# A rapid review of evidence regarding clinical services commissioned from community pharmacies

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Commissioned by the Chief Pharmaceutical Officer for England to inform the Murray Review of clinical services in community pharmacy

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# 1. Background

Community pharmacies in England are primarily funded through the National Health Service (NHS) and this consists of national contracts for 'Essential services' and 'Advanced services' and local contracts for 'Enhanced services'. 'Essential services' are largely based on the supply of medicines whilst 'Advanced services' are medicines optimisation interventions which are believed to be ubiquitously required. 'Enhanced services' are driven by the needs of the locally serviced population and consist of a mix of both public health and medicines optimisation interventions.

In 2005 the community pharmacy contractual framework contract was developed to promote the provision of services through community pharmacy which were in addition to medicines supply. (1, 2) Nationally funded advanced services include medicine use reviews (MURs), new medicines service (NMS), stoma appliance customisation (SAC), appliance use reviews (AUR) and flu vaccination.(3) For the purposes of this review MURs, NMS and flu vaccination services have been considered. SACs and AURs represent a very small amount of resources and evidence for effectiveness of either is not available.

There are a wide range of locally funded services provided in England, including domiciliary visiting services, chlamydia testing, emergency hormonal contraception supply, minor ailments treatment, disease management and support, medication review, case finding, harm reduction services, weight management, brief alcohol interventions and smoking cessation.(3) Some services are commissioned by local government which is responsible for the provision of public health services or clinical commissioning groups (CCGs) which are led by primary care physicians..

The aim of this literature review is to consider the evidence for both effectiveness and costeffectiveness which underpins current 'clinical services, and some both from within the UK and internationally.

It should be noted that this rapid review was completed before the community pharmacy reforms were implemented on December 1st 2016.

# 2. Aim

In relation to research evidence relating to potential Essential, Advanced and Enhanced community pharmacy services the aim of the review is to:

- Describe the breadth and quality of evidence currently available in the UK and internationally
- Quantify the evidence for service effectiveness and cost-effectiveness
- Identify how the effectiveness and cost-effectiveness of services may be enhanced
- Review the effectiveness of different funding models
- Identify gaps in research which would enhance the evidence base

# 3. Methodology

The literature review primarily used systematic reviews, where available, and good quality literature reviews as its primary evidence source. Where a systematic review was not available then the primary literature was searched for within:

- Pubmed
- Embase
- Pharmaceutical Journal
- Pharmacy Management Journal
- International Journal of Pharmacy Practice via Wiley on-line

Evidence for effectiveness and cost-effectiveness for each service or element of the service was sought. Only peer reviewed published papers were included within the primary literature search, with conference abstracts used when they had been part of a systematic review. Further information which underpinned published papers and was readily available was accessed where deemed necessary.

As a rapid review of the literature evidence and therefore for reasons of pragmatism the review did not include less robust information on service developments available in the 'grey literature'.

Qualitative papers were accessed where the information provided was identified as providing information regarding service context.

### 4 Essential & Advanced services

#### 4.1 Repeat dispensing scheme

In 2002 a repeat dispensing scheme was introduced in England whereby General Practitioners (GPs) could authorise the repeat supply of medicines through community pharmacies for a defined period of time and set interval. The GP would only need to sign one prescription (legal document) with copies (batch issues) used by the pharmacist for each supply to claim their remuneration. The aim was to enable patients to be able to obtain their medicines for a set period of time without having to access their medical practice every time and thereby save GP time in authorising and signing repeat prescriptions. The process was also designed to minimise wastage as medicines which weren't collected would not require reimbursement.(4) The process transfers responsibility for repeat prescription authorisation from practice staff to the community pharmacist and provides an opportunity for patient monitoring by a healthcare professional each time a patient collects their prescription.

Initial trial of the process found that GPs were very receptive to the innovation and that all but one GP believed that medication control had either been maintained or improved. Similarly whilst over forty percent of GPs believed their relationship with pharmacists had improved the majority believed that it had not changed.(5) A systematic review of evidence for the repeat dispensing scheme in 2006 found that both GPs and patients were positive to the repeat dispensing scheme, practice workload ultimately reduced and patient adherence was improved.(6) In 2009 one medical practice with only 2886 patients, which reported on its experience of transferring 45% of its prescription items to the repeat dispensing scheme, estimated that it had saved 2 weeks of GP time and 150 hours of receptionist time in one year. In the view of the medical practice team the initial workload required to implement the scheme was more than justified by the future time saved.(7)

With an average of 9% of patients registered for the service the NHS England Medicines Optimisation Dashboard has identified wide variation by CCG in uptake of repeat dispensing scheme (0% - 63.28% repeat dispensing items). The remuneration for this service is fixed at  $\pounds$ 1,500 per community pharmacy per year and is therefore independent of the number of patients accessing it. Whilst the cost-effectiveness of this service has not been modelled, with a fixed service delivery cost the greater number of patients who receive the service the greater the value of the service. Current remuneration models do not however incentivise community pharmacists or GPs to increase service uptake. Whilst it is the GP who is

expected to consent patients for the service, community pharmacists and GPs could be incentivised to work together to achieve better implementation rates.

#### 4.2 Medicine Use Reviews

Medicines use reviews (MURs), defined as 'a patient-pharmacist consultation to discuss the patient's use of medicines and improve their knowledge about their purpose', were introduced in 2005(2) to improve patient satisfaction with medicines related information and adherence, thereby improving patient outcomes and reducing medicines wastage. Medicines use review may be performed by an accredited pharmacist once a patient has received more than one medicine from a pharmacy for three consecutive months and may be repeated on an annual basis. Additionally if a significant adherence problem is identified at any point during the dispensing process and a patient is prescribed one or more medications, a prescription intervention MUR may be performed for patients who have not used with the pharmacy for three consecutive months. Whilst in essence this is an MUR and the community pharmacist still has to provide a consultation with the patient and complete the same paperwork, they can perform these on any patient.

The implementation of MURs was unstandardised from the outset(8) resulting in significant variability in delivery.(9, 10) Initial reception of MURs by patients, pharmacists and general practitioners was mixed. Whilst patients were found to be broadly positive regarding the provision of MURs,(11) general practitioners were less so and this was due to duplication of work which they had already performed and pharmacists making clinical recommendations which went beyond the original remit of the MUR.(8, 12) Lack of both support for MURs by GPs and collaboration with community pharmacists have been identified as reasons for pharmacists not undertaking MURs(13) and the potential of MURs not being maximised.(14) The introduction of summary care records(15) which can be accessed by community pharmacists should reduce some of the duplication which has been identified but will not remedy the lack of collaboration between the two professions.

MURs were positively recognised by community pharmacists as providing an opportunity to transform their role from the routine process of dispensing to the provision of direct patient care.(9, 16, 17) Some confusion as to whether the focus of MURs was clinical or adherence was identified and appropriate emphasis for trainers was recommended.(17) MURs were however expected to be delivered 'in addition to' Essential services (where demand continues to increase), rather than 'instead of' and therefore there was a resultant increase in pharmacy staff workload and pressure.(16, 17) With an initial slow uptake, significant variations in the provision of MURs by different providers have been identified with independently managed pharmacies less likely to offer them.(10, 18) A founding principle of

the NHS is equity in access to services for patients and initially at least, this does not seem to be achieved through the national provision of MURs.

MURs were introduced in 2005 with requirement that they were held in a private and confidential location at a point in time when most pharmacies did not have consultation rooms. (17) By 2013 and largely as a result of the need to deliver advanced and enhanced services 90% of community pharmacies reported having addressed this deficit.(19) Additionally the UK government responded to the previously identified variation in the communication skills of pharmacist (20) which underpin MURs through the provision of a national training pack and assessment process.(21)

In April 2015 the government re-focussed the requirements for the provision of MURs stating that instead of the previous 50% requirement, 70% of MURs were to be targeted to patients prescribed high risk medicine(s) (NSAIDS, anticoagulants and diuretics), patients recently discharged from hospital who had changes made to their medicine(s) while they were in hospital and those with respiratory conditions such as asthma and Chronic Obstructive Pulmonary Disease (COPD), patients at risk of or diagnosed with cardiovascular disease and regularly being prescribed at least four medicines.

