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Review Article

Evaluating outpatient pharmacy services: a literature review of specialist heart failure services

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REZUMAT

Obiectiv: Să fie identificate metodele cele mai potrivite pentru evaluarea serviciilor de specialitate ale farmaciilor faţă de pacienţii cu infarct miocardic trataţi ambulatoriu.

Metoda: Un studiu larg din literatura de specialitate a fost luat în calcul pentru a indentifica datele publicate despre evaluarea serviciilor farmaceutice de specialitate, inclusiv cele destinate bolnavilor care au suferit un infarct, într-un model de îngrijire ambulatorie.

Ce a reieşit din acest studiu: Au fost luate în consideraţie 6 studii diferite. Serviciile oferite de farmacii în aceste condiţii, celor care au suferit un infarct, nu au fost clar definite. Impactul farmacistului este mai degrabă la nivelul „îngrijirii de bază". Serviciile respective au fost în primul rând orientate către medicaţie şi educarea modului de viaţă, monitorizarea efectelor adverse şi reacţia pozitivă la medicaţie. În toate aceste studii s-a putut vedea o îmbunătăţire în timp a rezultatelor obţinute. Un studiu evaluativ ideal ar fi un proces controlat randomizat, care ar compara efectele serviciilor farmaciştilor cu „îngrijirile de bază" pe care le primeşte ambulatoriu pacientul (fără aportul unui farmacist). Este necesară identificarea componentelor specifice acestor servicii şi extinderea lor, pentru că ar aduce numeroase beneficii pacienţilor.

Concluzii: Serviciile specializate ale farmaciştilor pentru cazurile tratate in ambulatoriu nu sunt suficient definite şi evaluate în literatură. Există date controlate randomizat în număr limitat.

ABSTRACT

Objective: To identify appropriate methods to evaluate a specialist pharmacy service for heart failure patients in an ambulatory care setting.

Method: An extensive literature review was undertaken to identify the published data on evaluative studies of specialist pharmacy services, including those directed at heart failure patients in an ambulatory care model of service provision.

Key findings: Six studies were identified evaluating outpatient pharmacy services for heart failure. The pharmacy services provided in these settings were not well defined. The impact of the pharmacist was compared to 'usual care', that is care delivered without a pharmacist, by either a prospective randomised controlled trial (RCT), or before and after studies. In most cases the service was delivered by one pharmacist at one site. Services were primarily targeted at patients and focused on medication and lifestyle education, adverse drug reaction monitoring, and compliance/adherence.

In all studies, there was a trend for improvement in the outcomes measured. Different study endpoints were examined, including process indicators such as compliance and outcome measures such as morbidity (clinical), quality of life (humanistic), and hospital admissions (economic). The ideal evaluative study would be an adequately powered, prospective, randomised controlled trial, comparing the effect of the pharmacist service to usual care (without the specified pharmacy service).

Appropriate study endpoints including process indicators and outcome measures are needed. Identification of specific components and the extent of the service that would provide the most benefit to selected patient groups would be of interest.

Conclusions: Specialist ambulatory care pharmacy services have not been well defined or evaluated in the literature. Limited randomised controlled data exist.

INTRODUCTION

Heart failure is a progressive clinical syndrome that is the end-stage of all diseases of the heart. (1) Heart failure occurs when the ventricles of the heart are unable to fill with or pump an adequate amount of blood, and therefore oxygen, to the rest of the body at a rate necessary to meet the requirements of the metabolising tissue at rest or during light exercise. (1,2) Patients with heart failure present with a variety of non-specific symptoms. (3) Accurate diagnosis of heart failure cannot be based on presenting symptoms alone and requires objective evidence such as ventricular function measurement. (3) The New York Heart Association (NYHA) classification of heart failure is used to categorise patients according to functional capacity, and may be used as an indicator of severity and prognosis. (4) Coronary heart disease and hypertension are considered to be two of the most important risk factors for heart failure. (2)

Although no national data are available on the prevalence and incidence of heart failure in

Australia, extrapolation of overseas information predicts/estimates that over 300 000 Australians are affected with heart failure, with about 30 000 new cases diagnosed annually. (3) Furthermore, the incidence of heart failure in Australia has been estimated to increase by about 70% by the year 2010.5 Importantly, the prevalence of heart failure increases dramatically with increased age, with an approximate doubling in the prevalence of heart failure with each decade of ageing,1 and as such heart failure represents a major morbidity in the elderly population. Recently a prospective study of an Australian primary care population found the prevalence of heart failure in patients aged 60 years and over to be 13.2%. (6)

