Hospital Referral of Older Patients to Community Pharmacy: Outcome Measures in a Feasibility Study

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There has been increased recognition in recent years of the problems older people face on discharge from hospital, including those related to medication (1). In 2011 post-discharge Medicines Use Reviews (dMURs) were introduced into the English national community pharmacy contract with the aim of improving medicine support to recently discharged patients who had experienced changes to their medicines in hospital (2).

However, early reports showed minimal uptake of dMURs, even after signposting by hospitals (3). Furthermore, there is little evidence of their impact on patient outcomes, with only one recent study indicating that patients receiving a follow-up consultation with the community pharmacist may have lower rates of readmission and shorter hospital stays if readmission did occur (4). The authors stated that a randomised controlled trial (RCT) of the referral service would be required to fully investigate the impact on patients but recommended that prior to this, a feasibility study should be conducted to determine how best to design the trial and identify outcomes that would be feasible to collect and allow assessment of effectiveness.

Prior to the publication of that research, we had already designed a randomised controlled feasibility study to evaluate a referral process from hospital to community pharmacy, and have published data relating to patient recruitment, community pharmacist perceptions of delivering the service, and the potential clinical and economic impact of interventions made (5-7). This paper reports on potential patient outcome measures, used during the feasibility study, that could be utilised in future evaluations.

Aim

Identify potential outcome measures to investigate the impact of a hospital to community pharmacy referral service for older patients that utilises the dMUR.

Ethics Approval

Ethics approval for this study was obtained from the Northwest Research Ethics Committee (Ref 13/NW/0779).

Method

Recruitment ran from April 2014 to January 2015. During this period all pharmacists working on medical wards at Southport and Ormskirk Hospitals NHS Trust (SONT), England, identified in-patients aged over 65 years who, in their professional opinion, could benefit from a dMUR. Inclusion and exclusion criteria have previously been reported (5). It was intended to recruit between 60 and 100 patients to the feasibility study, in keeping with the usual sample size for pilot and feasibility trials registered in the UK Clinical Research Network Database. Baseline demographic data were collected and compared between participant groups using the chi-squared test for categorical data and an unpaired t-test for continuous data (Table 1).

Informed consent was obtained from all individual participants included in the study. Participants were randomised to receive either a dMUR or standard discharge care. For those to receive a dMUR, a referral form and discharge prescription was faxed to their nominated community pharmacist to allow completion within 28 days as per the national service specification.

All participants were followed up at four weeks and six months post-discharge by the lead researcher (HR). At each follow-up point, any hospital admissions or accident and emergency (A&E) visits since discharge were identified via the hospital's electronic patient administration system. If a re-admission had occurred, a consultant geriatrician and HR reviewed the patient's notes to evaluate contributing medication problems. Published criteria on evaluating medication related hospital admissions (amended Hallas criteria for causality and Hepler criteria for preventability) were used during these sessions (8).

All participants were sent a postal questionnaire at each follow-up. Questionnaires combined questions relating to self-management of medicines and medication reviews participated in since discharge, with scales measuring medication adherence and health-related quality of life (HR-QoL).

Medication adherence was measured using the validated 8-item Morisky Medication Adherence Scale (MMAS) and HR-QoL, using the 12-Item Short-Form Health Survey, version 2 (SF-12v2) (9,10).

Additionally, a measurement of patient enablement following dMUR was derived for the intervention group participants at the 4 week follow-up, using the Patient Enablement Index (PEI) (11).

Data on readmissions, A&E visits, adherence and HR-QoL for each participant were collated in an Excel spreadsheet. It was acknowledged that the small number of participants to be recruited during this feasibility study meant that it would be underpowered to detect statistically significant differences in quantitative outcomes between groups. However, for methodological rigour, and in preparation for any future RCT, various statistical tests were applied:

- The proportion of participants in each group having one or more readmission during the follow-up period (dichotomous data) was compared using Chi-squared at both 4-week and 6-month follow-up.
- The total number of readmissions in each group (ordered discrete data) was compared at both follow-up points using the Mann-Whitney U-test.
- The mean length of readmission episodes in each group was compared using the Mann-Whitney U Test.
- The proportion of participants in each group having one or more A&E visit (but being discharged from here rather than admitted to a hospital ward) was compared using Chi-squared at both follow-up points.
- The total number of A&E visits in each group was compared at both follow-up points using the Mann-Whitney U-test.
- SF12-v2 and MMAS scores were treated as continuous numerical data and compared between groups using an unpaired t-test at both follow-up points.
- Previous studies have reported the mean PEI with a 95% CI. Therefore the same practice was employed here for intervention group participants who received a dMUR and returned a scorable questionnaire.