A service with similar aims to MURs, MedsCheck has been set up within Ontario Canada(22) with patients being required to be prescribed at least 3 medicines and being allowed to be included if discharged from hospital within previous 2 weeks, referred in by a GP or nurse or who have a hospital appointment. The stated expectation is that each MedsCheck takes beween 20 and 30 minutes. Evidence for the effectiveness of MedsCheck is however not available. One non-randomised cluster controlled study which used MedsCheck to reduce cardiovascular risk using four appointments per year (which is greater than the one allowed) found that out of the 252 control patients and 203 intervention only 108 control and 97 intervention completed the trial. No significant differences were seen in outcomes between the two groups although reductions in virtually all end points were seen in the intervention arm.(23) A cohort study, which used MedsCheck prior to admission to hospital to improve medicines reconciliation found that this reduced clinic time within the hospital by an average 7.6 minutes. Data were available for analysis in less than one quarter of the originally screened sample because only two thirds were deemed suitable for the service and the majority of these did not eventually access it.(24) The authors did not consider the cost of setting up and administering the service when reporting the time saved within the clinic. Similarly 20 to 30 minutes of pharmacist time in the community may be more expensive than 7.6 minutes of medical resident time in hospital. The primary outcome reported was the number of drug problems identified which is a measure of the process rather than a meaningful patient outcome.

#### **Quantitative research**

Table 1 provides a summary of the studies which have quantified the effects of medicines use reviews from the perspective of the patient in both the UK and internationally. It can be seen that whilst there have been no randomised controlled trials (RCTs) reported to date one is currently underway in Italy.(25) Evaluations have focussed on process outcomes which are those measures which, if improved, should result in better patient outcomes. Clinical outcomes, those which are focussed on specific disease states, e.g. change in blood pressure, may not be expected to be measured within evaluations of MUR services as the service is not disease specific. However, these could be used where MURs are focussed on specific patient groups. Humanistic outcomes, such as quality of life, which enable outcomes from totally different services to be compared have however also not been collected and consequently it is not possible to estimate the cost per additional year of perfect quality of life (Cost per QALY), which is required by government to determine which services should be commissioned.(26)

One study which used a natural control(27) i.e. those who had not accessed an advanced service were compared to those who had, found that both satisfaction with information and self-reported adherence was greater in the group who had received such a service . Non-receipt or access of an advanced service may however be a proxy for patient attitude to managing their health and consequently using non-service recipients as a control may not be entirely appropriate due to patient self-selection bias.

Blenkinsopp *et al.* in order to create control groups to determine the effectiveness of postdischarge MURs sequentially allocated patients to one of four arms (hospital pharmacist counselling, usual care + MUR, hospital pharmacist counselling + MUR and usual care). A number of barriers to recruiting patients to the MUR arms were identified and consequently due to small numbers the researchers focussed on the effectiveness of the hospital pharmacist pre-discharge counselling rather than the MUR. Problems with recruiting patients to post-discharge MURs have been reported elsewhere in another similar feasibility study.(28)

Whilst all evaluations determined effect on medicines knowledge and all but one on adherence, only one study used standardised and validated tools.(27) A review of systematic reviews of one off interventions similar to that of the medicines use review

concluded that whilst such interventions improved patient knowledge there was less evidence supporting the assertion that they improve actual patient adherence.(29)

Table 3 provides examples of 'MUR like' services provided by community pharmacists, identified through the outlined search strategy, which have been evaluated for effectiveness or cost-effectiveness using randomised controlled trials. In all cases the community pharmacists provided numerous consultations to improve medicines use rather than single one off interventions and in effect were providing sustained medicines related support. Within one of the studies it was found that patients who received the intervention were willing to pay twice the cost associated with it due to its ability to reduce hyperglycaemic and hypoglycaemic episodes.

Study No.	Country	Author	Year	Duration	Study design	N#	Process outcomes	Clinical Outcomes	Humanistic outcomes
1	UK	Portlock et al.(30)	2009	6 months	Service evaluation via survey	965	~	×	×
2	UK	Youssef et al.(31)	2010	3 months	Service evaluation via survey	81	~	×	×
3	UK	Twigg et al. (27)	2016	8 weeks	Survey of patients with and without advanced service (105 MUR, 51 NMS, 114 neither)	232	~	×	×
4	UK	Elson et al.(32)	2016	5 months	Controlled trial post discharge MUR service	14 MUR 70 Non- MUR	~	×	×
5	New Zealand	Hatah et al.(33)	2014	4 years	Retrospective review of MUR records	353	~	×	×

 Table 1
 Summary of quantitative research from the perspective of patients regarding Medicines Use Reviews

# Number completing study or returning questionnaires

Study No.	Medication knowledge	Adherence	Other	Main message(s)	Limitations
1	V	V	Interventions made	87% of patients reported knowing more about their medicines 91% understood their medicines better	No patient follow up Patients unblinded to intervention, Social desirability bias may explain some of the differences seen. Non validated outcome measures
2	~	✓ 	Interventions made and implemented	<ul> <li>68% agreed they had learned more about their medicines</li> <li>58% agreed more aware about side effects</li> <li>83% agreed they took their medicines in the right way</li> <li>5 out of 15 interventions implemented</li> </ul>	81 (53%) out of 152 surveys returned Patients unblinded to intervention, questionnaire returned to service provider. Social desirability bias may explain some of the differences seen. Non-validated outcome measures
3	~	×		Patients who receive an advanced service significantly more satisfied with information about medicines. Patients receiving advanced service twice as likely to report being adherent	232 (63.2%) out of 367 surveys returned. Recruitment by pharmacy staff may have introduced selection bias. Patients unblinded and social desirability bias may account for some of the differences seen.
4	V			Unable to compare MUR versus non-MUR due to sample size Barriers to uptake of MUR identified	Exploratory study. Non-validated outcome measures
5.	~	<b>√</b>	Perceptions to medicines	All three outcomes improved at second visit. This however was not maintained.	Out of 353 patients at start on? only 47 included at year 4. Score for each outcome provided by service provider not the patient. Non-validated outcome measures

# Table 2 Summary of process measures utilised, main messages and study limitations

Study No.	Country	Author	Year	Duration	N	Patient group	Main outcomes
1	UK	Ali et al.(34)	2012	12 months	Intervention=23 Control=23	Diabetes	Significant improvements in systolic blood pressure, HBA1C, quality of life, satisfaction with medicines information and beliefs about medicines.
2	Australia	Stewart et al.(35)	2014	Six months	Intervention=207 Control=188	Hypertension	Significant reduction in Blood pressure Adherence higher in intervention arm but statistically non- significant
Cost-e	ffectiveness	studies			·		
3	Australia	Hendrie et al.(36)	2014	Six months	Intervention=83 Control=114	Diabetes	Significant reduction in number of days with glycaemic episodes Cost per day of glycaemic episodes avoided AUS\$36 to \$51

# Table 3 Randomised controlled trials of MUR like services provided by community pharmacists

#### 4.3 New Medicines Service

In 2011 the community pharmacist led New Medicines Service (NMS) was introduced in England as a nationally funded 'Advanced service'. Based on underpinning health behaviour therapy, the service was designed to improve medicines adherence and persistence with newly prescribed medicines in patients newly prescribed asthma, hypertension, chronic obstructive pulmonary disease, type 2 diabetes and antiplatelet/anticoagulant therapy.(37)

Patients identified as eligible for the service are offered a one to one consultation seven to fourteen days post supply and again fourteen to twenty one days after that. The questions which the pharmacist is expected to ask the patient at each stage are prescribed within the service specification and are provided to enhance the effectiveness of the intervention and improve service standardisation. Whilst the service was designed to be provided face to face, early implementation identified that, for the follow up consultation, patients and pharmacists preferred using the telephone.(38)

Pharmacists are not required to undertake further training to be allowed to deliver the NMS but are required to be already accredited for the delivery of MURs. The NMS was based on a similar telephone based service provided by two pharmacists trained to provide a theory based intervention which had been shown to be very likely to be cost-effective.(39)

As part of the NMS implementation process the UK government commissioned a definitive study to ascertain the effectiveness and cost-effectiveness of NMS. Powered to identify a 10% change in adherence/persistence the study recruited and retained 216 patients in the control arm and 235 in the intervention, which was greater than the 200 identified as being required. At 6 weeks a 7% difference in composite adherence (appropriate adherence and persistence) was seen(40) between the intervention and control arms and this difference had reached 10% at 10 weeks, which was statistically significant.(38) The study was unblinded and randomised at patient level, where cluster randomisation at pharmacy level may have been more appropriate to minimise contamination within the control arm. Similarly use of a primary outcome measure which relies on self-report in an unblinded study could be questioned as those in the intervention arm know what the intervention is trying to achieve and consequently social desirability bias may have increased the level of self-reported adherence in the intervention arm.

