicines legislation lays down provisions for the emergency supply of prescription-only medicines[1]. For the purposes of this proposal, an emergency supply is defined as a request from a patient to provide a prescribed medicine when no prescription is presented at the time of the request. Here the term is inclusive of both the supply of medicines without a prescription under the emergency supply regulations at the request of a patient (as defined in the Medicines Act), and the loan of medication made by community pharmacists prior to a prescription being obtained. It is a means by which pharmacists are able to assist patients out of hours, or when they are away from home, to ensure that their supplies of medicines are not disrupted. The provision of this service can cause dilemmas, as pharmacists are obliged by law to ensure there is an 'immediate need' for the requested medicine, whilst simultaneously considering the well-being of the patient and the consequences of not supplying.

Review of the literature

An initial literature search regarding emergency supply indicates very limited studies, which are over ten years old. A 1998 survey by O'Neill et al[2] examined the frequency and characteristics of emergency supply, and the pharmacists' views of the process. The survey (of 243 pharmacists in the South East) found that the frequency of emergency supplies requested by patients ranged from no requests in the last 12 months, to at least one a day, with approximately two thirds reporting receiving requests at least monthly, and a third of these at least once a week. 'Loans', where no payment is taken for the medicine, but a prescription is promised, were considered separately in the survey. These showed even higher figures (73% at least monthly, and 47% at least once a week), with 11% reporting that loans were made on a daily basis. A range of reasons were given for the refusal to supply, most commonly that immediate need had not been established (73% of respondents reported this as a reason for non-supply). The majority of participants perceived this as an important service for patients, although over three quarters felt that the process was open to misuse. A contemporaneous study by Osman *et al*. reported that 75% of pharmacists interviewed had 'loaned' reliever inhalers to asthma patients[3].

The use of pharmacy medication records (PMRs) to facilitate the emergency supply process was documented by Rogers *et al.* in 1994[4], and pharmacists described legal and ethical dilemmas relating to emergency supplies in interviews by Hibbert *et al.* in 2000[5]. More recent work also highlights the process of emergency supply as a site of ethical and legal dilemmas (Cooper et al, 2007[6]; Chaar, 2009[7]; Deans, 2010[8]). Evidence for the extent to which the dilemmas posed by emergency supply are still experienced by pharmacists can be found in pharmacy-related networks and educational provision: The *Chemist and Druggist* has included three emergency supply related scenarios in its 'Ethical Dilemmas' section, and the *Locum Voice* internet discussion area had a long running thread on the topic. Many of the studies referenced here emphasise the wide range of decision-making and justifications cited by pharmacists, yet there remains no clear guidance as to what constitutes 'immediate need'. Similarly, whilst the majority of accounts show that pharmacists consider themselves to act in the patient's best interests, the literature does not explore what impact supply or refusal may have on patients.

NW Primary Care Pharmacy Research Group

This project has been developed by a workgroup of the NW Primary Care Pharmacy Research Group, which is facilitated by the NW Primary Care Research Network (PCRN). This workgroup is actively involved in building research capacity among community pharmacists in the Region. The steering group includes academic members from the Region's three Schools of Pharmacy (Liverpool John Moores University, the University of Manchester, and the University of Central Lancashire), practising community pharmacists, and a primary care trust pharmacist.

The research group and PCRN have recruited their first cohort of ten community pharmacists to prepare themselves and their practice setting for doing research – both as participants in other trials, and as leaders of their own research. These Research-ready pharmacists have been recruited from both independent and multiple pharmacy companies in Cheshire and Merseyside. Each of these pharmacies were chosen because they were close to a GP practice that is recognised as a research-active practice, and three of the pharmacies in the pilot are co-located with the medical practice.

AIMS AND OBJECTIVES

The overarching aim of the study is to inform best practice regarding the delivery of an emergency supply service of prescription-only medicines in community pharmacies, including the support required by pharmacists, and to identify how it may be integrated into established health and social care provision in order to fulfil its potential to maximise adherence.

The study has primary and secondary aims with associated objectives. The Primary aim is to explore the operation of the emergency supply service undertaken by community pharmacists. The secondary aim is to engage and enhance community pharmacists' involvement in, and experience of, pharmacy practice research.

The objectives associated with the primary aim are:

- To describe and analyse emergency supply activity regarding:
    - The frequency and characteristics of requests (P1);
    - The views and attitudes of service providers, including the incidence and resolution of dilemmas (P2);
    - The views of service users and other stakeholders, including general practitioners (P3).

- To explore how this convenient, patient-focused service does, and could, form an integral and coordinated component of health and social care pathways (P4)

The objectives associated with the secondary aim are:

- To become familiar with the following aspects of research methodology:
    - Developing a coding framework (S1);
    - Processes of obtaining informed consent (S2);
    - Necessity of protecting the confidentiality of the data (S3);
    - Recruitment of patients to pharmacy-based studies, including reflection upon avoiding subtle coercion by virtue of their power in providing the service (S4);
    - Presenting findings to a mixed audience in an accessible manner, and not over-stating results (S5).

- To become adept at the following data collection techniques:
    - Consistent and complete recording of robust quantitative data about their practice (S6);
    - Techniques associated with semi-structured telephone interviewing, such as following the topic guide and using follow-up prompts effectively, how to record the interview (S7);
    - Taking feedback in order to inform recommendations of the study (S8)

OVERVIEW OF THE STUDY

This multi-phased study utilises both quantitative and qualitative approaches and the data collection, in the main, is by novice research-orientated community pharmacists. Triangulation of the data from each phase of the study will provide a rounded understanding of the service enhancing the validity and reliability of the study outcomes.

Qualitative methodology has been included in this study because of the lack of published literature in this area. Using semi-structured interviews and focus groups will encourage participants to give their own understanding and experiences of the relevant topics enabling them to voice aspects that have not been predicated or prioritised.

The participants involved in the various phases of the study are patients, community pharmacists and general practitioners and practice staff. The number of participants in each phase varies and is considered to be appropriate for reaching theoretical saturation whereby there are no new data emerging from the study, and for the resources allocated to this project. A schematic of the study with approximate dates for each phase is attached (Study schematic, version 1, 1st October 2012).

An experienced research assistant (RA), with support from the Research Team, will facilitate the recruitment, management, support and training of the community pharmacists, as well as complete a literature search, obtain relevant governance approval, undertake data collection and analysis, and report writing.

Phase 1: Clinical audit of emergency supply of prescribed medicines

This phase involves community pharmacists, specifically recruited to the study, documenting the emergency supply of prescribed medicines to patients, in order to quantify the number and types of emergency supply being undertaken.

This phase addresses the following primary and secondary objectives P1, S1 and S6 (see Aims and Objectives above).

This audit phase of the study has been included to ensure a comprehensive overview of the study.

Phase 2: Interviews with service providers

Phase 2 involves up to three community pharmacists from Phase 1 undertaking recorded telephone interviews with the other pharmacists from Phase 1. The focus of the interview is to review the incidence of dilemmas and concerns that have arisen in the emergency supply of medicines, principally to determine if and how these were resolved.

This phase of the study addresses the following primary and secondary objectives: P1, P2, S2, S3 and S7.