Results

A total of 59 participants (30 intervention and 29 control) were recruited to the study. There were no significant differences in baseline characteristics between study groups (Table 1). However, the intervention group tended towards being more likely to live alone, and to have had a previous admission within the last 30 days (not significant due to small participant numbers).

Insert new Table 1 here

All participants were followed up with respect to readmissions and A&E visits at both time points. Fifteen participants (6 intervention and 9 control) did not return the 4-week questionnaire and 23 participants (9 intervention and 14 control) did not return the 6-month questionnaire. In just under half of cases the reasons for this are known, and included death (n=2), participant admitted to a care home (n=3), participant no longer responsible for managing their own medication (n=4), and participant in hospital at time of final follow-up (n=2). The number of usable questionnaires returned represents a 61% return rate. Results of an intention to treat analysis including all randomised participants showed no significant differences in any of the quantitative outcomes studied between intervention and control groups at either four-week or six-month follow-up (Tables 1 and 2).

Insert new table 2 here

The mean PEI for intervention group participants who received a dMUR and returned a scorable questionnaire (n=16) was 3.69 (95% confidence interval (CI) 1.68-5.70).

Overall, 19% of the total study population (control and intervention) were readmitted at least once within 4 weeks of their original discharge, rising to 53% by 6 months, representing 49 readmissions. Case-notes for 48 readmissions were located and analysed. Twelve (25%) of these were possibly, probably or definitely medication related according to the amended Hallas criteria (8). Seven (58.3%) of the medication related readmissions were classed as at least possibly preventable using the Hepler criteria (8). There were no preventable medication related readmissions involving participants who had received a dMUR as part of the study.

Discussion

This study is the first to investigate ways of measuring the effect on patient outcomes of hospital referrals to community pharmacies for dMUR in older patients. Importantly for a feasibility study, we have demonstrated that recruitment of older patients to a randomised study of this nature is possible. The fact that 41% (n=24) of participants completed this study as per protocol is in keeping with research conducted by others indicating that studies involving older patients experience high attrition rates (12). Death, or deterioration in health leading to participants being readmitted, moving address to live in locations where their care needs can be better met, or simply being no longer able to complete follow-up measures all contribute to this and were all observed during this study.

In addition, difficulties with the delivery of the dMUR intervention to housebound patients by community pharmacists in this study meant that only fourteen intervention group participants (47%) received their dMUR as per study protocol and a further 6 received it after the 4-week time-point. The format of the current nationally commissioned service appears to hinder accessibility to this patient group, specifically via the facilitation of domiciliary visits, as discussed in our previous publications (5-7).

Taking this factor into consideration, the outcome measures selected and the use of postal questionnaire to collect data from participants appear appropriate to take forward to a future scaled up evaluation.

The lack of significant differences in outcomes between control and intervention groups reported is not unexpected, as the study was not designed or powered to detect such differences. However, findings do indicate trends worthy of further investigation; in particular, the trend towards shorter length of stay on readmission for the intervention group, which was also seen in Nazar et al's evaluation (4). In the present study, one in seven readmissions occurring within the 6-month

follow-up period were judged as both medicines related and preventable, which is consistent with previous reports and indicates that the criteria used were successful in identifying such readmissions. The finding that no preventable medication related readmissions occurred among patients who completed a dMUR suggests that they could be effective in preventing such readmissions. Therefore, preventable medication related readmissions is an appropriate outcome measure for any future large study.

The MMAS scores in both study groups indicated overall medium to high adherence at both follow-up points, which may reflect over-reporting of adherence by participants or recruitment bias, whereby adherent patients were more likely to agree to participant in the study. In a future larger study it is recommended that, in addition to actual MMAS score, the proportion of patients falling into the categories of low versus medium or high adherence should be analysed between groups. This would allow comparison of results with those of the English community pharmacy New Medicines Service evaluation, which also used the MMAS (13). Consideration should also be given to using a second measure of adherence, such as pharmacy refill records, to provide an internal check on validity.

In this study, mean physical HR-QoL score at six months was 5.39 points higher in the intervention group than the control. Scale up of this study is needed to see if these findings can be reproduced and represent real change in physical health-related quality of life following dMUR referral.

The mean enablement score following dMUR in this study, although similar to the scores of patients aged $\geq$ 65 in Howie et al's original study of GP consultations, fell short of the score ($\geq$ 6) deemed necessary for clinically meaningful enablement (11). This could be due in part to the high levels of adherence reported by participants, leaving little capacity for improvement or enablement.