Whilst the study was criticised for not demonstrating a significant improvement in composite adherence at 6 weeks,(41) it was not powered to detect the smaller but perhaps still clinically

important difference seen. It did however fail to report adherence at 26 weeks and this data is not provided within the underpinning report(40) but was stated in the trials protocol submitted prior to trial implementation.(42) This lack of data at 26 weeks may represent difficulties in completing the trial within the timeframe required by commissioners rather than a deliberate decision to not publish the data.

Almost half of the study participants were recruited through a small multiple chain, were from only one of the four sites?? and were located close to GP surgeries. With such unbalanced recruitment the generalisability of the results can therefore be questioned.(40) Whilst the feasibility of a very similar service had been demonstrated before the main trial was introduced the researchers were not given the opportunity to pilot their study design and consequently the subsequent problems with the final study sample could not be predicted or subsequently easily addressed within the trial itself. Similarly without a pilot researchers are estimating recruitment rates which frequently means that study timeframes are more ambitious than can be delivered.

With all assumptions regarding effectiveness and cost-effectiveness based on the difference identified at 10 weeks being maintained, it was estimated that that likelihood of the cost per QALY associated with NMS being below the NICE threshold for service adoption(26) was greater than 90%.(40) A peer reviewed publication regarding this economic analysis has not been published to date.

Whilst GPs were found to be more receptive to the NMS, the same inter-professional barriers to effective implementation were identified with the NMS as with MURs.(43)

#### 4.4 Influenza vaccinations

In 2015 the government made the supply of influenza vaccination through community pharmacies a nationally funded service. Community pharmacies provide influenza vaccinations to the general public who are considered at higher risk of contracting influenza or putting those in their care at risk of contracting the disease and this includes:

- people aged 65 years and over (including those becoming age 65 years by 31 March 2016);
- People with long term conditions such as asthma and diabetes.
- pregnant women;
- people living in long-stay residential care homes or other long-stay care facilities

The provision of influenza vaccinations through community pharmacies in England has been shown to increase uptake (44), to increase choice for patients and to be provided at lower cost than via the traditional route.(45) A recent systematic review of interventions to improve influenza vaccine uptake found that nurses or pharmacists providing vaccinations and related education significantly increased the likelihood of vaccine uptake. (46) in 2015 over 500,000 patients were vaccinated in community pharmacies with no reports of harm reported.

Assuming that similar outcomes would be achieved from a community pharmacy based vaccination service compared to those provided via the traditional route then a costminimisation analysis would favour the community pharmacy route. General practitioners who traditionally provided influenza vaccinations and were remunerated accordingly were less supportive of community pharmacies undertaking this role.(45)

Table 4 provides a summary of information relating to 'Advanced services'. 'Clinical effectiveness' is defined as demonstrates clinical benefits for the patient whilst 'effectiveness' is defined as evidence for improvement in process measures. 'Cost-effectiveness' is defined as Cost per QALY highly likely to be less than £20,000 or assuming outcomes are equivalent from the service provided by community pharmacy and others then providing cost of delivery through community pharmacy is equivalent or less then it is likely to be a cost-effective option.

# Table 4Summary of findings of evidence for advanced services

Service name	Evidence for clinical effectiveness	Evidence for effectiveness	Evidence for safety	Evidence for cost- effectiveness	Additional information
Medicines use review	Not applicable	~	None available	None available	Workload duplication Inequity in service provision
New Medicines Service	Not applicable	$\checkmark$	$\checkmark$	~	Long term evidence not available and evidence from one study only
Influenza vaccination	Not applicable	~	~	~	

# 5 Clinical Enhanced Services

#### 5.1 Domiciliary visiting services

Domiciliary visiting services which are aimed at housebound patients consist of counselling on prescribed medicines, compliance review, appropriate provision of multi-compartment compliance aids, medication review and responding to patient queries. In 2008 almost 30% of local primary care organisations who responded to the survey had commissioned a domiciliary visiting service by community pharmacists with two thirds of those still in operation at the time of the survey.(47) Lack of referrals was regularly reported as a reason for service discontinuation. Conversely the greater the number of referrers from the primary care team the more likely the service would be continued.(47) The current national picture with respect to the provision of domiciliary visits is however unknown. Models of delivery by primary care pharmacists rather than community pharmacists are being reported.(48) Although it may be reasonable to ask which mode of delivery is the most cost-effective (community pharmacist or primary care based pharmacist) the better question may be whether long term monitoring and support for housebound patients provided by the patient's community pharmacist is more or less cost-effective than one-off domiciliary visits by a pharmacist for housebound patients identified at risk from their medicines.

Medicine use reviews can be performed as domiciliary visits for housebound patients providing the community pharmacist has permission from their local NHS England team to provide this.(49) There are reports in the literature of domiciliary based MUR services being provided in the UK by community pharmacists which propose that hospitalisations are being prevented.(50, 51) These are invariably conducted without a control arm and the method used to determine hospitalisation prevention is via the use of expert panels(50) or not stated.(51)

In 2005 a definitive randomised controlled trial of pharmacists visiting patients at home two to eight weeks post-discharge in England (The Homer trial) found that patients who had received a domiciliary visit either from a community or hospital based pharmacist were more likely to be re-hospitalised(52) and that the likelihood of the service being cost-effective at the £30,000 threshold was only 25%.(53) The author of the trial proposed that the increase in hospitalisation rate seen may be due to patients being confused by the visiting pharmacists who had been identified as demonstrating unsatisfactory consultation skills.(20) With mortality seen to be improving in the intervention arm, although it did not reach

significance, the more plausible explanation was that in a time where hospitals were not incentivised to prevent 30 day readmission the community pharmacist by visiting the patient earlier than would normally be expected by a healthcare professional identified that they needed to be seen by their GP and were then rehospitalised. This hypothesis was supported by the large number of interventions relating to asking the GP to visit the patient.(54) Whilst the study demonstrated a need to enhance consultation skills of pharmacists it also demonstrated the importance of selecting the most appropriate outcome measure. If the study had been powered on mortality rather than rehospitalisation then the final sample size may have big enough to detect the difference in mortality detected.

A recent study to determine the feasibility of determining the effectiveness of multicomponent compliance aids for patients with unidentified unintentional non-adherence reported the identification of unexpected significant adverse drug events in the intervention arm. It was postulated that the doses of the prescribed medicines had been tailored on unidentified non-adherence and consequent improvements in adherence resulted in over dosage and adverse events.(55) This result suggests that when services are provided in order to improve adherence they must be underpinned with an assessment of risk which takes into account how well the patient's condition is currently controlled with their medication and whether increasing adherence is more likely to improve clinical control or increase the likelihood of dose related side effects.