Phase 3: Follow-up interviews with service users

This phase of the study involves the RA completing a recorded telephone interview with patients who have requested an emergency supply of prescribed medication from pharmacists involved in Phase 1 of the study. The focus of the follow-up interview, which will be no longer than 15 minutes, will be to determine patients' views and experiences of the service (including how they knew it existed), as well as the impact it might have on the continuity of their medicines supply, and resulting adherence.

This phase of the study will address primary and secondary objectives P3 and S4.

Phase 4: Dissemination of interim study findings to local general practice teams

Phase 4 involves the community pharmacists from Phase 1 presenting the interim study findings to their local general practice team, and using focus group methodology, to obtain their views of the emergency supply service and its impact on the medical practice workflow and patient wellbeing. A further meeting, following the same format and involving up two volunteer cohort pharmacists, will be arranged with the Clinical Commissioning Group (CCG) team operating in the study area.

This phase will address primary and secondary objectives P3, S5 and S8.

Phase 5: Wider stakeholder workshop: interactive feedback session

This final phase involves an interactive workshop session to present the headline findings of the whole study to the wider stakeholder community. These stakeholders will help the research team to reflect upon and formalise how the emergency supply service could form an integral and coordinated component of established health and social care pathways; wider implications for policy and practice; how to tackle challenges and barriers.

This final phase addresses primary objective P4.

This phase of the study has been included to ensure a comprehensive overview of the study.

METHOD

Phase 1: Clinical audit of emergency supply of prescribed medicines

The aim of this phase is to complete a clinical audit of all patient requests for the emergency supply of prescribed medicines. The audit will be undertaken by community pharmacists in the NW over two 4-week data collection periods. Community pharmacists from a cohort who through the Research Ready project have been selected by the North West Primary Care Pharmacy Research Group and North West Primary Care Research Network (PCRN) to prepare themselves and their practice setting for undertaking research will be eligible for participation.

Recruitment of participants

Community pharmacists will be recruited via the North West PCRN and a weighted snowballing technique will ensure that a diverse sample of pharmacies is obtained, with regard to contract type and location/setting. This sampling technique will ensure (as far as is possible) that independent/small/large/national chain pharmacies with a variety of opening hours at various locations in the North West will be incorporated into the study. Ensuring that the resulting community pharmacist who are involved in the study are diverse in experience, gender, length of time since first registered, pharmacy location, prescription volume and pharmacy type. A minimum of 10 pharmacies will be recruited to the study to ensure that a minimum of 500 emergency supply requests are recorded within the clinical audit.

Each community pharmacist will be sent a letter (and information pack) inviting them to take part in the study (Phase 1: Invitation letter: version 1, 1st October 2012), informing them of this phase, as well as further phases of the project and potential levels of participation within the other phases. The information pack will contain a study information leaflet and consent form (Phase 1: Study information leaflet: version 1, 1st October 2012). The RA will then telephone each pharmacist to see if they would like to take part in the study or if they have any questions and/or concerns regarding taking part. Those who agree to take part in the audit will be asked to sign a consent form (Phase 1: Informed consent form, version 1, 1st October 2012) to indicate they understand the nature and requirements of the audit, and specifically that patient details will be anonymised. In addition, their possible involvement in the later phases of the study will be reviewed (see overview of study above).

The RA will then visit each community pharmacist who has agreed to take part in phase 1, explain what that phase involves and what data are required to be collected. Aspects regarding the robustness and validity of the data will be explained as will the need for maintaining confidentiality and assuring anonymity of patient details.

In order to ensure that at least ten pharmacists complete both data collection periods of this phase, up to twenty community pharmacists will be recruited.

Data collection

A minimum of 500 requests will be recorded, from a minimum of 10 pharmacies, over two 4-week periods. These periods of time have been selected to include at least one Bank Holiday in which, anecdotally, patient requests for the emergency supply of medicines increase. All requests will be logged (Phase 1: data capture form: version 1, 1st October 2012) and any request for multiple medicines from a patient will be linked within the database.

During the main data collection periods the community pharmacists will be contacted (either by telephone or in person) on a weekly basis by the RA to facilitate their engagement, and as an opportunity to discuss any issues that arise. This has been shown by previous research studies to be a valuable activity to facilitate high quality data collection. Each community pharmacist will populate a pre-designed spreadsheet with the data they have collected, and will forward this to the RA on a weekly basis. This will facilitate central quality assurance of the data, with the RA being able to intervene if any fields are consistently missed and to give feedback if necessary to the participating pharmacists. These spreadsheets will be collated into a large single database, with each pharmacist being identifiable by a unique coded reference.

Data capture form

The Emergency supply data capture form (Phase 1: data capture form: version 1, 1st October 2012) will quantify the number and types of emergency supply undertaken and will gather the following data:

- Demographic details: patient age, gender, residential status and location (including partial postcode that can be mapped to the MOSAIC UK consumer classification system);
- Medication(s) requested, therapeutic class, dose prescribed, and length of treatment supplied;
- Reason for request for emergency supply and the action taken by the pharmacist.

These data, in the main, relate to the information that pharmacists are required to obtain from a patient when supplying an emergency supply of prescription only medicines under the regulations of the Medicines Act. No patient-identifiable information will be collected during the course of this phase of the study.

In addition, community pharmacists will record any related issues or dilemmas that arise at the time of the supply, including a rating of the level of complexity in resolving them. To facilitate this aspect, the recruited community pharmacists will be provided with a short in-house training session (undertaken by members of the research team) to facilitate and structure the consistent recording of their thought processes at the time of the emergency supply. To identify the various levels of concern or dilemma inherent in each emergency supply, the pharmacist will be asked to rate each supply. To standardise this process, the pharmacists will devise a shared coding framework during the course of the training session.

Data analysis

Statistical analysis, using SPSS software will be undertaken by the RA, of the quantitative data collated from the clinical audit of emergency supply conducted. This will involve descriptive and, where appropriate, comparative statistics to identify trends in the emergency supply of medicines. Comparative analyses, where valid, may explore any association between frequency and characteristics of requests with pharmacy or pharmacist variables, such as ownership or location.

Phase 2: Interviews with service providers

The aim of this phase is to review the incidence of dilemmas and concerns that have arisen in the emergency supply of medicines, principally to determine if and how these were resolved. This phase involves semi-structured telephone interviews with community pharmacists including those involved in phase 1.

Interviewers and participants

Up to three volunteer pharmacists, recruited by the RA, will receive training in qualitative telephone interviewing skills. Each will then be asked to recruit and interview at least two other pharmacists, the intention being to interview all pharmacists involved in the Phase 1 clinical audit. These interviews will be recorded and conducted in the month following the first 4-week period of data collection and each will be no more than 20 minutes in duration.

Recruitment of participants

The RA will send out an information pack explaining this phase of the study to all community pharmacists involved in Phase 1. Each pack will contain a copy of the study information sheet (Phase 2: participant information leaflet: version 1, 1st October 2012), two copies of the informed consent form (Phase 2: informed consent form – pharmacist: version 1, 1st October 2012) and a reply paid envelope. Those pharmacists who are willing to be interviewed will return a completed copy of the informed consent form to the RA; the other copy will remain with the pharmacist. Once the completed consent form is received the RA will contact a pharmacist interviewer to initiate arrangements to complete the interview. Those pharmacists who wished to be interviewed will be given at least 24 hours to reflect on their decision. Pharmacists who indicate they are not willing to be interviewed will not be contacted further.