Heart failure has a significant impact on hospital services. In 1998-1999 heart failure was the principle diagnosis in 0.7% (41 894) of all hospitalisations in Australia, accounting for 10% of all national hospitalisations for cardiovascular disease. (2) Heart failure was the primary reason for hospital admission in American adults older than 65 years, 7 and was reported as accounting for 58% of acute hospitalisations in nursing home residents. (8) Furthermore, from a descriptive follow-up study of an Australian tertiary level metropolitan teaching hospital, it was estimated that the annual readmission rate for heart failure was approximately 36%. (9)

The morbidity and mortality associated with heart failure is high, reaching greater than a 50% one-year mortality in severe heart failure.4 In Australia, heart failure was the third largest cause of cardiovascular deaths, contributing to 2% of all annual deaths in 1998.2 However, the death rate from heart failure in Australia has been declining. (2)

The cost burden of heart failure worldwide has been significant. (7,10) Hospital admissions were the primary driver of overall cost; however, out-of-hospital care was also substantial. Clearly, the observed trend in death rate, coupled with both a projected increase in the prevalence of heart failure and the resultant increase in hospital admission and outpatient service utilisation, will significantly increase the cost burden associated with heart failure. Significant efforts have therefore been made to optimise the management of patients with heart failure.

Disease management programmes are being advanced to improve the care and clinical outcomes of patients with heart failure. Traditionally, heart failure management was based on the costly and suboptimal approach of episodic treatment and crisis intervention. (11) In contrast, disease management programmes approach heart failure as an active condition and focus on treating the underlying disease process, (11) therefore aiming to shift the care of the patient from the in-hospital environment to an outpatient service. Implementation of disease management programmes has been shown to be most effective when delivered by a multidisciplinary team. (12) The landmark study in 1995 by Rich and colleagues showed that a multidisciplinary team could significantly reduce overall readmissions of elderly heart failure patients, primarily due to a reduction in heart failure-related admissions. (13) Similar results have subsequently been shown by other investigators. (14–16) Furthermore, a recent study has shown that a multidisciplinary approach has intrinsic benefits when inpatient hospital care has been standardised, (17) and produces significant cost savings compared to optimal medical care. (18)

The role of the pharmacist in the management of heart failure has been described. (19–21) Heart failure patients are typically taking more than four medications daily and have numerous comorbidities. (22) Consequently, an increased potential for drug interactions and adverse events exists. (22) Furthermore, lack of adherence to medications or diet has been identified as a leading preventable cause for hospitalization in patients with heart failure. (23,24) It has therefore been suggested that a pharmacist may have the most relevant training to provide adequate patient education with regard to the safe and appropriate use of medicines. (22) Furthermore, the pharmacist can focus on improving adherence by simplifying medication regimens, (19) and can monitor for adverse drug events. (21,22,25) Pharmacists can also offer lifestyle advice, eventually leading to overall improved patient self-management. (19) Additionally, despite the value and cost-effectiveness of the correct use of medications as a component of heart failure management, (21) underutilisation and submaximal doses of these agents are still being reported. (6,26) Pharmacists may help to achieve optimal patient outcomes acting as a 'conduit to bridge the gaps between evidence and practice'. (20,21) With the advent of multidisciplinary management of heart failure patients, the traditional dispensing role of the pharmacist is being extended to providing patient-focused disease management. The delivery of this service is being proposed both in specialist heart failure clinics and as a part of home-based care, both of which have been utilised in multidisciplinary management studies. With the

emergence of such specialist outpatient or ambulatory pharmacy services, rigorous evaluation of these services is warranted to ensure quality care and efficient expenditure of healthcare resources.