Within Australia, accredited primary care based pharmacists can undertake home medicines reviews or residential medication management reviews (within care facilities) in order to ensure judicious, safe and efficacious use of medicines. The service includes identifying of patients using set inclusion criteria, referral by GP, pharmacist visit where they obtain a comprehensive medication history, documenting the findings and presenting a report to the GP. The GP and patient then formulate a medication plan based on the pharmacist review. Evidence demonstrates that such reviews improve medication appropriateness and reduce the drug burden. There is no evidence for improvement in clinical outcomes or patient centred outcomes.(56) The importance of high level collaboration and communication between the pharmacists and GPs was identified as central to the effectiveness of these reviews.(56)

#### 5.2 Medication review

Clinical medication review is defined as 'a structured evaluation of a patient's medicines, aimed at reaching agreement with the patient about drug therapy, optimising the impact of medicines and minimising the number of medication-related problems'(57). Systematic

reviews of medication reviews provided by pharmacists have failed to demonstrate meaningful clinical improvements. (57, 58) A recent Cochrane review which considered medication review based interventions to improve polypharmacy found robust evidence for improvement in medication appropriateness only.(59) Evidence for improvement in clinical outcomes and reductions in healthcare resource usage as a result of medication review is not available.

In 2014, 620 patients prescribed four or more medicines (FOMM study) were offered a medication review service through 25 community pharmacies located in the North West of The service included identification of medicines which required medication England. discontinuation or initiation according the standardised criteria, a review of pain medication, interventions to reduce falls risk and adherence interventions. Data was available at six months for analysis for 441 patients with 179 dropping out over the six month service period for a variety of reasons. In the remaining patients, statistically significant improvements in medication adherence, number of reported falls and quality of life were found. Without a control arm it is however difficult to determine whether the improvements seen may have occurred without the intervention or whether they would have actually deteriorated further. Assuming however that the effects seen at 6 months remained over 12 months then the likelihood of the cost per QALY was below £20,000 was estimated to be 81.0%. When the upper limit of £30,000 was used this increased to 90.5%.(60) With four distinct elements to the intervention it was not possible to identify the contribution each made to the final outcome. Such information, obtained by evaluation of process, enables services to be optimised and cost-effectiveness to be enhanced yet further.

#### 5.3 Chronic disease management

The involvement of community pharmacists in chronic disease management in the UK is well recognised(61, 62) and in Scotland a chronic disease management service focused around the provision of pharmaceutical care was set up in 2010.(63)

In 2014 the Dispensing Doctor's Association recommended that community pharmacists should assume responsibility for the management of patients with hypertension who are prescribed three drugs or fewer and are controlled. Furthermore once an appropriate communication system between community pharmacists had been implemented the service should be piloted and subject to full academic evaluation,(64) The transfer of workload from general practices to community pharmacies was seen as an opportunity to create capacity for other services provided through general practice.(64) With summary care records now

being rolled out(15) it would seem appropriate to commission the recommended pilot and future definitive study.

There is a significant international evidence base demonstrating that community pharmacists can effectively support patients with diabetes through (65)medication review, monitoring and adherence interventions and improve both control of HbA1C and blood pressure.(36, 66-68)

A systematic review of economic evaluations of pharmacist managed services in people with type 2 diabetes in 2015 found that such services were likely to reduce costs from the perspective of insurers and provided improved quality of life. Whilst the authors believed that such services were likely to be cost-effective they questioned the quality of economic evaluations performed to date and stated further economic studies of high quality were required.(69)

Chronic Obstructive Pulmonary Disease is another chronic condition which if managed suboptimally results in significant unnecessary health service resource utilisation. In 2014 a before and after evaluation of UK based community pharmacist led support service which consisted of medication review, signposting to smoking cessation services and improving access to rescue therapy to be used during acute exacerbations, demonstrated improvements in patient reported adherence, quality of life and visits to the general practitioner, accident and emergency (A&E) and hospital.(70) The cost of service delivery was calculated to be more than offset by the costs saved therefore suggesting that such a service was very likely to be cost-effective. Initially provided to 306 patients, data for analysis was only available for 137 at six months, representing significant drop out from the service within its six month time span. With no control it is not possible to determine if this would have occurred equally in a non-intervention arm. Furthermore with three distinctly different elements to the intervention and no detailed evaluation of the process it is not possible to identify the potential contribution of each of the elements to the final outcome i.e. a similar outcome may have been achieved with a less intensive intervention thereby reducing cost of delivery further.

#### 5.4 Care homes services

Medicines management in care homes has routinely been identified to be sub-optimal with a landmark study in the UK finding that for each event involving prescribing, dispensing or administration of a medicine, there was an 8%–10% chance of an error.(71)

A 2016 systematic review of care home based interventions provided to optimize medicines use found that whilst such services were likely to reduce medication related problems and improve medication appropriateness there was less evidence to demonstrate improvements in clinical outcomes.(72) The authors recommend that a high quality cluster randomized controlled trial testing clinical decision support systems and utilizing a multi-disciplinary intervention was required.

Two services, tested by randomized controlled trial and involved community pharmacists were included within the review process. Crotty et al. in 2004 using a cluster randomized controlled trial with 154 residents in residential homes in the intervention arm found that a multidisciplinary medication review significantly improved medication appropriateness but did not enhance resident behaviours.(73) Strikweda et al. in 1994 in the Nederland's found that community pharmacist feedback on prescribing for residents in nursing homes significantly increased the number of medicines stopped. Clinical or humanistic outcomes were not measured.(74)

An effective model for improving pharmaceutical care within care homes has not been identified and whilst evidence for involvement of community pharmacists suggests that they can improve the quality of prescribing, the cost-effectiveness of this intervention is unknown.

#### 5.5 Minor ailments service

The potentially inappropriate use of general practices and A&E services for the treatment of minor ailments has led to the introduction of minor ailment management schemes through community pharmacies both at national [Scotland] (75) and local levels.(76)

A systematic review published in 2013(77) found a large number of studies testing the effectiveness of minor ailments scheme but only one randomised controlled trial.(78) Outcomes focussed on referral and reconsultation rates rather than clinical or humanistic outcomes. Similarly cost analysis were largely undertaken from the perspective of the pharmacy and were largely cost-minimisation analysis which assumed that the outcome from both medical practices and community pharmacies would be the same and therefore

the service which cost the least to deliver should be acquired, Reconsultation rates were found to be similar within those services provided by community pharmacists when compared to published rates from medical practices suggesting that such assumptions may be justifiable. Patient satisfaction with minor ailment schemes provided through community pharmacies was found to be routinely high.

Whilst the impact of the service on the types of GP consultation was reported and shown to reduce the number of consultations for minor ailments there was less evidence for this affecting GP workload.(77) As previously stated(64) the transfer of workload provides opportunities for GPs to provide other services and consequently expecting a resultant reduction in GP workload is probably unrealistic. Watson *et al.* identified the need for future robust evaluations of minor ailments services which measure clinical outcomes and include long term follow up.(77)

A recent study by Thornley *et al.* found that community pharmacists could effectively swab the throats of patients presenting with a sore throat to differentiate between those who required antibiotic treatment and those who could be symptomatically treated within the pharmacy. Just under half of the patients swabbed and found to be negative reported that they would have attended their medical practice for antibiotic therapy.(79) This study therefore demonstrates that with appropriate screening and advice community pharmacists through the provision of a minor ailments service and potentially prevent unnecessary demand on GP services and improve antimicrobial stewardship.

A further 2015 study by Watson *et al.* to compare the health related and cost related outcomes of consultations for minor ailments between community pharmacy, general practice and accident and emergency found that the mean costs from an NHS perspective were significantly lower if patients were treated through community pharmacies. Additionally symptom resolution and improvement in quality of life was found to be the same in all three settings.(80) The results therefore suggest that all patients with minor ailments should preferably be treated through community pharmacies. However as a cohort study patients had already selected the setting within which they preferred to be treated. Patients presenting at Accident and Emergency perceived their condition to be more serious and those presenting at community pharmacy were significantly more likely to have had the symptom before. Additionally the community pharmacy cohort included those patients who directly asked for a medicine rather than just presenting with symptoms which required exploration.(80) Consequently it may not be entirely appropriate to assume that the outcomes from the settings would be the same if patients had been randomised.