A follow up telephone call will be made to those pharmacists who have not forward a reply within 5 days of the initial posting.

It is anticipated that each pharmacist will interview three, but no more than five, other pharmacists during this phase. The interviewer will thank those pharmacists who do not wish to be interviewed them for their time.

Development of the interview schedule

Due to the lack of published research and the time to be spent interviewing each patient (no more than fifteen minutes) the interview schedule (Phase 2: interview schedule: version 1, 1st October 2012) is based on the objectives of this phase as noted above. One interviewer will pilot the interview schedule with no more than two pharmacists. Once transcribed, the RA will discuss the findings with the Research team to ensure that the relevant information is being collected and the procedures are pertinent. Any minor alterations will be made to the interview schedule at this stage. Major alterations to the interview schedule will only be undertaken after consultation with the relevant NHS ethics committee and before any further data collection takes place.

Data collection

It is proposed to undertake the data collection over a period of five to six weeks once the first data collection period of Phase 1 has been completed.

Each interview will begin with the pharmacist outlining the aim of the study and asking the potential interviewee if they still agree that the interview can be audio recorded. If the interviewee does not agree, the pharmacist will thank the interviewee for considering taking part in the study and destroy the two copies of the signed informed consent form. For those interviewees who remain willing to continue with the interview the pharmacist will first, thank them for agreeing to take part. Secondly, remind them that they can withdraw from the interview at any time before commencing with the interview (Phase 2: interview schedule: version 1, 1st October 2012). At the end of the interview, the pharmacist will thank the interviewee for their time and ask if they have any questions they wish to raise regarding the content and process of the interview.

Each interviewer will use a series of prompts to encourage the interviewee to fully describe their experiences and concerns. In addition, some personal details of the interviewee will be collected, for example gender, age, when registered, place of work. The interview will be

informed by the ratings of the complexity of resolution made by the interviewee pharmacists during the course of Phase 1.

Transcription and analysis of the data

Each telephone interview will be professionally transcribed, the interviewer and interviewee being identified only by their unique coded reference. The study will aim for theoretical saturation, anticipating that after 25-30 cases no new themes will emerge.

The transcripts will be thematically analysed by the RA for trends and emergent patterns, using a constant comparison approach from Grounded Theory[9&10]. This will be linked to the pharmacists' shared coding framework generated in Phase 1. In addition, thematic analysis of the transcribed data undertaken by the RA will examine common and contrasting perceptions of the emergency supply process. This will further describe the frequency and characteristics of a range of emergency supplies through participants' description of the context of the issues and dilemmas. Members of the project team, in conjunction with the RA, will review the emergent themes and underlying quotations to ensure robustness and transparency regarding coding and reconstruction.

Feedback to the interviewers

The project team will review any issues that arise from undertaking the interview or from the recorded data and, if appropriate, additional support will be provided. The RA will review the first recorded interview or transcript from each pharmacist to perform quality assurance. The RA will provide feedback to each interviewer. This feedback will focus on enhancing their interview technique: for example, where additional prompting or enquiries into generalisation would enhance their abilities.

Phase 3: Follow-up interviews with service users

The aim of the follow-up interview with patients, which will be no longer than 15 minutes, will be to determine their views and experiences of the service (including how they knew it existed), as well as the impact it had on the continuity of their medicines supply, and resulting adherence. These recorded telephone interviews will be undertaken by the RA to ensure they are no conflicts for the pharmacist providing the service.

Participant criteria

Pharmacy users (16 years of age or older) who have requested an emergency supply of prescribed medicine from community pharmacists recruited to Phase 1 will be asked to take part in this phase. This recruitment will occur outside of the two Phase 1 data collection periods. Individuals under 16 years of age or those who refuse consent for participation will be excluded.

Recruitment of participants

Individuals who request an emergency supply of prescribed medication from pharmacists involved in the study will be recruited following provision of the service. Pharmacists will either hand or send them an invitation letter and information sheet (Phase 3: Invitation letter version 1, 1st October 2012; participant information sheet, version 1, 1st October 2012). These will invite them to participate in the follow-up interviews about the service and include a consent form and request their telephone contact details (Phase 3: informed consent form version 1, 1st October 2012). The signed consent form will be returned to the RA in a Freepost envelope. Once the signed informed consent forms are received, the RA will contact each patient to determine a mutually convenient time to undertake the recorded telephone interview. At the time of the telephone interview, they will be asked to reaffirm verbally their consent to take part in the interview and to be recorded.

Each pharmacist will recruit up to ten patients to be interviewed. These ten patients will not be part of the Phase 1 cohort of patients. Pharmacists will be asked to give or send information

and consent documents to 30 consecutive emergency supply patients, in order to achieve a response from 10.

Interview schedule

Due to the lack of published research and the time to be spent interviewing each patient (no more than fifteen minutes) the interview schedule (Phase 3: interview schedule: version 1, 1st October 2012) is based on the objectives of this phase as noted above. The RA will pilot the interview schedule with no more than two patients. Once transcribed, the RA will discuss the findings with the Research team to ensure that the relevant information is being collected and the procedures are pertinent. Any minor alterations will be made to the interview schedule at this stage. Major alterations to the interview schedule will only be undertaken after consultation with the relevant NHS ethics committee and before any further data collection takes place.

Procedure

It is proposed to undertake the data collection over a period of twelve to thirteen weeks once the data collection period of Phase 2 has been completed.

Each interview will begin with the RA outlining the aim of the study and asking the potential interviewee (patient) if they still agree that the interview can be audio recorded. If the patient does not agree, the RA will offer to take written notes of the interview. If this is still not agreeable the RA will thank them for considering taking part in the study and destroy the two copies of the signed informed consent form. For those patients who remain willing to continue with the interview the RA will first, thank them for agreeing to take part. Secondly, remind them that they can withdraw from the interview at any time before commencing with the interview (Phase 3: interview schedule: version 1, 1st October 2012). At the end of the interview, the RA will thank the patient for their time and ask if they have any questions they wish to raise regarding the content and process of the interview.

The RA will use a series of prompts to encourage the interviewee to fully describe their experiences and concerns. In addition, some personal details of the interviewee will be collected, for example gender, age and diagnosed medical conditions.

Data collection and analysis

The recorded interviews will be professionally transcribed. The patient and recruiting pharmacist (who were involved in the emergency supply) will be only identified by a unique reference code. The transcribed data will be thematically analysed by the RA for emergent themes and compared to those from Phase 2 to highlight commonality and diversity.

Phase 4: Interactive feedback: interim study findings to local GP teams & CCG

Phase 4 involves the community pharmacists from Phase 1 presenting the interim study findings to their local general practice team. The aim, utilising focus group methodology, is to obtain the views of the local general practice team regarding the emergency supply service and its impact on the medical practice workflow and patient wellbeing.

The RA, in conjunction with the research team, will undertake the triangulation of the findings from the previous phases. A short PowerPoint presentation will be generated that overviews the study and the salient findings, with a set of notes to prompt the main points for each slide.

Participants

Each of the selected pharmacists in the North West 'Research Ready' scheme is paired with a local GP practice that is research-active, and this should facilitate the participation of such practices in this activity. Pharmacists will engage with the practice at the beginning of the study. From the outset of the project, contact will also be established by the project team with the CCG team to facilitate their engagement in later stakeholder aspects.