OUTPATIENT PHARMACY SERVICES DEFINED

From a broad perspective, an outpatient pharmacist has been defined as a pharmacist who works in an ambulatory care setting, such as a community pharmacy or hospital outpatient clinic. (27) For the heart failure patient, an outpatient pharmacy service may encompass care provided by the pharmacist that is beyond the traditional dispensing role, and which is delivered either prior to discharge with subsequent telephone or home based follow-up, (25,28) exclusively home-based programmes, (29) or from a specialist clinic attached to a hospital. (22,30,31)

EVALUATING OUTPATIENT PHARMACY SERVICES

The evaluation of outpatient pharmacy services has been reported for a variety of conditions. These include diabetes, (32–34) hypertension, (35–37) and dyslipidaemia. (38) Additionally, outpatient pharmacists assisting outpatients at risk of medication-related problems, such as elderly patients with polypharmacy (39) and patients prescribed non-steroidal anti-inflammatory drugs (NSAIDs) and salicylates, (35) have also been evaluated. In all of the above studies some generic characteristics were evident. Firstly, the impact of the pharmacy service was compared to 'usual care', that is care delivered without the pharmacy service, by either a prospective randomised controlled trial, or before and after studies. Secondly, with one exception, (35) there was usually one pharmacist delivering the services from a single site. Thirdly, the services delivered were primarily targeted at patients and focused on medication and lifestyle education, adverse drug reaction monitoring, and compliance/adherence. In all of these studies, there was a trend for an improvement in the outcomes measured.

Study outcomes used to evaluate the impact of the pharmacy service included clinical markers of disease control (clinical), quality of life (humanistic), and healthcare utilization (economic). In general, such study endpoints may be also described as measures or indicators, which can be classified as process, impact, or outcome measures or indicators.

AIM

The objective of this review was to identify appropriate methods to evaluate a specialist pharmacy service for heart failure patients in an ambulatory care setting.

METHOD

An extensive review was undertaken to identify the published data on evaluative studies of specialist pharmacy services, including those directed at heart failure patients in an ambulatory care model of service provision.

A literature search for published studies evaluating specialist outpatient heart failure pharmacy services was undertaken using Medline, Embase, the Cochrane database and International Pharmaceutical Abstracts. The search strategy included medical subject headings (MeSH) and keyword terms: 'pharmacist'; 'pharmacy'; 'pharmacy service, hospital'; 'outpatient clinics, hospital'; 'ambulatory care'; 'heart failure, congestive'; and 'pharmaceutical services'. The search was limited to those studies published in English between 1966 and April 2003. The inclusion criterion was studies that specified evaluation of the specialist heart failure pharmacy service as an aim of the study. Reference lists of primary studies or review articles identified during the search were also checked for relevant articles. Studies that were descriptive only were excluded in this review. The initial search was undertaken by one of the authors (TH), and inclusion in this review was determined by consensus among all authors (TH, AB, JB).

RESULTS

Seventeen studies were identified. Several studies described multidisciplinary and pharmacy services for heart failure patient groups. However only six studies were identified that evaluated outpatient pharmacy services for heart failure. (22,25,28–31) These studies were reviewed in detail for the methodological approach applied.

All of these six studies have evaluated the effect of pharmacy services compared to usual care. The description of usual care however was generally not well-defined, and simply implied care without pharmacy service. Clearly, the extent of usual care may have affected the type of difference seen in measured outcomes with the inclusion of the pharmacy service. Investigation into whether outpatient pharmacy services can deliver the equivalent improvement in outcomes when compared to other healthcare professions has not been undertaken.

STUDY DESIGN

The study design employed in the studies evaluating outpatient pharmacy services for heart

failure was frequently a prospective randomised controlled trial. (22,25,28–30) Randomisation occurred at the patient level. Allocation concealment was generally attempted, however the direct intervention nature of the studies may have prevented complete concealment. (22) One of these studies utilised a less rigorous before and after design. (31)

The settings for the studies evaluating outpatient pharmacy services for heart failure were most frequently based in an outpatient clinic attached to a hospital. (22,29–31) Two of the studies used single or multiple home-based interventions. (28,29) Rainville used pharmacist-led telephone follow-up only, suggesting that specialist clinics delivering intensive services may not be 'feasible or cost-effective' for all patients with heart failure. (25) Studies have not been conducted to identify whether the different settings (as opposed to the pharmacy services provided) account for differences in measured outcomes.

The appropriateness of study design for a particular setting may be informed by a preliminary qualitative study. This may be important where different clinical settings may afford the opportunity for collection of process-oriented data.