Table 5 provides a summary of clinical enhanced services. Clinical effectiveness' is defined as demonstrates clinical benefits for the patient whilst 'effectiveness' is defined as evidence for improvement in process measures. 'Cost-effectiveness' is defined as Cost per QALY highly likely to be less than £20,000 or assuming outcomes are equivalent from the service provided by community pharmacy and others then providing cost of delivery through community pharmacy is equivalent or less then it is likely to be a cost-effective option.

Service name	Evidence for clinical effectiveness	Evidence for effectiveness	Evidence for safety	Evidence for cost- effectiveness	Additional information
Domiciliary visiting	Not applicable	X#	X#	X#	<sup>#</sup> Robust evidence suggest increases hospitalisation and is highly unlikely to be cost-effective
Medication review	?*		None available	?*	* FOMM suggests maybe
Chronic disease management	~			×	
Care home service	None available	✓	None available	None available	
Minor ailments service	None available	√*	√*	√*	* Evidence could be enhanced. Requires assumptions which may not be reasonable

# 6 Public health based Services

### 6.1 Emergency hormonal contraception (EHC) supply

A structured literature review of emergency hormonal contraception supply through community pharmacies in 2006(81) found that community pharmacies provide timely access to treatment and the service is well received by women. The one identified randomised controlled trial showed that provision of EHC through community pharmacies did not reduce the use of other contraceptives, lead to an increase in risky sexual behaviour or increase the incidence of STIs.(82) Lewington and Marshall in 2003, from an observational study, showed that the average time to access EHC was 16 hours through community pharmacies compared to 41 hours through family planning clinics.(83)

Whilst evidence for cost-effectiveness of EHC supply services provided through community pharmacy is not available it can be seen that the service is unlikely to provide unwanted effects, is well received and is related to reduce access times which is known to improve treatment effectiveness.

#### 6.2 Chlamydia screening and treatment services

Chlamydia screening which is designed to identify the frequently symptom free condition and treat it before it progresses to pelvic inflammatory disease (PID) and ultimate infertility was introduced in England in 2010 as a national program. The model, assuming PID progression to be 10% was believed to be cost-effective.(84) Community pharmacies have been included within the program in different parts of the country in order to increase local uptake. A systematic review of the literature regarding community pharmacy provided chlamydia screening and treatment services found community pharmacists to be convenient to provide the test and that patients found community pharmacies to be convenient and accessible.(85)

### 6.3 Case finding

### Type II diabetes screening

It has been shown that community pharmacists can effectively screen for type II diabetes (86, 87) and therefore aid earlier identification. Research in the UK suggests that whilst screening with intervention for diabetes and impaired glucose tolerance for those between 45 and 75 is likely to be cost-effective, the cost-effectiveness of diabetes screening alone is uncertain.(88)

Strategies to improve cost-effectiveness of diabetes screening services include focussing screening on those at greater risk, using screening methods with greater sensitivity and

specificity and utilising different approaches to participant identification and inclusion ref. Within the UK the government recommends that diabetes screening should be focussed on patients from known high risk ethnic groups with increased body mass index.(89) Patients with pre-diabetes are also more likely to be prescribed lipid lowering and hypertensive treatments.(90) The community pharmacist has access to sufficient information to enable them to use such criteria to focus a diabetes screening and intervention service.

Krass *et al.* based in Australian community pharmacies showed that risk assessment followed by blood test in community pharmacy resulted in fewer referrals and greater uptake by patients than when using risk assessment only.(91) A risk assessment tool had also been used in the UK to identify those patients who are most appropriate for subsequent physical testing(86). A community pharmacy service model which includes risk assessment, testing and intervention has not been tested by randomised controlled trial. Similarly the costeffectiveness of such a model being provided through community pharmacy is required.

#### Chronic Obstructive Pulmonary Disease (COPD) case finding

A COPD case finding service with intervention delivered through 21 community pharmacies between 2012 and 2013 to 238 patients, identified 135 with potentially undiagnosed COPD of which 88 were smokers. The identification of COPD was believed to incentivise patients to access smoking cessation services which they were signposted to and as a result quality of life was improved and significant reductions in future costs to the NHS were realised.(92) Community pharmacists used a validated risk assessment tool to identify those who were more likely to have COPD and underpin referrals to the GP. They also substantiated their decision using micro spirometry. Earlier identification of COPD, which is possible through community pharmacies who frequently encounter recurrent requests for cough medicines, antibiotic prescriptions for chest infection, patients purchasing nicotine replacement therapy, can prevent disease progression where health service resource utilization significantly increases.

#### Health checks

The NHS health check service was introduced free of charge in 2009 for all patients who meet the eligibility criteria (i.e. are between 40 & 74 years of age, not pregnant, have not received another NHS health check within five years and have not been pre-diagnosed with medical conditions such as hypertension and diabetes).

Whilst the evidence underpinning NHS Health Checks has been questioned(93) and in particular cost-effectiveness,(94) two national evaluations of the NHS Health Check have shown modest population level improvements in key behavioural and psychological risk factors resulting from their introduction.(95, 96) A study by Robson *et al.* demonstrated significant benefits from early diagnosis of key conditions such as hypertension and type 2 diabetes.(95)

With uptake of the NHS Health Checks identified as requiring improvement community pharmacists were identified as one potential provider for this service and it has been shown that they identify appropriate patients and that patients are positive regarding receiving this service through this environment.(97)

#### 6.4 Harm reduction services

Community pharmacists contribute to the public health of patients dependent on opioids through the supervised consumption of opioid substitution medicines to ensure that the individual prescribed the medicine actually takes it and prevent diversion to other users which can result in accidental over dosage. Supervision is usually remunerated locally and a review of its effect on methadone related deaths between 1993 and 2008 found that the number of deaths in Scotland reduced from 20 per 1 million defined daily doses of methadone to 2 and in England from 25 to 6.(98) The reduction has been sustained and with the main change in practice being the introduction of supervised consumption this can largely be attributable to the contribution made by community pharmacy. The cost-effectiveness of the service is currently unknown and therefore the question is whether the cost is justified by the significant reduction in deaths resulting from methadone seen.

Needle and syringe programmes, which may or may not include the provision of other related materials to minimise harm to users are commissioned throughout England by local authorities.(99) Needle exchange services are a cost-effective use of resources.(100-102).

#### 6.5 Weight management

The recent systematic review of public health interventions by community pharmacists by Brown *et al.* reported that community based weight management services were as effective as other primary care strategies.(103) The actual cost of service delivery however seemed to be greater than private providers and consequently the cost-effectiveness of commissioning services via this route was stated to be unclear.(103)

#### 6.6 Brief alcohol interventions

Whilst interventions for brief alcohol interventions have been developed and implemented within community pharmacies in the UK(104), two randomised controlled trials based in the UK demonstrated no long term benefits(105, 106). A recent systematic review identified the need for more research and evidence for brief alcohol interventions in community pharmacies before they can be adopted.(103)

#### 6.7 Smoking cessation

The provision of smoking cessation through community pharmacies is one of the most frequently commissioned enhanced pharmacy services. (107) Consisting of smoking cessation advice element and provision of nicotine replacement therapy (NRT) community pharmacists are reimbursed for provision of NRT and remunerated for service provision.

Researchers have repeatedly demonstrated the effectiveness and cost-effectiveness of community pharmacy led smoking cessation services. (108, 109) Underpinned by 12 randomised controlled trials the most recent systematic review(103) found that, on average, patients were 1.21 times more likely to quit through community pharmacy based service compared to an active control arm and 2.56 times more likely when compared with usual care. All four studies included in the review which estimated cost-effectiveness reported that the smoking cessation service they have evaluated was likely to be cost-effective.

Training for the community pharmacy team was reported in most trials and frequently consisted of behaviour change counselling. Furthermore the intervention was frequently underpinned by theoretical models used within the treatment of addiction. The actual elements of the smoking cessation services which are effective are unknown.(103)

Table 6 provides a summary of evidence which underpins public health services. Clinical effectiveness' is defined as demonstrates clinical benefits for the patient whilst 'effectiveness' is defined as evidence for improvement in process measures. 'Cost-

effectiveness' is defined as Cost per QALY highly likely to be less than £20,000 or assuming outcomes are equivalent from the service provided by community pharmacy and others then providing cost of delivery through community pharmacy is equivalent or less then it is likely to be a cost-effective option.