Training session

A half-day training session will be provided to community pharmacists from Phase one recruited to take part in this phase, which will outline the salient points of the study and discuss how this would be relevant to general practice staff. An opportunity to role-play presenting the salient findings of the study would be provided to enable and enhance facilitator skills.

Recruitment, data collection and analysis

Prior to the interactive feedback session with the practice teams/CCG to discuss interim findings, a letter will be sent to each practice explaining the purpose of the study and specific details about the phase (Phase 4: Invitation letter, version 1, 1st October 2012; Phase 4: participant information sheet, version 1, 1st October 2012). This will be followed up with a telephone call from the pharmacist to determine a mutually convenient time for the meeting. At the meeting, attendees will be asked to sign a consent form to permit the group discussion to be recorded (Phase 4: consent form, version 1, 1st October 2012).

At the start of the meeting, a community pharmacist will give an overview and the salient findings of the study. A recorded discussion (Phase 4: discussion guide, v1 1st October 2012) will then take place regarding participants' opinions and experiences of the Emergency Supply activity undertaken by community pharmacists and how this has impacted on patient care and on the activities within the practice. The RA will be present at the meeting to take field notes and provide support to the pharmacist (facilitator). The recorded focus group will be professionally transcribed.

The practice staff and the community pharmacist will be only identified by a unique reference code. The transcribed data will be thematically analysed by the RA for emergent themes and compared to those from Phase 3 to highlight commonality and diversity.

Phase 5: Wider stakeholder workshop: interactive feedback session

The aim of this final phase of the study is to reflect upon and formalise how the emergency supply service could form an integral and coordinated component of established health and social care pathways; wider implications for policy and practice; and how to tackle challenges and barriers.

Participants

It is anticipated that the participants would include representatives from, for example, Department of Health (DH), CCGs, Strategic Health Authority (SHA), Royal Pharmaceutical Society (RPS), Pharmaceutical Service Negotiating Committee (PSNC), National Pharmaceutical Association (NPA), and out-of hours services providers.

Data collection and analysis

During this phase, participants will undertake group work, facilitated by the project team and the participating community pharmacists. They may, for example, wish to reflect upon the lack of advertising of this service. Data collection proformas will be collected from each group as part of the data for the study. The data will be analysed by the RA for emergent themes. The participants in this phase will be only identified by a unique reference code.

ETHICAL CONSIDERATIONS

Ethical approval for this project will be sought from NHS and/or Liverpool John Moores University Research Ethics Committees as required. Appropriate procedures to ensure good ethical practice will be adhered to throughout the duration of the research.

Confidentiality & Anonymity

All information given to the research team will remain confidential and anonymous. During the transcribing of the recorded interview any identifier details (for example names, addresses and/or description of places) will be removed.

All signed informed consent forms, recorded personal details and transcripts will be kept in a secure filing cabinet in the research office within the School of Pharmacy and Biomolecular Sciences, Liverpool John Moores University. This cabinet will be locked whenever Dr Charles Morecroft and the RA are not present. All electronic files relating to this study will be password protected, such that only Dr Charles Morecroft and the RA will have access. All data relating to the study will be destroyed ten years after the study has been completed. Personal data will be securely destroyed as soon as the study analysis has been completed.

Any identifying features or quotations taken from the transcripts when used in the reporting and disseminating of this study will be anonymised.

Management and supervision of the study

The day-to-day management regarding the research activities of the community pharmacists involved in the study will be undertaken by the RA. However, the overall supervision of the study will be undertaken by the Chief Investigator (Dr Charles Morecroft) to which the RA, all members of the research team, participating community pharmacists and participants will report any concerns they may have regarding the research process and content. Any major concerns regarding the research process and content will be relayed to both the Research Governance and the relevant ethics committees by the Chief Investigator. If interviewees and pharmacists prefer to inform their concerns directly, the information leaflet, which is given to all participants involved in the study, will have the details of the complaints procedure.

In the unlikely event that the collection of issues or dilemmas causes distress, Dr Charles Morecroft has the necessary skills for supporting pharmacists. Similarly, should any inappropriate practice be identified, this will be reviewed by the research team and an appropriate course of action will be undertaken that is compliant with the General Pharmaceutical Council's current Code of Ethics for pharmacists.

Personal Safety

The majority of interviews will be undertaken by telephone at little risk to the interviewer. If an interviewee requested a face-to-face interview this would be conducted at the University or in a convenient private space within a convenient community pharmacy involved with the study. The RA will be reminded of the School of Pharmacy and Biomolecular Sciences, Liverpool John Moores University's safety procedures regarding research and undertaking meetings off-campus.

RESEARCH TEAM

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An evaluation of the role of community pharmacists in optimising safe and appropriate medicines use in response to patient requests for emergency supplies

Please complete for each 'Emergency' request for prescribed medication where no valid prescription is available to cover the supply:

PHARMACY REFERENCE:

PHARMACY STAMP

RESIDENTIAL CODES
1. Lives at home
2. Nursing home
3. Residential home
4. Sheltered accommodation
5. Other (specify)

REASON FOR REQUEST CODES
1. Forgot to order
2. Meds out of sync
3. Lost/misplaced
4. Insufficient quantity prescribed
5. Taking more than prescribed dose
6. Other (please specify)

LENGTH OF TREATMENT CODES
1. 28/30 days
2. 56/60 days
3. 84/90 days
4. other (please specify)

ACTION TAKEN CODES
1. Supply made: Rx expected (loan)
2. supply made: no Rx expected
3. patient invited for MUR
4. Intervention form completed
5. Patient referred to GP
6. OTC supply made
7. Compliance aid suggested
8. Other (please specify)

Request No.	Date of request	1st part of postcode e.g. L3, CH62	Patient's age	Residential status (if known) see codes above	Relevant long term condition	Name of surgery	Medicine(s) requested	Dose prescribed	Reason for request (see codes above)	Length of treatment usually prescribed (see codes above)	Action taken (see codes above)	No. of disp staff incl pharmacist(s)

Any queries please contact Liz Stokes or Charles Morecroft School of Pharmacy & Biomolecular Sciences LJMU Byrom Street Liverpool L3 3AF 0151 231 2248 e.c.stokes@ljmu.ac.uk or c.w.morecroft@ljmu.ac.uk

Phase 1: Data Capture Form: version 1, 1st October 2012

Phase 2 Interview Schedule: Service providers

Hello/Hi, I'm …….. , one of the community pharmacists involved in the research project about the emergency supply service. I'm ringing back as we arranged to complete the interview about how you find providing the service.

- Are you still happy to take part? *If yes*

Many thanks for agreeing to be interviewed. The necessary (ethics and governance) approvals have been obtained and the interview will take about 20 minutes to complete.

The questions will focus on your views and experiences of providing an emergency supply service, and allow you to reflect on some of the dilemmas and challenges you come across during your practice. I hope that the fact I am also a practising community pharmacist will enable you to be open and honest in your answers.

Just a few points before we begin:

- The interview will be recorded so that it can be written up. We will keep this recording and the written transcript secure and will not show them to anyone. We may use quotes from what you say in our reports, but no-one will be able to tell that it was you who said it as these will be anonymised.