PATIENT SELECTION AND CHARACTERISATION

The patients in the studies evaluating outpatient pharmacy services for heart failure were recruited from either prospective hospital admissions where congestive heart failure (CHF) was the primary diagnosis, (25,28,31) outpatient clinic attendance, (22,29) or both. (30) The total number of patients recruited in these studies ranged from 34 to 181. (22,29) Study power calculations were not reported. Patient mean age varied from 62 (54–72) years to 84 (± 4.5) years. (29,31) Severity of heart failure, which was usually defined by NYHA symptom classification, varied among studies. This may be important because it has been suggested that not all heart failure patients require the same level of intervention. (15) For instance, a decreased severity in symptoms and a higher ejection fraction have been found to be independent predictors of the uptake of self-management strategies such as a heart failure diary and a schedule of daily weighing. (40) Identification of patient groups that would benefit most from an outpatient pharmacy service for heart failure has not been studied. Furthermore, the presence of comorbidities varied between the studies, with some studies selecting patients based

on the absence of more serious medical conditions. (25,29,30) The effect of comorbidities on the study endpoints has not been investigated.

The outpatient pharmacists participating in these studies evaluating outpatient pharmacy services for heart failure were generally not well described. The qualification or specialist training of pharmacists delivering the service has been identified as a primary element in successfully evaluating pharmaceutical services. (41) It was often unclear how many pharmacists delivered the service in a given study.

PHARMACY SERVICES DELIVERED

The targets of the outpatient pharmacy services for the studies evaluating outpatient pharmacy services for heart failure were the patients. Healthcare professionals may also be the target of pharmacy services. (27) In four of the studies, consultations by pharmacists with physicians about medication optimization occurred, although the extent of physician education or uptake of information provided by the pharmacist was not directly reported. (22,25,30,31)

The services delivered by pharmacists in all of these studies evaluating outpatient pharmacy services for heart failure addressed, to varying degrees, the education of patients about the importance of their prescribed medications and compliance. (22,25,8–31) Furthermore, education about non-pharmacological management and self-monitoring was emphasised in four of the studies, (25,28,30,31) although this information was delivered by the accompanying nurse in the study by Stewart and colleagues. (28) With few exceptions, (22,30) the pharmacy services were not explicitly defined, making comparison between the studies difficult. For instance, vague terms such as 'counselling' according to 'protocol', (29) 'review of educational material', (31) or 'provision of a patient information brochure' (25) were reported. The services may be implied, but from a scientific perspective replication of the experimental conditions may be difficult. Furthermore, no study has been designed to identify whether components of the outpatient pharmacy services have a differential impact on study endpoints. This is particularly relevant for the studies that provided more extensive detail about the services, (22,30) and studies where similar services were simultaneously delivered by other healthcare professionals. (25,31)

The number of pharmacy services delivered and length of follow-up varied among the studies

evaluating outpatient pharmacy services for heart failure. For instance, Stewart and colleagues assessed a single home-based consultation by a pharmacist and nurse one week after hospital discharge, with outcome measures recorded 6 months later. (28) Similarly, in two of the six studies, a single consultation occurred either prior to discharge (25) or in a clinic; (22) however, telephone follow-up and data collection over 6–12 months was also included as a part of the pharmacy service. In contrast, Goodyer and colleagues assessed a three-month home-based counselling programme (29) while Varma and colleagues assessed a 12-month clinic-based programme. (30) The remaining study had an unspecified number of consultations, with the number of clinic visits and telephone follow-up individualized to patient functional status; however, the mean follow-up period was 4.9 months. (31) The optimum number of consultations and length or intensity of follow-up has not been investigated.

ENDPOINTS

Process indicators were measured in four out of the six studies evaluating outpatient pharmacy services for heart failure patients. (22,29–31) Frequency of prescribing and fraction of target doses of angiotensin-converting enzyme inhibitors (ACE-Is) and beta-blockers were measured in two studies. (22,31) Patient knowledge of prescribed medications was assessed by questionnaire in two studies, although descriptions of these tools were not provided. (29,30)