# Table 6Summary of evidence for public health services

Service name	Evidence for effectiveness	Evidence for safety	Evidence for cost- effectiveness	Additional information
Emergency hormonal contraception	✓	×	√*	* Assuming cost of service delivery is no greater than service provided by others
Chlamydia testing	✓	Not applicable	None available	
Case finding	~	~	√*	* Providing intervention provided concomitantly
Health checks	✓	Not applicable	X	
Addiction support				
Supervised consumption	✓	✓	None available	
Needle exchange	$\checkmark$	~	✓	
Weight management	✓	Not applicable	✓*	Evidence underpinned by recent systematic review *Cost greater than provision by private providers based in primary care
Brief alcohol interventions	X	Not applicable	X	Evidence underpinned by recent systematic review
Smoking cessation	✓	Not applicable	×	Evidence underpinned by recent systematic review

# 7 Funding models for community pharmacy based services

The current funding models associated with Essential, Advanced and Enhanced pharmacy services are largely focused on payment for activity and consequently the driver is based on quantity or volume rather than quality or patient outcomes. There are however examples of funding models for some locally commissioned services which are focussed on outcomes i.e. payment per quitter within smoking cessation services. The advantage of this approach is that it incentivises the service supplier to both obtain positive patient outcomes and to deliver the service as efficiently as possible. In sharp contrast, the payment of a set fee for delivery of a service irrespective of size e.g. that seen within the repeat dispensing service is a perverse incentive which is likely to reduce productivity rather than increase it.

Whist there is international recognition for the need for community pharmacists to assume some responsibility for chronic disease management the models which are currently used rely on payment for service volume rather than outcomes or value and consequently the models currently used in England for community pharmacy do not differ from our international colleagues.(110)

Volume based contracts, where the pharmacy is paid a fee per service provided, are known to result in increased pressure from employers on the pharmacy teams to deliver more of the services and this is particularly not well received when the team receive no incentive for the increased productivity themselves.(111) Additionally, evidence suggests that providers delivering services paid for by volume deliver them as efficiently as possible in order to increase their profit margin with limited concern regarding the outcome for the payer or patient.(111) Within the USA, providers are paid to deliver Comprehensive Medication Reviews (CMRs) to patients under the Medicare system who meet certain criteria, including number of medicines received. To improve efficiency the review is more commonly delivered by providers over the telephone than through face to face contact in the community pharmacy although the telephone delivery method has been shown to be less effective with respect to persuading patients to accept generic substitution.(111) One study in the USA which reviewed pharmacy participation in a pharmaceutical care program found that increases in claims resulted from simplification of the claim system and better organisation with respect to claiming by some pharmacies. Furthermore the majority of interventions which were claimed for were very brief in duration.(112) The increase in claims seen was not in response to patient demand or a desire to improve patient care.

In order to move to a values based contract it is important to identify the outcomes which the payer wants from the service. Within the USA a primary outcome with respect to prescribing from the payer perspective is cost and prescribers are incentivised to reduce costs by sharing savings with the service commissioner which are realised through efficient prescribing. Whilst this could be used for community pharmacists who provided CMRs it would mean the prescriber would have to share any savings with the pharmacist and understandably this was identified as unlikely to be acceptable to prescribers. If cost cannot be used as an outcome measure for a values based contract then it is necessary to identify appropriate health outcome measures which can be captured in time to enable rapid payment.(111) Table 7 provides some examples of outputs which could be used as indicators for current pharmacy services in England.

Within the UK payments for GP services, which could be considered as a values based approach, have been incentivised through the Quality Outcomes Framework (QOF) which is designed to improve the quality of service provided through the provision of a number of key indicators by which GP practices can be measured and assessed. Whilst the approach has been shown to reduce inequity in service provision between providers to patients in deprived and non-deprived areas(113) and improve the quality of care for those conditions which are within the framework it results in reduced quality of care for those excluded from it.(114) Furthermore continuity of care has been seen to diminish as GPs have transferred roles to other members of the team e.g. nurses to maximise their outcomes.(114)

One of the main criticisms levelled at QOF was its focus on processes rather than outcomes i.e. how often reviews and blood tests were undertaken rather than whether the patient was controlled and consequently it was originally a volume based contract. This has recently changed with a movement to measuring patient outcomes.(115)

Major limitations which persist with OQF however are the use of targets which are not aligned with current evidence i.e. clinical expectations are lower than evidence based requirements, and the fact that only a proportion of patients have to meet the requirements to receive the maximum funding. This results in focussing on those patients who are easy to manage and treat and the exemption of patients who are hard to reach, who are frequently the ones with greatest needs.(115)

These criticisms could be addressed by joint working between community pharmacists and general practitioners. Hard to reach patients still visit their community pharmacy to obtain their medicines and consequently could be managed through this route. Furthermore the monthly collection of medicines from community pharmacies provides an opportunity for closer monitoring and support. Development of a joined up QOF between community

pharmacists and GPs with higher expectations with respect to number of patients seen and targets met i.e. in line with NICE guidance, could be one approach to enhancing both quality of care, particularly for those harder to reach patients, and collaboration between the two professions. The strategic use of the QOF to overcome some of the inter-professional barriers identified which prevent closer working between GPs and community pharmacists was identified in a Scottish government report which had considered how to effectively introduce its own Chronic Medication Service.(116)

Service	Potential outcome	Comment	
New medicines	Patient reported improvement	Survey automatically electronically	
service	in medicines taking	sent to patients post intervention.	
Chronic disease	Patient within target range	Identified through medical practice.	
management			
Emergency Hormonal	Number of underage	Identified through local	
Contraceptive supply	pregnancies*	government.	
Chlamydia testing	Positive test result	Remuneration based on number of	
		tests usually undertaken to obtain	
		one positive result.	
Supervised	Number of accidental deaths*	Identified through local	
administration		government.	
Case finding	Patient reported positive	Survey automatically electronically	
	outcome from intervention	sent to patients post intervention.	

Table 7 Potential outcome measures f	for current UK pharmacy services
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\* In both cases local service reimbursement may remain but it may be appropriate to provide additional local funding to incentivise medical practices and community pharmacies in the same locality to work collectively to ensure local targets continue to be met.

### 8 Discussion

Lack of availability of robust evidence does not mean that the service is not effective, safe or cost-effective, it means that evidence is required. Interestingly, however, there is a reasonable evidence base underpinning most community pharmacy provided essential, advanced and locally commissioned services and services are generally shown to deliver what is expected from them. Safety of pharmacy services is frequently assumed and therefore there is often less evidence available to support this. Whilst safety is a significant concern with respect to the patient, from a health economist perspective it presents as costs through unnecessary additional use of resources. Consequently where cost-effectiveness is demonstrated the use of resources has been captured and it could be argued that safety has been considered. Litigation costs are frequently however not included in economic models and therefore evidence of no increased harm is useful for commissioners.

The question however for service commissioners is not so much whether the service works, it would be unrealistic to promote a service which did not do what it set out to, but whether allocation of resources to that service represents good value for money from the perspective of the NHS i.e. is it cost-effective? The accepted threshold for introduction of new interventions in the UK is that the cost to provide one additional year of perfect quality of life (Cost per QALY) is less than £20,000 and in exceptional cases this can be increased to £30,000.(26) With an NHS cost of approximately £90M for MURs in 2015/16 and £20M for NMS it is important that this is the most appropriate use of these resources.