- All information you provide will be handled in accordance with the Data Protection Act (1998) and will not be passed on to any third party.

- You are free to end the interview at any time without giving a reason, and you can ask for any information you have already provided be erased from the recorder.

- So is it okay to turn on the tape-recorder?

TURN THE TAPE ON – CHECK THAT IT IS WORKING

Personal details

1. To begin with, if I could just ask for a few brief personal details:

    a. **Gender** (circle response) **:** Male/Female

    b. **Age group** (circle response) **:** 18-25 26-35 36-45 46-55 56-65 >66

    c. **Place of work** (pharmacy code)**:**

    d. **In what year did you register as a pharmacist?**

    e. **How long have you worked in a community pharmacy?**
    Prompts: < 1 year, 1-2 years, 3-5 years, 6-10 years, 11-20 years >20years

Frequency & characteristics of emergency supply

2. How often do you tend to receive a request from a patient for an emergency supply of prescription-only medicine?

   Prompts: Once a day or more? About twice a week? About once a week? About once or twice a month? Less than once a month?

3. Can you tell me what types of medication you most frequently get requests for?
   Prompts: inhalers, contraceptive, insulin,

4. From which client group are requests most frequently received?

   Prompts: older people, carers of older people, the patient themselves or a parent/carer

Dilemmas & concerns

5. Can you describe any occasions which have caused dilemmas as to how to proceed?

   Prompts: Related to…repeat emergency supplies, someone who does it regularly, too many repeated requests for emergency supply

   How have you resolved these issues?

6. Can you remember any instances in which you have had to refuse an emergency supply?

   Prompts: patient not present, controlled drugs, proof of prescription not available, too many repeated requests.

   How did you communicate this to the person making the request?

7. Have you ever had to contact someone else to get advice about an emergency supply?

   Prompts: who was it, was it helpful?

Emergency supplies and adherence

8. What impact, if any, do you think the emergency supply service has on patient adherence?

Concluding questions

What changes would you suggest to the system?
How will that change things?

What further support would you like when making emergency supplies?

Would you like to say anything else about emergency supplies?

Ask the interviewee if they have any questions?
At the end of the interview – whilst the tape continues to record: explain that the tape will be written out in full and any identifying details removed.
Thank you for taking part.

PARTICIPANT INFORMATION SHEET

An evaluation of the role of community pharmacists in optimising safe and appropriate medicines use in response to patient requests for emergency supplies

As a community pharmacist providing an emergency supply service, you are being invited to participate in this research study. Before you decide to take part, it is important that you understand why the research is being done and what it involves. Please take time to read the following information carefully. Ask us if there is anything that is not clear or if you would like more information.

What is the purpose of the study? – This study is exploring the operation of the emergency supply service of prescription-only medicines undertaken in community pharmacies to inform best practice, including the support required by pharmacists and how it may be integrated into established health and social care provision in order to fulfil its potential to maximise adherence. This phase aims to review the incidence of dilemmas and concerns that have arisen in the emergency supply of medicines, principally to determine if and how these were resolved.

Why have I been chosen? - We are asking pharmacists who have dealt with patient requests for emergency supply of prescribed medication, if they would like to be interviewed about their experiences of providing the service.

Do I have to take part? - No. It is up to you to decide whether or not to agree to be interviewed. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you do agree, you can change your mind at any time without giving a reason. If after a few days of being interviewed, you feel that would like to withdraw you can ask for your answers to be removed by contacting the team using the contact details at the end of this information sheet.

What will happen if I take part? – if you wish to take part, please return one copy of the consent form to Liz Stokes, by email, fax or post using the reply-paid envelope provided. Once the form is received by the research team a trained pharmacist interviewer will call you to ask if you are willing to be interviewed about the emergency supply service and to arrange a mutually convenient time for the interview. The telephone interview should take no more than 20 minutes. You can decide to withdraw from the interview at any time or decide not to answer specific questions.

Are there any benefits/ risks involved? – No risks or disadvantages are anticipated related to you agreeing to be interviewed.

The information from this research study will allow the research team to advise on improving the emergency supply service. You may benefit from materials produced to support pharmacists in delivering the service in the future.

What if there is a problem? - If you have a concern about any aspect of this study, you should ask to speak with the researcher who will do their best to answer your questions (see below). If you remain unhappy and wish to complain formally, you can go through the NHS complaints Procedure or contact the Chief Investigator (see below).

Will my taking part in this study be kept confidential? - All information that is collected during the course of this research study will be kept strictly confidential. We will follow the Data Protection Act (1998) at all times.

During the interview, your responses to the questions will be recorded. After the interview has been completed, the recorded interview will be converted to written text (transcribed). At this stage, any names or addresses you mention will be changed so that no-one will be able to tell that it was your call. We will delete any recordings of the telephone calls once the final report is written. We may quote you from your telephone call, but we will make sure that no-one will be able to tell that it was you who said it.

What will happen to the results of the research study? - All documentation will be kept in a secure filing cabinet in an office within Liverpool John Moores University. This cabinet will be locked whenever Dr Charles Morecroft or Research Assistant are not present. All electronic files relating to this study will be password protected, such that only Dr Charles Morecroft or Research Assistant will have access. All data relating to the study will be destroyed ten years after the study has been completed. All audio recordings of the telephone calls will be securely destroyed once the final report is written

A written report of this study will be submitted to The Pharmaceutical Trust for Educational and Charitable Objects (PTECO), the funders of this project and used to consider improvements to the emergency supply of medicines to pharmacy customers. In addition, the findings of the study will be presented to pharmacy networks, at professional conferences and submitted to professional journals. However, participants of the study will not be identified when reporting and distributing the findings to academic and professional journals and conferences. Any quotations from the recorded information when used in reporting the findings of this study will be anonymised.

Who is organising and funding the research? -This project has been developed by a workgroup of the North West Primary Care Pharmacy Research Group, which is facilitated by the NW Primary Care Research Network (PCRN) and includes academic members from Schools of Pharmacy at Liverpool John Moores University, the University of Manchester and the University of Central Lancashire. This research is being carried out by Dr Charles Morecroft as Chief Investigator alongside other members of the research team at Liverpool John Moores University and the wider steering group. Funding for the research study is provided by The Pharmaceutical Trust for Educational and Charitable Objects (PTECO).

Who has reviewed the study? – This study has also been approved by the (*Insert LREC name and address*, *date and reference number)*. In addition, approval has been obtained from Liverpool John Moores University Ethics committee (*insert date and reference number)*.

Contact Details for further information - If you would like any more information or have concerns about the content or procedure of this study, please contact any of the following:

Chief Investigator: Dr Charles Morecroft FRPharmS PhD
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Email: C.W.Morecroft@ljmu.ac.uk

Research Assistant: Liz Stokes
School of Pharmacy and Biomolecular Sciences
James Parsons Building, Byrom Street
Liverpool John Moores University, Liverpool, L3 3AF

Telephone: 0151 231 2152
Email: E.C.Stokes@ljmu.ac.uk

Contact details of NHS Complaints

Mr Clive Moss-Barclay
Project Director, NW Pharmacy Workforce
Workforce Development Team, NHS North West
Emerson Business Centre, Suite 21, 5th Floor,
St James's House, Pendleton Way, Salford, M6 5FW
Tel: 0161 212 6042
clive.moss-barclay@salford.nhs.uk

Consent form – If you are happy to take part in this study, please complete and sign the consent form, and return a copy to the Research Assistant.