Additionally, medication compliance was measured by pill counts, (29) and patient self-report and drug use profiles using patient drug records. (30) The definition of compliance was dependent on which measure was used. For instance, when using pill counts, compliance was defined by the percentage of the maximum number of medications that should have been consumed, with an increased mean percentage indicating improved compliance. (29) On the other hand, Varma and colleagues defined compliance by comparing the expected finish date for a prescription and the date on which the next prescription was filled, using drug use profiles of patient medication records. (30) A score between 80% and 120% for each heart failure medication indicated satisfactory compliance. (30) Furthermore, compliance was defined in the same study by Varma and colleagues by patient self-reported skipping of doses, taking an extra dose, or running out of heart failure medications over the

study period. (30) Differences in definitions and the methods used to assess compliance may lead to inconsistent information. (42) For instance, the proportion of tablets taken during a study period (taking adherence) and the proportion of observed doses that are consistently timed (scheduled adherence) have been suggested to impact independently on hospitalisation risk for heart failure patients. (43) Concordance or adherence, that considers the patients as active decision makers in disease management rather than passive and obedient followers of instructions from healthcare providers, (42) were not addressed in any of these six studies.

By contrast, the outcome measures used as study endpoints for the studies evaluating outpatient pharmacy services of heart failure patients were clinical data such as exercise capacity, (29,30) hospital admissions, (22,25,28,30,31) and mortality, (22,25,28) humanistic indicators such as perceived health status (25,29) and quality of life, (25,29,30) and utilisation of healthcare services such as frequency of hospital admission as an economic indicator. (22,25,28,30,31)

The recurrence and duration of hospital admission, as reflected by mean number of hospital days and mean number of admissions, may relate to the burden of heart failure on the individual and on health services better than the more commonly used frequency of first hospital admission post-intervention. (44) Length of hospital admission was reported in only two studies, (28,31) and *post hoc* analysis of data produced from Stewart and colleagues determined readmissions for individual patients.

To effectively evaluate outpatient pharmacy services for heart failure, that is, to establish whether differences in outcome measures can be attributed to the pharmacy service, process indicators should be linked with outcome measures. (41) Of the six studies identified, two studies did not measure process indicators alongside outcome measures. (25,28) However, one study attempted to correlate the changes in compliance (process) with changes in exercise capacity (clinical). (29)

It is possible, however, to underestimate the influence of the pharmacist's contribution in a multidisciplinary service, as there may be indirect as well as direct impact on prescribers' behaviour.

STUDY OUTCOMES

The results of the studies evaluating outpatient pharmacy services for heart failure generally

showed improvement in both the measured process indicators and outcome measures.

Frequency of prescribing and fraction of optimal target doses for beta-blockers were both shown to improve, by 24% and 19% respectively. (31) In contrast, only the percentage of optimal target dose for angiotensin-converting enzyme inhibitors was shown to change. (22,31) Patient knowledge of prescribed medication was also shown to improve in both studies after pharmacist-led education. (29,30) This is consistent with a recent randomised controlled trial evaluating theeffects of systemic nurse and pharmacist-led education on heart failure patients' knowledge after 6 months. (45) However in the study by Varma and colleagues, baseline knowledge of medications was already statistically higher for the intervention group. (30)

The effect of the outpatient pharmacy service on medication compliance varied, with Goodyer and colleagues reporting a statistically significant improvement for the patients receiving pharmacist medication counselling (93% versus 51%), (29) and Varma and colleagues also reporting statistically significant differences for patients in the intervention arm when drug use profiles of patient medication records were used. (30) However, no statistically significant difference between the intervention and control groups was reported by Varma and colleagues when patient self-reports were used as a tool. (30) Variation in assessment tools and compliance definitions may account for the observed differences. Indeed, the lack of a valid method for measuring non-compliance is recognised as a major barrier to compliance research. (42)

With respect to the outcome measures of the studies evaluating the outpatient pharmacy services for heart failure, clinical indicators of functional status were shown to have statistically significant improvement after the three-month home-based programme. (29) However, this was not maintained in a longer clinic-based study by Varma and colleagues using different indicators of functional status. (30) When measured as out-of-hospital deaths, mortality decreased by 80% with the pharmacist- and nurse-led home-based visit study by Stewart and colleagues. (28) In contrast, a statistically insignificant effect on all-cause mortality by a pharmacist-led intervention was reported by Gattis and colleagues, but when reported as a composite endpoint with non-fatal heart failure events, a statistically significant reduction of 75% was shown. (22) A similar trend was reported by Rainville on the composite endpoint of death or heart failure readmission, with a 64% reduction. (25)