Whilst there is an estimated likelihood of the cost per QALY is available for some community pharmacy services and this strongly supports adoption of the service, in some cases the data underpinning this is less robust and in others it is just not available. The culture associated with the introduction of new community pharmacy services needs to be such that evidence for cost-effectiveness is obtained to ensure service continuity and this has been recently seen with the introduction of NMS(40) and recent evaluations of new services undertaken by the Community Pharmacy Futures group.(60, 70, 92)

Preferably, before a service is even piloted, there would already be some evidence available to suggest likelihood of cost-effectiveness. Australia has similarly required evidence for cost-effectiveness before the introductions of new interventions(117) and this has been in place since 1991 i.e. at least ten years before NICE developed a threshold in the UK(118). This may explain the greater emphasis on this within their new pharmacy-based service evaluations.(36, 101, 119) Cost-effectiveness models can be developed which do not require

a randomised controlled trial for their completion. However when underpinned by data from a trial, of whatever nature, the assumptions underpinning should reduce in number and hence the credibility of the final model is enhanced. The data from studies in Australia and other developed countries can be used to build models relevant to the UK or to provide evidence for the potential cost-effectiveness of future UK based services.

Screening services are usually introduced on the basis of cost-effectiveness models rather than randomised controlled trials due to the cost of such trials and the long term follow up required. Consequently for community pharmacies to be included in the provision of screening services they need to demonstrate outcomes for patients who access the service which are similar to other service providers and a comparable cost for delivery. The increased access provided by community pharmacy can then be used as the rationale for adoption within the sector.

Considering the implementation and delivery of different enhanced and advanced services in detail should enable us to learn from the experiences and inform future service introductions to enhance the likelihood of successful adoption and optimise the service effectiveness, safety and cost-effectiveness.

The repeat dispensing scheme was introduced to reduce GP workload, increase access to repeat medicines for patients and to improve control over the repeat prescription authorisation. Whilst there is reasonable evidence to support all of these expectations the level of service uptake is very low. with barriers to uptake identified repeatedly as the time taken to set it up(6, 7, 120) and the need for greater trust and collaboration between GPs and community pharmacists.(120) Whilst some GPs also expressed concerns about transferring repeat prescription authorisation to community pharmacists whom they didn't know the service was seen by some GPs as improving their working relationships.(120) The current model for the Repeat Dispensing Scheme does not incentivise community pharmacists to increase provision of the service and equally without any incentives for GPs will not encourage them to invest the initial time required for introduction which may be required when the benefits are seen in the longer term. The recently proposed electronic scheme for prescription production which removes the need for a physically signed document may make the system easier to operationalise but patients will still need to be identified and consented to receive the service.(121)

The government commissioned and NHS England has subsequently maintained the MUR service without direct evidence for effectiveness, safety or cost-effectiveness and consequently such evidence has not been required. The small amount of evidence which is

available suggests that, in line with their intended purpose, patient knowledge and selfreported adherence may improve following MURs. The extensive research base supports this finding with one off education interventions known to improve patient knowledge.(29) There is however little evidence which supports the belief that such one off interventions actually improve adherence.(29)

Adherence and improved knowledge outcomes are essentially measures of process which are predictors of potential patient benefit i.e. the reader is expected to assume that by improving these processes there will be improved clinical outcomes. Clinical effectiveness is however difficult to demonstrate for generic interventions which cover a wide range of clinical conditions and is only really appropriate for disease specific interventions. Whilst it is possible to measure effect of MURs on quality of life, which then enables outcome comparison between disparate services, this has not been undertaken.

A recent study has shown that providing multi-compartment compliance aids to increase adherence in patients who are unintentionally non-adherent may actually cause significant harm.(55) The hypothesis is that the doses the patients were prescribed had been tailored on unidentified non-adherence and once adherence is improved the full dose is received and the likelihood of adverse events increased. This seems intuitive and the adverse drug events reported strongly supported this hypothesis. It is therefore appropriate for practitioners providing any adherence intervention to assess the patient and determine whether they are clinically controlled on unidentified non-adherence and therefore improving adherence will provide no additional clinical benefits whilst increasing the risk of adverse drug events. There will be instances where access to patient medical records would be required to effectively perform such a risk assessment effectively.

The limited available evidence available suggests that MURs have not been well received by GPs largely due to the duplication in workload. The Isle of Wight study(30) reported that 70% of patients receiving an asthma based MUR had additionally received their yearly asthma review from the medical practice which should include some, if not all of the same elements. Consequently non-targeted MURs can represent a duplication of workload which is inappropriate in a resource limited NHS. The problems of work duplication may be partially addressed through the implementation of summary care records (15) although these currently may not have sufficient information to identify and prevent workload duplication. Within the literature there are repeated calls for GPs to identify and refer patients for MURs so that workload is not duplicated. (30, 122) However this is unlikely to occur unless there is greater collaboration between community pharmacists and GPs.

GPs are unlikely to recommend a service unless it improves the care of their patients and represents good value for money for the NHS. Whilst the government changed criteria for the provision of MURs to target them at those with greatest need to improve the value provided by MURs there is currently no evidence for the clinical or cost-effectiveness of MURs.

The only intervention which is known to effectively improve adherence is dose simplification (29) and whilst this is likely to be an element within MURs for it to be implemented the prescriber has to accept the recommendation. Negative perceptions regarding the value of MURs by GPs may result in non-implementation of recommendations which further reduces their cost-effectiveness.

A founding principle of the NHS is equity of access to services and this is a reasonable expectation of MURs which are nationally provided, research however has shown that access to MURs is not equitable with different providers providing different levels of access.(18)

With no evidence for clinical effectiveness or cost-effectiveness, unnecessary duplication of workload between different healthcare professionals and known inequity in access to MUR provision, national funding of the MUR service requires review.

The search for evidence for MURs however identified community pharmacy based services which were focussed on chronic disease management. These require repeated and sustained interventions which include medication review and adherence support and evidence is available for the clinical and cost-effectiveness of such models of pharmaceutical care. These services could be used to develop models of chronic disease management which could then be tested for safety, efficacy and cost-effectiveness. Integration of the repeat dispensing scheme into such models of care might enhance patient access to their medicine and hence improve acceptability of chronic disease management by the community pharmacist and further reduce GP workload. The integration of the repeat dispensing service is seen as a central component of the Scottish Chronic Medication Service.(116)

The NMS was set up with underpinning evidence from a similar service which could be considered to be the feasibility stage. Piloting the research methods may have identified some of the recruitment anomalies seen and provided reasonable insight into the time taken to deliver the study consequently avoiding some of the criticisms which can be aimed at the

evidence which is of limited robustness. Interestingly similar to MURs collaboration with GPs was again seen as a barrier to optimising the effectiveness of the NMS

Assuming, however, that the effect on adherence seen within 10 weeks of NMS delivery were real and sustained then the service is likely to be cost-effective. With the service focussed on newly prescribed medicines then the concerns regarding increased adherence are not relevant. The prescribed dose is selected on the assumption of 100% adherence and consequently the NMS is designed to support this.

Provision of influenza vaccinations via pharmacists is known to increase service uptake and providing outcomes are no different from other routes and cost of delivery is the same or less then it is appropriate for the service to be commissioned through community pharmacies. The transfer of income from influenza vaccination from GPs to community pharmacies is however unlikely to enhance collaboration between the two professions.

With a number of reported trials of community pharmacist provided services for patients with diabetes and one successful model reported in the UK(34) it would seem appropriate to commission development of different models of diabetes care, feasibility test and pilot them. The results of these then used to undertake a smaller number of full scale trials to determine their cost-effectiveness.

GPs are willing to allow pharmacists to undertake some of their workload and conditions which are either relatively straight forward to manage e.g. hypertension or represent significant costs to the health system if not managed effectively e.g. diabetes, chronic obstructive pulmonary disease may provide suitable models for developing and testing community pharmacists supporting chronic disease management.

Public health interventions such as emergency hormonal contraception supply, chlamydia testing and needle exchange are believed to represent good value for money for commissioners and therefore providing community pharmacy services can be delivered at a comparable cost to other providers, we are confident that patient satisfaction is similar and there are no safety concerns then these services should be commissioned wherever they are deemed to be necessary.

Case finding of patients through community pharmacy with chronic diseases which if identified earlier can result in significant reductions in future NHS resource utilisation may represent appropriate future services for community pharmacists to provide. To ensure

service value however the screening has to be appropriately targeted and the use of risk assessment tools used within reported services(86, 92) should be an integral element.