Thank you for considering taking part in this study.

Phase 3 Interview Schedule: Follow-up with service users

The service user having already completed and signed an informed consent form (Phase 3: informed consent form: version 1, 1st September 2012) as indicated in the research protocol (research protocol: version 1, 1st September 2012).

The conversation between the research assistant and the service user will continue as follows:

Hi, I'm Liz and I'm from Liverpool John Moores University. I'm ringing you today to follow up a consultation you had with the pharmacist a couple of weeks ago for an emergency supply of a prescription medicine. Afterwards you agreed to be contacted by LJMU to take part in a follow-up telephone interview about your use of the service.

- Are you still happy to take part?

  If no: thank them for considering taking part in this phase of the study.

  If yes: any thanks for agreeing to be interviewed. The necessary (ethics and governance) approvals have been obtained and the interview will take about 15 minutes to complete.

- Is it convenient to do the interview now? (or phone back)

The questions will focus on your views and experiences of the emergency supply service on this occasion.

Just a few points before we begin:

- The interview will be recorded so that it can be written up. We will keep this recording and the written transcript secure and will not show them to anyone. We may use quotes from what you say in our reports, but no-one will be able to tell that it was you who said it as these will be anonymised.

- All information you provide will be handled in accordance with the Data Protection Act (1998) and will not be passed on to any third party.

- You are free to end the interview at any time without giving a reason, and you can ask for any information you have already provided be erased from the recorder.

- So is it okay to turn on the tape-recorder?

TURN THE TAPE ON – CHECK THAT IT IS WORKING

1. Can you tell me a little about why you used the emergency supply service on this occasion?
   Prompts: Out of hours/away from home…

2. How did you know about the service?
   Prompts: *Used before?*
   Heard from family/friends? GP? Other health professional?
   Told about by pharmacist/other member of pharmacy staff?

3. How did you find the way the pharmacist dealt with your request on this occasion?

Prompts: Did the pharmacist give you the medicine you required?

If yes… > Did you have to pay for the medication? *Prompt: or provided as a 'loan'?*

How did your use of this emergency supply impact on your routine for taking your medicines?

If no… > What impact did this refusal have?
Prompts: When were you able to get the medicines you required?

4. What do you consider to be the impact of that event on your care?
5. What would you have done if the service had not been available?
6. Have you used the service before?
7. Do you think the service is an important role that community pharmacist play in your on-going care?
8. Why do you think that?
9. Is there anything else that you would like to say about the service or the way it was run?

Thank you for taking part. Just to confirm, I'm going to write up what you've said and will delete the recording once the final report has been completed. I'll make sure that no-one can tell that these were your answers.

PARTICIPANT INFORMATION SHEET

The role of community pharmacists in making emergency supplies to patients.

As a community pharmacy/chemist customer who has used the emergency supply service, you are being invited to participate in this research study. Before you decide to take part, it is important that you understand why the research is being done and what it involves. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Please take time to read this information sheet before deciding whether or not you wish to take part in the study.

Why are we doing the study? - This study is looking at how the emergency supply service at community pharmacies can be improved. We want to hear what the people who have used the service think of it and whether it has helped them.

Why have I been chosen? - We are asking people who requested an emergency supply of prescribed medication at this pharmacy, if they would like to be interviewed about their experiences of using the service.

Do I have to take part? - No. It is up to you to decide whether or not to be interviewed. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you do agree, you can change your mind at any time without giving a reason. A decision to withdraw or not to take part will not affect you or the quality of care you receive from the pharmacy or staff in any way.

What will happen if I take part? - We will call you within two weeks of your visit to the pharmacy to ask you what you thought about the emergency supply service and how you found using it on this occasion. The telephone call should take no more than 15 minutes. We will check that you are happy to take part again at the beginning of the interview. You can decide to withdraw from the interview at any time or decide not to answer specific questions.

What do I have to do if I decide to take part? - If you are happy to be telephoned, please provide your contact details on the telephone contact sheet. We will then call you in a couple of weeks and you can decide if you want to be interviewed then. If you want, you can ask the researcher to call you back another time that is better for you.

Are there any benefits/ risks involved? - We don't think that there are any risks related to you agreeing to be interviewed, but you may become upset talking about your experience of the emergency supply service. If this happens, the researcher will ask you if you want to continue and you can decide to skip any questions which you would prefer not to answer.

You could also contact the local Patient Advice and Liaison Service (PALS) for further support (see below).

The information from this research study will allow the research team to advise pharmacist how to improve the emergency supply service.

What if there is a problem? - If you are worried about any aspect of this study, you should ask to speak with the researcher who will do their best to answer your questions (see below). If you remain unhappy and wish to complain formally, you can go through the NHS Complaints Procedure or contact the Chief Investigator (see below).

Will my taking part in this study be kept confidential? - All information that is collected in this research study will be kept strictly confidential. We will follow the Data Protection Act (1998) at all times and will **not** tell anyone whether you took part or not. We will **not** tell the pharmacy staff or pharmacist what you said.

The interview will be recorded if you are happy for us to do this. After the interview has been completed, the recorded interview will be typed up word-for-word (transcribed). At this stage, any names or addresses you mention will be changed so that no-one will be able to tell that it was your call. We will delete any recordings of the telephone calls at the end of the study. We may quote you from your telephone call, but we will make sure that no-one will be able to tell that it was you who said it.

What will happen to the results of the research study? - All paper forms will be kept in a secure filing cabinet in an office within Liverpool John Moores University. This cabinet will be locked whenever Dr Charles Morecroft or the Research Assistant are not present. All electronic files relating to this study will be password protected, so that only Dr Charles Morecroft or the Research Assistant will have access. All information we collect in the study will be destroyed ten years after the study is finsihed.

A written report of this study will be submitted to The Pharmaceutical Trust for Educational and Charitable Objects (PTECO), who have paid for this project and used to think about improvements to the emergency supply of medicines to pharmacy customers. The findings of the study will also be presented to pharmacy networks, at professional conferences and in professional journals. However, patients in the study will not be identified when reporting the findings. Any quotes will be kept anonymous.

Who is organising and funding the research? -This project has been developed by a workgroup of the North West Primary Care Pharmacy Research Group, which is organised by the NW Primary Care Research Network (PCRN) and includes researchers from Schools of Pharmacy at Liverpool John Moores University, the University of Manchester and the University of Central Lancashire. This research is being carried out by Dr Charles Morecroft as Chief Investigator alongside other members of the research team at Liverpool John Moores University and the wider steering group. Funding for the research study is provided by The Pharmaceutical Trust for Educational and Charitable Objects (PTECO).

Who has reviewed the study? – This study has also been approved by the NRES Committee West Midlands - The Black Country (24/10/12; Ref: 12/WM/0364*)*. In addition, approval has been obtained from Liverpool John Moores University Ethics committee (30/10/2012; Ref: 12/PBS/005*)*.