All studies using frequency of hospital admissions as an outcome measure demonstrated statistically significant reductions. (22,25,28,30,31) However the magnitude of effect varied amongst the studies, ranging from 36 (43% reduction) after six months, (28) to 20 (23% reduction) at 12 months. (25) The effect of the pharmacy service on hospital admission as an outcome measure was difficult to compare among the studies, due, in part, to variation between the studies when classifying the aetiology of admission. Furthermore, the health status of the patient population, and the resultant length of time needed to recover in hospital has been shown to affect hospitalization frequency. (14) For the two studies reporting length of hospital stay as an outcome measure, statistically significant reductions (42% and 17%) were reported. (28,31) Hospital admissions are important clinical outcomes, and may also be used as data in economic analyses. In the studies identified for this review, no economic evaluations were found.

Humanistic indicators of perceived health status (25,29) and quality of life (30) were not shown to have statistically significant changes following the addition of an outpatient pharmacy service to usual care. (25,29,30) A variety of validated and non-validated assessment tools was used which may impact on the interpretation of the results. Further research may be warranted. Additionally, patient satisfaction with the pharmacy service as a humanistic indicator has not been addressed for the any of the identified studies evaluating outpatient pharmacy services for heart failure. (22,25,28–31)

For the study attempting to relate the process indicator of compliance with the improved clinical outcome measure of exercise capacity, no correlation was found. (29) The lack of correlation may be due to the tool used to assess compliance, and the subsequent definition of compliance, or the responsiveness, or lack of response, of the patients to changes in drug therapy. (29) Additionally, exercise capacity may not be an appropriate measure to assess the effect on the patient when compliance to medication is changed.

DISCUSSION

Ideal evaluative study design

From a review of the literature evaluating outpatient pharmacy services for heart failure, it would seem that the ideal evaluation study design would be an adequately powered, prospective, randomised controlled trial that could compare the effect of pharmacy service to the usual care provided without specified pharmacy services. The study

would define the pharmacy service in terms of specific goals of the service such as education/counselling, adherence and medication review. Furthermore, study endpoints would need to be appropriately described and include process indicators and outcome measures indicative of the service. Such measures would need to be feasible to collect in a clinically meaningful timeframe. Possible process indicators include the number of consultations, the effect on prescribing habits and measures of concordance. Outcome measures may include clinical indicators of health status, economic indicators that incorporate both direct and indirect costs, and humanistic indicators such as quality of life and patient and staff satisfaction.

It would be of interest to identify whether differences in setting for means of delivery were associated with differences in defined study endpoints, as well as defining the optimum number of pharmacy services and length of follow-up producing sustainable benefit. As the number of patients actually able to be cared for may be limited by time and resource constraints, identification of patient groups that would benefit the most from the pharmacy service, would also be beneficial. Finally, identification of specific components of the service that have the most impact on outcome measures is recommended, to enable delivery of a more time- and therefore more cost-efficient outpatient pharmacy service for heart failure. Indeed such research objectives would probably be obtained from a series of adequately designed studies rather than a single ideal study.

Despite the establishment of specialist outpatient pharmacy services for heart failure, it is apparent from the literature that clear definition and robust evaluation of these services is lacking. Limited randomised controlled data exist. Without such fundamental information, the true value of these services can not be reliably ascertained.

Although this review has focused on outpatient pharmacy services for heart failure, the issues highlighted and recommendations made may be more generally applicable to outpatient pharmacy services that are being proposed for other conditions such as diabetes and hypertension. Indeed, such analysis of current literature is key to the successful design, implementation and interpretation of a study evaluating outpatient pharmacy services.

Healthcare services have developed to incorporate ambulatory care-based models of service. Hospital-based pharmacy services are most often planned based on traditional inpatient pharmacy service delivery. As specialist pharmacy services are introduced, particularly in the ambulatory care setting, there is a need for prospective, well-designed studies to be conducted to evaluate the impact and outcomes of these services. This review has focused on heart failure services, but the methodological approach may be applied to a range of clinical areas, including asthma and chronic lung disease clinics, diabetes services and anticoagulation services.

CONCLUSION

Specialist ambulatory care pharmacy services have not been well defined or evaluated in the literature. Future studies to evaluate these services should be well-designed trials. Development of an evidence base for this practice may support the integration of specialist ambulatory care pharmacy services into co-ordinated programmes for chronic disease patients.

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