Whilst evidence for public health interventions through community pharmacies such as brief alcohol interventions does not currently support this service, and the cost of weight management through community pharmacy requires careful consideration, smoking cessation services provided through community pharmacies are known to be both effective and cost-effective. These services are currently locally commissioned. With a national demand and strong evidence base and argument for nationally commissioning this service could be made.

Minor ailment schemes through community pharmacies have been shown to be well received by patients, to have similar outcomes as those seen in other settings and to change the pattern of GP work. We don't however know whether the transfer of patients from GP practice to community pharmacies is cost-effective. Community pharmacy based minor ailment services are introduced on the assumption that outcomes are the same and that costs are less if delivered through a community pharmacy. No large scale long term randomised controlled studies have been undertaken to effectively measure costs and outcomes resulting from patients accessing community pharmacies, medical practices or accident and emergency. Further research is warranted to both determine how to appropriately change patient behaviour with respect to accessing care for minor ailments and to identify the most cost-effective service provider.

With legislation introduced in both 2003 and 2006 in the UK to allow pharmacists with accredited additional training to prescribe medicines(123) there has been limited uptake by community pharmacists in the UK. Whilst there is evidence from an exploratory randomised controlled trial of primary care based pharmacist prescribing in chronic pain demonstrating improvements in outcomes in England(124) the barrier to provision of this is access to a NHS prescribing budget. The possibilities associated with this opportunity have therefore not yet been explored. Provision of prescribing rights would enable pharmacists to implement interventions, rather than transfer workload back to GPs, could widen the number of conditions which they could treat within the community pharmacy and may enable them to more effectively manage chronic conditions. Consequently when considering the introduction of new community pharmacy based services the opportunity provided by additional prescribing rights should be considered.

Evidence suggests that funding services on volume, which is that currently seen with most community pharmacy services, may not be the most cost-effective approach. Providing set

payments and targets for number delivered results in easier, less complex patients being targeted to minimise cost of delivery and consequently maximise profit margins. A fair payment system underpinned by evidence and based on outcomes may be more effective at ensuring that NHS resources are being appropriately targeted. Combining GP and community pharmacy funding and incentive schemes to encourage co-operation and innovation may be helpful as both professional groups are NHS contractors and evidence strongly suggests that many community pharmacy based services would be enhanced by closer working between the two. Similarly community pharmacies could help GPs to target their 'hard to reach' patients and to further improve patient outcomes.

#### New service introduction

Current guidance for the introduction of complex interventions, i.e. those which have a number of different elements are introduced into complex systems and provided by different members of the healthcare team is that they are first tested for feasibility.(125) This is to ensure that the concept is acceptable to patients and providers, to develop the intervention and identify potential outcome measures. Once the feasibility study has been completed successfully it is necessary to pilot the service to identify recruitment and retention rates, agree the most suitable primary outcome measure and to refine the intervention further. The final definitive study is then performed providing the data from the first two stages suggest that the trial is likely to be completed on time and is able to obtain meaningful data to inform a final decision on effectiveness and cost-effectiveness.

The process should be seen as a pyramid rather than a linear progression i.e. because a service has been designed and tested should not automatically be taken to full introduction and evaluation. Consequently a large number of feasibility studies, will result in a smaller number of pilots and ultimately this will result in a smaller number of full service introductions and evaluations.

The traditional approach to pilots and exploratory studies throughout healthcare has been to attempt to demonstrate benefits through an underpowered 'early design stage' project. Resulting data may then be misused by commissioners to implement a larger service based on flawed assumptions and evidence which is frequently derived from testing a service delivered by a small number of enthusiastic individuals.

The problems found with MURs largely derived from training, service introduction and service targeting. These all need to be carefully considered and addressed within any newly

commissioned community pharmacy services and this is achieved through feasibility testing and piloting which is focussed on the process and not the outcomes.

NMS was based on a previous study which suggested feasibility however no piloting was undertaken and this may explain the fact that 26 week data was not available as promised.

Feasibility and piloting of the Four or More Medicines service (FOMM) and COPD management services may have identified the reasons for the relatively large patient drop out and enabled this to have been addressed before the final evaluation. Provision of services to patients who do not return for follow up is likely to significantly reduce the cost-effectiveness of the intervention.

There are many models for community pharmacy services available which could be used to inform the design of new services for feasibility testing and piloting.

When new services are introduced which are in effect complex interventions with different distinct elements within them then evaluation of the process (process evaluation) must be included to enable the identification of the contribution of each element to the final outcome (126) and thereby enable final service optimisation.

The greatest barrier to new service introduction however is the fact that community pharmacies are not integrated within the primary healthcare team and frequently do not work closely with GPs and other members of the team other than with respect to the supply of medicines. The Scottish working party reported that this can only be achieved through robust communication routes between the two professions, appropriate referral pathways, integration of community pharmacy services into current care pathways and provision of appropriate incentives to encourage collaboration.(116) Consequently, when any new community pharmacy based services introduced in the future these elements must be a primary focus within the design.

# 9 Summary

### Evidence for effectiveness and cost-effectiveness

- The evidence suggests that nearly all of pharmacy services included within this review are effective
- The repeat dispensing service, where implemented, is likely to represent good value for money for the NHS and therefore strategies for improving uptake are required
- There is no robust evidence for cost-effectiveness of MURs
- The New Medicines Service is likely to be effective and cost-effective
- There are a number of community pharmacist chronic disease management service models which have been previously tested which demonstrate effectiveness and potential cost-effectiveness.
- Chronic disease management services would be more effectively delivered if combined with the repeat dispensing service
- Medication review based services for different patient groups are yet to be shown to be clinically or cost-effective and are probably most useful when provided within a more holistic service
- Services such as delivery of emergency hormonal contraception and chlamydia screening and treatment should be commissioned providing the cost of service delivery is comparable with service provision from other providers
- Case finding services for conditions which have significant consequences if not identified early are likely to be cost-effective if risk assessment tools are used within the screening process and providing the pharmacist is able to provide interventions to prevent disease progression
- Weight management services can be provided more cheaply in primary care from private providers with equal effects
- The current evidence based for Brief Alcohol Interventions is insufficient to warrant commissioning of this service

### Service implementation

- All new community pharmacy based services must be designed to facilitate greater collaboration between community pharmacists and general practitioners.
- Training, implementation and delivery of MURs could have been improved and these problems should have been identified if the service had been appropriately feasibility tested with a view to service refinement
- The evidence supporting the New Medicines Service may have been enhanced if the service and trial had been piloted

- Services which are focussed on improving medication adherence must include risk assessment based on the clinical control of the patient to ensure that the likelihood of improved patient outcomes is greater than any increased risk of dose related adverse events
- It is important that national services are designed to be delivered equally accessible from all community pharmacy settings

### Service funding

- 'Value based contracts' are more likely to improve service cost-effectiveness than 'volume based contracts' if they are appropriate to be used for that service.
- When using 'value based contracts' the funding should accurately reflect the cost of service delivery i.e. based on an appropriate number of patients seen to achieve a positive outcome
- The model of funding chosen (value or volume) should be the most appropriate for the service being remunerated and in some instances this could be a hybrid of the two
- A joined up quality outcomes framework between general practitioners and community pharmacists could be used to introduce a 'values based contract' which addresses some of the concerns which currently exist with respect to the GP Quality Outcomes Framework
- The current funding model for the repeat dispensing scheme does not incentivise practitioners to increase its uptake
- Prescribing rights for pharmacists provides a number of new opportunities to improve patient care but the barrier of access to a prescribing budget prevents innovation in this area

### **Research evidence**

- Economic evaluations surrounding new services need to be more robust and be able to withstand detailed scrutiny by commissioners.
- If evidence for cost-effectiveness is not available this should be incorporated into the service introduction process to ensure that future decisions regarding service continuity are fully informed
- New services should always be feasibility tested and piloted first with a focus at this stage on training, implementation and delivery rather than outcomes.
- Process evaluations should be undertaken to ensure that the contribution of each element of a new service to the outcomes are fully understood

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