Contact Details for further information - If you would like any more information or have concerns about the content or procedure of this study, please contact any of the following:

Chief Investigator: Dr Charles Morecroft FRPharmS PhD
Principal Lecturer, Clinical Pharmacy Practice
School of Pharmacy and Biomolecular Sciences
James Parsons Building, Byrom Street
Liverpool John Moores University, Liverpool, L3 3AF
Telephone: 0151 231 2296
Email: C.W.Morecroft@ljmu.ac.uk

Research Assistant: Liz Stokes
Telephone: 0151 231 2152
Email: E.C.Stokes@ljmu.ac.uk

Contact details of NHS Patient Advice & Liaison Services (PALS)

NHS Liverpool/NHS Sefton/NHS Halton & St Helens
Merton House
Stanley Road
Bootle, L20 3DL
Tel: 0800 218 2333

NHS Knowsley
Knowsley Health & Wellbeing
1st Floor, Nutgrove Villa
Westmorland Road
Huyton, Knowsley, L36 6GA
Tel: 0800 073 0578

NHS Western Cheshire
1829 Building
The Countess of Chester Health Park
Liverpool Road
Chester, CH2 1YZ
Tel: 01244 650368/ 0800 132996

NHS Wirral
Old Market House
Birkenhead Wirral
CH41 5AL
Tel: 0151 647 4251/ 0800 085 1547

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Contact details of NHS Complaints

Mr Clive Moss-Barclay
Project Director, NW Pharmacy Workforce
Workforce Development Team, NHS North West
Emerson Business Centre, Suite 21, 5th Floor,
St James's House, Pendleton Way, Salford, M6 5FW
Tel: 0161 212 6042
Email: clive.moss-barclay@salford.nhs.uk

Consent form – If you are happy to take part in this study, please complete and sign the consent form, and fill out the telephone contact details sheet and return these to us in the reply-paid envelope provided.

Thank you for thinking about taking part in this study.

STUDY INFORMATION SHEET

An evaluation of the role of community pharmacists in optimising safe and appropriate medicines use in response to patient requests for emergency supplies

This study is exploring the operation of the emergency supply service of prescription-only medicines undertaken in community pharmacies. The purpose of the evaluation is to consider how the service can best be delivered in order to fulfil its potential to maximise adherence, including identifying how it may be integrated into established health and social care provision. The information from this research study will allow the research team to advise on improving the emergency supply service.

The study is multi-phased to provide a rounded understanding of the service. Previous phases have involved:

1. Clinical audit of all patient requests for the emergency supply of prescribed medicines to patients over two 4-week periods (including bank holidays), in order to quantify the number and types of emergency supply being undertaken.
2. Interviews with service providers to review the incidence of dilemmas and concerns that have arisen in the emergency supply of medicines, principally to determine if and how these were resolved.
3. Follow-up interviews with service users to determine patients' views and experiences of the service (including how they knew it existed), as well as the impact it might have on the continuity of their medicines supply, and resulting adherence.

Interactive feedback session

We would like to present the interim study findings from these phases to the practice team and to obtain your views of the emergency supply service and its impact on the medical practice workflow and patient wellbeing. A meeting of approximately one hour will be arranged at a mutually agreed time. A community pharmacist from the research participation initative pharmacy paired with practice will present a short Powerpoint presentation providing an overview of the study and salient findings. Following this, there will be an opportunity to feedback your reaction to these - and their relevance to general practice during a group discussion facilitated by the pharmacist.

Please note: Attendees will be asked to sign a consent form to permit the group discussion to be recorded and the research assistant to take field notes. All the information that is collected during the course of this research study will be kept strictly confidential. Any information you provide will be handled in accordance with the Data Protection Act (1998) and will not be passed on to any third party. Participants of the study will not be identified when reporting and distributing the findings to academic and professional journals and conferences. Any quotations from the recorded information when used in reporting the findings of this study will be anonymised.

Contact Details for further information - If you would like any more information about this study, please contact:

Chief Investigator: Dr Charles Morecroft FRPharmS PhD
Principal Lecturer, Clinical Pharmacy Practice
School of Pharmacy and Biomolecular Sciences
James Parsons Building, Byrom Street
Liverpool John Moores University, Liverpool, L3 3AF

Telephone: 0151 231 2296
Email: C.W.Morecroft@ljmu.ac.uk

Research Assistant: Liz Stokes

Telephone: 0151 231 2152
Email: E.C.Stokes@ljmu.ac.uk

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Mr Clive Moss-Barclay
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St James's House, Pendleton Way, Salford, M6 5FW
Tel: 0161 212 6042
clive.moss-barclay@salford.nhs.uk

Thank you for considering taking part in this study.

Part 1: Introduction to study

- Introduce yourself – placing emphasis on role today as pharmacist researcher.
- **Session Aim:** the purpose of today is to get your views about emergency supplies and loans, as well as to present a selection of the interim findings to you
- Hand out aim of session sheet +Check all have signed consent forms (explain about recording)

- The study has collected data from across the Cheshire and Merseyside region and the findings I'll discuss today have been drawn from the whole data set **– so although some data will be local to here, there are many other patients, pharmacies and surgeries involved.**
- Data on emergency supply requests were collected in 22 pharmacies, over two x 4 week periods, incl over Easter Bank Holiday period. During this time, there were 525 requests.
- We've interviewed 26 community pharmacists about their experience of providing emergency supplies/ loans and done follow-up interviews with 25 patients who have had ES/loans in the past few months.
- The final stage of this part of the study is to present the findings from this work to you and to get some feedback from the practice teams – we're doing this in around 10 surgeries across the study region.

- I'd like to give you some definitions to help clarify things: (refer to BNF excerpt)
- **Emergency Supply** CP satisfied that: Previously prescribed, Not practical to get Rx, Not schedule 1/2/3 CD (excl epilepsy), Immediate need *but note:* variability in decisions down to professional judgement of CP (satisfied)
- **Loans** – medicines are supplied under the emergency supply regulations but no charge is made and the supply is subsequently reconciled against an NHS prescription (Loans constitute the vast majority of cases – Phase 1 data: 488/525 cases recorded; 93%).
- The RPS have also issued guidance that pharmacists should consider the clinical consequences of not making a supply when deciding whether to issue a medicine as an emergency supply.
- For purposes of this study – formal emergency supplies and loans considered together.

Initial discussions:

At this stage, I'd like to find out a little about what your current experiences and thoughts are in relation to emergency supplies and loans: **Allow any discussion then use** *Prompts:*

- *Do you recall an occasion where a patient has been given a supply of medication without an NHS prescription?*
- *Can you think of a patient/situation where a problem may have been averted by an emergency supply or loan?*
- *What are your initial thoughts on Emergency supplies and loans made by pharmacies? (good/bad)*

Tip: focus on their patients' experiences and the views that they already had before you arrived
When the conversation/comments from the introductory discussion slow down (remember to give them time to talk), move on

Part 2: Characteristics of emergency supplies made

Right, now, I'd like to talk about some of the data we've collected on emergency supplies that have taken place over the study period.

- Hand out charts: days of week distribution + patient age distribution

Tip: Take care not to over-discuss the charts – just point out some headline facts

Days of week distribution: Looking at this chart, you can see the spread of the requests across the week highlighting that in those pharmacies open on Saturdays, nearly one request is made per hour of opening. Mondays and Fridays are also peak periods across all 22 pharmacies, in comparison to other weekdays.