This work is limited by the small-scale nature of the study, involving one hospital and the associated community pharmacists. This means that the findings cannot be generalised to other settings. However this was not the purpose of the study, which was designed to assess the feasibility of the

dMUR referral service and the chosen outcome measures in preparation for a future RCT, the results of which would be generalisable.

Additionally, difficulties with delivery of the dMUR in the intervention group mean that confounding is possible in that patients who were well enough to attend the pharmacy for a dMUR may have been intrinsically less likely to be readmitted to hospital. It is not known whether a dMUR would have prevented readmissions among intervention group participants who were unable to attend their dMUR, had they completed the intervention as planned.

Conclusion

Recruitment and follow-up of older patients in a randomised study of referral from hospital to community pharmacy, using the protocol described, is feasible. The outcome measures used to analyse readmissions, medicines adherence, HR-QoL and patient enablement appear appropriate for evaluation of the service.

This feasibility study should be scaled up to a full pilot study, followed by an adequately powered RCT, in order to further investigate the effect on patient outcomes of dMUR referral.

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Conflicts of Interest: Helen Ramsbottom, Ray Fitzpatrick and Paul Rutter declare that they have no conflict of interest.

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Tables

Table 1: Participant Baseline Characteristics

Baseline characteristics	Overall (n=59)	Intervention (I) (n=30)	Control (C) (n=29)	P value (2-tailed) for I vs C	Test used
Female (%)	33 (56)	16 (53)	17 (59)	0.6826	Chi-squared
Mean Age in years (Range)	78 (65-92)	79 (68-92)	77 (6-89)	0.1142	T-test
Living alone (%)	19 (32)	13 (43)	6 (21)	0.0628	Chi-squared
Mean number meds (Range)	9 (2-19)	9 (3-16)	9 (2-19)	NA	NA
Mean MCI (Range)	20 (5 - 41.5)	21 (7.5–41.5)	19 (5-40.5)	0.3476	T-Test
Cognitive impairment (%)	11 (19)	7 (23)	4 (14)	0.3469	Chi-squared
Mean number co-morbidities (Range)	4 (2-8)	4 (2-8)	4 (2-8)	NA	NA
Admission in last 30 days (%)	11 (19)	8 (27)	3 (10)	0.108	Chi-squared
Admission in last 12 months (%)	29 (47)	15 (53)	13 (45)	0.6908	Chi-squared
Mean length baseline admission in days (Range)	7 (1-27)	6 (2-19)	7 (1-27)	0.7730	T-test

Table 2: Participant Outcomes

Outcomes at 4-Week Follow-up	**Intervention (I) (n=30)**	**Control (C) (n=29)**	**p-value (2 tailed) for I vs C**	**Test used**
Patients having ≥ 1 non-elective readmission	6 (20%)	5 (17.2%)	0.7377	Chi-squared
Total number of non-elective readmissions	8	6	0.8026	Mann-Whitney
Mean Length of Readmissions (days)	4.38	7.00	0.1713	Mann-Whitney
Patients having ≥ 1 A&E attendance	7 (23.3%)	8(27.6%)	0.7643	Chi-squared
Total number of A&E attendances	9	9	1	NA
Outcomes Assessed Via Questionnaire	***n=24***	***n=20***		
Morisky Medication Adherence Score (MMAS)	7.20	7.54	0.3475	T-test
Health related Quality of Life (SF-12v2) Physical	34.77	34.50	0.9174	T-test
Health related Quality of Life (SF-12v2) Mental	44.41	42.68	0.6164	T-test
Outcomes at 6-Month Follow-up	**Intervention (I) (n=30)**	**Control (C) (n=29)**	**p-value (2 tailed) for I vs C**	**Test used**
Patients having ≥ 1 non-elective readmission	15 (50%)	16 (55.2%)	0.7924	Chi-squared
Total number of non-elective readmissions	26	23	0.9690	Mann-Whitney
Mean Length of Readmissions (days)	5.67	7.04	0.4487	T-test
Time to First Readmission (days)	72.87	57.81	0.4315	T-test
Patients having ≥ 1 A&E attendance	16 (53.3%)	17 (58.6%)	0.7909	Chi-squared
Total number of A&E attendances	36	32	0.9690	T-test
Outcomes Assessed Via Questionnaire	***n=21***	***n=15***		
Morisky Medication Adherence Score (MMAS)	7.40	7.22	0.5916	T-test
Health related Quality of Life (SF-12v2) Physical	40.80	35.41	0.0983	T-test
Health related Quality of Life (SF-12v2) Mental	43.42	45.34	0.5384	T-test