Age distribution chart: Looking at this chart showing the age distribution of the 452 patients who made emergency supply requests, you can see a trend towards more requests from the elderly; but significant numbers of young and middle aged people.

Most common types of medicines requested:

- Vast majority of requests are for treatments used in long term health conditions, which broadly mirror the range of medicines prescribed.

Reasons for requests:

Tip: Place emphasis on process difficulties (no blame)

- Patient difficulties in renewing repeat medication
  - Forgetfulness and not ordering in sufficient time (48 hours) (most common – 363/525 cases; 69%)
  - Pharmacy errors in ordering (8 cases; 1%)
  - Items missed off prescriptions (in error) or insufficient quantities prescribed (38 cases; 7%)
  - Multiple items out of sync with different repeat dates (31 cases; 6%)
- Lost or misplaced medication (26 cases; 5%)
- Prescribed dose had been increased, but quantities had not been increased correspondingly, or patient had required more 'as needed' medication than anticipated when prescription issued (unusual: very small percentage of cases – 7/525; 1%)
- In the case of supplies where charges were made (as opposed to loans; 17 cases; 3%), this was largely because the patient was on holiday and had forgotten their medicines; or it was the Bank Holiday period and surgeries were closed.

Further discussion:

- I'd like to ask for your views again at this point, do you have any additional thoughts?
- Is there anything that you said earlier that you would like to add to or discuss further?

Prompts:

- *Does any of that surprise you?*
- *How does the clinical indication or medicine type matter?*
- *What do you think about the reasons that supplies are requested?*

Tip: Use charts to prompt discussion.

Part 3: Community pharmacists' experiences and thoughts

Concerns/dilemmas:

When we talked to community pharmacists about requests that they receive for emergency supplies, they raised a few issues that make it difficult to decide whether to make a supply and how this might affect the welfare of the patient including clinical implications of a break in supply. Issues included:

- **Repeated requests from the same patients**
- **Dosage queries and uncertainty regarding clinical particulars of the supply** – unsure of correct dosage eg. differed from dose last dispensed (shown on PMR), instances where dose changed/patient newly commenced medicine > contact with prescribing GP to verify imperative.

In some cases, pharmacists will refuse to make supplies. I'm just going to read out some of the reasons the pharmacists we interviewed gave for refusal:

- **Request for Controlled Drugs or other medicines with potential for abuse** – opiod and compound analgesics; benzodiazepines.
- **Insufficient evidence/record of previous prescription available** – CPs go to some lengths to find prescription information with refusal if all avenues exhausted: initial checking of PMR to see if supplied medicines to this individual in the past > possibility to verify with GP surgery during

opening hours > or from prescription information obtained from repeat slip, empty box or as in one case identified in this study from a hospital discharge letter.

- **Medication review required** – either GP has requested one (on repeat order slip) or CP has identified a clinical issue for review
- **Not considered an emergency by the pharmacist** – examples given: items which could be bought as OTC item and prescribed medicines like statins, where missing a couple of doses would not have any important clinical implications. Distinction also made between supplies requested by someone in genuine need vs. for patient's convenience.

Signposting: Where refusing a supply CPs would generally advise the patient which might be the most appropriate service where they could obtain more support (not possible to refer via any formal pathway) – including during opening hours directed to prescribers, particularly apparent where pharmacy situated at/close to health centre.

Further discussion:

- I'd like to ask for your views again at this point, do you have any additional thoughts?
- Is there anything that you said earlier that you would like to add to or discuss further?

Prompts:

- *What do you think about those concerns that the pharmacists are raising?*
- *What do you think about the reasons they are giving for refusal/supply? Robust enough?*
- *Are there any other circumstances in which you'd like to see refusals? Or are they being over-cautious?*

Part 4: Patients' views and experiences

I'd just like to remind you that the patients were recruited from pharmacies across Cheshire and Merseyside and the following comments and quotes are drawn from all of these – not specifically your patients.

We asked the patients about why they had obtained an emergency supply:

- All patients had received loans (no charges had been made; NHS prescription followed)
- Most supplies related to being unable to obtain a prescription
    - Ordering timeframes
    - Multiple medications (out of sync)
    - Forgetfulness
    - Also other unforeseen circumstances, such as: a lady who discussed her carer role providing 24 hour care to her husband therefore getting behind with her own prescription; lost/misplaced medicines – a working male left medication at his holiday home.
- More than half of those interviewed mentioned that they had used it on a previous occasion
- Others were either offered a supply in response to a problem (pharmacy staff informing of service) or had been directed to the pharmacy by the GP surgery reception staff

Some further comments/findings:

- All patients were happy with the service received and found pharmacy staff helpful
- Most supplies were from the patient's regular pharmacy
    - Reported advantages: established rapport with pharmacy staff and records of their previously dispensed medicines making it easy to confirm that medicines had been previously prescribed

We also asked patients what they would have done if an emergency supply hadn't been available:

- In about 50% of cases (12/25 interviewed) they would revisit the GP surgery (where available)
- In other cases (4/25; 16%) patients reported they would access OOH GPs/walk-in centres/A & E

- Around a quarter of patients interviewed (7/25; 28%) said they would manage without their medicines until their prescription was ready, although the type of medicine required affected this decision: ok to do so if medication considered non-urgent (eg. aspirin); ***but*** others felt interruption would have adverse impact: eg, one lady considered going without med to treat anxiety would affect her mood; another thought being without pain relief for osteoporosis would cause increased discomfort.
- Others (4/25; 16%) said they would purchase alternative OTC medicines – as a possible temporary replacement for those requiring pain relief and relief of constipation, though these were considered less effective than prescribed meds.
- One service user reported having previously borrowed medicines from friends taking the same medication (Warfarin – see case study quote A).

Further discussion

- I'd like to ask for your views again at this point, do you have any additional thoughts?
- Is there anything that you said earlier that you would like to add to or discuss further?

Prompts:

- *What are your thoughts about the patient experiences/views?*
- *What do you think about the alternative actions described by patients?*

Adherence/impact on health condition case studies – Hand out sheet with quotes

Following on from that, we've got a few example quotes from those interviews which provide specific cases to consider. I'll give you a chance to read them… NB: Didn't ask patients name of medicine they requested.

Discussion: case studies

Does anyone have any comments??

Part 5: Closing discussion

That takes us to the end of our brief rundown of the findings in the study so far. Thank you for your feedback so far – that's been very helpful.

Now, thinking about the future and the discussions we've had today, how would you like to see emergency supplies and loans evolve over time?

Prompts:

- *Are there any features you would add?*
- *Do you think that emergency supplies and/or loans are a good thing?*
- *Do you think there are changes that need to be made*
  - *Patient safety?*
  - *To fit better with NHS?*
- *Are there any changes you think should be made to the process?*
  - *Flow of information eg access to patient records in the pharmacy; GP informed that emergency supply been made (if they would like to see this, ask how they would handle this information – consider MUR feedback, would it just be 'more unnecessary information'?)*
- *Would you like to be able to stop ES for their patients (e.g. by agreement with local pharmacies)?*
- *How do you see things changing with introduction of electronic prescribing systems?*

Has anyone got any other comments before we finish?

Thank you very much for your time -

inform that Executive Summary of the final report will be sent to the GP practice team by Liz, RA.